INSTRUCTIONS FOR USE & CARE OF LARYNGOSCOPE FIBER OPTIC BLADES AND HANDLES
(Single use for single patient only)

▶ DESCRIPTION

FO GREEN SYSTEM DISPOSABLE LARYNGOSCOPE BLADES AND HANDLES

- Single patient use only.
- Latex free and safe in use.
- Especially very effective under emergency situations.
- Green system no direct contact of light.
- Stainless steel spatula and aluminium heel makes, practically unbreakable.
- Semi-metal blade also hold reinforcement metal hook to make it unbreakable.
- Low cost price with high quality.
- Round tip helps reduce trauma.
- Plastic optically fiber 5mm dia gives clear and maximum illumination.
- Black shrink tube on individual light guide protects light dispersion or reflection to doctor as well.
- Available in all sizes of Macintosh and Miller.
- Supplied surgically cleaned.
- Hygienically safe in use.
- Fully conforms to ISO 7376 and existing handles.
- Individually packed and labelled.
- Low profile shape of blades protects the patient from upper part of teeth.

These blades are not delivered sterile; and consequently it is necessary to sterilize them properly before use. Disposable Laryngoscope blades for use with a Fiber Optic Green System Handle having a blade portion made from stainless steel and a heel portion made from Medical grade plastic. These instructions are intended for use only by persons with the required specialist knowledge and training.

▶ INSPECTION AND FUNCTION TESTING:

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.

▶ INTENDED USE:

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.

▶ INTENDED PURPOSE:

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

▶ CONTRAINDICATIONS:

The following are only relative contraindication to tracheal intubation.

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

▶ INSTRUCTIONS

BEFORE USE

Use only with Lifeguard Emergency Products brand handles and blades.

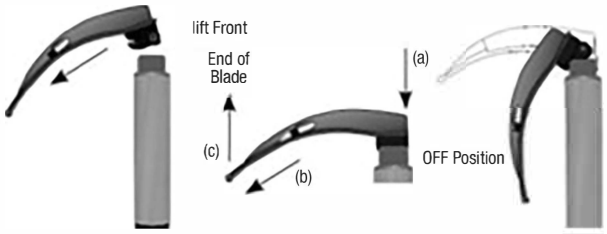
- Do not sterilize, reprocess, or reuse single-use blades.
- Carefully inspect blades for burrs, sharp edges, or other visually discernible defects.

BLADE ENGAGEMENT:

1. Engage the blade slot to the battery handle hook and push the blade by nondominanthand.
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.

▶ TRANSPORTATION, STORAGE, HANDLING, AND CARE

If the laryngoscope blades 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.

⚠ WARNING:

- 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.
- These devices are made for single patient use only, do not try to reuse.

⚠ 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:

- Not for use in vicinity of MRI equipment or other intense magnetic fields.
- 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.
- Ensure that the product is operated and used only under assistance of the person 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).
- 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.

▶ 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

▶ STERILIZATION:

Devices can be sterilized using the following methods:-

100% ETO Cycles

Concentration ETO:	850 ± 50 mg/l
Temperature:	37 °C - 47 °C
Exposure time:	3 - 4 hours
Humidity:	70% RH minimum

Above-mentioned sterilization cycles represent industry standards and should be capable of producing a sterile device. Due to variations in sterilization equipment and device bioburden in clinical use, we are not able to produce specific cycle parameters. It is the responsibility of each user to perform a validation and verification of the sterilization cycle to ensure an adequate sterility assurance level for our 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. This laryngoscope handle is pre-loaded with alkaline button cell batteries. Unscrew the head of handle anti clockwise and make it separate from handle. Remove the battery and dispose of properly.

▶ WARRANTY/ AFTER SALE SERVICES:

Single use laryngoscope Blade are warranted free from defects in desigining and materials, under normal use and with appropriate maintenane. 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: Disposable Laryngoscope Blades
Trade/Brand Name: FO Green System Disposable Laryngoscope Blades

Catalogue number		Description	Size
REF	N2 7111	COLD BLADE METAL ECO disposable cold light, Macintosh	1
REF	N2 7112	COLD BLADE METAL ECO disposable cold light, Macintosh	2
REF	N2 7113	COLD BLADE METAL ECO disposable cold light, Macintosh	3
REF	N2 7114	COLD BLADE METAL ECO disposable cold light, Macintosh	4
REF	N2 7115	COLD BLADE METAL ECO disposable cold light, Macintosh	5
REF	N2 7120	COLD BLADE METAL ECO disposable cold light, Miller	0
REF	N2 7121	COLD BLADE METAL ECO disposable cold light, Miller	1
REF	N2 050	COLD BLADE ECO LED Einweg Kaltlichtgriff	medium

SYMBOLS USED ON LABEL

	Manufacturer
CH REP	Swiss Authorised Representative
REF	Item number
LOT	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	CE marked

CE MD

Erstellt am/created on: 2023-03-16

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