

INSTRUCTIONS FOR USE & CARE OF FIBER OPTIC GREEN SYSTEM REUSABLE LARYNGOSCOPE BLADES AND HANDLES

► DESCRIPTION

FIBER OPTIC GREEN SYSTEM REUSABLE LARYNGOSCOPES

- All blades in green system crafted from finest non-magnet stainless steel minimize the risk of contamination.
- Cool and brighter light with no chance of tissue burning during long intubation procedures.
- Superior quality of glass fiber optic gives maximum bright illumination to view the larynx of human body.
- Removable light guide can be autoclave separately, which makes long life of blade.
- Autoclaveable at 134° C 5 min, for 2000 - 3000 cycles at maximum light output.
- All blades and handles are made to comply with ISO 7376, allow compatibility with existing blades and handles.
- Complete range of handles also equipped with LED lamps.
- LED technology has longer additional life time with 50,000hrs and continuous 2hrs operating time.
- Brighter than Xenon lamp with 8,000 – 10,000 LUX transmission light at the tip of the blade.

► DESCRIPTION

LARYNGOSCOPE FIBER OPTIC BLADES

These blades are not delivered sterile; and consequently it is necessary to sterilize them properly before use. Laryngoscopes blade of the reusable variety for use with a Fiber Optic Green System. These instructions are intended for use only by persons with the required specialist knowledge and training.

LARYNGOSCOPE BATTERY HANDLES (REUSABLE)

These handles are not delivered sterile; and consequently it is necessary to sterilize them properly before use

- Diamond knurled barrel gives strong grip to the user.
- LED brighter illumination with 80,000 LUX.
- LED operating time over 50,000 hrs.
- 2 hrs operating time at maximum illumination.
- Viewing angle at 130 with colour temperature colour temperature 6500 K.
- Conforms to all Green System blades as per ISO 7376 standard.
- Simple change of batteries at the base of the handle.
- Crafted from high quality chrome plated brass.
- Battery usage is minimized due to the low power consumption.
- Fully autoclavable at 134° C for 5 minutes.

The reusable laryngoscope handle is an accessory used with compatible reusable laryngoscope blades which are used to examine and visualize a patient's airway and aid placement of a tracheal tube.

► INSPECTION AND FUNCTION TESTING

LARYNGOSCOPE BLADES

Reusable laryngoscopes blades are designed to be used for many procedures and endure many sterilization cycles. Before each sterilization cycle, visually inspect for damage and wear. An instrument should be considered at its end of use if it shows signs of deterioration, corrosion, discoloration, pitting, cracking, nicking of edges, or excessive deformation.

Visually inspect and check all Devices for damage; blade edges are free of nicks and light guide (Acrylic Tube / Fiber Optic tube) align correctly; locking mechanisms fasten securely and open easily without excessive force:

LARYNGOSCOPE HANDLES

Visually inspect and check all Devices for damage; edges are free from sharpness.

▲ **WARNING:** Discard any component that shows evidence of damage or deterioration.

1. Contact your specialist dealer for component replacement.
2. Reassemble batteries into handle.
3. Attach handle to a clean and disinfected test blade assembly in known working condition.

Verify that:

- Blade assembly engages and locks onto handle.
- Blade assembly deploys into its locked position on handle and lamp illuminates.
- Light output is satisfactory. If the lamp fails to light or output is low, check or replace the batteries.

► INTENDED PURPOSE

LARYNGOSCOPE BLADES

These reusable laryngoscope blades and handles are used to examine and visualize a patient's upper airway and aid placement of tracheal tube during intubations.

LARYNGOSCOPE HANDLES

These reusable laryngoscope blades and handles are used to examine and visualize a patient's upper airway and aid placement of tracheal tube during intubations.

► CONTRAINDICATIONS

- Diseases or injuries of cervical spine.
- Moderate or marked respiratory obstruction.
- Absolute contraindication to laryngoscopy would include patients who have supraglottic or glottic pathology. This type of pathology would not allow an endotracheal tube to be advanced successfully into the trachea or the placement of an endotracheal tube might cause further damage to the area. Patients with blunt trauma to the larynx area also would be excluded from direct laryngoscopy as this would further aggravate the injury. A patient with this injury would be more suited for surgical intervention such as cricothyrotomy for securing an airway.
- A relative contraindication to laryngoscopy includes difficulties in performing the procedure, such as patients with anatomy that does not allow successful laryngoscopy use, injuries to the area, or physiologic status that is not conducive to the procedure.

► INSTRUCTIONS

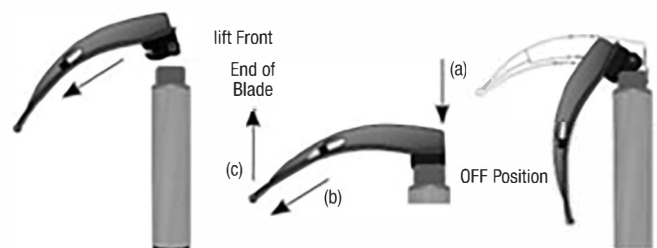
Before Use

Use only with Lifeguard Emergency Products brand handles and blades.

- Do not sterilize, reprocess, or reuse single-use 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.

► BLADE ENGAGEMENT

1. Engage the blade slot to the battery handle hook and push the blade by nondominant hand.
2. Apply sufficient force upward by using the dominant hand.
3. Now your laryngoscope unit is ready for use.
4. Apply the reverse procedure to disassemble blade and handle.
OR
1. Attach selected blade onto properly operational handle by placing "hook" on bladebase 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.



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

► BATTERY INSTALLATION

1. Unscrew the end cap of battery handle anti-clockwise.
2. Install alkaline batteries by aligning positive end upwards.
3. Close the end cap by screwing clockwise.

► 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



► 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.



► BATTERY REPLACEMENT

1. Unscrew bottom cap carefully and remove batteries.
2. Replace with appropriate size batteries and re-screw bottom cap tightly. Alkaline batteries should be used for maximum performance.
3. If handle is not intended to be used for a month or longer time, kindly remove the batteries before storage.

► REUSABLE GREEN SYSTEM (FIBER OPTIC) LARYNGOSCOPE BATTERY HANDLE (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 moistened in alcohol. Do not autoclave the lamp and LED cartridge.



► TRANSPORTATION, STORAGE, HANDLING, AND CARE

If the laryngoscope blades and handles are to be stored prior to use, transport it to where it is to be stored, using care to prevent re-contamination and damage prior to and during storage. The area should be clean and dry.

⚠ WARNINGS

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

- Lamp may become 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).
- Always remove the Bulb from blades while disinfecting and autoclaving the blade.
- Devices must be used for their specified purpose and incorrect use could damage the device and may cause injury to the patient as well.
- Our devices are designed for use by competent surgeons or trained medical staff, which have a good knowledge of their features and how they should be used. Any other use can compromise the safety of the user and the patient. It is the responsibility of the surgeon to choose the most suitable device for the intubation technique being performed, based on his experience and expertise.
- Never clean the laryngoscope with ultrasonic.
- Do not exceed temperature 134°C/270°F and pressure of 28psi during steam sterilization.
- Flash autoclaving and hot air sterilization are not recommended.
- Do not drop the blades otherwise bulb will break and in result light will not work.
- Consult cleaning and disinfecting agent manufacturer instructions for their proper preparation and use.
- High level disinfection and/or sterilization are not achieved by these methods.
- Discard any component that shows evidence of damage or deterioration.
- Do not modify this equipment. Any modification of this equipment may lead to patient injury. Any modification of this equipment voids the product warranty.
- Personnel shall follow their facility policies and procedures and wear

appropriate personal protective equipment when handling potentially contaminated equipment.

- Laryngoscope equipment is not suitable for use in intense magnetic fields.

⚠ All serious incidents related to the device should be reported to the manufacturer and to the competent authority of the Member State in which the user and/or the patient is established.

► CAUTIONS

Caution! Failure to follow these instructions may cause damage to this handle.

Caution! Do not immerse/soak handle, damage to handle may occur.

Caution! Repeated testing of this device prior to use may result in a shortened operational time, reducing the life of the product and possibly resulting in operational failure.

Caution! Ensure that the product is operated and used only under assistance of the person with the requisite training, knowledge or experience.

Caution! Read, follow and keep the instructions for use.

Caution! Use the product only in accordance with its intended use, see Intended use.

Caution! Prior to use, visually check the product for bent, broken, cracked or missing component.

► COMPLICATION

As in many procedures, complications may arise. The laryngoscope may cause blunt or penetrating trauma to the oropharynx, larynx, and trachea. Direct laryngoscopy involves the possibility of vocal cord damage as well as arytenoid cartilage dislocation, complications may also include as:

- Dislodgement or chipping of teeth.
- Failure to perform procedure.
- Light source failure.
- Injuries to local tissues like teeth, tongue and palate.

► MANUAL CLEANING / DISINFECTION

Remove the batteries and blade by following steps. Immediately after use, blade should be rinsed in clean tap water to remove any residue, after that immerse in a detergent solution for 2 minutes. The blade should then be gently scrubbed with a soft bristle brush while immersed. Dry all components with soft cloth/towel.

► CHEMICAL CLEANING / DISINFECTION

COLD SOAK SOLUTION:

- Blades and Battery handles are compatible with most cold soak solutions. For recommend exposure time and solution strength, follow the solution manufacturer's guidelines. As per our recommendation immerse the blades and handles into activated 2.4% Glutaraldehyde solution for 45 minutes at room temperature. Rinse all parts two times in sterile distilled water. Dry with clean and soft cloth.

► MECHANICAL CLEANING / DISINFECTION BY WASHER / DISINFECTOR MACHINES

Water Sterilization: If a machine washer/sterilizer or chemical cleaners are used, follow the machine manufacturer's instructions regarding concentration Temperature and duration. Normally Disinfect at temperatures up to 95° C (200° F).

PLEASE NOTE: Do not dry heat. Air cool for 5 minutes or blot dry.

► STEAM STERILIZATION (AUTOCLAVE)

After cleaning the laryngoscope blade as above listed procedure, then put blade into the autoclave unit by using the carrying tray. Set the autoclave cycle in accordance with the following specifications:

Temperature: 134° C/270° F

Cycle Time: 30 minutes

Dry Time: 6 minutes

► 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.

► DISPOSAL

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

► WARRANTY/AFTER SALE SERVICES

- Laryngoscope blades and handles are warranted free from defects in designing and materials, under normal use and with appropriate maintenance till 5 years.
- However in any case you found damaged or sub-standard quality device or part that will be repaired or replaced at free of charges.

NOTE: The warranty is not liable, if the device is not maintained properly or used in the high class other than described in the instruction manual of the device.






















► **RECYCLING**

When reprocessing medical devices please follow your local government Health & Safety procedures.













► **ARTICLES TO WHICH THIS IFU APPLIES**

Generic Name: Reusable Laryngoscope blades and handles

Trade/Brand Name: FO Green System/ Reusable Laryngoscope blades and handles

Artikelnummer	Artikelbezeichnung	Größe
 15 03000	Cold light laryngoscope blade, Macintosh	0
 15 03001	Cold light laryngoscope blade, Macintosh	1
 15 03002	Cold light laryngoscope blade, Macintosh	2
 15 03003	Cold light laryngoscope blade, Macintosh	3
 15 03004	Cold light laryngoscope blade, Macintosh	4
 15 03005	Cold light laryngoscope blade, Macintosh	5
 15 05001	Cold light laryngoscope blade, Macintosh	1
 15 05002	Cold light laryngoscope blade, Macintosh	2
 15 05003	Cold light laryngoscope blade, Macintosh	3
 15 05004	Cold light laryngoscope blade, Macintosh	4
 15 05005	Cold light laryngoscope blade, Macintosh	5
 15 4450	Cold light laryngoscope blade, Miller	0
 15 4451	Cold light laryngoscope blade, Miller	1
 15 4452	Cold light laryngoscope blade, Miller	2
 15 0800	LED battery handle cold light, standard	30 mm Ø
 15 0801	LED battery handle cold light, standard, slim	20 mm Ø
 15 0802	LED battery handle cold light, stubby	33 mm Ø
 15 050	Battery handle cold light, standard	30 mm Ø
 15 051	Battery handle cold light, slim	20 mm Ø
 15 0602	Replacement bulb, Halogen	
 15 0803	Replacement bulb, LED	


SYMBOLS USED ON LABEL

	Manufacturer
	Item number
	Batch code
	Read instructions for use
	Do not use if package is damaged
	Keep dry
	Keep away from sunlight
	Date of manufacture
	Use by date
	Non sterile
	Latex free
	CE marked



Erstellt am/created on: 2022-01-11



 servoprax GmbH, Am Marienbusch 9, 46485 Wesel, Germany
www.servoprax.de, info@servoprax.de

1-15 03000ff-091-2-0001-2201