symmetry surgical™

INSTRUCTIONS FOR USE

CAUTION: Federal (U.S.A.) law restricts this device to sale, distribution, and use, by, or on the order of a physician.

DEVICE(S)
The following instructions are for the Ultra ReVeal Systems (Lumbar, ACF, and LoPro Retractor systems) supplied by Specialty Surgical Instrumentation (SSi) unless stated otherwise with the packaging of the product. These instructions are intended for use only by persons with the required knowledge and training in a health care facility.

INTENDED USE
Surgical Instruments are intended for use in the surgical setting for clamping, cutting, dissecting, grasping, probing, retracting and suturing.

CONTRAINDICATIONS
The improper use of a surgical instrument during handling, surgical use or reprocessing, for which they are indicated, may result in patient injury and damaged or broken instruments.

WARNINGS
• If this instrument is/was used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD), the instrument cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination. Consult WHO and local regulations for further information.
• The surgical instrument must be inspected, cleaned and sterilized before each surgical procedure.

PRECAUTIONS
• When reprocessing surgical instruments, always handle with care, wearing protective clothing, gloves and eyewear in accordance with local Health & Safety procedures.
• Instruments manufactured from different metals should be processed separately to avoid electrolytic action between the metals resulting in pitting and rusting of stainless steel instruments.
• Delicate surgical instruments require special handling to prevent damage to the tips. Use caution during cleaning and sterilization. A non-fibrous sponge should be used to wipe off all blood and debris.
• Do not use excessive stress or strain at joints; misuse will result in misalignment or cracks at the box locks or jaws.
• Aluminum and titanium instruments that are color anodized may lose their color over time through normal use and reprocessing.
• Keep ebonized instruments separate from other stainless steel instruments to avoid scratches to and removal of the ebonized coating.

LIMITATIONS ON REPROCESSING
• Repeated processing has minimal effect on the instrument life.
• End of useful life for metal surgical instruments is normally determined by wear and damage due to the intended surgical use.
• Always inspect instruments between uses to confirm proper functioning.
• Any specific limitations on the number of reprocessing cycles shall be made available with the instrument.

REPROCESSING INSTRUCTIONS

FROM POINT OF USE
Wherever possible, do not allow blood, debris or body fluids to dry on instruments. For best results and to prolong the life of the surgical instrument reprocess immediately after use. If they cannot be reprocessed immediately, use an enzymatic foam spray cleaner to help prevent soil from drying.

PREPARATION FOR DECONTAMINATION
• Reprocess all instruments as soon as it is reasonably practical following use.
• Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used. Wherever possible avoid use of mineral acids and harsh, abrasive agents.
• Do not use high acid (pH 4.0 or lower) or high alkaline (pH 10 or higher) products for disinfection. Neutral pH detergents 7.0 – 9.0 are preferred.
• If appropriate, disassemble prior to cleaning and sterilization, without the use of tools unless specifically provided by the manufacturer. Additional instructions required for disassembly will be made available with the product or the manufacturer.
• Open jaws of hinged instruments for cleaning. Give special attention to joints and serrations.
• Remove gross contaminants with a steady stream of lukewarm/cool water, not to exceed 35º C (95º F). Rinse each instrument thoroughly. Do not use saline or chlorinated solutions.
• Do not soak instruments in hot water, alcohol, disinfectants or antiseptics to avoid coagulation of mucus, blood or other body fluids. Do not exceed 2 hours soaking in any solution.
• Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents.

CLEANING: AUTOMATED
• Use only validated washer-disinfector machines and low-foaming, non-ionizing cleaning agents and detergents. Follow the manufacturers' instructions for use, which includes warnings, concentrations and recommended cycles.
• Load instruments carefully, leaving box locks and hinges open so that any openings in instruments can drain.
• Place heavy instruments on the bottom of containers, taking care not to place on delicate instruments or overload wash baskets.
• Place instruments with curved surfaces facing down to prevent pooling of water.
• Where available, use appropriate cleaning accessories to flush instruments with channels or lumens.
• Ensure that soft, high purified water that is controlled bacterial endotoxins is used in the final rinse stage.
Note: Automated cleaning may not be suitable for all lumens and channels, in which case clean manually with a water jet, if available, and an appropriate brush (and stylet if provided) that reaches the depth of the feature. After manually cleaning, pass all instruments through an automatic cleaning cycle to achieve disinfection.

CLEANING: MANUAL
• Manual cleaning is not advised if an automatic washer- disinfector is available. If this equipment is not available, use the following process for manual cleaning:
• Use a double sink system (wash/rinse) dedicated for instrument cleaning (not used for hand washing). Ensure that the water temperature does not exceed 35º C (95º F).
• In the first sink, keeping the instrument totally immersed, with an appropriately-sized autoclavable soft nylon brush, apply validated cleaning solution to all surfaces until all soil has been removed. Pay particular attention to serrations, teeth, ratchets, box locks and hinges, always brushing away from the body and avoiding splashing.
• Ensure rongeurs and hinged instruments are thoroughly cleaned in both open and closed positions.
• Use a large syringe or water jet to thoroughly flush all channels and lumens with cleaning solution to remove debris.
• In the second sink, rinse instruments thoroughly with soft, high purified water which is controlled for bacterial endotoxins, so that the water reaches all parts of the instrument, then carefully hand dry or use a drying cabinet.

CLEANING: INSPECTION
After cleaning, visually inspect all surfaces, ratchets, box locks, holes, channels and lumens for complete removal of soil and fluids. If ANY soil or fluid is still visible, return the instrument for repeat decontamination.

DRYING
Instruments must be thoroughly dried and all residual moisture must be removed before they are sterilized. Use a soft absorbent towel or cloth to dry external surfaces.

LUBRICATION
Apply surgical grade (non-silicone, water soluble) lubricants to hinges, box locks and moving parts as per the lubricant manufacturer's instructions.

INSPECTION AND FUNCTION TESTING
• Visually inspect and check: all instruments for damage and wear; cutting edges are free of nicks and present a continuous edge; jaws and teeth align correctly; all articulated instruments have a smooth movement without excess play; locking mechanisms (such as ratchets) fasten securely and close easily; long, slender instruments are not distorted; any component parts fit and assemble correctly with mating components.
• Close instruments with a ratchet lock in the first ratchet position before sterilization to avoid temperature-induced stress cracks in the box locks.
• Consider removing for repair or replacement any blunt, worn out, flaking, fractured, corroded, stained, discolored or for damaged instruments.
Note: If an instrument is returned to the manufacturer / supplier, the instrument must be decontaminated and sterilized and be accompanied with the relevant documented evidence, otherwise a cleaning charge may apply and delay processing of the repair.

PACKAGING
All instruments to be wrapped or packaged following local procedures; examples described in ANSI/AAMI ST46-1993.

STERILIZATION
• Use a validated, properly maintained steam sterilizer. Always follow instructions of the machine manufacturer.
• Do not exceed 140° C (284° F) during sterilization cycle.
• Effective sterilization can be achieved following the steam cycle listed below:

Cycle Type	Minimum Temperature	Minimum Exposure Time/Dry Time*
Prevacuum	132°C (270°F)	**Time:** 5 Minutes **Dry Time**: 20 Minutes dry time for metal or metal/ plastic trays and 45 minutes dry time for all plastic trays

* AAMI/AORN steam sterilization cycles with longer times than those listed are also acceptable.

STORAGE
Non-sterile instruments or sterile wrapped instruments should be stored in dry, clean conditions at an ambient room temperature.

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 PROVIDED MUST BE PROPERLY EVALUATED FOR EFFECTIVENESS AND POTENTIAL ADVERSE CONSEQUENCES.

Please Contact Symmetry Surgical for additional information.

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