

## CLEANING INSTRUCTIONS

The following instructions are specific to our **REUSABLE** laryngoscope blades and handles. These instructions are intended for use only by authorized personnel with the required knowledge and training. **PRODUCTS MARKED “☒ / DISPOSABLE / SINGLE PATIENT USE / DO NOT AUTOCLAVE” SHOULD NOT BE REPROCESSED.**

## WARNINGS

1. Follow instructions and warnings as issued by the manufacturer of any decontaminants, disinfectants and cleaning agents used. Wherever possible avoid use of mineral acids and harsh, abrasive agents.
2. Do not use chemical sterilants with caustic ingredients such as - surgical scrub solution, povidone-iodine solution, bleach, peroxide solution, virox 3 and sporox. Do not use garment or surface disinfectants.
3. Do not autoclave with sub standard stainless steel surgical instrument as this may cause a reaction and lead to rust or discoloration.
4. Ultrasonic and plasma cleaning are not permitted, as this will cause damage to the fiber optic light guide and lamp.
5. Do not flash autoclave or dry heat blade or handle, this will invalidate the warranty .
6. Our laryngoscopes are suitable for sterilization by Ethylene Oxide (ETO), Sterris and Sterrad sterilization procedures.

**When reprocessing medical devices, handle with care, wearing protective clothing and face visors or goggles. BATTERIES AND LAMPS MUST BE REMOVED FROM THE HANDLE / BLADE PRIOR TO CLEANING.**

**LIMITATIONS ON REPROCESSING:** Repeated autoclaving, especially for extended periods will affect the fiber optic light guide ends which may lead to a reduction in light output.

**FROM POINT OF USE:** If possible, soiled blades should be placed in a holding solution (combined disinfectant / enzyme solution) immediately after use and prior to cleaning.

**PREPARATION FOR DECONTAMINATION:** Reprocess all blades as soon as it is reasonably practical following use. We recommend disassembling the fiber optic light guide from Modular blades for separate cleaning.

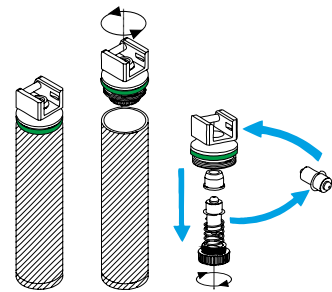
**CLEANING-AUTOMATED:** Use only validated washer-disinfector machines and cleaning agents, following the manufacturer's instruction for use, warnings and recommended cycles. Load blade and handle carefully, ensure the fiber optic light guides are not liable to damage during loading procedure. Bulbs should not be cleaned in these machines.

**CLEANING-MANUAL:** Use a sink dedicated for instrument cleaning (not used for hand washing), rinse excess soil from blades & handles (water temp <35°C) Keeping the blades submerged, with a brush, apply cleaning solution to all surfaces. Pay particular attention to underside of the blade and heel. Always brush away from the body. Do not use a wire brush. Take great care not to brush against the Fibre ends in the blades to avoid scratching or damage. Rinse blade thoroughly with clean water, so that the water reaches all parts of blade, then carefully hand dry or use a drying cabinet.

**DISINFECTION:** To disinfect Cidex® OPA or 2.4% Glutaraldehyde solution may be used. Always follow the manufacturers instructions. After application, dry with a clean cloth or filtered air.

**LAMP CLEANING:** Lamps should only be cleaned manually. Soak surgical grade cotton swab in decontaminant and apply to wipe off lamp gently. Repeat this procedure twice on every cleaning cycle. Carefully hand dry lamp before placing back in position.

## LAMP REMOVAL IN LED HANDLES



excessive force. Lamps should be placed back in their original housing securely.

**INSPECTION AND FUNCTION TESTING:** Visually inspect and check all lamps and fibre optic light guides for damage and wear. To check functionality, connect the laryngoscope blade to the handle and pull upward to the ON position. If the unit fails to light or flickers, check the lamp and component fittings battery.

**PACKAGING:** All blades and handle should be packed following local protocols.

**STORAGE:** Ensure blades and handles are dry before storage and stored one in dry, clean condition at an ambient room temperature.

**ADDITIONAL INFORMATION:** Other forms of cleaning (alkaline and neutral) and sterilization (Cidex OPA, Ethylene oxide Up to 65° C for anesthetic devices) are permitted. However, always follow the instructions for use as issued by the manufacturer and always consult with them if in any doubt over the suitability of any process used.

**It is the responsibility of the reprocessor to ensure that the reprocessing has actually been performed using appropriate equipment, materials and personnel and the desired results have been achieved. This requires validation and routine monitoring of the process. Likewise any deviation by reprocessor from the instruction provided, must be properly evaluated for effectiveness and potential adverse consequences.**

**The above listed sterilization guidelines, provided by manufacturer, are intended as suggestions only. They are based on procedures compatible with specific materials. Sterilization must be performed to approved hospital protocol. Manufacturer cannot guarantee that any of the recommended methods will guarantee sterility. This must be validated by the hospital and / or sterilization equipment manufacturer.**

## BATTERY INFORMATION :

Remove the screw cap to insert appropriate batteries into handle shaft. For medium handles use two 'C' size batteries, for small and stubby handles use two 'AA' size batteries. When inserting batteries the '+ve' terminal must be inserted into the tube first on both of the batteries so that the '-ve' terminal is facing the open end. For stubby handles - batteries should be inserted following the negative '-ve' and '+ve' terminals as shown on plastic battery housing provided in all stubby handles. Replace the base cap and ensure it is securely tightened.

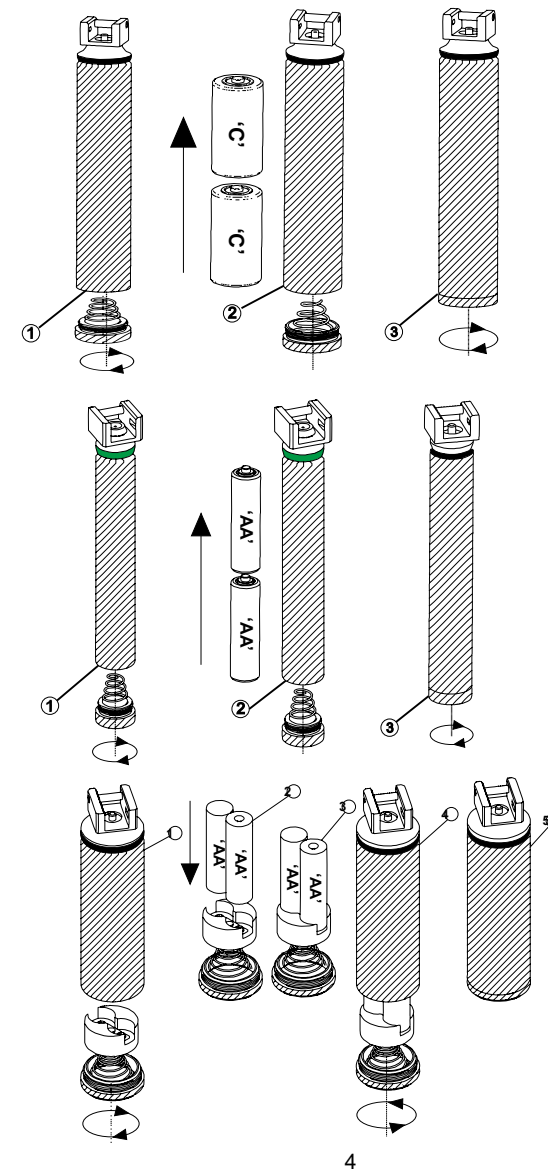
**Alkaline Batteries:** are commonly referred to as disposable or non-rechargeable batteries.

**Rechargeable Batteries:** typically include Nickel – Cadmium (Ni-Cad) or Lithium Ion Batteries.

**DO NOT AUTOCLAVE BATTERIES UNDER ANY CIRCUMSTANCES.**

**WE RECOMMEND USING ONLY “DURACELL” BATTERIES IN OUR LARYNGOSCOPE HANDLES.**

## BATTERY SIZE & INSTALLATION



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- Replace batteries with the size and type specified in your product's User Manual. Remove all batteries from the product at the same time.
- Charge rechargeable batteries with the instructions and correct charging equipment supplied with your product.
- **Store batteries in a cool, dry place at normal room temperature, Remove batteries from handles that will be stored unused for extended period of time.**
- Dispose off batteries according to the local laws and regulations of your region. Some batteries may be recycled, and may be accepted for disposal at your local recycling centre. If you are not able to identify the applicable rules in your area, please check the instructions of the battery manufacturer.
- Contact supplier if you have questions about proper handling of batteries. Batteries may present a risk of fire, explosion, or chemical burn if mistreated.
- Do not disassemble, puncture, modify, drop, throw, or cause other unnecessary shocks to batteries.
- Do not dispose off batteries in a fire or trash incinerator, or leave batteries in hot places such as an automobile under direct sunlight.
- Do not store batteries near an oven, stove, or other heat source.
- Do not connect batteries directly to an electrical source, such as a building outlet or automobile power-point.
- Do not place batteries into a microwave oven, or into any other high-pressure container.
- Do not immerse batteries in water or otherwise get them wet.
- Do not short circuit batteries; do not carry loose batteries in a pocket or purse with other metal objects, which may inadvertently cause a battery to short circuit.
- Do not use batteries, or charge rechargeable batteries, that appear to be leaking, discoloured & rusty, deformed; emit an odour; or are otherwise abnormal.
- Do not touch leaking batteries directly; wear protective material to remove the batteries and dispose off them properly immediately.
- Do not mix old/used with new batteries, or install used batteries in other equipment.
- Do not charge non-rechargeable batteries, or use unspecified charging instructions or equipment for rechargeable batteries.
- Do not continue to charge batteries beyond the specified time.
- Do not give batteries to young children, or store batteries where children may access them.
- Do not put batteries in mouth. If swallowed please contact physician or local poison control centre immediately.

## Warning

**Power outputs from some rechargeable batteries can fall rapidly during use, resulting in rapid failure of illumination.**

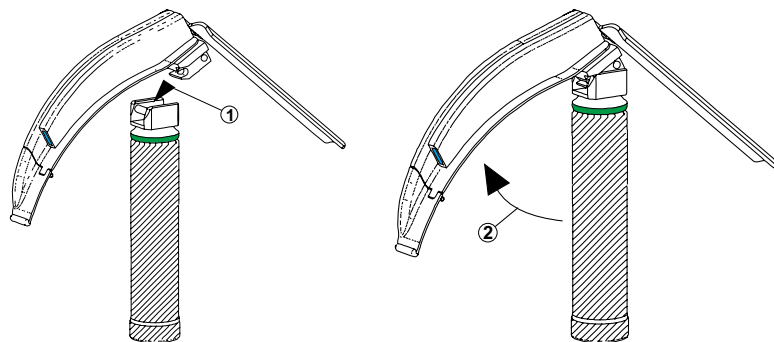
**Recycling is the best option from both an economic and environmental standpoint for most batteries. Check with companies to make sure that they will take back old batteries when new ones are bought. If batteries cannot be recycled (with the exception of alkaline batteries), make sure they are tagged for collection by designated personal.**

**Scope Medical Devices Pvt. Ltd.**

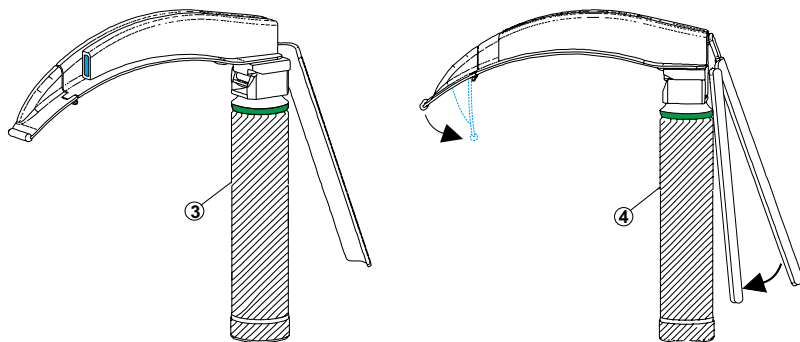
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## FLEXION BLADE HANDLE ENGAGEMENT

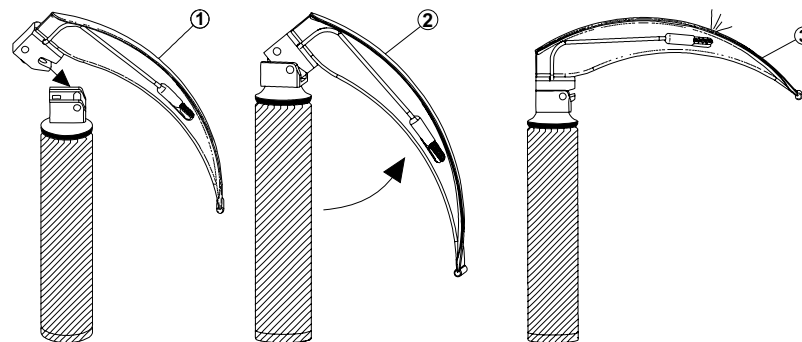


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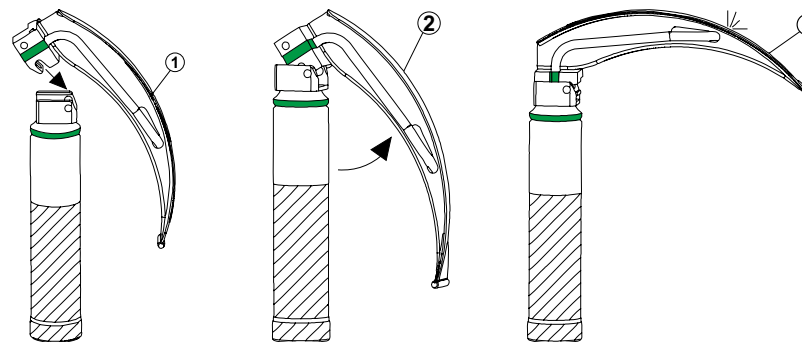


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## BLADE HANDLE ENGAGEMENT



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## WARRANTY STATEMENT

Our Laryngoscope products and parts are made from medical grade material/alloys and warranted to be of good quality and free from manufacturing defects in material and workmanship for specified period from week of manufacture, as it appears marked on the product. (i.e. LOT 0708) – means manufactured in 07 week of year 2008.

Replacement product will be provided without charge for any of our product not meeting this warranty, subject to the following terms and exceptions :

- ➔ **Integrated / Modular fibre optic blades & light guides, Flexion Blades, Conventional Blades, all Fibre Optic Handles and Conventional Handles** covering all sizes, are warranted to perform for a period of 24 months from week of manufacture as it appears etched in the form of LOT number.
- ➔ **MR Conditional** battery packs are warranted by the manufacturer as mentioned on battery packs.
- ➔ **All Disposable Laryngoscope Blades and Handles** are warranted for a period of 18 months from week of manufacture as it appears on the package.

All of the above warranties are conditional to the product being used, cared for, handled, cleaned, disinfected and / or sterilized according to the manufacturer's instructions as they appear in the **INSTRUCTIONS FOR USE** that accompany each of our product.

The above warranty does not cover products that have been deemed defective due to misuse, improper cleaning and handling, neglect, accident, improper storage or application, unauthorized repair or unreasonable damage.

We will have no obligation under this warranty for:

- ➔ Consumables such as Bulbs, LED's or Batteries,
- ➔ **Products labelled "ⓧ / Disposable / Single Patient Use / Do not Autoclave" where any attempt has been made to reprocess them.**
- ➔ Reusable products that have been reprocessed without following the appropriate use, care, repair and reprocessing guidelines and instructions provided by manufacturer in the Instructions or User Manual.

We reserves the right to inspect prior to repair or replacement any product that is deemed by the customer to be subject to manufacturing or materials defect. Our obligation shall be the warranty specifically defined in this statement and shall not be liable for any consequential, incidental, direct or indirect damages or loss arising out of the design, manufacture, sale, use or repair of the products.

Only use genuine accessories and lamps with our products. Alternatives may shorten product life and may invalidate product guarantee. Our sole obligation under this warranty is to repair or replace, at our discretion, any component (e.g. laryngoscope blade handle, battery, lamp), which is found upon our inspection to be, defective in material or workmanship during the period prescribed above. Such product will be repaired or replaced without charge to the user provided that, (1) prior written approval is acquired before returning any product, (2) freight to the manufactory is pre-paid and (3) any product returned must be decontaminated and sterilized and be accompanied with relevant documented evidence. This warranty does not apply to battery or bulb depletion, wear or failure occurring as a result of any of the following:

Abuse, misuse, any alteration or modification made to the product without our express written consent, attempted disassembly, neglect, improper installation, or any other use inconsistent with the specification or warnings or recommended operating practices specific to the blade / handle, battery or bulb.

**THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES (EXCEPT OF TITLE) EXPRESSED, IMPLIED, OR STATUTORY INCLUDING ANY WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE.**

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## INSTRUCTIONS FOR USE

Thank you for your purchase. Our Laryngoscopes are **ISO:7376:2009 compatible and manufactured with great care in a US-FDA Audited, ISO:9001:2015 and 13485:2016 certified facility and are designed for a prolonged, trouble free life.**



### INTENDED USE

Laryngoscopes are medical devices and should only be used by authorized personnel, who have received adequate training in tracheal intubation.

**Use only MR conditional Laryngoscopes in MRI environment.**

It is the users responsibility to read and understand these instructions prior to use of this product and comply with the medical waste disposal guidelines and federal laws which are applicable.

**Note:** Great care must be taken when holding these devices. Do not drop or allow to come into direct contact with sharp objects that would otherwise damage the product. After autoclaving, the product should be allowed to slowly cool. Rapid cooling may result in damage to the product or reduced product life. United States "Centre for Disease Control & Prevention" classified Laryngoscopes as "Semi-Critical" items ( items that directly or indirectly contact patient mucous membrane of the respiratory tract ) they should be sterilized or subject to high level of disinfection before reuse.

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On October 24, 2011 Joint Commission issued a new standard related FAQ addressing the processing & storage of Laryngoscope Blades. As per "AORN" the Joint Commission surveyors / auditors will evaluate processes related to Laryngoscope blades cleaning to ensure they are safe for use on next patient – this include checking that Laryngoscope are processed properly either by sterilization or high level of disinfection, and packed and stored in such a way that would prevent decontamination.

### PRE-USE CHECKS:

Check all blades and handles for flaws or sharp edges. Attach blade to handle and switch ON to check light intensity. If low light intensity or flickering is observed, replace handle batteries. Ensure light is bright and steady. In the event of pre-use check failure, return defective device to supplier for further inspection.

**HANDLE:** Our fiber optic handles are Greenspec compliant and have a lamp located in head harness which is further fitted with an automatic ON – OFF mechanism. Conventional light laryngoscope handles have a metal contact pin in the center of head harness to perform as an automatic ON – OFF.

**BLADE:** Conventional light laryngoscope blade has a metal casing LED lamp near its distal end. Modular F/O blade has a detachable metal F/O light tube on blades, which is secured into green plastic block with grub screw onto blade heel. Integrated F/O blade has its fibre optic channel completely sealed into the blade itself. This has no removable part and is very ideal from cleaning point of view.

**LAMP:** Great care should be taken to ensure direct contact with the lamp glass is avoided with the exception of an appropriate laryngoscope blade. Only use genuine lamps with these laryngoscopes. Allow lamps to cool before replacing.

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