SPENCER®

User's Manual

Conventional light laryngoscopes

CE This appliance conforms with the Directive 93/42/CEE "Medical Devices".

Guarantee of Quality system for the production and the final control of the products certified by the notifying body TÜV SÜD Product Service GmbH.

INDEX

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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, will not only attain adequate use of the appliance, he 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 together with the product, for the whole life of the device, 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
	General or specific warning
	See instructions for use
	Lot number
	Product code
	The product is compliant with the specifications of the Directive 93/42/CEE
	Information to the users in compliancy with comma 13 of the Italian Legislative Decree n. 151 of 25 July 2005, "Fulfilment 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 use, maintenance and installation, please contact the Spencer Customer Care Service on tel. 0039 0521 541111, fax 0039 0521 541222, e-mail info@spencer.it or write to Spencer Italia S.r.l. - Strada Cavi, 7 - 43044 Collecchio (Parma) - ITALY. In order to facilitate the assistance service, please always indicate or communicate the serial number (SN) or lot number (LOT) shown on the label applied on the box or on the device.

1.5 Demolition

Information to the users in compliancy with comma 13 of the Italian Legislative Decree n. 151 of 25 July 2005, "Fulfilment 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 it's 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

Each device has got an identifying label, positioned on the device itself and/or on the box. This label includes information about the Manufacturer, the product, CE mark, lot number (LOT). It must never be removed or covered.

2. WARNINGS

2.1 General warnings

- The product must be used by trained personnel only, having attended specific training for this device and not for similar products.
- Training routines must be registered on a special register in which the names of those trained, of the trainers, date and place are indicated. This register which will certify the eligibility of the operators to use the Spencer device has to be kept for a period of 10 years after the disposal of the device itself. This register will be made available to the Competent Authorities and/or Manufacturer if requested.

- Spencer Italia S.r.l. is always at your disposal to plan trainings on products.
- Before carrying out any kind of operation on the appliance (training, installation, use), 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.
- If the instructions belong to another device and not the device received, inform the Manufacturer immediately and avoid use of the device.
- In the case of any doubts as to the correct interpretation of the instructions, please contact Spencer Italia S.r.l. for any necessary clarifications.
- Do not allow untrained persons to help during the use of the device, because they could cause damage to the patient or to themselves.
- Regularly check the appliance, carry out the prescribed maintenance and respect the average life span, as indicated by the Manufacturer in this User's Manual.
- Before each use of device the perfect operating state of the device must be checked as specified in the Instruction manual. If any damage or abnormalities which could in any way influence the correct functioning and the safety of the device, of the patient and or of the user are detected, the device must be immediately removed from service and the Manufacturer must be contacted.
- If any failure or incorrect functioning of the device is detected, it must be immediately substituted with a similar item so that the rescue procedures are guaranteed without any interruption.
- Use of the device in anyway other than described in this manual is forbidden.
- 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 (modification, adjustment, addition, replacement). In such cases all responsibility will be denied for any malfunctions or injuries caused by the appliance itself; moreover CE certification and product warranty will be considered void.
- Those who modify or have modified, prepare or have 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.
- Handle with care.
- Ensure that all the necessary precautions are taken in order to avoid the hazards that can arise as the result of contact with blood or body fluids.
- Register and store with these instructions: lot number, place and date of purchase, first date of use, date of checks, name of users, any comments.
- When the device is being used, the assistance of qualified staff must be guaranteed.
- Do not store the device underneath any heavy objects which could cause structural damage.
- Store in a cool, dry, dark place and do not expose to direct sun.
- Store and transport device in its original packaging.
- The device not be exposed to or come into contact with any source of combustion or inflammable agents.
- Position and adjust the device taking care not to cause any obstruction to rescuers and or any other rescue equipment.
- Attention: laboratory testing, post production tests, instruction manuals cannot always consider every possible scenario for use. This means that in some cases the performance of the product could be notable different from results to date obtained. Instructions are continually being updated and are under tight surveillance of fully qualified staffs with adequate technical formation.
- With reference to the D. Lgs. 24th February 1997, n. 46 emended by D. Lgs. 25/01/2010, n. 37 – Acknowledgement of Directive 93/42/CEE and 2007/47/CE, we remind both public and private operators that they are obliged to report any accident that involves any medical device to the Ministry of Health and to the Manufacture as specified and within time given by the European regulations.
  In addition, both public and private operators are obliged to inform the Manufacturer of any measures that should be adopted to make the steps necessary to guarantee the safety and the health of the patients and the users o any medical device.
- As a Distributor or End Users of products manufactured and/or marketed by Spencer Italia S.r.l., you are strictly required to have a basic knowledge of any legal requirements applying to the devices contained in this supply that are in power in the goods final destination Country (including laws and norms regarding technical specifications and/or safety requirements) and therefore you are also strictly required to have the necessary knowledge to guarantee all aspects regarding the total conformity of the products to the regulations in the relevant territory.
- Promptly notify Spencer Italia S.r.l. regarding any revisions to be made by Manufacturer in order to guarantee the conformity of the product to the territory's legal specifications (including those resulting from rules and/or norms of other nature).
- Act, with all due care and diligence, and contribute to ensure conformity to general safety requirements of all devices marketed in the territory, by providing final users with all necessary information for carrying out periodical checks on their devices, as specified in the relevant User Manual.
- Actively contribute to product safety checks on products sold, by communicating any relevant risk analysis information both to the Manufacturer and to any competent authorities so that the necessary action can be promptly taken.
- You are aware that in the event of any failure to conform to the above mentioned requirements you will be deemed fully responsible for all damages that might occur. Therefore we expressly disclaim any responsibility and/or liability for your non-compliance with the present "Regulatory provisions".

2.2 Specific warnings

- Establish a maintenance program and periodic testing, identifying an reference employee. The person to whom the ordinary maintenance of the device is entrusted must ensure the basic requirements foreseen by the Manufacturer in the user's manual.
- Training routines must be registered on a special register in which the names of those trained, of the trainers, date and place are indicated. This register which will certify the eligibility of the operators to use the Spencer device has to be kept for a period of 10 years after the disposal of the device itself. This register will be made available to the Competent Authorities and/or Manufacturer if requested.
- Use only accessories/spare parts that are original or approved by Spencer Italia S.r.l., in order to carry out any operation without causing any alteration or modification to the device, otherwise we assume no responsibility for the proper functioning or damage resulting from device to the patient or the operator and warranty and will be considered void according to the compliance to the Medical Device Directive 93/42/CEE.
- Never leave the patient unassisted on the device, because he may be injured.
- The device and all its components, after washing, should be allowed to dry completely before storing, away from sunlight and direct heating sources.
- Always check the integrity of all the parts before each use of the device.
- Keep and provide on request adequate product origin tracking documentation for a period of ten years valid from the date of acquisition by the end user.
- Use the device 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 light.
- Do not apply an excessive force to mount the blade on the handle.
- We recommend that a spare blade is available as a backup in case of failure.
- 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 the still have an adequate charge).
- The blades are compatible with all handles according to ISO 7376/1.

2.3 Contraindications and side effects

The use of this device, if used as described in this manual, does not present any contraindications or collateral effects.

3. DESCRIPTION OF PRODUCT

3.1 Intended use

The device allows to visualize the first part of the airways and to introduce an endotracheal tube, illuminating the pharyngeal cave, with a lighting source at one end, and bringing the image to a lens at the other end.
Energy for the lamp is supplied by an electric circuit within the handle, that is activated when the handle and the blade are connected. Exclusive tungsten bulbs are used, easy to be replaced.

3.2 Main components

The conventional light 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 (Macintosh) or straight (Miller).

1. Handle
2. Blade
3. Light

Fig. A

3.3 Models

3.3.1 Handles

DG03100A L-handle conventional light handle, adult
DG03101A L-handle conventional light handle, paediatric

3.3.2 Blades

DG05000A C-blade Macintosh blade size 0
DG05001A C-blade Macintosh blade size 1
DG05002A C-blade Macintosh blade size 2
DG05003A C-blade Macintosh blade size 3
DG05004A C-blade Macintosh blade size 4
DG04000A S-blade Miller blade size 0
DG04001A S-blade Miller blade size 1
DG04002A S-blade Miller blade size 2
DG04003A S-blade Miller blade size 3
DG04004A S-blade Miller blade size 4

These basic models could be modified, with reference to codes and/or descriptions without any previous notification.

3.4 Reference standards

Reference	Title of document
MDD 93/42/CEE	European Directive about Medical Devices
MDD 2007/47/CEE	Modifications to 90/385/CEE Directive about active implants, Directive 93/42/CEE about medical devices and Directive 98/8/CE about the introduction of biocides onto the market
Legislative Decree 24/02/1997, n. 46	Application of the 93/42/CEE Directive about Medical Devices
Legislative Decree 25/01/2010, n. 35	Modifications and additions to the 20/02/97 Decree n. 46
UNI EN ISO 9001	Managing systems for quality: requirements
UNI EN ISO 9000	Managing systems for quality: basis and vocabulary
UNI EN ISO 13485	Medical Devices - Managing systems for quality – Requirements for regulamentation requirements
UNI EN ISO 14971	Application of risks managing to medical devices
UNI CEI EN 980	Graphic symbols used for medical devices labelling
UNI CEI EN 1041	Information supplied by the medical devices manufacturer
CEI EN 62366	Medical Devices - Application of the utilisation characteristics of engineering to medical devices
MEDDEV 2.4/1a-b	Guideline for the classification of medical devices
NB-MED 2.5.1 /Rec 5	Technical Documentation
MEDDEV 2.7.1	Clinical Data
MEDDEV 2.12/1	Medical Devices vigilance system
UNI EN 14155	Clinical evaluation of the medical devices for human beings - Part 2: Clinical evaluation plans
BS OHSAS 18001	Managing systems for safety and health at workplace
UNI EN ISO 7376	Laryngoscopes for endotracheal intubation

3.5 Environmental conditions

Functioning temperature: from 0 to +40 °C
Storage temperature: from -10 to +60 °C
Relative humidity: from 5 to 85%

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, bumps or falls during the transport itself.
Keep the original packaging for use in case of any further transport and for storage. 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 device must be stored in a dry, cool area away from direct sunlight. It must not be placed in contact with any substances or chemical agents which could cause damage and reduce safety characteristics.

4.2 Preparation

On receipt of the product:

- Remove the packaging and display the material so that all components are 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. In particular, check:

- General functionality of the device

- Cleanliness of the device (remember that the failure of cleaning may cause the risk of cross infections)
- Handle and blade can be connected correctly?

If the above conditions are met, the device may be considered ready for use, otherwise you must immediately remove the device from service and contact the Manufacturer.

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. B). 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. C) 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. D).

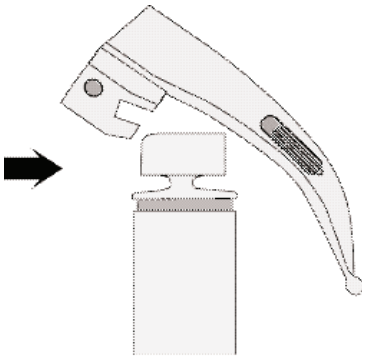

Fig. B

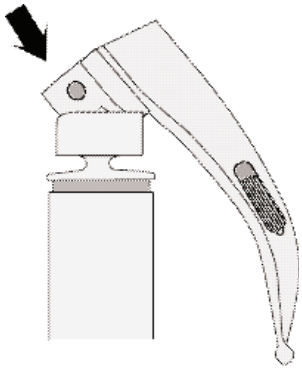

Fig. C

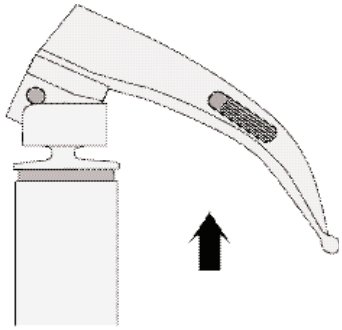

Fig. D

Do not apply an excessive force to mount the blade on the handle.

Handles are not supplied preloaded with batteries. They require following alkaline batteries:
Adult handles C 1,5 volts
Paediatric handles 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 char ged). To insert the batteries, simply unscrew the handle head block, insert the batteries and replace the head block before operation. In order to grant a longer life span of the device, the use of alkaline batteries is required.

4.4 TROUBLESHOOTING

PROBLEM	CAUSE	REMEDY
The lamp does not light up	Low battery	Replace the battery
	The lamp is damaged	Replace the lamp
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 user's manual
	The blade is broken	Replace the blade
	The handle is broken	Replace the handle

5. MAINTENANCE AND CLEANING

5.1 Cleaning

Failure to carry out the correct cleaning routine could increase the risk of cross infection.

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

The operator must always wear adequate personal protection such as gloves and mask etc. during all checking and cleaning procedures.

The metal parts exposed to external agents undergo surface treatment and/or painting in order to obtain better resistance. Wash exposed parts with warm water and mild soap, never use solvents or stain removers. In case of any disinfecting procedures do not use solvents wih corrosive action on the materials constituting the device. Rinse thoroughly with warm water making sure that you have removed all traces of detergent, which may deteriorate or compromise the integrity and durability of the device. Allow to dry thoroughly before storing.
Drying after washing or after use in wet environments must be natural and not forced, do not use flames or other sources of direct heat.

CLEANING METHOD	BLADES	HANDLE
Washing with detergent (avoiding detergents containing chlorine - alcohol	Yes	Yes
Sterilization with ethylene oxyd, through a validated cycle (UNI EN 550)	Yes	Yes
Sterilization in autoclave, through a validated cycle (UNI EN 554)	Yes	Yes

The laryngosopes 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 person who carries out the precautionary maintenance of the appliance (user in person, Manufacturer/supplier or a third party) has to guarantee the following basic requirements:

- Technical knowledge of the appliance and of the periodic maintenance procedures as described in these instructions.
- Specific qualifications and training in the maintenance operations of the appliance in question.
- The use of components/replacement parts/accessories that are either original or approved by the supplier, in such a way that each operation causes no alteration or modification to the appliance.
- Possession of the checklist of operations carried out on the appliance.
- Guarantee complete adherence to the instructions of the Directive 93/42/CEE which includes also the obligation towards the Manufacturer to maintain post sales records and traceability of the appliance if requested.

During all checking, maintenance and cleaning procedures, the operator must wear adequate personal protection such as gloves, mask, glasses etc.

Checks to be carried out before and after each use, and at least every 3 months, are as follows:

- General functionality of the device
- Cleanliness of the device (remember that failure of the cleaning operation may cause the risk of cross infections)
- Handle and blade can be connected correctly?

The inspection frequency is determined by factors such as legal requirements, the type of use, frequency of use, environmental conditions during use and storage. Please note that you must do the cleaning as described in paragraph 5.1 and verify functionality before and after each use. Spencer Italia S.r.l. declines any responsibility for the proper functioning or damages caused to the patient or user by the use of devices not subject to routine maintenance, warranty and will void the compliance to the Medical Device Directive 93/42/CEE.

5.2.2 Periodic maintenance

The device does not require periodic review of the planned interventions by the Manufacturer or an authorized centre, but is prescribed to clean it and check it as described on the paragraphs "Cleaning" and "Maintenance".

5.2.3 Special servicing

Only the Manufacturer or centres with written authorisation are authorised to complete any special servicing operations.

For any operations that are not carried out directly by the Manufacturer but by an authorised centre, we have to underline that a report regarding all operations carried out must be requested. This will permit both Spencer Italia S.r.l. and the end user to keep a log book regarding the operations carried out on the device.

The device, if used as indicated in the following instruction manual, has an average life span of 5 years. The life span can be expanded only following a general revision of the product that must be carried out by the Manufacturer or by a centre authorised by the Manufacturer.
Spencer Italia S.r.l. will accept no responsibility for the incorrect functioning and/or damage caused by the use of any device which has not been repaired, or certified on expiry date by the Manufacturer or by one of the Manufacturer's Authorised Service centres. Warranty will be considered void in compliance with the Medical Device Directive 93/42/EEC.

6. ACCESSORIES AND SPARE PARTS

DG00100A	LSK 1 Laryngoscope kit, ten blades, empty
DG00101A	LSK 2 Laryngoscope kit, paediatric, empty
CB04141B	LSK 4 Laryngoscope kit, professional, empty
GD01000E	LSK 5 Laryngoscope kit, empty holster
DG05503B	TFJ spare lamp for size 0 blade
DG05500B	TFJ spare lamp for size 1-2-3-4 blade