

**User's Manual****TOTAL / TOTAL KON**  
Backpackable recovery stretchers

TOTAL



TOTAL KON



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

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## 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

### 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 [service@spencer.it](mailto: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 or communicate the 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, 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. 24<sup>th</sup> 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 of 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 a 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.
- Always respect the maximum capacity of the device, as indicated in this user's manual. Maximum load capacity means the total weight distributed according to the human anatomy. In determining the load of the total weight on the product, the operator must consider the weight of the patient, the equipment and the accessories. Moreover, the operator must consider that the overall dimensions of the patient do not reduce the functionality of the device.
- 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.
- Do not use the device if it is excessively worn out.
- The product must be used by trained personnel only.
- The maximum weight sustained by each rescuer must comply with requirements prescribed by the law of the Country, concerning Health and Safety at Work.
- The device is not designed as a spinal immobilization device. If a spinal injury is suspected, secure the patient to an approved spinal immobilization device prior to placing him/her in the total stretcher.
- Never suspend the stretcher by a single grommet. Use the slings and webbing in the manner for which they are provided.
- The device should be stored in the transport bag, as prolonged exposure to sunlight (UV rays) can damage all plastics.
- Always use a tag line when hoisting the device using the dedicated lifting system, because without it all litters can spin.
- These instructions do not in any way substitute an appropriate course from a qualified instructor.
- The recovery stretchers **Total can be hoisted only with devices anchored to the ground**. Never lift a patient without an approved device for this use.

- Once reached an area that allows the use of a device for the correct immobilization of the patient, move him on them and continue the evacuation.

**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.

**2.4 Physical requirements of the operators**

Spencer Total and Total Kon recovery stretchers are destined to professional use only. The rescue operators must have the following minimum requirements:

- physical capacity for operating the device
  - be able to seize the device firmly with both hands
  - have strong back, arms and legs for lifting, pushing and pulling the stretcher
  - have a good muscular coordination
- The operators must be trained in efficient, effective and safe patient transport.



**The capacities of the various operators must be considered before determining his role in the employment of the stretcher.**

**3. DESCRIPTION OF PRODUCT**

**3.1 Intended use**

Total and Total Kon, backpackable recovery stretchers have been configured as extremely flexible, robust and compact rescue systems. They can be used in any context where patient transport is needed and they are particularly useful in morphologic and difficult climatic situations where a fast recovery is requested. The Total stretcher can be lifted **only by a device fixed to the ground** and using the dedicated lifting system and can substitute the traditional rescue or basket stretchers and have a guaranteed excellent performance. The half body version Total Kon cannot be used in extrication manoeuvres but even so it is an essential accessory in difficult rescue situations, thanks to its special silhouette. The Total and Total Kon systems are compatible with spine boards, scoop stretchers, spinal supports and other immobilization devices. When not in use, the Total and Total Kon recovery stretchers must be stored inside the dedicated backpack transport bag (which is supplied with the product).

**3.2 Main components**

| n° | Description of component            | Materials    |
|----|-------------------------------------|--------------|
| 1  | Loading surface in plastic material | Polyethylene |
| 2  | Eyelets in metal                    | Steel        |
| 3  | Lifting system in nylon rope        | Nylon        |
| 4  | Transport handles                   | Polyester    |
| 5  | Harness bands for the patient       | Polyester    |
| 6  | Rope for prolonged towing           | Polyester    |
| 7  | Total Bag transport bag             | Polyester    |



Fig. A

**3.3 Models**

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

- Total Recovery stretcher, yellow
- Total Recovery stretcher, military
- Total Kon Recovery stretcher, halfbody, yellow

### 3.4 Technical data

| Characteristics                          | Total           | Total Kon       |
|--|-----------------|-----------------|
| Dimensions (mm)                          | 970 x 3 x h2430 | 920 x 3 x h1200 |
| Weight (kg)                              | 6               | 2               |
| Weight with belts and transport bag (kg) | 8               | 4               |
| Load capacity (kg)                       | 200             | 200             |
| Number of transport handles              | 5               | 5               |
| Material                                 | Polyethylene    | Polyethylene    |
| Total Bag transport bag                  | Yes             | Yes             |

### 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 980                       | Graphic symbols used for medical devices labelling  |
| UNI CEI EN 1041                      | Information supplied by the medical devices manufacturer  |
| UNI CEI EN ISO 15223-1               | Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements                                      |
| 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   |
| MEDDEV 2.7.1                         | Clinical Data   |
| UNI EN 14155                         | Clinical evaluation of the medical devices for human beings - Part 2: Clinical evaluation plans   |

### 3.6 Environmental conditions

Functioning temperature: from -10 to +40 °C

Storage temperature: from -10 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, bumps or falls during the transport itself. Make sure you have wrapped up and locked the device through the appropriate seat belt provided, before putting it into the backpackable bag for transportation.

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.

After use, replace the stretcher inside its container, in order to repair the plastic material from potential decays caused by elevated exposure to ultra-violet rays.

### 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.

### 4.3 Functioning

#### 4.3.1 To unroll and lay flat the stretcher (Total and Total Kon)

- Remove the device from pack and place it on the ground (fig. 2).
- Unfasten retainer strap, step on foot end of the stretcher, and unroll completely to opposite end (fig. 3).
- Before starting the rescue operations, bend the device in half and back roll it. Repeat with opposite end of the stretcher. The device will now lay flat.

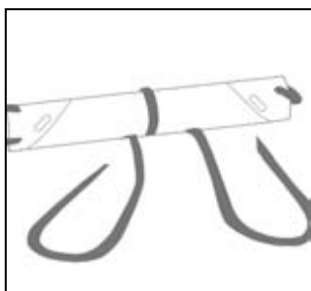


Fig. 2

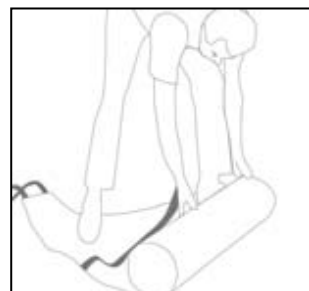


Fig. 3

### 4.3.2 How to place the patient (Total and Total Kon)

#### LOG ROLL method (rolling)

- Place the device next to patient. Insure head end of stretcher is adjacent to head of patient. Place cross straps under the stretcher.
- Log roll patient and slide Total as far under patient as possible. Gently roll patient down on to the stretcher (fig. 4).
- Slide patient to centre of the stretcher. Be sure to keep spinal column as straight as possible (fig. 5).
- Pull straps out from under the device and fasten to buckles (fig. 6).

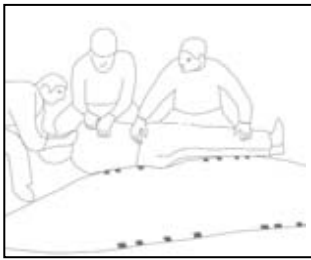


Fig. 4

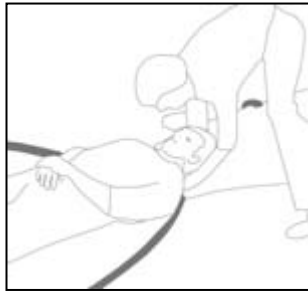


Fig. 5

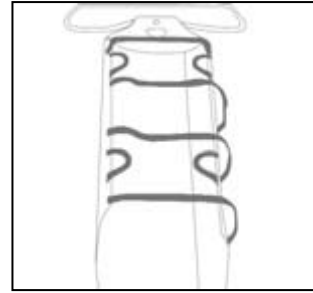


Fig. 6

### 4.3.3 How to place the patient (Total and Total Kon)

#### SLIDE Method (sliding)

- Position foot end of the stretcher at head of patient.
- Have one rescuer straddle Total stretcher and support patients head, neck and shoulders.
- Grasp foot straps of total stretcher and slide it under patient (fig. 7).
- Centre patient on Total stretcher and fasten straps to buckles.



Fig. 7

### 4.3.4 How to position and fasten straps to buckles (Total and Total Kon)

- Unroll the stretcher and lay flat.
- Lift sides of the device and fasten the four cross straps to buckles directly opposite the straps (fig. 8).
- At the end of the stretcher there will be a few unused metal rings, which can be used for fixing the belts for feet immobilization (only for Total).
- Fasten properly all the restraint straps.

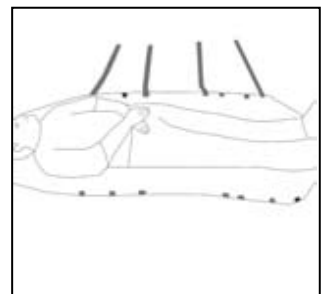


Fig. 8

### 4.3.5 Lifting operations and positioning on the ground (only for Total)

#### Horizontal lift

Two nylon belts are used for anchoring and transport of the structure. The belt to be used for the upper part (head) is about 10 cm shorter than the one used for the lower part (feet).

- Insert one end of head strap through lift slot at head end of stretcher (fig. 9).
- Bring strap under the stretcher and through lift slot on opposite side of the device.
- Make sure the two ends of the belt are equally long and repeat the operation at the other end of the stretcher (fig. 10).
- Make sure the four ends of the two belts are equally long and fix them to the buckles (fig. 11).

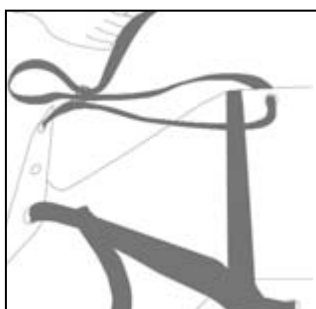


Fig. 9



Fig. 10

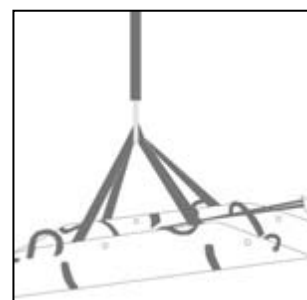


Fig. 11

### 4.3.6 Lifting operations and positioning on the ground (only for TOTAL)

#### Vertical lift

Use the supplied rope with a length of 9 meter with eight knots in the centre.

- Pass each end of the rope thru grommets at the head of the stretcher. Pull the knot up against the stretcher.
- Continue feeding rope thru unused grommets and carrying handles all the way to the foot end of the total stretcher. Insure both ends of rope are even.
- Pass the rope ends thru grommets at the foot end of stretcher from the inside outward. Tie the ends of the rope together with a square knot.
- Bring ends of rope up over end of the stretcher. Pass thru carrying handles and secure with a square knot. Safety each side with an over hand knot (fig. 12).

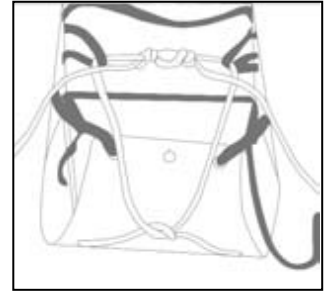


Fig. 12



**The device, useable for rescue operations in narrow spaces, rough terrains and in water, may never be lifted with one ring only.**

### 4.3.7 Manual transport (Total and Total Kon)

Thanks to a set of four handles, it is possible to transport the device manually. The free metal rings of the Total stretcher can be used as anchorage for the handles.

Transport belts can be connected to the handles in order to slide the stretcher on the ground.

### 4.3.8 Storage of the device (Total and Total Kon)

- Lay stretcher out and place retainer strap, buckle side down under foot end of the stretcher.
- Starting at the head end, roll the stretcher up as tight as possible.
- Continue to roll the stretcher up using knee to keep stretcher from unrolling.
- Fasten pre-placed retainer strap to buckle and place the stretcher in back pack.

## 4.4 Troubleshooting

| PROBLEM   | CAUSE        | REMEDY  |
|---|--------------|---|
| Damages to the loading surface                              | Improper use | Take the device out of service immediately and contact the service centre   |
| Damages to the metal rings dedicated to the belts and ropes | Improper use | After every use, check the condition of the rings; in case permanent deformations are detected, take the device out of service immediately and contact the service centre |
| Damages to belts and ropes                                  | Use          | Periodically change components dedicated to extrication and lifting   |

## 5. MAINTENANCE AND CLEANING

### 5.1 Cleaning

Failure to carry out the correct cleaning routine could increase the risk of cross infection, due to presence of body fluids and/or residuals.



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

Wash exposed areas with warm water and mild soap, never use solvents or spotting.

In case of disinfection, use products that do not have solvent or corrosive action to the materials constituting the device. 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.



**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 month, are as follows:

- General functionality of the device
- Cleanliness of the device (remember that the failure of cleaning may cause the risk of cross infections)

- Absence of cuts, holes, tears on the structure, including the straps
- Correct fixation of straps
- Correct fastening of straps

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.

The person responsible for routine maintenance can only replace the parts listed in paragraph 6.2 "Spare Parts". For other replace/repair activities contact the manufacturer or an authorized centre. Use only accessories/original spare parts approved by Spencer Italia S.r.l., otherwise we 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.

### 5.2.2 Periodic maintenance

It is not required any programmed periodic review at the Manufacturer or authorized centre, but it is required to carry out cleaning and inspections indicated on paragraphs "Cleaning" and "Precautionary 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, making void the guarantee and the conformity to the Medical Devices Directive 93/42/CEE.

## 6. ACCESSORIES AND SPARE PARTS

### 6.1 Accessories

ST04093C Total Bag Transport bag  
 ST04524B STX 538 Floatation system, three pieces (only for Total)

### 6.2 Spare parts

ST04091C Polyester rope Ø 12 mm  
 ST04092C Straps/handles and restraints with buckles kit



**ATTACHMENT A – TRAINING REGISTER**



The product must be used by trained personnel only, having attended specific training for this device and not for similar products.



Keep this document at least 10 years from the end of life of the device.

| Operator's name | Training date  |                   | Training method (user's manual, during service, former class, etc.) | Trainer |
|-----------------|----------------|-------------------|---|---------|
|                 | Basic training | Advanced training |   |         |
|                 |                |                   |   |         |
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**ATTACHMENT B – MAINTENANCE REGISTER**

Keep this document at least 10 years from the end of life of the device.



Perform the required maintenance and to respect the life span of the device, as indicated by the Manufacturer in the User’s Manual.

|   |  |
|---|--|
| <b>Code and description of the device</b> |  |
| <b>Purchase date</b>                      |  |
| <b>Lot (LOT) or serial number (SN)</b>    |  |
| <b>Bought by</b>                          |  |

| <b>SERVICE DATE</b> | <b>KIND OF SERVICE<br/>(Maintenance/<br/>check/<br/>extension of life span)</b> | <b>OPERATIONS MADE ON THE<br/>DEVICE</b> | <b>RESULT</b> | <b>PERSON IN<br/>CHARGE OF<br/>SERVICE<br/>(Operator/<br/>Authorized centre/<br/>Manufacturer)</b> |
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