User's Manual

Dolphin

⇒ Universal linear lifesaver

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 and maintenance manual

The instruction and maintenance manual must be kept together with the product, for the whole life of the device, inside a dedicated container and above all, away from any substances or liquids which could compromise perfect legibility.

1.3 Symbols used

Symbol	Meaning
	General or specific warnings
	See instructions for use
LOT	Lot number
REF	Product code
CE	The product is compliant with the specifications of the Directive 93/42/CEE

1.4 Servicing request

For any information regarding the correct interpretation of the instruction manual, the use, maintenance, installation and restore of the product, please contact the Spencer Customer Care Service tel. 0039 0521 541111, fax 0039 0521 541222, e-mail service@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 the serial number (SN) or lot number (LOT) shown on the label applied on the box or on the device.

1.5 Demolition

When the devices are no more suitable for being used, if they haven't been contaminated by any particular agents, they can be disposed of as normal solid waste, otherwise follow the current regulations about demolition.

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, the CE mark, the serial number (SN) or lot number (LOT). It must never be removed or covered.

2. WARNINGS

2.1. General warnings

- The product must be used by trained water rescue personnel only, having attended specific training for this device and not for similar 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 to the device received, inform the manufacturer immediately and avoid use of the device.
- In case of any doubts about the correct interpretation of the instructions, please contact Spencer Italia S.r.l. for any necessary clarifications.
- Regularly check the device.
- 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.
- 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.

- 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.
- 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.
- 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.
- Use of the device in anyway other than described in this manual is forbidden.

2.2 Specific warnings

- All maintenance and periodic check activities must be registered and collected together with their intervention reports (see Maintenance Register) these documents have 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.
- 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.
- 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 of the user are detected, the device must be immediately removed from service and the manufacturer must be contacted.
- The device not be exposed to or come into contact with any source of combustion or inflammable agents.
- Store in a cool, dry, dark place and do not expose to direct sun.
- Do not store the device underneath any heavy objects which could cause structural damage.
- Store and transport device in its original packaging.
- Position and adjust the device taking care not to cause any obstruction to rescuers and or any other rescue equipment.

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 DEVICE

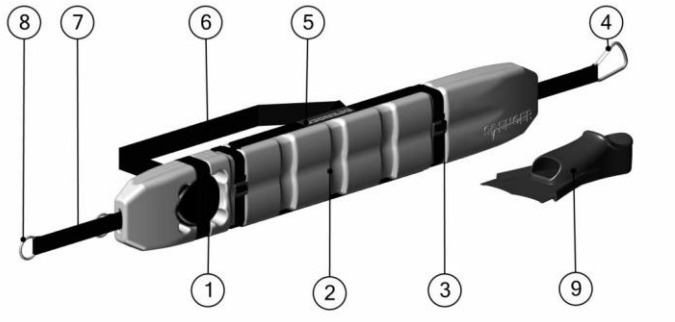
3.1. Destination of use

Dolphin is a device designed for water rescue. It is a floating device equipped with restraint seat belts and handles that allows trained staff to carry out rescue maneuvers in the water. The device is only intended for rescue operations in the water. Immobilizing and transport of the patient must be carried out using specific medical devices.

3.2. Main components

1. Housing for Spencer Mask with EVA pouch
2. Polyethylene main body
3. Straps for securing fins
4. Carabineer
5. Main handle
6. Shoulder strap
7. Strap closure
8. Rings for carabineer lock
9. Possible housing

fig. 1



3.3. Models

DY32400D Dolphin – Universal linear lifesaver
DY32500D Dolphin - Universal linear lifesaver with Flex Mask and handles

3.4. Technical data

Main body	Expanded polyurethane with closed cells
Straps	Polyester
Length of main body (m)	1,2
Length with closure straps(m)	1,75
Length of shoulder strap	1,5
weight (kg)	1,8

3.5. 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 14971	Application of risks managing to medical devices
UNI CEI EN ISO 15223-1	Medical devices - Symbols for use in the medical device labels, labelling and information to be provided. Part 1: general requirements
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

3.6 Environmental conditions

Functioning temperature: from 0 to +50 °C
Storage temperature: from 0 to +50 °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, 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
- Absence of cuts, holes, tears on the structure, including the straps
- Correct fastening of straps
- Integrity of components
- Integrity of handles (Are they torn or show signs of tear? The seams are intact?)

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

Dolphin is equipped with innovative solutions for this type of rescue tools.
√ The system of straps and belts that it has, allows the housing of "half-fins" as shown in Fig.2.

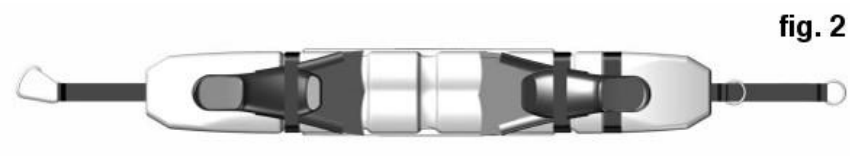


fig. 2


fig. 3

- ✓ It features a slot specifically for Flex Mask (Fig. 3), which is essential for the most critical phases of first aid. (For the use of the Flex Mask refer to the instruction manual for the device).
  The facemask is a standard accessory for Dolphin DY32500D.
- ✓ The side handles allow the transport of Dolphin also with a shoulder strap

In order to make the shoulder strap transportation more comfortable, adjust the distance between the two perimeter straps as shown in FIG. 5 In this way the belts lateral gain greater freedom of movement and will adapt better to transporting.

fig. 4

- ✓ Closing Dolphin.

In some emergency situations, it may be important to anchor Dolphin to the victim. This is possible thanks to the belts equipped with carabineers (n ° 8 to Section 3.2), which can be coupled to either of the two rings (n ° 4 Section 3.2). Select the appropriate ring in relation to patient's physique and the rescue requirements.

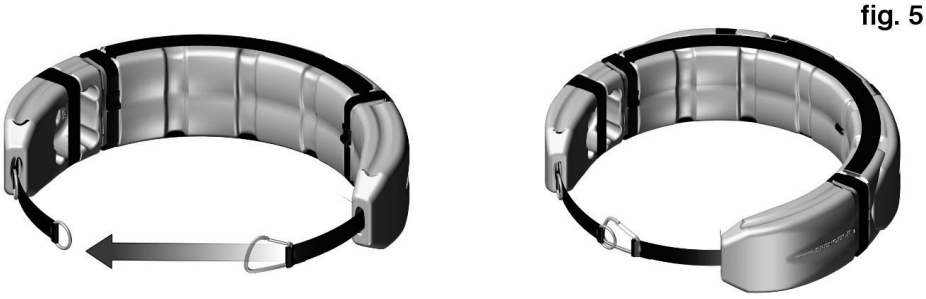


fig. 5

During surveillance of swimmers, Dolphin must always be ready to use.
To do this, make sure it is kept free from any obstructions.
Focus the position of the victim and never lose sight of him, because once you enter the water localization is more complex.

4.3.1 Life saving from the ground

The safest (but not always possible) way to rescue is to not get in the water, but extend to the subject in difficulty (if conscious), one end of the Dolphin to which he should then cling to.
To do this you can follow these steps:
a) Grasp the shoulder belt.
b) Pass Dolphin to the subject in distress, standing or kneeling and making sure keep your weight back so as not to be dragged into the water (Fig. 6).
c) Tell the victim to grab Dolphin. You can do this either through the terminal strap or with the handles on the sides as shown in fig.8.
Slowly pull the victim to a safe area.

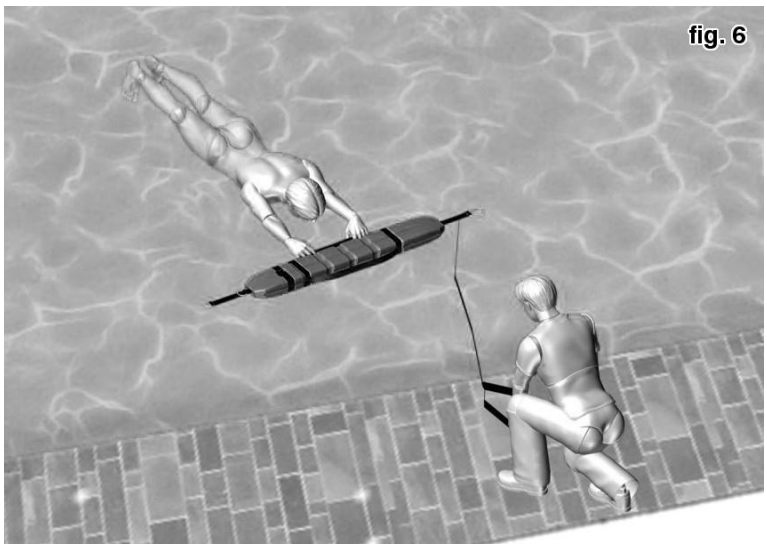
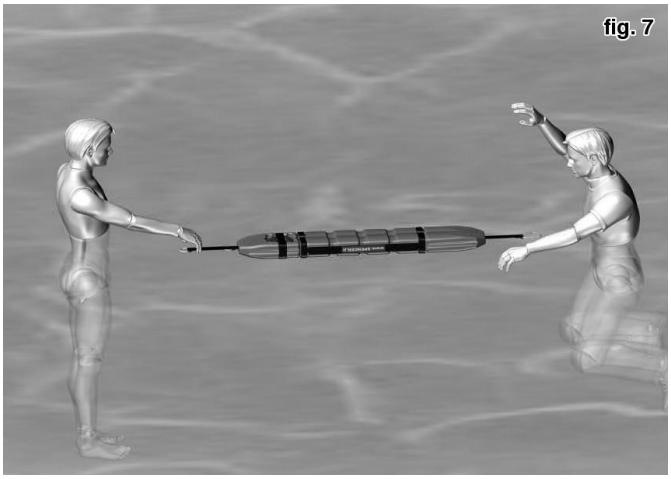
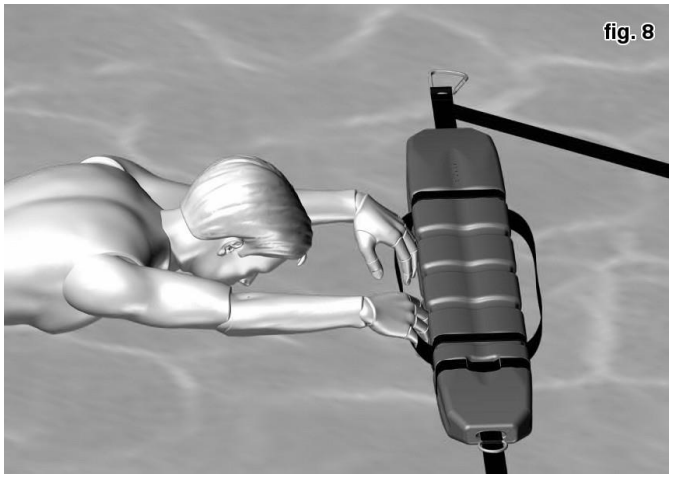


fig. 6

4.3.2 Life saving by swimming without contact

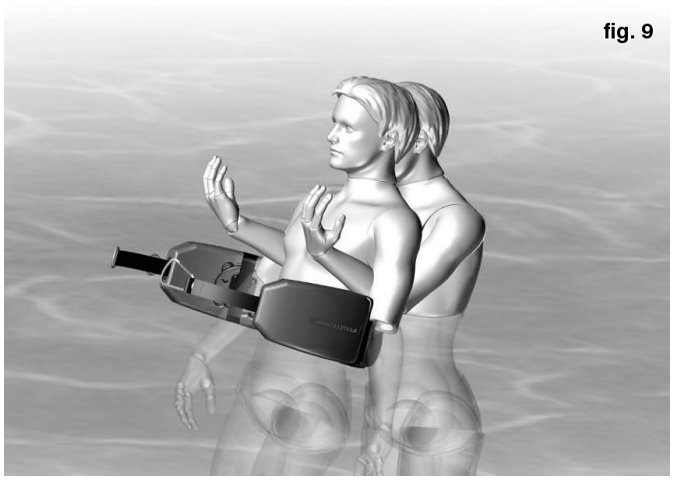
This method is particularly useful in cases where the person to be rescued is panicking.
a) Enter the water using the most suitable technique based on the recommendations of your training courses.
b) swim to be in front of the victim.
c) Hand Dolphin to the victim, who can grasp the terminal part of the belt or the handles on the sides as shown in fig.8. These handles provide greater security for the victim.
d) Instruct the victim to grab the end of Dolphin and if able to, to make swimming movements with the legs.





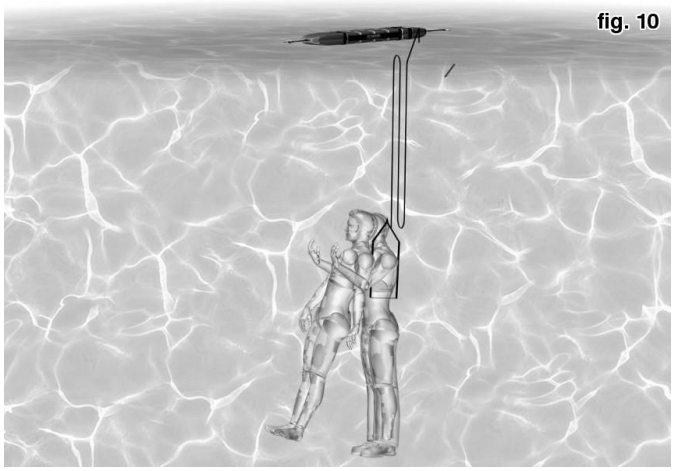
4.3.3 Life saving from rear position

a) Approach the victim from the rear.
b) Hold the back of the victim by passing your hands under his armpits.
c) Slide Dolphin under the back of the victim (Fig. 8).
d) Hold the head slightly shifted to the side, in such a way as that he does not hit you in the event the victim moves his head backwards.
e) You can connect the Dolphin with the special clasp.
f) Move the victim to safety.



4.3.4 Saving a victim in under shallow water

a) Position yourself closer to the side of the victim.
b) Make sure you are wearing the strap and let go of the Dolphin
c) If the victim is face down, grab it, and then proceed to rotate until the face is out of water.
d) Once emerged with the face out of the water, continue rescue procedure as indicated in step 3.



4.3.5 Saving a victim in deep water

a) Approach the victim under water wearing only the strap of the dolphin.
b) Approach the victim from his rear side.
c) Hold the victim wrapping your arms around his chest.
d) rise to water surface by pulling the strap on Dolphin
d) Slide Dolphin under the victim's back and procedure in the life saving procedures indicated in step 3.

The procedures described here, are just for general information and do not in any way replace the instructions given during the training courses that must be compulsorily be carried out in order to use the device.
Spencer Italia S.r.l. disclaims any liability arising out of incorrect use of the device.

4.4 Troubleshooting

PROBLEM	CAUSE	REMEDY
The device is torn	Exposure to solvents and/or incorrect storage conditions	Immediately remove the device from use and contact the service centre
The belts on the device are damaged	Wearing and incorrect use	Immediately remove the device from use and contact the service centre

5. MAINTENANCE AND CLEANING

5.1 Cleaning

The operator must always wear adequate personal protection such as gloves and mask etc. during all checking and cleaning procedures. Clean the exposed parts with water and delicate soap. Rinse thoroughly with warm water making sure that you have removed all traces of detergent, which could degrade or compromise the integrity and durability of the device. The use of high pressure water should be avoided. Water penetrates the joints and removes the oil, creating the risk of corrosion of components.

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.

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.

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.

5.2.2 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. Spencer Italia S.r.l. 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.

6. ACCESSORIES AND SPARE PARTS

6.1 Accessories

DY32401B Dolphin – High visibility bag with reflective labels

6.2 Spare parts

TA09050A Flex Mask with blue eva case

Warning

The information contained in this document could be modified without any warning and is not to be intended as a commitment on behalf of Spencer Italia S.r.l. Spencer products are exported to many countries and the same identical regulations are not always valid. For this reason there could be differences between the description here described and the product actually delivered. Spencer continually strives to reach the perfection of all items sold. We therefore hope you will understand if we reserve the right, at any time, to modify the shape, equipment, lay-out or technical aspects that are herein described.

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