

EN

INSTRUCTIONS FOR USE & REPROCESSING
Reusable Laryngoscope Blades and Handles

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Reusable Laryngoscope Blades and Handles
Device(s)

1	Green System Reusable Laryngoscope Blade with integrated Light Guide, Solid Stainless Steel Construction (MacIntosh, Foregger-Wisconsin, Miller & Flexible Tip)
2	Green System Reusable Laryngoscope Blade with interchangeable Light Guide, Solid Stainless Steel Construction (MacIntosh, Foregger-Wisconsin, Miller & Flexible Tip)
3	Green System Reusable Laryngoscope Stainless Steel Handle, with high power LED lamp (Medium, Small & Stubby)
4	Green System Reusable Laryngoscope Stainless Steel Handle, with Xenon LED lamp (Medium, Small & Stubby)
5	Conventional Reusable Laryngoscope Blade with Warm Light Lamp, Solid Stainless Steel Construction (MacIntosh, Foregger-Wisconsin, Miller & Flexible Tip)
6	Conventional Reusable Laryngoscope Handle, Stainless Steel Construction (Medium, Small, Stubby & Large)

Intended Use

Starkling Laryngoscope is a two-part, hand held device consisting of a handle that contains batteries and a detachable blade. Laryngoscopes are designed to provide illumination within the larynx during the process of performing intubations. This instruction book covers both standard and fiberoptic type laryngoscopes.

Contraindications
The following are only relative contraindication to tracheal intubation

- Severe airway trauma or obstruction that does not permit safe passage of an endotracheal tube.
- Cervical spine injury, in which the need for complete immobilization of the cervical spine makes endotracheal intubation difficult.

Warnings

A warning statement in this manual identifies a condition or practice which, if not corrected or discontinued immediately could lead to patient injury, illness, or death.

- Please observe laws (federal law in USA) which restricts this device to sale by or on the order of a physician or licensed healthcare practitioner.
- Only trained personnel should use a laryngoscope for intubation.
- Conventional blades & handles and green system blades & handles are not interchangeable with each other.
- Lamp may be come hot during use (risk of burn).
- Remove batteries when not in use.
- Stop using a handle if it becomes hot (and may or may not function).

Cautions

- Ensure that the product is operated and used under assistance of the person

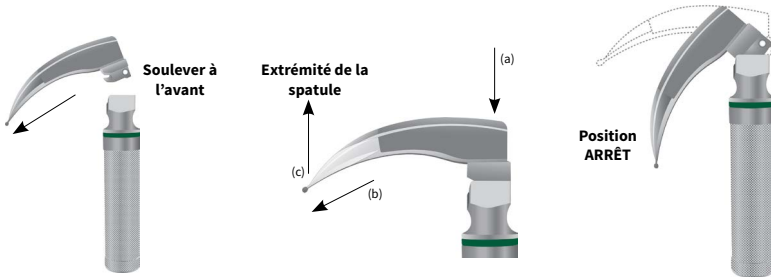
- Before using the product take off the protected polybag.
- Do not use the product if it is damaged or defective.
- Make sure that excessive force is not placed on this product. Excessive force can result in failure.
- Starkling recommends that spare lamps, batteries, and replacement parts always be available for emergency use.
- Be sure lamp's glass envelope is clean and free of any fingerprints after assembly. If necessary, the glass may be cleaned with a soft cloth or cotton ball moistened in alcohol.
- Halogen lamps are pressurized to provide maximum efficiency/illumination. Protect lamp's glass against abrasion and scratches. Dispose of lamps with care.
- Before using the laryngoscope handle with LED, ensure that the batteries are inserted with correct polarity.

Instructions
Before Use

- Use only with Starkling handles & blades.
- Carefully inspect device for burrs, sharp edges, or other visually discernible defects.
- Ensure that spare blades and handles are always available in case of failure or emergency.

Positioning & Mounting of Blade to Handle

1. Attach selected blade onto properly operational handle by placing "hook" on blade-base underneath bar on handle as shown. (a)
2. Apply downward/forward pressure to seat securely. (b)
3. Lift the front end of blade until it clicks and locks under the bar. (c)
4. Verify the blade is lit properly.
5. Reverse the above instructions to remove the blade.



with the requisite training, knowledge or experience.

- Read, follow and keep the instructions for use.
- Use the product only in accordance with its intended use, (see intended use).
- Prior to use, visually check the product for bent, broken, cracked or missing component(s).

Note: Incorrectly mounting the blade may result in damage to blade or malfunction of device.

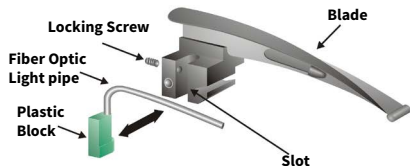
Maintenance Instructions
Laryngoscope Blades

Laryngoscope blades are produced from enduring stainless steel. To ensure maximum life and performance the following instructions should be adhered to.

Fiber Optic Light Guide Replacement

(Green-System Interchangeable Tube Type Blades)

1. Remove locking screw by rotating counterclockwise with the appropriate hexagonal screwdriver.
2. For replacement or cleaning, pull light guide & plastic block away from base of laryngoscope blade and slide distal end of guide out of blade.
3. Push new or cleaned light guide with plastic block into the slot and replace locking screw.
4. Rotate locking screw clockwise until secure.



remove the batteries before storage.

Accessories / Replacement Parts

- Vacuum Frosted Lamp (for conventional blades)
- LED Cartridge Assembly (for Green-System LED handles)
- Xenon Lamp (for Green-System Xenon handles)
- Light Guide Tube (for interchangeable blades)
- Plastic Cases (for Sets)



Lamp Replacement (Conventional Blades)

For correct illumination, alignment, and assurance of watertight seal during immersion/autoclave, we recommend using only Starkling replacement lamps for conventional blades.

1. Remove the lamp collet from the cartridge (if not fixed in the top).
2. To remove lamp on conventional blades, grip lamp collar and rotate lamp counterclockwise until free.
3. Replace the lamp with a new Starkling lamp.
4. Verify that lamp is sufficiently tightened before use.

Laryngoscope Handles

Lamp Replacement (Xenon Lamp Handle)

1. Unscrew the top from the handle.
2. Unscrew the cartridge from the top.
3. The lamp is exposed.
4. Replace the existing lamp with a new one.
5. Screw in the cartridge and top before using.



CAUTION Xenon lamps are pressurized to provide maximum efficiency and illumination. Protect lamp's glass against abrasion and scratches. Dispose of lamp with care.

LED Cartridge Replacement

1. Unscrew the top from the handle.
2. Unscrew the LED cartridge from the top.
3. Replace the existing LED cartridge with a new one.
4. Screw in the LED cartridge and top before using.



CAUTION Be sure lamp's/LED's glass envelope is clean and free of any fingerprints after assembly. If necessary, the glass may be cleaned with a soft cloth or cotton ball moistened in alcohol.

Battery Replacement

1. Unscrew bottom cap carefully and remove batteries.
CAUTION If you see liquid coming out of batteries or inside the handle. Try to clean inside the handle with a cloth. If handle is visibly damaged, stop and do not use further.
2. Replace with appropriate size batteries and re-screw bottom cap tightly. Alkaline batteries should be used for maximum performance. However ordinary carbon-zinc batteries may also be used.
3. If handle is not intended to be used for a month or longer time, kindly



Reprocessing, Cleaning and Sterilization

Point of use

The sterilization guidelines included in this instruction booklet, are intended as procedures compatible with specific materials. Sterilization must be performed to approved hospital protocol. Starkling, cannot guarantee that any of the recommended methods will guarantee sterility. This must be validated by the hospital and / or sterilization equipment manufacturer.

- Infection hazard for patients and/or users due to reuse without sterilization.
- Risk of injury, illness or death due to contamination.
- Laryngoscopes must be sterilized prior to every use. See sterilization instructions
- Do not soak laryngoscope in hot water (> 40°C) or alcohol to avoid coagulation of mucus, blood or other body fluids
- Do not exceed temperature of 134°C & pressure of 28 p.s.i.
- Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents to remove soil as these may damage the product and lead to corrosion.
- Ensure that LED/Xenon unit and battery holder are removed prior to reprocessing.

- Remove surface contamination with a disposable cloth / paper towel. It is recommended to reprocess the products as soon as possible after they have been used.
- Directly after use, they can be disinfected by hand in order to reduce the risk of infection for the user. Here, the products are placed in a disinfection solution. Make sure that the products are fully immersed in the disinfection solution, and that no air bubbles are formed. Follow the instructions of the manufacturer of the disinfection solution.

Ultrasonic cleaning is not recommended for laryngoscopes.

- In conventional blades, lamp has to be screwed tightly completely before cleaning and sterilization.

Preparation for cleaning

Laryngoscope Blades Conventional (Reusable)

In conventional blades, lamp has to be screwed in tightly before cleaning and sterilization. Conventional Blades are cleaned & sterilized with lamp attached/affixed.

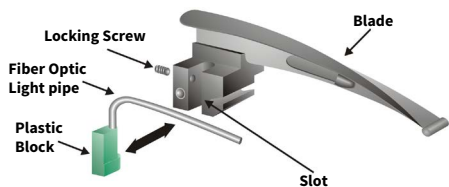
Laryngoscope Integrated Blades Green System (Reusable)

Disassembly not required for these blades.

Laryngoscope Interchangeable Blades Green System (Reusable)

- To ensure appropriate cleaning, remove interchangeable light guide.
- Clean / Sterilize interchangeable light guide separately from blade.

- Loose a locking screw by rotating counterclockwise with a screwdriver.
- Pull light guide & plastic block away from base of laryngoscope blade and slide distal end of guide out of blade.



Thermal disinfection can be achieved by exposure to hot water steam when a proven program for thermal disinfection is used (minimum of 3 min. at 134 °C to achieve the A value of > 3,000) if possible

Conventional Laryngoscope Battery Handles

Remove the batteries and disassemble the bottom cap.



2. Chemical disinfection
3. Thermal and chemical disinfection

Green System (Fiber Optic) Laryngoscope Battery Handles (with LED or with Xenon Lamp)

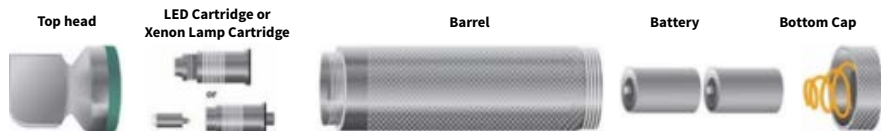
The Green System (Fiber Optic) handle consists of 2 sections; the main handle and the LED cartridge or Xenon lamp cartridge assembly. The LED cartridge assembly/Xenon lamp cartridge assembly and batteries must be removed prior to cleaning and Disinfection/Sterilization.

Lamp glass and LED cartridge can be cleaned with a soft cloth or cotton ball

ISO 15883-4 standard defines the temperature (usually < 65°C), chemical concentration and time to achieve disinfection.

Rinsing

Rinsing should be done in a way, which reduces the concentration of process chemicals on the load to a level not exceeding that specified by the manufacturer, or supplier, of the process chemical(s) as safe in the context of the



moistened in alcohol. **Do not autoclave the lamp and LED cartridge.**

intended use of the load.

Cleaning, Disinfection & Drying

Pre-Cleaning

- General contamination must be removed from the product directly after use within maximum of 2 hours of use.
- Use running water (<40°C) or disinfectant solution (aldehyde free).
- Only use a soft brush or a soft clean towel intended for this purpose to manually remove impurities. Never use metal brushes or steel wool.

Drying

(as and when appropriate)

Manual Cleaning, Disinfection & Drying

CAUTION Ultrasonic cleaning is not recommended for laryngoscopes.

Cleaning

A manual method, even when using an ultrasonic bath, should only be used, if mechanical/automated methods are unavailable, due to much lower effectiveness and reproducibility of manual method.

Automated Cleaning, Disinfection & Drying

An automated/mechanical method (RDG) of cleaning and disinfection / disinfectant should be used when possible to clean and disinfect instrument. Ensure the choice of type of Washer disinfection equipment according to ISO 15883.

The specified performance shall be achieved by an operation cycle under the control of an automatic controller, including:

- Cleaning
- Disinfection
- Rinsing
- Drying (when appropriate)

Prepare the cleaning bath with detergent like Enzol Enzym (Johnson & Johnson) using one ounce of product per gallon of water or two ounces of product per gallon of water for cleaning devices with dried-on matter or prepare according to the manufacturer's instructions.

- Rinse the products with cold tap water (<40°C) until all visible soil has been removed. If needed a soft bristle brush should be used to remove stuck dirt/soil.
- Place products in the prepared cleaning bath so that they are completely submerged. Observe residence time 2-3 minutes or according to the manufacturer's instructions.
- Clean the instrument in the bath manually using a soft brush. Brush all surfaces/channels and insides of instruments several times.
- Rinse the instrument under running tap water to remove the detergent.
- Inspect the instruments for good cleaning result and repeat procedure if necessary.

Instrument is now ready for high-level disinfection.

Sequence of operations

1. Place the instruments into equipment make sure that the instruments do not touch each other
2. Start program
3. When program ends remove the instruments from the equipment
4. Visually inspect the instruments and pack them as soon as possible after remove or after the additional drying (as needed)

Cleaning

1. Flushing stage

The inflowing water shall be maintained at temperature low enough to preclude the occurrence of protein coagulation (temperature higher than 45°C can cause protein coagulation during flushing stage causing cleaning problems).

2. Washing stage

Disinfection

1. Thermal disinfection

Disinfection

- Follow the germicidal wipe manufacturer's instructions to clean all exposed surfaces of the handle and end cap.
- If necessary, brush with the dry, soft-bristled brush and re-wipe to loosen/remove excessive visible soil.
- After all visible soil is removed, re-wipe to wet all surfaces and allow adequate contact time for disinfection as directed by the germicidal wipe manufacturer.
- Do not use bleach (sodium hypochlorite), Betadine, or peroxide. Solutions doing so may damage the instrument.
- Only use quaternary ammonium isopropanol based germicidal wipes.

Drying

- Products must be thoroughly dried, and all residual moisture must be removed before they are stored
- Use a soft, absorbent towel/cloth to dry external surfaces
- Compressed air may be used to aid the drying process.

Inspection & Functional Testing

- Prior to use, visually check the product for damage, deterioration and missing component(s).
- Laryngoscope blades and handles should always be tested (as outlined in "Directions of Use") after cleaning / disinfection / sterilization and prior to use. If the unit fails to light or flickers, check the lamp, batteries and the electrical contacts. Be sure adequate supplies of LED cartridge assembly spare lamp, batteries, and replacement parts are readily available.
- Visually check the insertion of batteries in LED type Laryngoscope handles with correct polarity.
- Do not use the product if it is damaged or defective.

Packaging

Packaging should be done in compliance with ISO 7153. A standard packaging material should be used. Ensure that the pack is large enough to contain the instrument without stressing on it. When used as intended, these instruments do not need an outer wrap or additional protection.

Always use protective caps for packaging / storage of clean instruments, where needed.

Sterilization

Laryngoscope Blade and handle must be processed in completely open position to allow sterilant contact of all surfaces

Steam Autoclave is appropriate with saturated steam with a fractionizing vacuum (EN ISO 17665)

Recommended temperature: 134 °C

Recommended pressure: 3 bar

Exposure Time: ≥ 5 min

Drying time: ≥ 15 min

NOTE:

- **Flash autoclaving and hot air sterilization should be avoided.** These procedures may damage the instruments.
- Securely tighten bulb in conventional blades prior to autoclave.
- Remove LED/Lamp Cartridge before autoclaving.

After sterilization, check the packaging of the sterilized products for damage. Check the sterilization indicators.

Note: Sterilization can only be maintained if the instruments remain packaged or wrapped, impermeable to microorganisms, following a validated sterilization.

Reassembly

Reverse the disassembly instructions to re-assemble the Green System Laryngoscope Blades and Laryngoscope Handles as outlined in "Preparation of Cleaning".

Storage

The instruments can be packed and stored as per the approved practices of hospitals. Laryngoscope blades and handles have to be stored under following listed conditions

- Stored in dry area.
- Between -20°C to 45°C and 10% - 95% relative humidity.

Protected from direct sunlight, moisture and excessive airflow.

Contamination & Transportation

No special requirements.

Limitations on Re-processing

Frequent re-treating has little effect on the product. The end of the product lifetime is usually determined by wear and damage from use. They are then to be disposed of according to hospital procedure. Do not use any damaged products.

Additional Information

When sterilizing multiple products in one autoclave cycle ensure that the sterilizer's maximum load is not exceeded.

Compatibility

Starkling Laryngoscopes conform to current ASTM F965, ISO 7376 standards. They are compatible with virtually all major brands of illumination hook on blades and handles. For easy visual identification, all green system models are clearly delineated by a green indicator on both handle and blade.

Disposal

Handle & Blade

It is the user's responsibility to ensure that the used product is disposed of in accordance with medical waste disposal guidelines where applicable.

Handle's Battery

Turn bottom lid of handle counter clockwise until the lid separates from the body of the handle. Remove the battery and dispose of properly.

Classification & Applicable Standards

- Class 1 (CE - MDD 93/42 EEC & FDA)
- ISO 7376 (Current)
- ASTM F965 (Current)

Symbols

Symbols may be used on some package labeling for easy identification.



Manufacturer

(Company responsible for a device marketed under its own name regardless of whether "manufactured for" or "manufactured by" the company.)



Catalog number



Expiry date



Lot number



Temperature limitation



Non-Sterile



Do not use if package is damaged



Latex Free



Keep dry



Caution see warnings or precautions



Federal (USA) law restricts this device to sale by or on the order of physician or practitioner



Do not Discard, Recycle. Contact the local city or town offices for instructions on proper disposal.



Type B Equipment: Indicates equipment providing a particular degree of protection against electric shock.



Consult instructions for use

These instructions provided above have been validated by the medical device manufacturer as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing is actually performed using equipment, materials and personnel in the processing facility to achieve the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

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