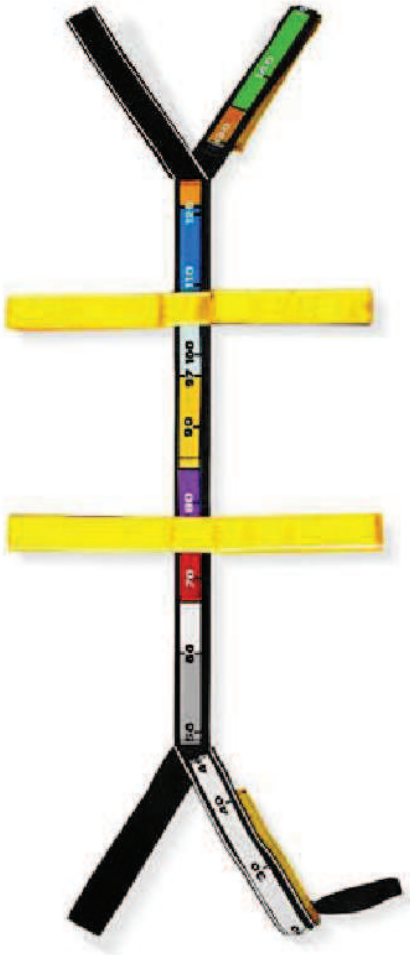
User's Manual

# RSP Rock Straps Paediatric

## Spider straps system for spine boards



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 warnings |
|  | See instructions for use |
| LOT | Lot number |
| SN | Serial 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 info@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 lot number (LOT) or serial number (SN) 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 lot number (LOT) or serial number (SN). 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. 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.
- 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.
- The device and all its components, after washing, should be allowed to dry completely before storing.
- Follow the procedures approved by the Emergency Medical Service for the immobilization and transport of the patient.
- Do not wash the device in the washing machine.
- Do not use drying machines.
- Avoid contact with sharp objects.
- Do not use the device if it is pierced, torn, frayed or eccessively worn out.
- Avoid pulling the device on rough surfaces.
- Select accurately the fixation points of the straps.
- The RSP Rock Straps Peadiatric system must be applied by at least two adequately trained operators.

### 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

The RSP Rock Straps Paediatric system represents an efficient method for the fixation of paediatric patients on immobilization supports.
Recommended for all operations which require quick application without the risks related to metal buckles (damage to the rescuer's gloves, incomplete closure due to spring lock systems, loss of ergonomics, etc.). Designed and adapted to the needs of versatility and adaptability to connection points, dimensions and pathology of any type of paediatric patient.

### 3.2 Models

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

ST02018A RSP Rock Straps Paediatric

### 3.3 Technical data

| | |
|---|---|
| Height | 1,5 mm |
| Width of system | 900 mm |
| Width of strap | 50 mm |
| Weight | 350 g |
| Material | nylon – polypropylene |
| Floatation | yes |
| Type of fixation | central strap |
| Number of fixation straps | 8 |
| Use | with spine boards with at least 4 handles on each side |
| Manufacturing system | sewing |
| Immobilising direction | vertical - lateral |

### 3.4 Environmental conditions

Functioning temperature: from -20 to +50 °C
Storage temperature: from -40 to +60 °C
Relative humidity: from 20 to 80 %

### 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 9001 | Managing systems for quality: requirements |
| UNI EN ISO 13485 | Medical Devices - Managing systems for quality – Requirements for regulamentation requirements |
| UNI EN 1865-1 | Directives for stretchers and other patient transport equipment on ambulances |
| 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 |
| 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 |
| BS OHSAS 18001 | Managing systems for safety and health at workplace |
| UNI EN 1789 | Medical vehicles and their equipment |

# 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.
For correct storage of the device, proceed as follows:

1. Place all female elements on the male Velcro® elements.
2. Fold all straps towards the central strap.
3. Fold all straps according to the central strap.
4. Fold the small holding strap around the package to fix all straps together.

## 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
- 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
- Integrity of all components of the device
- Correct folding of straps
- Correct connection of connecting parts
- Easy regulation of the device

## 4.3 Functioning

**The RSP Rock Straps Paediatric restraint system must be applied by at least two operators. The restraint system must be used only if in perfect working order and the correct maintenance scheme has been carried out.**
**Follow the immobilising and transport procedures approved by the Emergency Medical Service.**

### 4.3.1 Use of the device without head immobiliser (with cervical collar, extrication device, etc.)

1. Position the point where the vertical strap and the V-Straps meet up immediately below the cervical collar.
2. Un roll the RSP Rock Straps Paediatric down towards the feet of the patient making sure to keep the vertical strap in the central position.
3. Distribute the perpendicular straps in correspondence with the point to immobilize (chest, knees, feet).
4. First of all block the strap over the chest area and simultaneously fix at each side so as to avoid the patient from rolling and to help symmetrical immobilising.
5. Block the strap around the knee area (preferably just above the knees).
6. Block the distal strap (T-Straps) around the feed so that rotational movement of the legs and movement on the longitudinal axis are counterbalanced by the V-Straps.
7. Immobilise the patient’s head by placing two cushions simultaneously on each side and fix them making traction on the V-Straps.

Fig. A

Fig. B

Fig. C

Fig. D

**4.3.2 Using the device with Pedi Roll head immobiliser (ST02605A)**

Follow the instructions given in the previous paragraph 4.3.1, and then proceed as follows:

1. Immobilise head with the Pedi Roll head immobiliser.
2. Thread the two V-Straps over the shoulders and then downwards towards the handles of the board which are positioned below the external articulation of the clavicle (acromio)

**Check the position and the hold of the restraints before transporting the patient. When immobilising very small patients, the central tape must be tight and wrapped around the T-Straps. The straps cannot be separated.**
**In the case of fractures or suspected fracture in the areas where the straps pass, reposition the straps so as not to interfere or cause harm to these parts.**

Fig. E

### 4.3.3 Use of colour coded measuring tape

On the opposite side of the longitudinal tape of the RSP (which is the side without any velcro attachments) a tape measuring from 0 to 150 cm has been applied. The tape measure is divided into colour coded segments. Each colour corresponds to a different height of the cushion at the base of the Baby Go paediatric spine board (ST02141B, ST02142B).

1. Position the head of the child in corresponence with the 0 (zero) on the tape and measure the child checking also the colour segment.
2. Based on the colour segment, position the patient on the Baby Go paediatric spine board choosing the logo in the same corresponding colour which is indicated on the cushion on the spine board. This operation is necessary to compensate the nucal space which in the paediatric patient is higher than that of the adult patient.

Fig. F

### 4.4 Troubleshooting

| PROBLEM | CAUSE | REMEDY |
|---|---|---|
| Extreme patient mobility | Too long straps | Check the fixation straps |
| | Straps out of position | Make sure the straps are positioned correctly |

## 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.

**During all checking, maintenance and cleaning procedures, the operator must wear adequate personal protection such as gloves, mask, glasses, etc.**

Clean after use and check the integrity of the device.

Clean both surfaces of the splint by using a soft clean cloth and disinfectants, but not the ones including alcohol.

Do not use aggressive substances, stain removers or solvents of any kind. Allow to dry thoroughly before storing. The drying after cleaning 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 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:

- 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
- Integrity of all components of the device
- Correct folding of straps
- Correct connection of connecting parts
- Easy regulation of the device

**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.

### 5.2.2 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 2 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.

# 6 ACCESSORIES AND SPARE PARTS

## 6.1 Accessories

There aren't any accessories for these devices.

## 6.2 Spare parts

There aren't any spare parts for these devices.