

SALSHA REUSABLE STANDARD LIGHT LARYNGOSCOPE BLADES & HANDLES CLEANING & STERILIZATION INSTRUCTIONS

Device(s): The following instructions are for all SALSHA reusable Standard Laryngoscope Blades & Handles.

GENERAL INSTRUCTIONS

Cleaning & Handling	Laryngoscope Blades & Handles should be handled and processed by qualified personnel who are specially trained & knowledgeable about hospital hygiene and sterilization technology. All reusable devices are supplied non-sterile and should be cleaned and sterilized before first use and after each subsequent use.
Warnings	<ul style="list-style-type: none"> • Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used. Whenever possible, avoid use of mineral acids and harsh, abrasive agents. • Do not use chemical sterilants with caustic ingredients. Do not use garment or surface disinfectants. • Do not autoclave with sub-standard stainless steel surgical instruments as this may cause a reaction and lead to rust or decolorization. • No part of the process shall exceed 140°C / 284°F. • Ultrasonic cleaning is not permitted, as this will cause damage to the plastic components in the blades & handles. • Do not flash autoclave blades or handles as this will invalidate the warranty. • Handle with care in accord with the facility’s protocol, determined by the user. Always wear protective clothing and face visors or goggles when reprocessing medical devices. • Always remove batteries from the handles before reprocessing.
Limitations on Reprocessing	<ul style="list-style-type: none"> • Repeated autoclaving, especially for extended periods, can affect the bulb and lead to a reduction in the light transmission from the blade or complete failure. • These reprocessing instructions will have a minimal effect on all other components of the blade and handle.

REPROCESSING INSTRUCTIONS

Point of Use	<ul style="list-style-type: none"> • Immediately after use, instruments should be rinsed. If not possible, soiled blades should be placed in a holding solution (combined disinfectant/enzyme solution) to prevent coagulation.
Preparation for Decontamination	<ul style="list-style-type: none"> • Following use, reprocess all blades and handles as soon as reasonably possible.
Cleaning: Automated	<ul style="list-style-type: none"> • Use only validated washer-disinfector machines, following manufacturer instructions for use and recommended cycles, and cleaning agents. • Load blades and handles carefully, ensuring bulbs are not damaged during the loading process.

SALSHA Laryngoscope Blades and Handles have been validated in the following washer-disinfector machine cycle:

Pre-Wash at 14.4°C / 58°F for 4min

Wash at 65.9°C / 150°F for 9min

Rinse at 58.8°C / 137.8°F for 16 sec.

Thermal at 92° C / 197.6°F for 6min, 14sec

Dry at 98.8°C / 209.8°F for 25min.

Cleaning: Manual	<ul style="list-style-type: none"> If an automatic washer-disinfector machine is not available, manual cleaning is acceptable. Use a sink dedicated for instrument cleaning (not used for hand washing). Rinse excess soil from blades and handles in water (temp <35°C/ <95°F). Keeping the blades submerged in a cleaning agent, apply solution with a soft brush to all surfaces, paying particular attention to the underside of the blade and block. Always brush away from the body. Do not use a wire brush. Take great care not to brush against the bulb in the blade as to avoid scratching or damage. Thoroughly rinse all parts of the blade(s) in clean water. Carefully hand dry or use a drying cabinet. <p>NOTE: When manual cleaning is used it may not be possible to disinfect the device prior to further handling.</p>
Cleaning Inspection	<ul style="list-style-type: none"> After cleaning, check all surfaces for complete removal of soil. If any soil is still visible, return the device for repeat decontamination.
Inspection & Functionality	<ul style="list-style-type: none"> Visually inspect all blades and bulbs for damage and wear. Damaged or deteriorated products should be removed for repair or replacement.
Packaging	<ul style="list-style-type: none"> All blades and handles should be packed following facility protocol in accordance with ANSI/AAMI ST79:2006 and ANSI/AAMI ST79/A1:2008 standards.
Sterilization	<ul style="list-style-type: none"> Ensure blades and handles are dry before sterilization. If the blades cannot be dried prior to sterilization, then use distilled/de-ionized water in the final rinse stage of cleaning. Use a validated autoclave according to the sterilizer manufacturer's instructions, operating within the following parameters: 134-137°C/ 273-279°F, for a minimum holding time of 3 minutes. SALSHA Laryngoscope blades and handles have been validated in the following cycle: 134°C/273°F for 3 minutes, 10 seconds. Normal dry time 5 min. Extended dry time 15 min. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer manufacturer's stated maximum load limit is not exceeded.
Storage	<ul style="list-style-type: none"> Ensure blades and handles are dry before storage. Store in dry, clean conditions at an ambient room temperature.
Additional Information	<ul style="list-style-type: none"> Other forms of cleaning (such as alkaline and neutral) and sterilization (such as Ethylene Oxide up to 65°C/ 149°F for anesthetic devices) are permitted. However always follow the instructions for use as issued by the manufacturer. If in any doubt, consult with the manufacturer for the suitability of any process used. Follow cleaning and sterilization guidelines as per ANSI/AAMI ST79:2006 and ANSI/AAMI ST79/A1:2008.

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, achieves the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the user from the instructions provided, must be properly evaluated for effectiveness and potential adverse consequences.