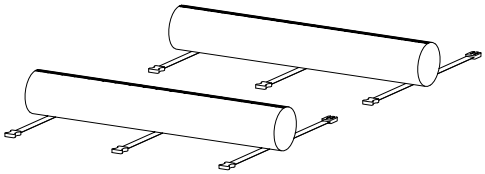
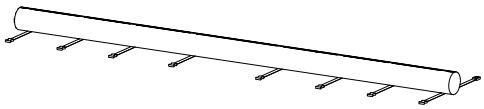
SPENCER

STX 518	*STX 537*
	

Manuale d'uso e Manutenzione
GALLEGGIANTI BARELLE BASKET E TAVOLE SPINALI IT

Use and Maintenance Manual
BASKET STRETCHER AND SPINE BOARD FLOATATION SYSTEMS EN

Betriebs- und Wartungshandbuch
SCHWIMMKÖRPER KORBTRAGEN UND SPINEBOARDS DE

Manuel d'utilisation et d'entretien
FLOTTEUR CIVIÈRE DE TRANSPORT ET TABLES SPINALES FR

Manual de uso y mantenimiento
FLOTADORES PARA CAMILLAS TIPO CESTA Y TABLEROS ESPINALES ES

Manual de Uso e Manutenção
FLUTUADORES, MACAS TIPO CESTO ("BASKET") E PRANCHAS DORSAIS PT

SPENCER ITALIA SRL – Via Provinciale n° 12
43038 Sala Baganza (PR) – Italy

1. MODELS

The following basic models may be subject to implementation or change without notice.

- STX 518 – 2-PIECE FLOATATION DEVICE
- STX 537 - 1-PIECE FLOATATION DEVICE

2. INTENDED USE

2.1 INTENDED USE AND CLINICAL BENEFITS

The floating devices are accessories for basket stretchers or spine boards, to be used to increase the degree of buoyancy in water of the device with which they are used. The device is not suitable for use with the Dakar, Dakota and Dakota Light basket stretchers because they cannot be used in water.

2.2 TARGET PATIENTS

The target patients are those for whom use of the basket stretcher of spring board in an aquatic environment.

2.3 PATIENT SELECTION CRITERIA

The selection criteria are those foreseen for use of the basket stretcher or spine board.

2.4 CONTRAINDICATIONS AND UNWANTED SIDE EFFECTS

No particular contraindications or side effects are known with relation to use of the device, as long as it is used in accordance with the user manual.

2.5 USERS AND INSTALLERS

The intended users are water rescue workers.

- Personnel trained for use of the device must also have training in managing lifting and handling suspended loads with people.
- Personnel who carry out interventions in situations classified as high risk or which are purely technical must be suitably trained and experienced in rescue.
- Personnel should be specifically trained in water rescue procedures.

These devices are not intended for lay people.
Operators must be able to provide the necessary patient care.

Operators must know how to swim.

- The product must be used only by personnel trained in the use of this product and not on other similar products.

3. REFERENCE STANDARDS

REFERENCE	DOCUMENT TITLE
EU Regulation 2017/745	EU Regulation on Medical Devices

4. INTRODUCTION

4.1 DEVICE LABELLING AND TRACEABILITY

Each device is provided with a label, placed on the device itself and/or on the packaging, which contains the Manufacturer's identification data, product, CE marking, serial number (SN) or lot number (LOT). This must never be removed or covered.

If the assigned Lot/SN cannot be traced, the device must be reconditioned, provided only under the responsibility of the manufacturer.

4.2 SYMBOLS

Symbol	Meaning	Symbol	Meaning
CE	Device in compliance with EU Regulation 2017/745		Danger – Indicates a hazardous situation that may result in a situation directly related to serious injury or death.
MD	Medical device		See the user manual.
	Manufacturer	LOT	Lot number
	Date of manufacture	REF	Product code
UDI	Unique Device Identifier	Rx only	Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner (only for USA Market)
	(01)08057711230006 (11) 200626 (10) 1234567890		Production identification Alphanumeric code that identifies the production units of the device, composed of: (01)0805771123 company prefix 000 progressive GS1 6 control number (11)200626 date of production (YYMMDD) (10) 1234567890 lot/SN

4.3 WARRANTY AND SERVICE

Spencer Italia S.r.l. guarantees that products are free from defects for a period of **one year from the date of purchase**.

Spencer Customer Service tel. +39 0521 541154, fax +39 0521 541222, e-mail **service@spencer.it**.
Warranty and service conditions are available at http://support.spencer.it.

5. WARNINGS/DANGERS

Product features

Use of the product for any purpose other than that described in the User Manual is prohibited.

- The product must not be tampered with or modified without the manufacturer's authorisation.
- Avoid contact with sharp or abrasive objects.
- Operating temperature: from -5°C to + 50°C.
- Storage temperature: -10°C to +60°C.

General warnings for medical devices

- Do not use if the device or parts of it are punctured, torn, frayed, or excessively worn.
- Do not alter or modify the device arbitrarily, as doing so could result in unpredictable operation and damage to the patient or rescuers and shall void the manufacturer's warranty and release the manufacturer from all liability.
- Participate in safety checks on products placed on the market, transmitting information regarding product risks to the Manufacturer as well as to the Competent Authorities for their respective actions.

6. SPECIFIC WARNINGS

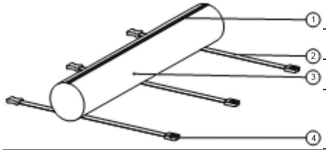
To use the floatation devices, you must also have read, understood and carefully follow all the instructions in the user manual.

- Never apply more weight than the buoyancy thrust offered by the product. Incorrect evaluations could cause the stretcher and patient to sink. When determining the applicable weight and thus the appropriate float, the operator should consider the weight of the patient, device, equipment, accessories and any other object attached to the stretcher.
- **Perform water rescue simulations with a stretcher and a patient simulating load and accessories before putting the device into service.**
- This device is a buoyancy aid and cannot be used to float the stretcher without the assistance and supervision of the operator.
- Make sure that the belts are properly fastened to the stretcher frame.
- Rescue operations must be carried out solely by personnel adequately trained and experienced in water rescue.
- To preserve the life of the device, protect it as much as possible from UV rays and adverse weather conditions.
- If the product is found to be malfunctioning, immediately use a similar device to ensure continuity of ongoing operations. Non-compliant devices must be taken out of service.

7. RESIDUAL RISK

No residual risks, or rather risks that could arise despite compliance with all warnings in this user manual, have been identified.

8. TECHNICAL DATA AND COMPONENTS



Component ID	Description
1	Casing zipper
2	Anchorage straps
3	Casing
4	Quick-release buckles

	STX 518	STX 537
Floatation device dimensions	Ø150x1020 ± 10mm (per piece)	ø150x3330 ± 10 mm
Total buoyancy thrust With floatation device fully immersed	300 N	550 N
Materials	PE, PVC, Nylon	PE, PVC, Nylon
Weight	2,2 ± 0,1 kg	3,1 ± 0,1 kg

9. PROPER USE

Before applying the floatation device, carefully evaluate that the buoyancy thrust of the supplied floatation device is sufficient to support the total weight connected to the floatation device itself.

9.1 STX 518 FLOATATION DEVICE APPLICATION

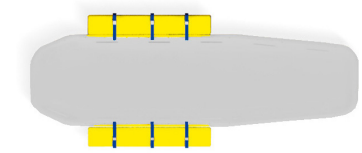
This type of floatation device is made up of two pieces, to be applied specularly to the right and left side of the basket stretcher or spine board.

- Application must be made on the straight section of the device, applying it as close as possible to the head side of the patient.
- Pass the belts through the handles or through the spaces between the frame tubes. Each belt must also wrap the floatation device itself.
- Finish the application by attaching the quick-release buckles, making sure they are properly locked.

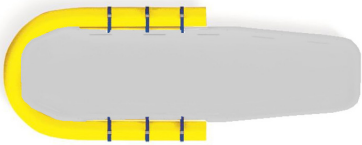
9.2 STX 537 FLOATATION DEVICE APPLICATION

This type of floating device consists of a single piece to be applied to the head side of the basket stretcher or spine board, taking care to position the right and left parts symmetrically.

- Pass the belts through the handles or through the spaces between the frame tubes. Each belt must also wrap the floatation device itself.
- Finish the application by attaching the quick-release buckles, making sure they are properly locked.



STX 518



STX 537

10. CLEANING AND MAINTENANCE

10.1 CLEANING

Failure to carry out the correct cleaning operations could increase the risk of cross-infection due to presence of body fluids and/or residues.
The operator must wear suitable personal protective equipment, such as gloves, goggles, etc. during all checking and cleaning operations.

Open the casing zipper, take out the inner element and rinse it with warm water and neutral soap. **Never use solvents or stain removers.**
In the same way, clean the floatation device casing and the respective belts.
Rinse thoroughly with lukewarm water, making sure you have removed all traces of soap, which may deteriorate or compromise conditions and durability. **Avoid using high pressure water,** as this may damage the device.
Let the parts dry separately completely before storing. Drying after washing must be natural and not forced. Do not use flames or other direct heat sources.
After drying, reposition the floatation element inside the casing, carefully closing the zipper.
If disinfecting, use products that do not have a solvent or corrosive action on materials constituting the device, in addition to being classified as medical-surgical devices. Be sure to take all precautions to ensure that there is no risk of cross-infection or contamination of patients and operators.

10.2 MAINTENANCE

The device does not require a routine maintenance program, but checks must be made to verify:

- General functionality of the device
- Cleanliness of the device (remember that the failure of cleaning may cause the risk of cross infections)
- Fulfilment of the requirements of the user manual in section Warnings and Specific Warnings.
- Fulfilment of the requirements of the manual in section on Proper use.

No periodic overhaul is foreseen for the device.

10.3 LIFE SPAN

The device, if used as described in the following instructions, has a life span of 10 years from the date of purchase.

11. TROUBLESHOOTING TABLE

PROBLEM	CAUSE	REMEDY
You cannot lock the belts in the buckles	Incorrect passage of the belt around the buckle	If you find that this is the problem, pull the belt out of the buckle, reverse the direction in which the belt passes through the buckle and check that it is working properly
Fabric or belts are torn	Normal wear or improper use.	Immediately remove the device from service and contact the manufacturer
It is not possible to attach one or more buckles	Possible incorrect buckle orientation or buckle failure	Check the correct orientation of the buckle and its conditions. If damaged, immediately remove the device from service and contact the manufacturer.

If a problem or fault is detected that does not correspond to the above, please contact Spencer Italia srl customer care service.

12. ACCESSORIES

There are no accessories for these devices.

13. SPARE PARTS

There are no spare parts available for these devices.

14. DISPOSAL

When devices and their accessories are no longer suitable for use, they can be disposed of as normal municipal solid waste if they have not been contaminated by special agents. Otherwise, follow the regulations in force regarding disposal.

Warning

The information contained in this document is subject to change without notice and is to be intended as a commitment by Spencer Italia S.r.l. subject to change. Spencer products are exported to many countries where the same rules do not always apply. For this reason, there may be differences between what is described herein and the products delivered. Images are included as examples and may vary slightly from the actual device.

Spencer is constantly working on improving all types and models of the products sold. We therefore rely on your understanding if we should reserve the right to make changes to the scope of delivery at any time in terms of form, equipment, set-up and technology. Spencer Italia S.r.l. assumes no responsibility for any errors contained herein or for any damages, accidents or consequential damages related to the supply, performance or use of this manual.

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