Swann-Morton LIMITED

Issue 8 December 2021

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

These reprocessing instructions are in accordance with BS EN ISO 17664-1 and apply to reusable metal surgical handles supplied by Swann-Morton Ltd and intended for reprocessing in health care facility settings.
These reprocessing instructions have been validated as being capable of preparing reusable Swann-Morton metal surgical handles for surgical use. It is the responsibility of the user/hospital/healthcare provider to ensure that reprocessing is performed using the appropriate equipment and materials and also 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 from these instructions should be evaluated for effectiveness to avoid potential adverse consequences.

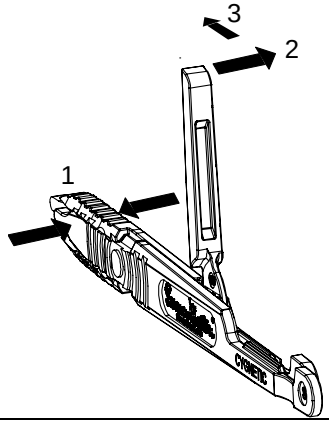
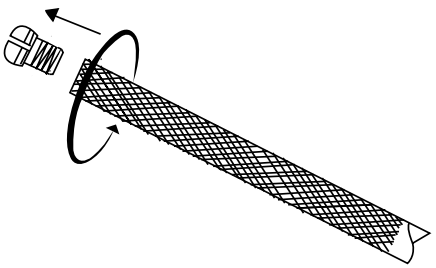
Intended Use CE 2797 UK CA MD	A reusable surgical metal handle intended to hold a surgical blade.
Warnings:	• These reusable handles are provided non-sterile and must be cleaned and sterilized in accordance with these instructions prior to use. • Personal protective equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated handles. When reprocessing medical devices always follow local Health & Safety procedures. • 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 handles. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluids and tissue debris to dry on used handles. • Metal brushes and scouring pads must not be used during manual cleaning. Only use soft bristle brushes to aid with manual cleaning. • Use of hard water should be avoided. Purified water should be used for final rinsing to prevent mineral deposits. • No part of the process is to exceed 140°C. • Some sensitive materials can be damaged by higher alkaline solutions (pH >10). • Instruments manufactured from different metals should be processed separately to avoid electrolytic action between the different metals. • Manual cleaning is not advised if an automatic washer/disinfector is available. • The use of the device for tasks other than those for which they are intended may result in failure or damage/breakage.
Limitations on Reprocessing	• Repeated processing according to these instructions has minimal effect upon metal surgical handles supplied by Swann-Morton Ltd. End of life for stainless steel surgical handles is generally determined by wear and damage incurred by the intended surgical use. • Non-foaming, neutral pH enzymatic and cleaning agents are recommended for processing Swann-Morton surgical handles.
Before Use:	Before each use and after cleaning and reprocessing, carefully inspect the critical, inaccessible areas and any moving parts for any damage, wear or non-functional parts. **DO NOT** use any damaged or defective handles.
Point of Use	• Do not allow blood and/or bodily fluids to dry on the handles; remove with a disposable wipe. • Reprocess as soon as reasonably practicable following use, (within 60 minutes is recommended). If they cannot be reprocessed immediately, use an enzymatic cleaner, (prepared according to the manufacturer), to help prevent any soiling from drying, paying particular attention to any joints, slots, holes and grooves.
Containment & Transportation	• Used handles must be transported to the decontamination area for reprocessing in closed or covered containers to prevent unnecessary contamination risk.
Step1 Preparation for Cleaning	• Ensure that any hinged parts are lifted and cleaned under and around. Instruments having more than one part or piece, or any removable parts, must be disassembled to expose all surfaces to the cleaning process. Retain all parts to facilitate reassembly. • 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.

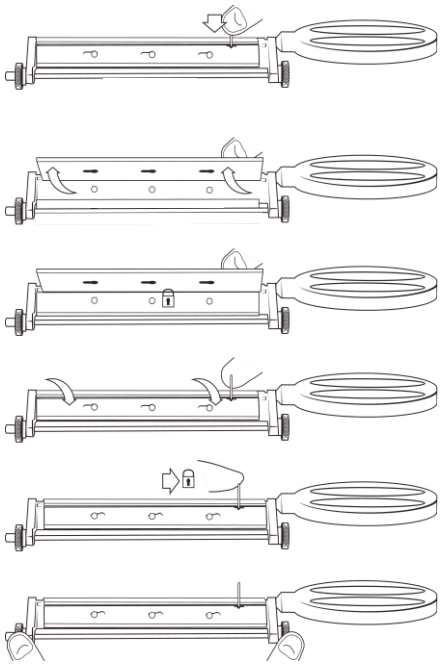
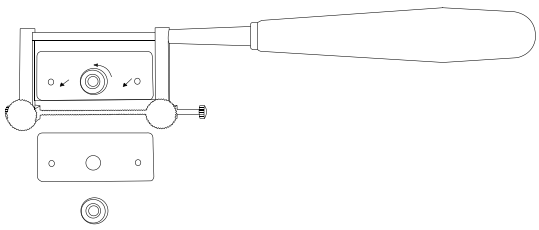
	• Remove any gross contaminants with a steady stream of lukewarm water (below 43°C.) Rinse each instrument thoroughly, do not use saline or chlorinated solutions. Give special attention to any joints, slots, holes and grooves.
Step 2 Manual Cleaning:	**Procedure** • Using Prolystica 2X Alkaline Detergent 2ml/L, wash using cold water for a minimum of 4 minutes as follows:- • 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.**
Step 3 Automated Cleaning:	Instruments having more than one part or piece, or any removable parts, must be disassembled to expose all surfaces to the cleaning process. Retain all parts to facilitate reassembly. Load instruments carefully so that slots, holes and grooves in the handle can drain. Ensure any hinged parts are loaded in their open position to allow cleaning to reach/penetrate all surfaces. Take care not to overload wash baskets. **Equipment Required** • Validated Steris Washer/Disinfector • Prolystica 2X Alkaline Detergent 2ml/L at a PH of approximately 12.0 **Procedure** • Load the instruments. • The following has been validated using the above washer disinfectant cycle to include: Wash 1 for15 seconds at 65.5°C Wash 2 for 6 minutes at 65°C Cool Rinse for 15 seconds in cold water Thermal Rinse for 1 minute, pure water at 90°C Drying for 20 minutes set on high temperature
Step 4 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.
Step 5 Packaging:	All instruments are to be packed following local protocol in accordance with relevant standards or decontamination manual process. Packaging should ensure sterility of instruments until opened for use at the sterile field and permit removal of contents without contamination.
Step 6 Sterilization:	Sterilization equipment used was a validated Getinge Steam Autoclave. 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. **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 Regulation 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 17664-1 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

Products:

Product Ref.	Material	Brief Description	Fitment Size in accordance with BS EN 27740/ISO 7740	Disassembly instructions
0905	Stainless Steel	No. 5B	No. 3 fitment (small)	N/A
0906	Stainless Steel	No. 6B	No. 4 fitment (large)	N/A
0907	Stainless Steel	No. 7	No. 3 fitment (small)	N/A
0909	Stainless Steel	No. 9	No. 3 fitment (small)	N/A
0913	Stainless Steel	No. 3L	No. 3 fitment (small)	N/A
0914	Stainless Steel	No. 4L	No. 4 fitment (large)	N/A
0933	Stainless Steel	No. 3 graduated	No. 3 fitment (small)	N/A
0934	Stainless Steel	No.4 graduated	No. 4 fitment (large)	N/A
0923	Stainless Steel	No. B3	No. 3 fitment (small)	N/A
5398	Stainless Steel	Cygnetic	N/A Fits Cygnetic Blades Only	
6051	Stainless Steel	SF1	N/A Fits Fine Blades Only	
6052	Stainless Steel	SF2	N/A Fits Fine Blades Only	
6053	Stainless Steel	SF3	N/A Fits Fine Blades Only	
6054	Stainless Steel	SF4	N/A Fits Fine Blades Only	
6061	Stainless Steel	SF13	N/A Fits Fine Blades Only	
6062	Stainless Steel	SF23	N/A Fits Fine Blades Only	
6055	Stainless Steel	2 Piece Long	N/A Fits Fine Blades Only	
6056	Stainless Steel	3 Piece Long	N/A Fits Fine Blades Only	
5810	Stainless Steel	PD	N/A Fits PD Blades Only	

0639	Stainless Steel	Major	N/A Fits Major Blades Only	N/A
0640	Stainless Steel	Major Long	N/A Fits Major Blades Only	N/A
9901	Stainless Steel	Braithwaite	N/A Fits Braithwaite Blades	
9902	Stainless Steel	Cobbett	N/A Fits Cobbett Blades	
9903	Stainless Steel	Watson	N/A Fits Watson Blades	
9908	Stainless Steel	No Name Watson	N/A Fits Watson Blades	
9909	Stainless Steel	Left Handed Watson	N/A Fits Watson Blades	
9911	Stainless Steel & Acetal	Silvers	N/A Fits Silvers Blades	
9912	Stainless Steel	Silvers	N/A Fits Silvers Blades	

Measurements:	Any measurements shown on the graduated handles are to be used as an indication only and NOT for valid measurement.
Serious incidents:	Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.
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