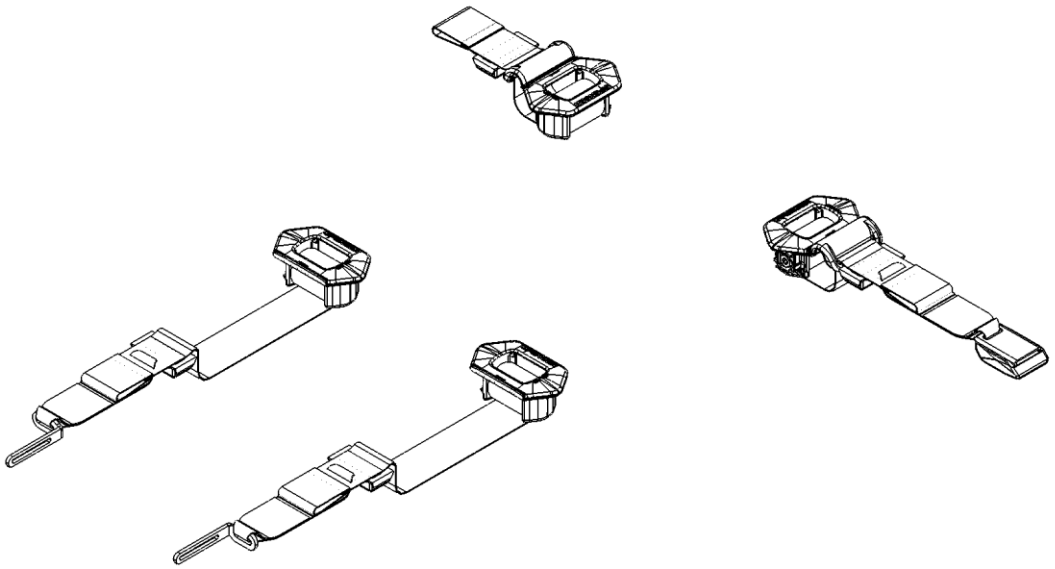
User's Manual

Belt with integrated re-winding system DNA-Strap and thorax DNA-Strap



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.

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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	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 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".
- 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.
- Regularly check the appliance. Carry out the prescribed maintenance in order to keep the appliance in good condition and to guarantee correct functioning and a long life.
- 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

- 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.
- Never leave an unassisted patient. The presence of at least one operator is essential at all times when the medical device is in use.
- Always immobilise the patient, after he/she has been positioned on the device.
- 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.
- The device does not meet the requirements of the standard EN 1789.

- 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.

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.

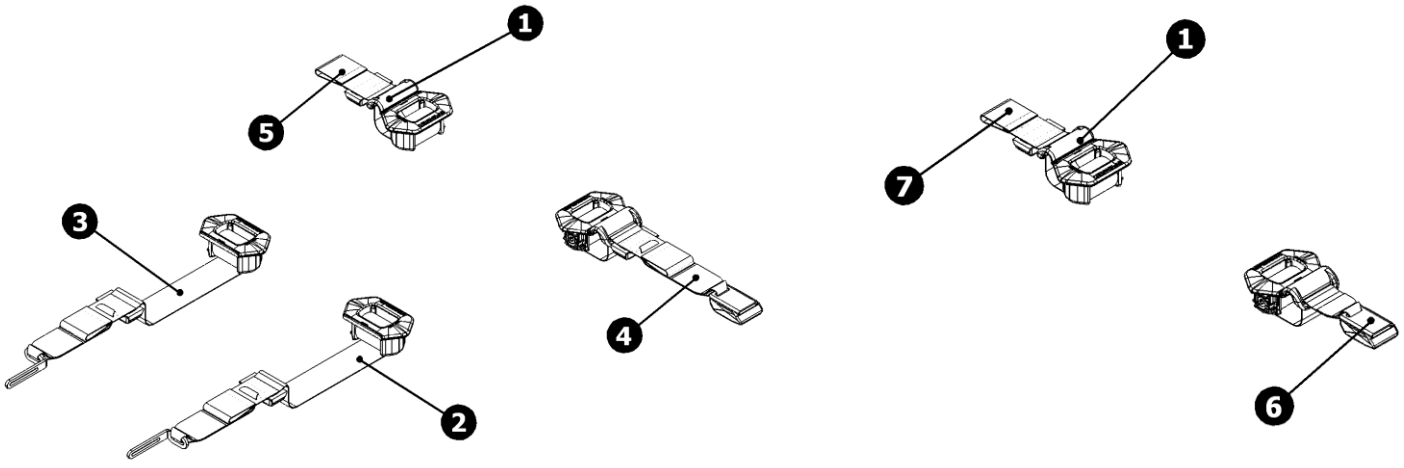
3. PRODUCT DESCRIPTION

3.1 Intended use

DNA Strap is a belt with integrated re-winding system, that allows to always have the patient straps ready for use and to store them automatically, avoiding interferences with the patient transport.

3.2 Main components

n°	Description	Materials	DNA Strap	Thorax DNA Strap
1	DNA re-winding system	Nylon	●	●
2	Left thorax belt with hinge	Nylon		●
3	Right thorax belt with hinge	Nylon		●
4	Thorax belt with female part	Nylon		●
5	Thorax belt with male part	Nylon		●
6	Belt with female part	Nylon	●	
7	Belt with male part	Nylon	●	



3.3 Models

ST00497B DNA Strap
ST00498B Thorax DNA Strap

3.4 Technical data

Dimensions	DNA Strap	Thorax DNA Strap
Width belt[mm]	50	50
Length left thorax strap with hinge [mm]	-	1180
Length right thorax strap with hinge [mm]	-	1180
Length male thorax strap [mm]	-	950
Length female thorax strap [mm]	-	870
Length male strap [mm]	920	-
Length female strap [mm]	700	-

Materials: **Nylon / Polypropylene / Steel**

3.5 Environmental conditions

Functioning temperature: from -15 to +50 °C
Storage temperature: from -20 to +60 °C
Relative humidity: from 15 to 90 %

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. In no way and under no circumstances should the device be considered as a work top.

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.
Before using the device, always check:

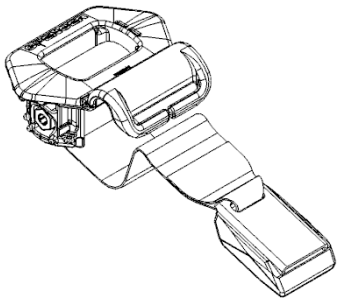
- General functionality of the device
- Functioning of the integrated re-winding system

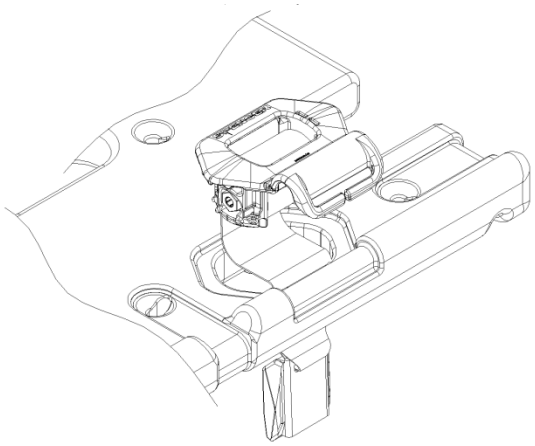
If everything is verified, the device can be considered ready for use.

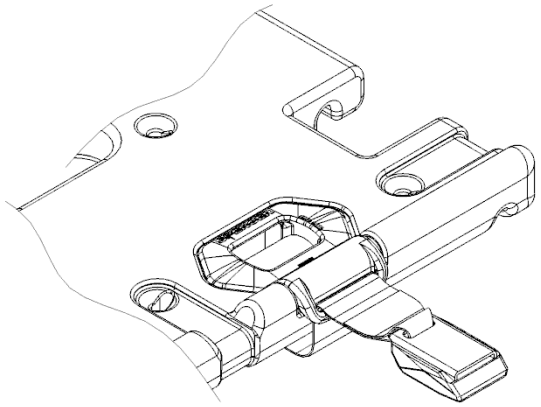
4.3 Functioning

4.3.1 Assembly

A - Release the strap from the re-winding system.
B - Insert the DNA system, maintaining the strap in tension, placed in the cavity in the body of the patient platform.
C - Reposition the strap into the dedicated area inside the DNA re-winding system, completing the installation.







4.3.2 Re-winding system of DNA Strap and Thorax DNA Strap

Mount the DNA system into the dedicated areas of the patient board, so that the re-winding system with male hook and the re-winding system with female hook are assembled respectively to the left and right side of the patient platform (fig. 1, 2).
The thorax re-winding systems with hooks must be mounted at the front end of the backrest platform, into the dedicated areas (fig. 1).

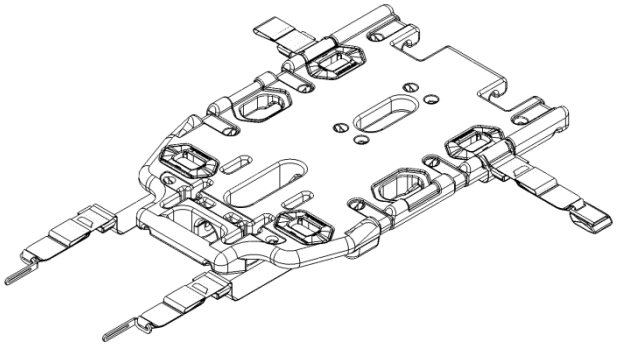


Fig.1

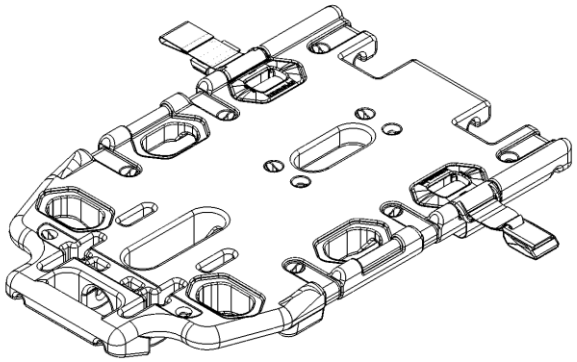


Fig.2

4.4 Troubleshooting

PROBLEM	CAUSE	REMEDY
The device does not roll/unroll	Movement is blocked or irregular	Remove device from service and contact the service centre
Buckle ends do not match up	Sediment in the attachments or failure of kinematic features	Proceed with accurate cleaning routine; if the problem is not resolved remove device from service and contact the service centre

5. MAINTENANCE AND CLEANING

5.1 Cleaning

Failure to carry out cleaning operations may cause the risk of cross infections due to the presence of secretions and/or other organic materials.
During all checking, maintenance and cleaning procedures, the operator must wear adequate personal protection such as gloves, mask, glasses etc.
Clean exposed parts with warm water, using a soapy sponge, use a mild detergent and avoid use of solvents and stain removers. Rinse thoroughly with warm water making sure to eliminate all traces of detergent, which might damage or compromise the integrity and durability of the device.
If disinfection is required, only products that have not corrosive or solvent action on the materials of the device. To get the brilliance of those parts, we recommended creams or waxes that are used for polishing cars.
Wipe dry with a soft cloth or chamois cloth and place it before they have reached a perfect drying. 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.
The use of high pressure water must be avoided. The water penetrates the joints and it eliminates the grease, creating the risk of possible corrosion of the components.

5.2 Maintenance

5.2.1 Precautionary Maintenance

The person who carries out the precautionary maintenance of the appliance 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.

Planned interventions are not required for periodic servicing by the Manufacturer or by an authorized centre, but we recommend to perform the following checks before and after each use and at least every **3 months**:

- Presence of cuts, holes, abrasions
- Conditions of seams
- Wear conditions of the re-winding system
- General functionality of the device
- Functioning of the re-winding system

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.

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.

5.2.1 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 2 years.
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

There are no accessories or replacement parts for this device.