Swann-Morton LIMITED

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GENERAL INSTRUCTIONS FOR CARE, HANDLING AND REPROCESSING OF SWANN-MORTON NON STERILE METAL SURGICAL INSTRUMENTS

Intended Use:	A reusable metal handle intended to hold a cutting edge device.
How Supplied:	Devices are supplied non-sterile and must be cleaned, inspected and sterilized prior to each use.
Before Use:	Inspect the device for any damage, wear or non-functional parts. Carefully inspect the critical, inaccessible areas and any moving parts. Damaged or defective devices should not be used.
Warnings: 	These devices are designed for use by appropriately trained, qualified and competent personnel. When reprocessing medical devices always follow local Health & Safety procedures. Always follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used. Avoid the use of mineral acids and harsh, abrasive agents. No part of the process is to exceed 140°C. Some sensitive materials can be damaged by higher alkaline solutions (pH >10). The use of the device for tasks other than those for which they are intended may result in failure or damage/breakage. Correct cleaning, handling and sterilization will ensure that the device performs as intended and extend its useful life. Instruments manufactured from different metals should be processed separately to avoid electrolytic action between the different metals. Wear appropriate protective gloves, eyewear and clothing when handling biologically contaminated devices. Manual cleaning is not advised if an automatic washer/disinfector is available.

Care and Handling: The following information is provided to give general guidance on how metal surgical instruments supplied by Swann-Morton Ltd. may be processed to prepare them for use. All these instruments must be sterilized prior to use. Equipment, operators, cleaning agents and procedures all have a contribution to the efficacy of the processing and the healthcare facility should ensure that the surgical instrument is safe for use at all times.

Pre-Cleaning:	Do not allow blood and/or bodily fluids to dry on the instruments. Reprocess as soon as reasonably practicable following use. If they cannot be reprocessed immediately, use an enzymatic cleaner to help prevent any soiling from drying, paying particular attention to any joints, slots, holes and grooves. Remove any gross contaminants with a steady stream of lukewarm water (below 110°F/43°C.) Rinse each instrument thoroughly, do not use saline or chlorinated solutions. Give special attention to any joints, slots, holes and grooves. Instruments having more than one part or piece must be disassembled to expose all surfaces to the cleaning process. Retain all parts to facilitate reassembly.
Cleaning:	The methods for cleaning Swann-Morton instruments are as described below. Whenever possible, the automated method should be used as it is a more reproducible process and therefore more reliable.
Cleaning Precautions:	• Avoid mechanical damage during transportation to the process area. • Transport to the processing area as soon as possible. • Do not soak instruments in hot water, alcohol, disinfectants or antiseptics to avoid coagulation of mucus, blood or other body fluids. • Do not use steel wool, wire brushes, pipe cleaners or other abrasive cleaners. • Only specifically formulated cleaning agents (detergents). Enzymatic agents with both bacterial and fungicidal properties are preferred for manual cleaning.
Manual Cleaning:	**Equipment Required** • Double Sink System (Not used for hand washing) dedicated for instrument cleaning. • Brushes – Soft and firm. • Personal Protective Equipment (PPE) as recommended by the cleaning agent supplier but as a minimum, overalls, gloves, face/eye shield. **Procedure** • Ensure the water temperature does not exceed 35°C. • In the first sink, keeping the instrument submerged, using a soft autoclavable brush, apply cleaning solution to all surfaces of the instrument until all soiling has been removed paying attention to any areas/surfaces and features where soil may be shielded from the brushing. • In the second sink, rinse instruments thoroughly with soft, high purity water which is controlled for bacterial endotoxins so that water reaches all parts of the instruments. • Dry instruments. • Visually inspect all areas of the instrument for any remaining soiling and if necessary, repeat the steps above.

	Note: manual cleaning is NOT a disinfection process; when manual cleaning is used it may not be possible to disinfect the device prior to further handling.
Automated Cleaning:	Use only a validated washer/disinfector machine with low foaming, non-ionising cleaning agents and detergents following the manufacturer's instructions for use, warnings, concentrations and recommended cycles. Load instruments carefully so that slots, holes and groves in the handle can drain. Take care not to overload wash baskets. Ensure that soft, high purity water which is controlled for bacterial endotoxins is used in the final rinse stage. **Equipment Required** • Validated washer/disinfector • Cleaning/rinsing agents as required by washer/disinfector **Procedure** • Follow manufacturer's instructions for water level, concentration levels of cleaning agents and temperature. • The quality of water used for diluting cleaning agents and for rinsing instruments should be carefully considered. Mineral residues from hard water can result in staining of the instrument or prevent effective cleaning and decontamination. • Load the instruments. • The following has been validated using a washer disinfectant cycle to include: One pre-wash stage at a minimum of 32°C One wash stage at >60°C Two rinse cycles at >60°C A final disinfectant rinse stage at >90°C for a minimum holding time of one minute and a minimum drying stage of thirty minutes. Use an aqueous alkaline wash detergent cleaner with a maximum of 12pH and use reverse osmosis water for the rinse.
Inspection:	Before preparing for sterilization all instruments should be inspected. Visual inspection under good lighting of all parts of the instruments should be performed to check for visible soiling, damage or wear. Particular attention should be paid to: • Soil traps and recessed features such as mating surfaces, holes, slots and grooves • Mating devices should be checked for correct assembly Discard and replace any instruments that are damaged or worn.
Packaging:	All instruments are to be packed following local protocol in accordance with relevant standards.
Sterilization:	Sterilization must follow a washer/disinfector process. If a washer/disinfector is not available, sterilization parameters must be followed. Packaging should ensure sterility of instruments until opened for use at the sterile field and permit removal of contents without contamination. The recommended sterilization parameters are a minimum of three minutes at a minimum temperature of 134°C. The three minutes is for exposure, it does not include ramp up times or dry cycle times needed. Always follow the instructions of the machine manufacturer. **Note: The final responsibility for validation of sterilization techniques and equipment lies directly with the healthcare facility. To ensure optimal processing, all cycles and methods should be validated for different sterilization chambers, wrapping methods and/or various load configurations.**
Storage Before use:	The shelf life is dependent on the sterile barrier employed, storage, environmental and handling conditions. A maximum shelf life for sterilized medical devices before use should be defined by the healthcare facility.
Warranty:	We confirm the raw materials and finished surgical instruments supplied by Swann-Morton Ltd comply with all relevant national/international standards. The instruments are in compliance with the EU Medical Device Directive as demonstrated by the CE logo either on the device and/or on its packaging.
Returning instruments to us:	Products returned to us after use must have a decontamination certificate which testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a delay of your enquiry being processed.
References:	• BS EN ISO 17664 Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilisable medical devices. • HTM 01-01 Management & decontamination of surgical instruments (medical devices) used in acute care. • BS EN ISO 15883: Parts 1 & 2: Washer-disinfectors
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