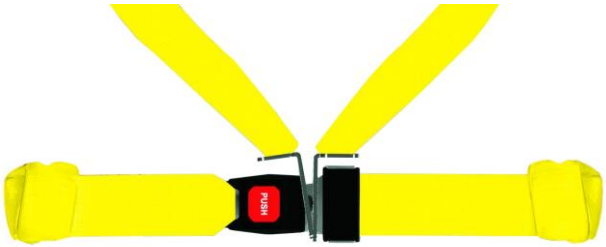
# User's Manual

# Spencer Straps
## Safety belts

Belt with plastic buckle


Belt with metal buckle

Belt with aluminium buckle




Thorax belt

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 |

### 1.4 Servicing request

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 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.
- At least every 6 months, is important to verify if updated User Manuals are available or there is any change involving your product. This information is freely available on the website http://support.spencer.it in the section "User manuals" and "Product Updates".
- Spencer Italia S.r.l. is always at your disposal to make training courses.
- 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 personnel to help when using the device as they may cause injury to the patient or to themselves.
- Do not leave the patient without the assistance of at least one operator when the medical device is in use.
- Perform the required maintenance at the times specified by the manufacturer to keep it in good condition and to ensure safe functioning and long life.
- Establish a maintenance program and periodic testing and identify a dedicated employee. A person to whom is entrusted the maintenance of the device must ensure the basic requirements foreseen by the manufacturer in the operating instructions.
- All maintenance activities, both ordinary and extraordinary, shall be recorded and documented with their reports of technical intervention. This documentation must be maintained for at least 10 years from the end of life of the device and will be made available to the competent authorities and/or the manufacturer when required.
- 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 (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.
- Handle with care.
- 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.

### 2.2 Specific warnings

- In order to meet the requirements of the standard UNI EN 1789, use only belts that have as anchor point the frame of the stretcher.
- 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.
- 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 or of the user are detected, the device must be immediately removed from service and the Manufacturer must be contacted.
- When the device is being used, the assistance of qualified staff must be guaranteed.
- Always check, even during use, the correct fixation of the buckle and all the other elements of the regulation system.
- The device and all its components, after washing, should be allowed to dry completely before storing.
- 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.
- Condensation, water, ice and dust accumulation can affect the correct functioning of the device.
- Do not store the device underneath any heavy objects which could cause structural damage.
- Store and transport device in its original packaging.
- Damaged or overused belts must be immediately replaced.
- Select the fixation points of the belts accurately.
- Position and adjust the device taking care not to cause any obstruction to rescuers or to any other rescue equipment.
- Use only components and/or accessories approved by Spencer Italia S.r.l., in order to avoid unforeseen situations and/or injury to the patient or operator, this will invalidate the warranty.

### 2.3 Contraindications and side effects

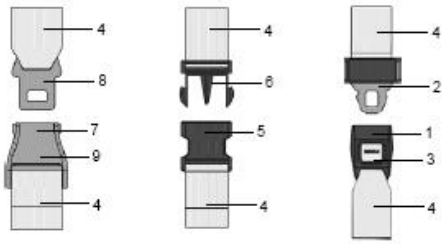
The use of this device, if used as described in this manual, does not present any contraindications or collateral effects.

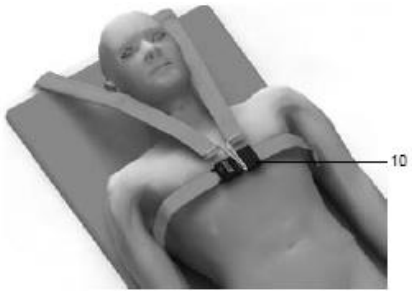
## 3. PRODUCT DESCRIPTION

### 3.1 Intended use

Spencer's safety belts have been developed for a stable and safe fixation of the patient on all transport and immobilization devices. It is recommended to use them with other Spencer devices.

### 3.2 Main components




1. Female part metal buckle and thorax belt
2. Male part metal buckle and thorax belt
3. Uncoupling button
4. Immobilization belt
5. Female part plastic buckle
6. Male part plastic buckle
7. Female part aluminium buckle
8. Male part aluminium buckle
9. Uncoupling lever
10. Thorax belt grafts

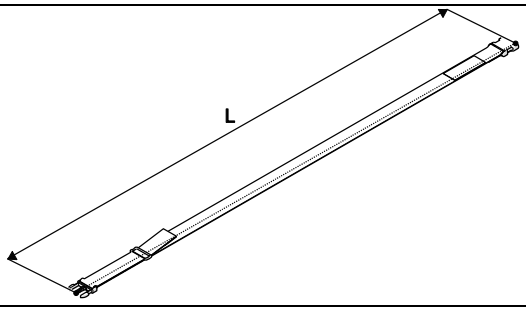
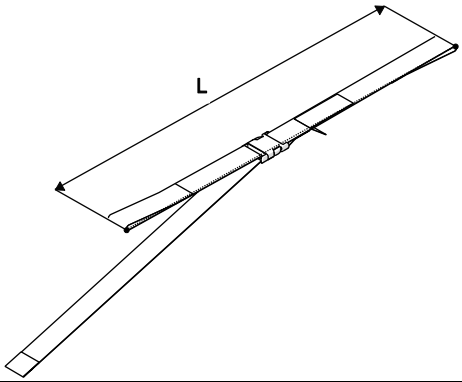
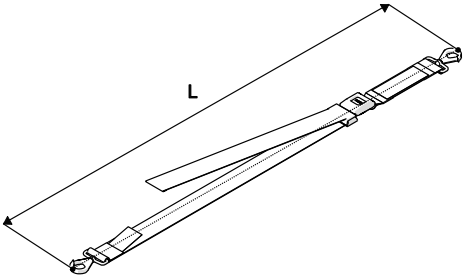
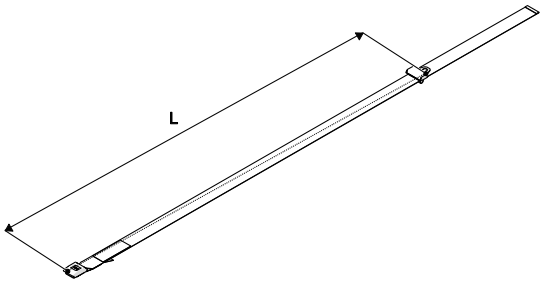
### 3.3 Models

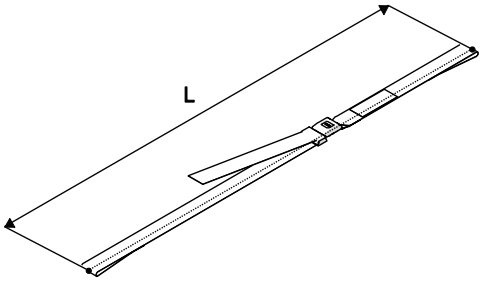
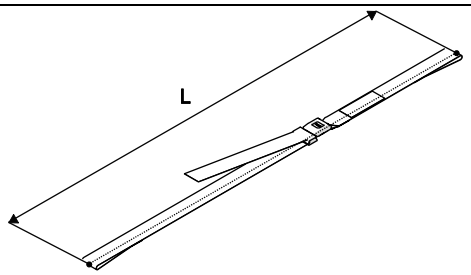
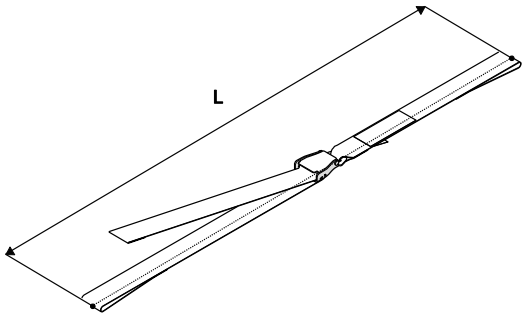
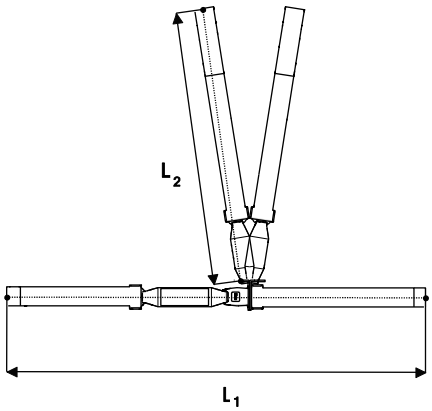
**The basic models listed here below may undergo modifications, concerning reference code number or description, without any previous notifications.**

| | |
|---|---|
| ST00597A | STX 597 One piece belt with plastic buckle, orange |
| ST00598A | STX 598 Two pieces belt with plastic buckle, yellow |
| ST00494B | STX 494 Two pieces belt with metal buckle, with spring catches |
| ST00591A | STX 591 One piece belt with metal buckle, orange |
| ST00592A | STX 592 Two pieces belt with metal buckle, gialla |
| ST00501C | STX 501 Two pieces belt with metal buckle, Biostrap |
| ST70002A | STX 702 Two pieces belt with metal buckle, black Reflex |
| ST00580A | STX 580 One piece belt with aluminium buckle, gialla |
| ST00594A | K Belt 1 Set of three belts, two pieces belts STX 598 |
| ST00523A | K Belt 2 Set of three belts, two pieces belts STX 592 |
| ST00593A | K Belt 3 Set of three belts, one piece belts STX 597 |
| ST00499B | STX 499 Universal thorax belt, adjustable, yellow |
| ST00496B | STX 499 GDT Universal thorax belt, adjustable |

**3.4 Technical data**

| COMPONENTE CINTURA | MATERIALE |
|---|---|
| Metal buckle | Chromed steel and thermoplastic |
| Plastic buckle | Nylon |
| Aluminium buckle | Aluminium |
| Webbing | Nylon, polyester, polypropylene |

| MODEL | | Max length (mm) | Min length (mm) |
|---|---|---|---|
| ST00597A and ST00593A |  | 1600 | 710 |
| ST00598A and ST00594A |  | 1500 | 710 |
| ST00494B |  | 1600 | 450 |
| ST00591A |  | 1850 | 350 |

| MODEL | | Max length (mm) | Min length (mm) |
|---|---|---|---|
| ST00592A and ST00593A |  | 1580 | 660 |
| ST70002A |  | 1500 | 680 |
| ST00580A |  | 1520 | 710 |
| ST00499B |  | **$L_1$ max (mm)**<br>1660<br>**$L_2$ max (mm)**<br>1160 | **$L_1$ min (mm)**<br>550<br>**$L_2$ min (mm)**<br>300 |

*Maximum lengths are refer to the belt without considering the device on which the belt is installed. The usable length of the belt can be significantly different from the value indicated in table, because of type of fixation.*

### 3.5 Environmental conditions

Functioning temperature: from -20 to +60 °C
Storage temperature: from -20 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.
During storage take care not to put heavy materials onto the device.

### 4.2 Preparation

On receipt of the product:

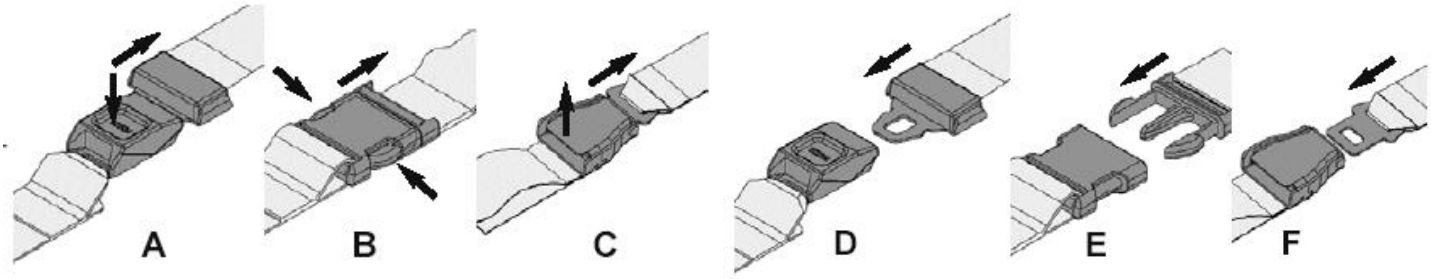
- Remove the packaging and display the material so that all components are visible.
- Check that all the components/pieces on the accompanying list are present.

The appliance must be checked before every use so as to reveal any working abnormalities and/or damage caused by transport and/or storage.
Therefore, before using the device, check it as indicated in paragraph 5.2.1.
If the device respects these conditions, it may be considered ready for use.

### 4.3 Functioning

#### 4.3.1 Opening and closing the buckles

| BUCKLES | OPENING | CLOSING |
|---|---|---|
| Metal | Press the "PRESS" button and extract the male part (fig. A) | Insert the male part into the female part, closing is to be completed with a "click" (fig. D) |
| Plastic | Press on both sides and extract the male part contemporarily (fig. B) | Insert the male part into the female part, closing is to be completed with a "click". Make sure both parts are connected correctly (fig. E) |
| Aluminium | Lift the buckle of the female part and extract the male part (fig. C) | Insert the male part into the female part, closing is to be completed with a "click" (fig. F) |




#### 4.3.2 Use of the belts with shackles

The belt with shackles may be used for immobilizing the patient on spinal boards and extrication devices equipped with "pins", or the Spencer Blue Matt vacuum mattress.

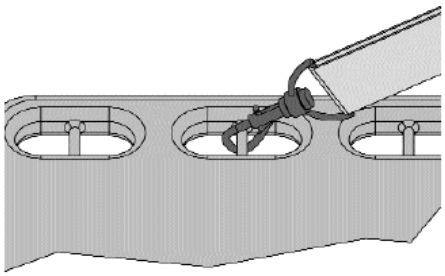


**Fig. G**

#### 4.3.2.1 Use with spine boards or extrication devices

Fix the belts to the device by fixing the shackle on one of the pins and fix the other part of the belt on the pin at the other side of the device (fig. G).

#### 4.3.2.2 Use with Spencer Blue Matt vacuum mattress

Fix the belts to the mattress, fixing the shackle in one of the triangular elements. Insert the other part of the belt in the element at the other side of the mattress. Make sure in any case the shackle has been closed correctly, before continuing the immobilization procedure.

#### 4.3.3 Belt length adjustment

In order to adjust the length of the belt, pull part x (in order to shorten) or y (in order to lengthen) of the belt, carrying out a perpendicular traction on the buckles (fig. I).

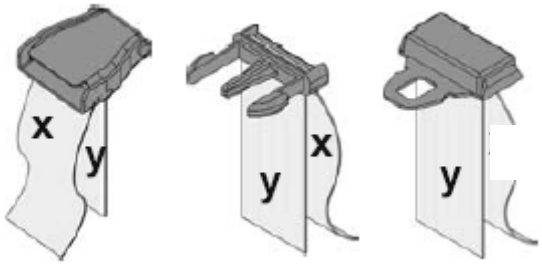



**Fig. H**

#### 4.3.4 Positioning and fixing the belts on the stretcher

Select the position of the belts carefully, in order to guarantee stable and safe patient fixations. In case of stretchers it is recommended to use frame (lateral tubes).
In order to meet the requirements of the standard UNI EN 1789, use only belts that have as anchor point the frame of the stretcher.
To optimize patient's immobilization, is necessary to use a thorax belt secured to the frame of the stretcher.

#### 4.3.4.1 Positioning one-piece belts

The belt should pass under the board, from one side to the other (fig. I).

**For stretchers, it is recommended to use two-piece belts and thorax belts.**

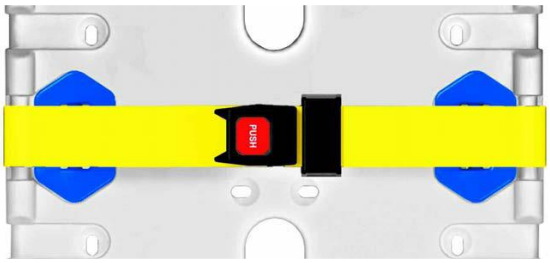



**Fig. I**

#### 4.3.4.2 Positioning two-piece belts

The ends of the belts should be fixed to the stretcher beside the patient position (fig. L).


**Fig. L**

#### 4.3.5 Positioning thorax belt

The four ends of the belt should be installed over the patient's shoulders and thorax. Rescuers should unite the two vertical pieces (shoulders) with the horizontal pieces (thorax) with the metal buckle (fig. M). The adjustable belts allow adjustment according to the size of the patient. To comply with the requirements of UNI EN 1789, it is necessary that the belts are anchored to the frame of the stretcher.


**Fig. M**

### 4.4 Troubleshooting

| PROBLEM | CAUSE | REMEDY |
|---|---|---|
| Difficulties with patient immobilization | The belt has not been adjusted correctly | Stretch the belts until correct immobilization becomes possible |
| | Presence of objects on one or both closing elements | Take away the objects and clean both closing elements |
| The belts do not close correctly | Damaged closing elements | Take the belts out of service immediately and contact the manufacturer |
| | Presence of objects on one or both closing elements | Take away the objects and clean both closing elements |
| The shackles do not close correctly | Damaged shackle | Take the belts out of service immediately and contact the manufacturer |

## 5. MAINTENANCE AND CLEANING

### 5.1 Cleaning

The metal parts, exposed to environmental influences, have been treated/coloured in order to increase resistance.
Not cleaning and sterilizing regularly, increases the risk of cross contamination. Do not use any aggressive and dissolving liquids for cleaning the device.
Before starting the cleaning operation, make sure to plan the following steps:
1 Disassembling belt/buckle
2 Cleaning-disinfection of the belt
3 Cleaning-disinfection of the buckle
4 Drying
5 Verification integrity of all components
6 Assembling belt/buckle
7 Verification of functionality

#### 5.1.1 Cleaning the belt

Clean the belt with lukewarm water and non-aggressive detergents.
Wash the belt with lukewarm water in order to take away any trace of detergents.
Make sure to dry the belt completely, in order to avoid the presence of detergents which may cause damage to the belt itself, limiting durability.

### 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.
The frequency of checks for precautionary maintenance depends on many elements, as the law regulations, the type of use, the frequency of use, the environmental conditions during in use and storage.
It is recommended to make the following checks before and after every use and at least once after three months:

- Presence of cuts, holes and abrasions
- Correct functioning of the regulation system
- Correct closure of the buckle

Please remind to perform the cleaning operation as described in paragraph 5.1 and check the functionality before every use.
All maintenance activities, both ordinary and extraordinary, shall be recorded and documented. This documentation must be maintained for at least 10 years from the end of life of the device and will be made available to the competent authorities and/or the manufacturer when required.
In the absence of such controls, the device may not respond to the requirements of security guaranteed by the manufacturer at the time of delivery.
Spencer Italia S.r.l. declines any responsibility for the proper functioning or damage caused by the use of devices that are not reviewed regularly.
Planned interventions are not required for periodic review by the manufacturer or by his authorized center.

#### 5.2.2 Special servicing

**Only the Manufacturer or centers with written authorization are authorized to complete any special servicing operations,** otherwise the device **loses the CE mark**, because the safety requirements can't be no longer guaranteed by the manufacturer.
Therefore, Spencer Italia S.r.l. can not be held responsible for any anomalies and/or damages to the patient and/or the operator.
For any operations that are not carried out directly by the Manufacturer but by an authorized 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 2 years.

## 6. ACCESSORIES AND SPARE PARTS

### 6.1 Accessories

| | |
|---|---|
| ST00522A | STX 22 Bag for belts with metal buckle, in orange PVC |
| ST00525A | STX 25 Bag for belts with plastic buckle, in orange PVC |
| ST00500C | Strap Up Belt cover with Spencer logo |

### 6.2 Spare parts

| | |
|---|---|
| ST00490A | Couple of male and female plastic buckle for belt |
| ST00590A | Male part for belt model STX 592 |