

# User's manual

## FIBER OPTIC LARYNGOSCOPES



This appliance conforms with the directive 93/42/CEE "Medical Devices and to the technical norms UNI EN ISO 7376 "devices for anesthesia and pulmonary ventilation" Laryngoscopes for tracheal intubation"

Guarantee of Quality system for the production and the final control of the products certified by the notifying body TUV SUD Product Service GmbH

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# Thank you for choosing a Spencer product.

## 1 GENERAL INFORMATION



### 1.1 AIM AND CONTENTS

The aim of this manual is to supply all the information necessary so that the client, apart from attaining an adequate use of the appliance, will also be capable of using the instrument in the most autonomous and secure way possible. This includes information regarding technical aspects, functioning, maintenance, spare parts and safety

### 1.2 CONSERVATION OF THE INSTRUCTION MANUAL

The instruction and maintenance manual must be kept with the product, inside the specially provided container and above all, away from any substances or liquids which could compromise perfect legibility.

### 1.3 SYMBOLS USED

SYMBOL	MEANING
	See instructions for use.
	Information to the users in compliance with comma 13 of the Italian Legislative Decree n. 151 of 25 July 2005, "Fulfillment of the Directives 2002/95/CE, 2002/96/CE and 2003/108/CE, regarding reduction of the use of dangerous substances in electric and electronic equipments and the disposal of their wastes"

### 1.4 SERVICING REQUESTS

For any information regarding the correct interpretation of the instructions, use, maintenance, installation, recall, please contact the Spencer Customer Care Service on 0039 0521 5411 - Fax 0039 0521 541222 - e-mail: info@spencer.it or write to Spencer Italia Srl - Strada Cavi, 7 - 43044 Collecchio (Parma) ITALY.

### 1.5 DEMOLITION



Information to the users in compliance with comma 13 of the Italian Legislative Decree n. 151 of 25 July 2005, "Fulfillment of the Directives 2002/95/CE, 2002/96/CE and 2003/108/CE, regarding reduction of the use of dangerous substances in electric and electronic equipments and the disposal of their wastes".

The crossed dustbin symbol applied on the product or on its packaging indicates that the item should be disposed of separately. The correct disposal of the item when use has terminated, is defined and organised by the manufacturer. The end user who has to proceed with disposal, must therefore contact the manufacturer and follow the system and procedures the manufacturer has organised for the separate collection, treatment and disposal at end-of-life. The correct separate collection of the out of use device which will permit recycling, treatment and destruction in an ecologically friendly manner and will contribute to avoiding possible negative effects on the environment and for health while privileging the reuse and/or recycling of the collected waste components.

Please note that the owner will be subject to administrative sanctions in case of unauthorised disposal of the item.

### 1.6 LABELLING

The serial number as indicated below can be found on each appliance and must not be removed or covered. In order to facilitate assistance please indicate or communicate the serial number (SN) or lot number (LOT) on the label.

## 2 WARNINGS

### 2.1 GENERAL WARNINGS

- Before carrying out any kind of operation on the product, the operator must carefully read the enclosed instructions, paying particular attention to the correct safety precautions and to the procedures to be followed for installation and for correct use.
- In the case of any doubts as to the correct interpretation of the instructions, please contact Spencer Italia Srl, for any necessary clarifications.
- Regularly check the appliance. Carry out the prescribed maintenance in order to keep the appliance in good condition and to guarantee correct functioning and a long life.
- In the case of any abnormalities or damage to the appliance, which could jeopardize the functioning, and the safety, the appliance must be immediately removed from service.
- Do not alter or modify in any way the appliance; any such interference could cause malfunctions and injury to the patient and/or rescuer.
- The appliance must not in any way be tampered with, in such cases all responsibility will be denied for any malfunctions or eventual injuries caused by the appliance itself.
- Who modifies or has modified, prepares or has prepared medical appliances in such a way that they no longer serve the purpose for which they were intended, or no longer supply the intended service, must satisfy the valid conditions for the introduction onto the market.
- Ensure that all the necessary precautions are taken in order to avoid hazards that can arise as the result of contact with blood or body fluids.
- Handle with care.

### 2.2 SPECIFIC WARNINGS

Only trained personnel shall use the device.

Use the Laryngoscope exclusively for endo-tracheal intubation.

As a precaution, the blades should be fully applied and tested on the handle before being used on a patient.

Before every use, verify the conditions of the electric energy source by turning on the fibre optic light.

The use of force should not be necessary to mount a blade correctly on a handle.

We recommend that a spare blade or handle is available as a backup in case of failure.

Do not attempt to dismantle the fiber optic tube.

After every use, decontaminate the device, following the instructions in paragraph 5.1.

After the handle has been used, the batteries may be removed and reused again (if they still have an adequate charge).

The blades are compatible with all handles according to ISO 7376.

**Disposable laryngoscopes may be used only one single time.**

### 2.3 CONTRAINDICATIONS AND SIDE EFFECTS

- 2 The appliance, if used as described in the manual, does not present any contraindications in use.

### 3 DESCRIPTION OF PRODUCT

#### 3.1 INTENDED USE

The device allows to visualize the first part of the airways and to introduce an endo-tracheal tube, illuminating the pharyngeal cave, with a lighting source at one end, and bringing the image to a lens at the other end.

Laryngoscopes equipped with optic fibres generate an extremely clear and shining light with an intensity twice as big as laryngoscopes using conventional lighting.

#### 3.2 MAIN COMPONENTS

The fibre optic laryngoscope consists of two parts, a handle (grip) and a blade (to be introduced in the mouth), adjustable one to another.

The shape of the blades can be of two types: curved (Mcintosh) or straight (Miller).

#### 3.3 MODELS

##### HANDLE FOR LARYNGOSCOPE FIBER OPTIC

HANDLE FOR LARYNGOSCOPE FIBER OPTIC ADULT

HANDLE FOR LARYNGOSCOPE FIBER OPTIC PEDIATRIC

HANDLE FOR LARYNGOSCOPE FIBER OPTIC ADULT SINGLE USE

##### FIBER OPTIC BLADE

FIBER OPTIC BLADE MACINTOSH available in all sizes

FIBER OPTIC BLADE MILLER available in all sizes

FIBER OPTIC BLADE MACINTOSH SINGLE USE available in all sizes

FIBER OPTIC BLADE MILLER SINGLE USE available in all sizes

#### 3.4 ENVIRONMENTAL CONDITIONS

During handling and storage:                      Temperature                      from -10° to +60°C

During operation:                                      Temperature                      from 0° to +40° C

### 4 OPERATING INSTRUCTIONS

#### 4.1 TRANSPORT AND STORAGE

Before transporting the appliance, make sure that it is correctly packaged ensuring also that there are no risks of shocks or falls during the transport itself. Keep the original packaging for any eventual further transport. Damage to the appliance caused during transport and handling is not covered by the guarantee.

Repairs or replacement of the damaged parts are the responsibility of the Client. The appliance must be stored in a dry place free from humidity.

#### 4.2 PREPARATION

On receiving the product:

Remove the packaging and display the material so that all is visible.

Check that all the components/pieces on the accompanying list are present.

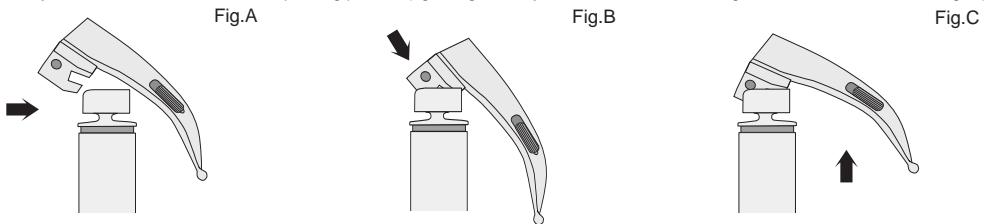
The appliance must be checked before every use so as to reveal any working abnormalities and/or damage caused by transport and/or storage.

#### 4.3 FUNCTIONING

The correct method of application of the blade is to tilt it at 45° to the handle, hook the blade hook onto the handle hook bar (Fig. A).

Push the blade down onto the bar until the blade is fully engaged (signalled by a click as the hook bar passes over the seating bearing in the blade Fig. B).

and only then to elevate the blade to its operating position (again signalled by a click as the block bearing seats itself on the handle - Fig. C).



**The use of force should not be necessary to mount a blade correctly on a handle.**

Handles are not supplied preloaded with batteries. They require following batteries:

HANDLE FOR LARYNGOSCOPE FIBER OPTIC ADULT                      C 1,5 volts

HANDLE FOR LARYNGOSCOPE FIBER OPTIC PEDIATRIC                      AA 1,5 volts

#### 4.3.1 Battery replacement

The batteries must be taken away after every use and, in case of non-disposable laryngoscopes, inserted again before the next use (if still charged). To insert the batteries, simply unscrew the handle head block, insert the batteries and replace the head block before operation.

In order to guarantee a longer lifetime of the device, the use of alkaline batteries is recommended.

#### 4.4 TROUBLESHOOTING

PROBLEM	CAUSE	REMEDY
The optic fibre does not light up	Low battery	Replace battery
	The optic fibre is damaged	Replace the blade
The blade does not fit perfectly on the handle	The blade is not fixed correctly	Remove and fix the blade again as described in the users manual
	The blade is broken	Replace the blade
	The handle is broken	Replace the handle

## 5 MAINTENANCE

### 5.1 CLEANING

Before any cleaning operation, please remind to remove the blade from the handle and to remove the batteries.

CLEANING METHOD		
	BLADE	HANDLE
Washing with detergent (avoiding detergents containing chlorine - alcohol)	YES	YES
Sterilization with ethylene oxyd, through a validated cycle (UNI EN 13060)	YES	YES
Sterilization in autoclave, through a validated cycle (UNI EN 12060)	YES	YES

Take care to dry blade and handle well so as to avoid the presence of residues of detergent which compromise the integrity and lifespan of the device.

The use of the autoclave as a sterilising method reduces the life span of the device.

Cleaning operations are not regularly carried out there is a risk of cross infection due to the presence of residues.

The laryngoscopes have to be tested after every cleaning operation and before every use.

Carry out the following checks:

Fix the blade on the handle and verify if the light turns on.

### 5.2 MAINTENANCE

#### 5.2.1 Precautionary Maintenance

The device does not require scheduled servicing.

#### 5.2.2 Servicing Maintenance

The person to whom the servicing of the appliance is entrusted must guarantee the following basic requirements:

- Adequate knowledge of the appliance, of its technical/construction features, of checks and final tests, of packaging, conservation and handling;
- Adequate knowledge of the technology used in the making of the appliance;
- Knowledge of the functions of the appliance, of any potential risks and of the probability of possible malfunctions or break-downs;
- To be in possession of all the instruments necessary for carrying out any kind of technical operation regarding servicing;
- To be in possession of original replacement parts or those authorized by the manufacturer;
- Specialized technical personnel trained by the manufacturer for the servicing of the appliance in question;
- Guarantee complete adherence to the instructions of the 93/42/CEE Directive also regarding the obligation towards the manufacturer to allow the aforementioned a post sales care and traceability of the appliance when requested.

**The device, if used as described in the following instructions, has a life span of 5 years.**

**However, the disposable type may not be used more than once.**

## 6 ACCESSORIES AND REPLACEMENT PARTS

### 6.1 ACCESSORIES

BLACK POUCH EVA W/SPENCER LOGO FOR FIBER OPTIC LARYNGO

#### Warning

The information container in this document can be modified without warning and is not to be intended as a commitment on the part of Spencer Italia S.r.l.

With the right to modify. The Spencer products are exported to many countries in which the same identical regulations do not exist. It is for this reason that there can be many differences between the description and the actual product delivered. Spencer works continuously perfecting all the models of the models sold. We therefore hope to have your understanding if we reserve the right to modify the shape, equipping, lay-out or technical aspects that are herein described, at any given time.