User's manual

VACUUM SPLINTS

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 TUV SUD 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, apart from attaining an adequate use of the appliance, 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 with the product, inside the specially provided container and above all, away from any substances or liquids which could compromise perfect legibility.

1.3 SYMBOLS USED

SYMBOL		
	WARNING	See instructions for use.

1.4 SERVICING REQUESTS

For any information regarding the interpretation of the instructions, use, maintenance and installation, please contact the Spencer Customer Care Service on 0039 0521 5411 - Fax 0039 0521 541222 - e-mail: info@spencer.it or write to Spencer Italia Srl - Strada Cavi, 7 - 43034 Collecchio (Parma) ITALY.

1.5 DEMOLITION

Follow the current regulations.

1.6 LABELLING

The serial number can be found on each appliance and/or packaging and must not be removed or covered. In order to facilitate assistance please indicate or communicate the lot number (LOT) or the serial number (SN) on the label.

2 WARNINGS

2.1 GENERAL WARNINGS

Before carrying out any kind of operation on the product, 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.

In the case of any doubts as to the correct interpretation of the instructions, please contact Spencer Italia Srl, 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, in such cases all responsibility will be denied for any malfunctions or eventual injuries caused by the appliance itself.

Who modifies or has modified, prepares or has 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.

Ensure that all the necessary precautions are taken in order to avoid hazards that can arise as the result of contact with blood or body fluids. Handle with care.

2.2 SPECIFIC WARNINGS

The product must be used by trained personnel only.

The device must not be exposed to or come into contact with thermal sources of burning and flammable agents.

The device must be used at least by two rescuers instructed for the purpose with a good handling and training.

2.3 CONTRAINDICATIONS AND SIDE EFFECTS

If the device is used following the instruction contained in this manual and the operator is familiar with first aid practices it does not present any usage contra-indications.

The patients can in no way action the vacuum splint.

3 DESCRIPTION OF PRODUCT

3.1 INTENDED USE

The vacuum splint RES Q SPLINT, RES Q SPLINT PLUS and EMSOFT are devices for treating fractures, dislocations and sprains of limbs. Spencer vacuum splint must be used at least by two rescuers instructed for the purpose with a good handling and training.

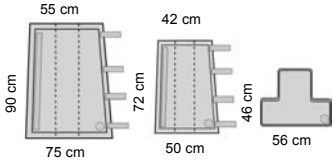
3.2 MAIN COMPONENTS

RES Q SPLINT	RES Q SPLINT PLUS	EMSOFT	EMSOFT PRO
adult arm or children leg	adult arm or children leg	Ankle, adult arm or children leg	adult arm or children leg
adult leg or newborn mattress	adult leg or newborn mattress	adult leg or newborn children mattress	adult leg or newborn mattress
foot	ankle	adult leg or children mattress	adult leg or children mattress

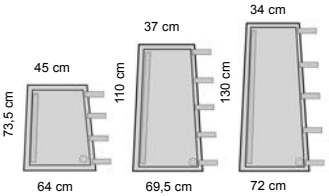
3.3 TECHNICAL DATA

The vacuum splint works on the evacuation principle. It is based on the increase of density of the splint when air is removed from it.
The increase in density causes the hardening of the splint irrespective of its position; this enable the first aid person to immobilise limbs at any angle ensuring a good level of restrain to the limb mobility in any direction is achieved.

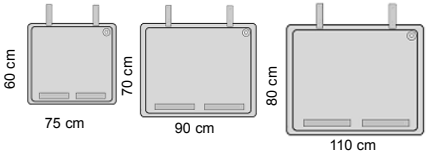
RES Q SPLINT



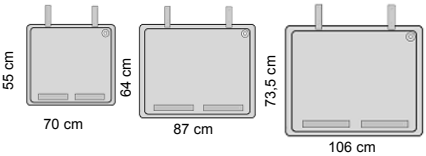
RES Q SPLINT PLUS



EM SOFT



EM SOFT PRO



3.3.2 WEIGHT

	RES Q SPLINT	RES Q SPLINT PLUS	EMSOFT	EMSOFT PRO
Misura S	0,35	0,7	0,6	0,85
Misura M	0,7	1	0,9	1,1
Misura L	1,2	1,15	1	1,5

3.4 ENVIRONMENTAL CONDITIONS

Functioning temperature	from -10 up to +50 °C
Storage andtransport temperature	from -20 up to +50 °C

4 OPERATING INSTRUCTIONS

4.1 TRANSPORT AND STORAGE

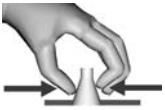
Before transporting the appliance, make sure that it is correctly packaged ensuring also that there are no risks of shocks or falls during the tran sport itself.
Keep the original packaging for any eventual further transport. Damage to the appliance caused during transport and handling is not covered by the guarantee. Repairs or replacement of the damaged parts are the responsibility of the Client. The appliance must be stored in a dry place free from humidity.

4.2 PREPARATION

On receiving the product remove the packaging and check that all the components/pieces are present and that the device is free from any cut, holes, abrasions or anomalies of the surface.
The device must be always checked before and after use, in order to detect working anomalies and/or damages caused by the transport and/or the warehousing.

4.3 FUNCTIONING

Evaluate the condition and size of the patient's limb to be immobilised. Expose completely the fractured area, cutting carefully the clothes away from the affected area. Check the pulsations, the paleness, the movement and the sensitivity below the fractured area.
Support the fractured area and the adjacent joint. Lift the limb gently sliding the vacuum splint in the open position open under it.
Wrap the vacuum splint around the injured limb in a way that the fracture and the patient pulse can be controlled .
Fasten the Velcro strips tightening lightly. Connect the vacuum pump to the device's valve; Evacuate the vacuum splint with the pump or an electrical aspirator. Establish the hardening sufficiently to limit the instinctive movements of the limb and check the pulse downstream the injured area (if not detected alter the compression of the device). Adjust the fastening strips on the new configuration and disconnect the pump from the valve.
Before storing away the vacuum splint ensure the device has been returned to the ambient pressure by opening the valve as shown in the picture below.

RES Q SPLINT / RES Q SPLINT PLUS	EMSOFT – EMSOFT PRO
	

4.4 TROUBLESHOOTING

PROBLEM	CAUSE	REMEDY
The patient's limb is not adequately immobilised	The vacuum splint has not been completely depressurised	Continue evacuating the device until the patient's limb is immobilised.
The patient's limb is not adequately immobilised	The vacuum splint has not been positioned correctly	Check the size of the vacuum splint and correct the positioning on the limb.

5 MAINTENANCE

5.1 CLEANING

If the cleaning operation is not properly performed the risks of cross contamination will increase due to the presence of body fluids and/or remains on the platform.

For the proper conservation of the device carry out the following operations:

Clean the internal and the external parts of the device with a clean cloth and with one of the disinfectants sold on the market (bactericide-germi cide). Remove the residuals of disinfectant with lukewarm water and leave it to dry.

5.2 MAINTENANCE

5.2.1Precautionary Maintenance

The device does not require scheduled servicing.

Before and after use, in order to detect any anomalies or damages, verify the correct functioning of the device by identifying and removing ano malies which could compromise its integrity and correct operation.

5.2.2Servicing Maintenance

The person to whom the servicing of the appliance is entrusted must guarantee the following basic requirements:

Adequate knowledge of the appliance, of its technical/construction features, of checks and final tests, of packaging, conservation and handling;

Adequate knowledge of the technology used in the making of the appliance;

Knowledge of the functions of the appliance, of any potential risks and of the probability of possible malfunctions or break-downs;

To be in possession of all the instruments necessary for carrying out any kind of technical operation regarding servicing;

To be in possession of original replacement parts or those authorized by the manufacturer;

Specialized technical personnel trained by the manufacturer for the servicing of the appliance in question;

Guarantee complete adherence to the instructions of the 93/42/CEE Directive also regarding the obligation towards the manufacturer to allow the aforementioned a post sales care and traceability of the appliance when requested.

The device, if used as described in the following instructions, has a life span of 5 years.

6 ACCESSORIES AND REPLACEMENT PARTS

CODE	DESCRIPTION
QM22540A	Carrying bag for Res Q Splint made of PVC orange
QM22594A	Carrying bag for Res Q Splint Plus made of PVC orange
QM22551A	Vacuum valve for Res Q Splint and Res Q Splint Plus
QM22703A	Carrying bag for vacuum splint.Emsoft made of PVC orange
QM22758A	Carrying bag for Kit Emsoft PRO made of PVC
QM22768A	Carrying bag for Kit Emsoft PRO made of PVC
QM22755A	Carrying bag for Emsoft PRO cm50x35 made of nylon BLU w/silk screen
QM22765A	Carrying bag for Emsoft PRO cm50x35 made of nylon YELLOW w/ silk screen
QM22756A	Carrying bag for Emsoft PRO cm70x50 made of nylon BLU w/ silk screen
QM22766A	Carrying bag for Emsoft PRO cm70x50 made of nylon YELLOW w/ silk screen
QM22757A	Carrying bag for Emsoft PRO cm95x70 made of nylon BLU w/ silk screen
QM22767A	Carrying bag for Emsoft PRO cm95x70 made of nylon YELLOW w/ silk screen
QM22704A	Straight connector Ø 10/11/12 KART mm for Emsoft
QM22130A	Mod.130 aluminum pump for vacuum splint

Warning

The information container in this document can be modified without warning and is not to be intended as a commitment on the part of Spencer Italia S.r.l.

With the right to modify. The Spencer products are exported to many countries in which the same identical regulations do not exist. It is for this reason that there can be many differences between the description and the actual product delivered. Spencer works continuously perfecting all the models of the models sold. We therefore hope to have your understanding if we reserve the right to modify the shape, equipping, lay-out or technical aspects that are herein described, at any given time.