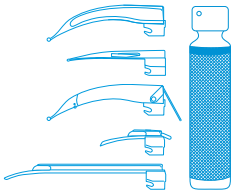
120mm

160mm

flexicare®
TOTAL QUALITY - TOTAL CARE

REUSABLE LARYNGOSCOPE HANDLES AND BLADES



INSTRUCTIONS AND GUIDELINES FOR REPROCESSING FLEXICARE REUSABLE LARYNGOSCOPE HANDLES & BLADES:

Reprocessing should be undertaken by specialists with the necessary training and understanding of the process and equipment. These instructions are intended for use by these specialists and should be read in conjunction with all other relevant manufacturer's instructions, hospital policies, local guidelines/ regulations.

Immediately after use and before cleaning, remove the batteries and light source from the laryngoscope.

To remove from a conventional blade, unscrew the bulb from the fitting.

To remove the light source from a fibre optic handle, unscrew the knurled housing from the underside of the blade block.

Remove the blade from the handle and immerse both soiled components in a holding solution of disinfectant/enzyme solution.

Precautions

- Use pre-approved packaging designed for use with your sterilisation equipment.
- Follow all manufacturer's instructions.
- Prior to sterilisation, ensure the handle and blade is completely dry and visually clean. If contaminants are visible, repeat the decontamination/ cleaning procedure.
- Always wear appropriate PPE and handle devices and materials with care.
- If the device will be unused for prolonged periods, remove the batteries prior to storing.
- Always check the condition of the batteries by switching on the light source before commencing clinical procedure.

Warnings and Cautions

- Avoid using mineral acids and abrasive agents.
- DO NOT use sterilants with caustic ingredients, such as surgical scrub solutions, peroxide solutions, bleaches, or povidone-iodine solutions.
- DO NOT sterilise along with sub-standard stainless steel instruments as this may cause severe damage.
- No part of the process should exceed 138°C.
- Ultrasonic cleaning and flash autoclaving is not recommended.

Decontamination/Cleaning

Clean the removed light source using a cloth dampened with 70% isopropyl alcohol.

Disassembled handles and blades should be decontaminated as soon as possible after use by either:

A. Automated washer/disinfector:
Use only validated washer/disinfectors and cleaning agents. Follow the washer/ disinfector manufacturer's instructions for use, warning and recommended cycles.

B. Manual processing:
Use dedicated equipment and Personal Protective Equipment (PPE).
Fully submerge the laryngoscope handle/ blade in a compatible dilute detergent solution. Brush/scrub/wipe all surfaces to remove all visual contamination.
Remove from the solution and allow to drain.
Rinse thoroughly with clean water and allow to drain before drying.

Sterilisation

Flexicare recommends reprocessing laryngoscopes blades and handles through sterilisation. Follow instructions and warnings as issued by manufacturers of any decontaminates, disinfectants and cleaning agents used.

Please adhere to the following laryngoscope autoclave parameters:

Temp: 134 -138°C, Pressure: 2.25bar, Cycle time: 3 minutes

Other forms of sterilisation may be available such as an Orthophthalaldehyde (OPA) soak and Ethylene Oxide (≤65°C). These are suitable only if used in accordance with the manufacturer's instructions. If in doubt, consult the manufacturer.

SYMBOLS GLOSSARY

Catalogue Number

Batch Code

Product conforms with Directive 93/42/EEC

Consult Instructions for Use

Caution

Non-sterile

Product not made with Phthalate DEHP

Product not made with natural rubber latex

Manufactured by

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Before Next Use

After reprocessing, refit the light source and reassemble the fibre optic handle/ refit the bulb into a conventional blade. To test function, fit the batteries and connect blade to the handle. Pull blade to open position. If unit fails to illuminate or light flickers, check the security of the bulb and batteries.

Batteries

Refer to the battery manufacturer's guidelines on use and disposal of batteries.

The following batteries are recommended:

PART NUMBER	BATTERY TYPE
040-021U/011U	2x C
040-022U/012U	2x AA
040-023U/013U	2x AA
040-813U	2x C
040-814U	2x AA
040-815U	1x CR 123 (Li-on)
040-811U/821U	2x C
040-812U/822U	2x AA
040-823U/824U	2x AA

WARRANTY STATEMENT

Flexicare Medical Limited warrants that the product purchased meets the labelled specifications of the product and will be free from defects in materials and workmanship that occur within five (5) years from the date of purchase. Consumables, such as bulbs and batteries, are excluded from the warranty.

This warranty does not cover damage caused by:

1. Handling during shipping.
2. Use or maintenance contrary to labelling and instructions, including but not limited to incorrect disassembly, reprocessing and reassembly.
3. Alteration or repair by anyone not authorised by Flexicare Medical Limited.

Abuse, misuse or accidental damage

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period described above, Flexicare Medical Limited will, at its discretion, repair or replace the defective product free of charge.

Written authorisation must be obtained from Flexicare Medical Limited to return the product prior to sending it with carriage paid to Flexicare Medical Limited's designated agent.

This warranty is in lieu of all other warranties, express or implied, including but not limited to, the implied warranties of merchantability and fitness for a particular purpose. Flexicare Medical Limited's obligation under this warranty is limited to repair or replacement of products containing a defect. Flexicare Medical Limited is not responsible for any indirect or consequential damages resulting from a product defect covered by the warranty.

This warranty shall be governed by and construed in accordance with Flexicare Medical Limited's Terms and Conditions.

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