Recommended Care, Cleaning and Sterilization Instructions for Reusable Instruments & Accessories

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(These instructions pertain to both Class I and Class II devices)

LCN 204233-0EN/GSymmetry Surgical Inc. ® Revised08/2020

Recommended Care, Cleaning and Sterilization Instructions for Reusable Instruments & Accessories

These instructions are in accordance with ISO 17664 and AAMI ST81. They apply to:

- Reusable surgical instruments and accessories supplied by Symmetry and intended for reprocessing in a health care facility setting. All Symmetry instruments and accessories may be safely and effectively reprocessed using the manual or combination manual/automated cleaning instructions and sterilization parameters provided in this document **UNLESS otherwise noted in instructions accompanying a specific instrument.**

In countries where reprocessing requirements are more stringent than those provided in this document it is the responsibility of the user/processor to comply with those prevailing laws and ordinances.

These reprocessing instructions have been validated as being capable of preparing reusable Symmetry instruments and accessories for surgical use. It is the responsibility of the user/hospital/health care provider to ensure that reprocessing is performed using the appropriate equipment, materials and that personnel have been adequately trained in order to achieve the desired result; this normally requires that equipment and processes are validated and routinely monitored. Any deviation by the user/hospital/health care provider from these instructions should be evaluated for effectiveness to avoid potential adverse consequences.

WARNINGS ⚠	
	• Symmetry reusable instruments are provided NON-STERILE (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 the first cleaning and sterilization. • Ethylene oxide (EO), gas plasma and dry heat sterilization methods are **not recommended** for sterilization of Symmetry reusable instruments. Steam (moist heat) is the recommended method. • Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated instruments. • Caution should be exercised while handling, cleaning, or wiping instruments with sharp cutting edges, tips, and teeth. • Saline and cleaning/disinfection agents containing aldehyde, chloride, active chlorine, bromine, bromide, iodine or iodide are corrosive and **should not** be used. • **Do not allow biologic soil to dry on contaminated devices.** All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluids and tissue debris to dry on used instruments. • Automated cleaning using a washer/disinfector alone **may not** be effective for instruments with lumens, blind holes, cannulas, mated surfaces and other complex features. A thorough manual cleaning of such device features is recommended

	before any automated cleaning process. • Metal brushes and scouring pads must not be used during manual cleaning. These materials will damage the surface and finish of the instruments. Use only soft bristle nylon brushes with different shapes, lengths and sizes to aid with manual cleaning. • When processing instruments do not place heavy devices on top of delicate instruments. • **Use of hard water should be avoided.** Softened tap water may be used for most rinsing however purified water should be used for final rinsing to prevent mineral deposits. • Do not process instruments with polymer components at temperatures equal to or greater than 140°C/285°F because severe surface damage to the polymer will occur. • Oils or silicone lubricants **should not** be used on surgical instruments.
Limitations on Reprocessing	• Repeated processing according to these instructions has minimal effect upon metal Symmetry reusable instruments and accessories unless otherwise noted. End of life for stainless steel or other metal surgical instruments is generally determined by wear and damage incurred during the intended surgical use. • Symmetry instruments comprised of polymers or incorporating polymer components can be sterilized using steam however they are not as durable as their metal counterparts. If polymer surfaces show signs of excessive surface damage (e.g. crazing, cracks or delamination), distortion or are visibly warped they should be replaced. Contact you Symmetry representative for your replacement needs. • Non-foaming, neutral pH enzymatic and cleaning agents are recommended for processing Symmetry reusable instruments and accessories. • Alkaline agents with a pH of 12 or less may be used to clean stainless steel and polymer instruments in countries where required by law or local ordinance; or where prion diseases such as Transmissible Spongiform Encephalopathy (TSE) and Creutzfeld-Jakob Disease (CJD) are a concern. **It is critical that alkaline cleaning agents are completely and thoroughly neutralized and rinsed from the devices or degradation may occur that limits the device life.**

REPROCESSING INSTRUCTIONS	
Point of Use	• Remove excess biologic soil from the instruments with a disposable wipe. Place devices in a container of distilled water or cover with damp towels. **Note: Soaking in an enzymatic solution prepared according to the manufacturer will facilitate cleaning especially in instruments with complex features such as lumens, mating surfaces, blind holes and cannulas.** • If instruments cannot be soaked or maintained damp then they should be cleaned as soon as possible (within 60 minutes is recommended) after use to minimize the potential for drying prior to cleaning.
Containment and Transportation	• Used instruments must be transported to the decontamination area for reprocessing in closed or covered containers to prevent unnecessary contamination risk.

Preparation for Cleaning	• Instruments designed to come apart must be disassembled prior to cleaning. Disassembly, where necessary, is generally self-evident however for more complicated instruments instructions are provided and should be followed. **Note: All recommended disassembly will be possible by hand. Never use tools to disassemble instruments beyond what is recommended.** • All cleaning solutions should be prepared at the dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning solutions. **Note: Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (turbid).**
Manual Cleaning Steps	• **Step 1**: Prepare a proteolytic enzyme solution according to the manufacturer's instructions. • **Step 2**: Completely submerge instruments in the enzyme solution and gently shake them to remove trapped bubbles. Actuate instruments with hinges or moving parts to ensure contact of the solution with all surfaces. Lumens, blind holes and cannulas should be flushed with a syringe to remove bubbles and ensure contact of the solution with all instrument surfaces. • **Step 3**: Soak instruments for a minimum of 10 minutes. While soaking scrub surfaces using a soft nylon-bristled brush until all visible soil has been removed. Actuate moveable mechanisms. Particular attention should be given to crevices, hinged joints, box locks, instrument teeth, rough surfaces and areas with moving components or springs. Lumens, blind holes and cannulas should be cleaned using a snug fitting round nylon bristle brush. Insert the snug fitting round brush into the lumen, blind hole or cannula with a twisting motion while pushing in and out multiple times. **Note: All scrubbing should be performed below the surface of the enzyme solution to minimize the potential of aerosolizing contaminated solution.** • **Step 4**: Remove the instruments from the enzyme solution and rinse in tap water for a minimum of one (1) minute. Actuate all moveable and hinged parts while rinsing. Thoroughly and aggressively flush lumens, holes, cannulas and other difficult to access areas. • **Step 5**: Prepare an ultrasonic cleaning bath with detergent according to the manufacturer's recommendations. Completely submerge instruments in the cleaning solution and gently shake them to remove any trapped bubbles. Lumens, blind holes and cannulations should be flushed with a syringe to remove bubbles and ensure contact of the solution with all instrument surfaces. Sonically clean the instruments at the time, temperature and frequency recommended by the equipment manufacturer and optimal for the detergent used. A minimum of ten (10) minutes is recommended.

	Notes: **- Separate stainless steel instruments from other metal instruments during ultrasonic cleaning to avoid electrolysis.** **- Fully open hinged instruments and use wire mesh baskets or trays designed for ultrasonic cleaners.** **- Regular monitoring of sonic cleaning performance by means of an ultrasonic activity detector, aluminum foil test, TOSI™ or SonoCheck™ is recommended.** • **Step 6**: Remove the instruments from the ultrasonic bath and rinse in purified water for a minimum of one (1) minute or until there is no sign of residue detergent or biologic soil. Actuate all moveable and hinged parts while rinsing. Thoroughly and aggressively flush lumens, holes, cannulas and other difficult to access areas. • **Step 7**: Dry instruments with a clean, absorbent non-shedding lint free cloth. Clean, filtered compressed air may be used to remove moisture from lumens, holes, cannulas and difficult to access areas.
Combination Manual/Automated Cleaning Steps	• **Step 1**: Prepare a proteolytic enzyme solution according to the manufacturer's instructions. • **Step 2**: Completely submerge instruments in the enzyme solution and gently shake them to remove trapped bubbles. Actuate instruments with hinges or moving parts to ensure contact of the solution with all surfaces. Lumens, blind holes and cannulas should be flushed with a syringe to remove bubbles and ensure contact of the solution with all instrument surfaces. • **Step 3**: Soak instruments for a minimum of 10 minutes. While soaking scrub surfaces using a soft nylon-bristled brush until all visible soil has been removed. Actuate moveable mechanisms. Particular attention should be given to crevices, hinged joints, box locks, instrument teeth, rough surfaces and areas with moving components or springs. Lumens, blind holes and cannulas should be cleaned using a snug fitting round nylon bristle brush. Insert the snug fitting round brush into the lumen, blind hole or cannula with a twisting motion while pushing in and out multiple times. **Note: All scrubbing should be performed below the surface of the enzyme solution to minimize the potential of aerosolizing contaminated solution.** • **Step 4**: Remove the instruments from the enzyme solution and rinse in tap water for a minimum of one (1) minute. Actuate all moveable and hinged parts while rinsing. Thoroughly and aggressively flush lumens, holes, cannulas and other difficult to access areas. • **Step 5**: Place instruments in a suitable validated washer/disinfector. Follow the washer/disinfector manufacturer's instructions for loading the instruments for maximum cleaning exposure; e.g. open all instruments, place concave instruments on their side or upside down, use baskets and trays designed for washers, place heavier instruments on the bottom of trays and baskets. If the washer/disinfector is equipped with special racks (e.g. for cannulated instruments) use them according to the manufacturer's instructions. • **Step 6**: Process instruments using a standard washer/disinfector instrument cycle

<table>
<tr><td></td><td>according to the manufacturer's instructions. The following minimum wash cycle parameters are recommended:

<table>
<tr><th>Cycle</th><th>Description</th></tr>
<tr><td>1</td><td>Pre-wash --▪-- Cold Softened Tap Water --▪-- 2 minutes</td></tr>
<tr><td>2</td><td>Enzyme Spray & Soak --▪-- Hot Softened Tap Water --▪-- 1 minute</td></tr>
<tr><td>3</td><td>Rinse --▪-- Cold Softened Tap Water</td></tr>
<tr><td>4</td><td>Detergent Wash --▪-- Hot Tap Water (64-66°C/146-150°F) --▪-- 2 min.</td></tr>
<tr><td>5</td><td>Rinse --▪-- Hot Purified Water (64-66°C/146-150°F) --▪-- 1 minute</td></tr>
<tr><td>6</td><td>Hot Air Dry (116°C/240°F) --▪-- 7 to 30 minutes</td></tr>
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Notes:
- The washer/disinfector manufacturer's instructions should be followed.
- A washer/disinfector with demonstrated efficacy (e.g. FDA approval, validated to ISO 15883) should be used.
- Dry time is shown as a range because it is dependent upon the load size placed into the washer/disinfector.
- Many manufacturers pre-program their washer/disinfectors with standard cycles and they may include a thermal low-level disinfection cycle after the detergent wash. The thermal disinfection cycle should be performed to achieve a minimum value A_0 = 600 (e.g. 90°C/194°F for 1 minute according to ISO 15883-1) and is compatible with Symmetry instruments.
- If a lubrication cycle is available that applies a water-soluble lubricant such as Preserve®, Instrument Milk or equivalent it is acceptable to use on Symmetry Instruments unless otherwise indicated.</td></tr>
<tr><td>Disinfection</td><td>• Symmetry Surgical instruments must be terminally sterilized prior to use. See sterilization instructions below.
• Low level disinfection may be used as part of a washer/disinfector cycle but the devices must also be sterilized before use.</td></tr>
<tr><td>Drying</td><td>• Dry instruments with a clean, absorbent non-shedding lint free cloth. Clean, filtered compressed air may be used to remove moisture from lumens, holes, cannulas and difficult to access areas.</td></tr>
<tr><td>Inspection & Testing</td><td>• After cleaning, all devices should be thoroughly inspected for residue biologic soil or detergent. If contamination is still present repeat the cleaning process.
• Visually inspect each device for completeness, damage and excessive wear. If damage or wear is observed that might compromise the function of the device, do not process them further and contact your Symmetry representative for a replacement.
• When inspecting devices look for the following:
o Cutting edges should be free of nicks and have a continuous edge.
o Jaws and teeth should align properly.
o Movable parts should operate smoothly throughout the intended range of motion.
o Locking mechanisms should fasten securely and close easily.
o Long thin instruments should be free of bending or distortion.</td></tr>
</table>

	○ Where instruments form part of a larger assembly, check that all components are available and assemble readily.
Maintenance and Lubrication	• After cleaning and before sterilization, instruments with moving parts (e.g. hinges, box-locks, sliding or rotating parts) should be lubricated with a water-soluble lubricant such as Preserve®, Instrument Milk or equivalent material intended for medical device application. Always follow the lubricant manufacturer's instructions for dilution, shelf life and application method.
Packaging for Sterilization	• Single devices may be packaged in an approved (e.g. FDA cleared or ISO 11607 compliant) medical grade sterilization pouch or wrap. Care should be used when packaging so that the pouch or wrap is not torn. Devices should be wrapped using the double wrap or equivalent method (ref: AAMI ST79, AORN Guidelines). • Reusable wraps are not recommended. • Instruments may be packaged in an approved (e.g. FDA cleared or ISO 11607 compliant) general-use perforated tray or case along with other devices under the following conditions: ○ Arrange all devices to allow access of steam to all surfaces. Open hinged devices and ensure devices are disassembled if it is recommended. ○ The case or tray must be wrapped in an approved (e.g. FDA cleared or ISO 11607 compliant) medical grade sterilization wrap by following the double wrap method or equivalent (ref: AAMI ST79, AORN Guidelines). ○ Follow the case/tray manufacturer's recommendations for loading and weight. Total weight of a wrapped case or tray should not exceed 11.4kg/25lbs. • Instruments may be packaged in an approved (e.g. FDA cleared or ISO 11607 compliant) rigid container systems (i.e. those with filters or valves) along with other devices under the following conditions: ○ The container manufacturer's recommendations should be followed regarding preparation, maintenance and use of the container. ○ Arrange all devices to allow access of steam to all surfaces. Open hinged devices and ensure devices are disassembled if it is recommended. ○ Follow the container manufacturer's recommendations for loading and weight. Total weight of a filled container system should not exceed 11.4kg/25lbs.
Sterilization	• Moist heat/steam sterilization is the recommended method for Symmetry instruments. • Use of an approved chemical integrator (class 5) or chemical emulator (class 6) within each sterilization load is recommended. • Always consult and follow the sterilizer manufacturer instructions for load configuration and equipment operation. Sterilizing equipment should have demonstrated efficacy (e.g. FDA clearance, EN 13060 or EN 285 compliance). Additionally the manufacturer's recommendations for installation, validation, and maintenance should be followed. • Validated exposure times and temperatures to achieve a 10^{-6} sterility assurance

level (SAL) are listed in the following table.

Cycle Type	Minimum Temperature	Minimum Exposure Time
United States Recommended Parameters		
Pre-vacuum / Vacuum Pulse	132°C/270°F	4 minutes
Cycle Type	**Minimum Temperature**	**Minimum Exposure Time**
European Recommended Parameters		
Pre-vacuum / Vacuum Pulse	134°C/273°F	3 minutes

Drying & Cooling

- The recommended drying time for single wrapped instruments is 20 minutes unless otherwise noted in device specific instructions.
- Drying times for instruments processed in containers and wrapped trays can vary depending upon the type of packaging, type of instruments, type of sterilizer and total load. A minimum dry time of 30 minutes is recommended but to avoid wet packs, extended dry times greater than 30 minutes may be needed for larger loads under certain conditions or if otherwise recommended in accompanying documentation. For large loads verification of dry times by the health care provider is recommended.

- A 30 minute minimum cooling time is recommended after drying but longer times may be necessary because of load configuration, ambient temperature and humidity, device design and packaging used.

Note: Disinfection/steam sterilization parameters recommended by the World Health Organization (WHO) for reprocessing instruments where there is a concern about TSE/CJD contamination are: 134°C/273°F for 18 minutes. Symmetry medical devices are compatible with these parameters.

Storage

- Sterile packaged instruments should be stored is a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin and temperature/humidity extremes.

Note: Inspect every package before use to ensure that the sterile barrier (e.g. wrap, pouch or filter) is not torn, perforated, shows signs of moisture or appears to be tampered with. If any of those conditions are present then the contents are considered non-sterile and should be re-processed through cleaning, packaging and sterilization.

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