

User's Manual**JEMS
CERVICAL COLLARS**

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 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, 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	MEANING
	See instructions for use.

1.4 SERVICING REQUESTS

For any information regarding the use, maintenance and installation, please contact the Spencer Customer Care Service on 0039 0521 541111 - Fax 0039 0521 541222 - e-mail: info@spencer.it or write to Spencer Italia Srl - Strada Cavi, 7 - 43044 Collecchio (Parma) ITALY.

1.5 DEMOLITION

Follow the current regulations.

1.6 LABELLING

The labelling 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 serial number (SN) or lot number (LOT) 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

- Do not use the device without previous training and reading all instructions.
- Follow all instructions in the training manual for paramedic personnel regarding the use of cervical collars and vertebral immobilization techniques.
- Follow up the suggestions of the local Emergency Aid authorities for the approved use of cervical collars.
- Check together with the medical personnel of emergency service the protocols regarding the use of cervical collars, especially the cases in which it is NOT recommended to use a cervical collar and change the position of the patient's head.
- Employ all adequate techniques for immobilization.
- Before applying the collar on the patient, the operator must determine the correct size of collar, based on the dimensions of the patient's neck. An incorrect collar will not immobilize the patient perfectly and could create serious damages to the patient.
- Beware of damaging the rubber parts with sharp, cutting objects.
- Do not expose to direct heat sources and/or high levels of humidity, salt or dust.
- Avoid long exposition to direct sunlight.
- Make sure to take all possible precautions in order to avoid any danger related to contact with blood and / or body liquids. Before every use, verify the integrity of the collar, in order to detect damages or anomalies in time.

2.3 CONTRAINDICATIONS AND SIDE EFFECTS

The appliance, if used as described in the manual, does not present any contraindications in use.

3 DESCRIPTION OF PRODUCT

3.1 INTENDED USE

The JEMS cervical collars are applied in many different first-aid and emergency rescue operations. These devices represent a rapid, secure and efficient solution for immobilizing the cervical rachis of traumatized patients. Moreover, these devices are equipped with a rapid mechanism which allows horizontal stocking of the device, avoiding the occupation of large amounts of space.

Generally the Jems cervical collars are made out of polymer material.

3.2 MAIN COMPONENTS

1. Immobilizing structure out of one piece
2. Velcro® fixation straps

3.3 MODELS

QC50102A	JEMS small (orange)
QC50103A	JEMS medium (orange)
QC50104A	JEMS large (orange)
QC50106A	JEMS small (white)
QC50107A	JEMS medium (white)
QC50108A	JEMS large (white)

3.4 TECHNICAL DATA

MODEL	CHARACTERISTICS			
	Mono-valve	Material		Material linkage
		Structure	Covering	
JEMS	X	PE sheet with stuffed borders	Leatherette-coated open cell polyurethane	Sewn

3.5 ENVIRONMENTAL CONDITIONS

Working temperature and stocking temperature: from -5 to +40 °C

Maximum relative Humidity: 95%

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 transport 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 display the material so that all is 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:
- The surface must be intact, without any cuts, holes or abrasions
- The buttonhole and the hook must be fixed correctly to the collar
- The collar must be clean in order to guarantee safe use

If the device does not appear suitable for correct and safe use, it must be taken out of service immediately and replaced.

4.3 FUNCTIONING

The use of the device should always start with the selection of the correct collar (related to the age and the characteristics of the patient) by trained and competent personnel. A simple method could be the vertical distance between chin and shoulder (measured by hand with the fingers). Once chosen the correct size, assemble all components in order to prepare the device for use.

In order to apply the collar to the patient, please follow the instructions hereunder:

1. Support the patient's head with both hands during the entire operation (see figure A).

While one operator supports the head, the other operator can apply the collar.

2. Grab the collar on the two ends, folding it around the patient's neck as shown in figure B, until both ends reach each other for complete fixation and immobilization.

Once concluded the operation, make sure the collar guarantees a correct immobilization, as a result of the chosen size.



4.4 TROUBLESHOOTING

PROBLEM	CAUSE	REMEDY
Detached Velcro®	Improper use	Take the device out of service immediately and contact the customer service centre.
Damaged structural components	Improper use	Check the state of the collar after every use. In case any damage is identified which may cause breaking, take the device out of service immediately and contact the customer service centre.
Wearing out of the Velcro® straps	Wear and tear	Take the device out of service immediately and contact the customer service centre
The collar does not immobilize the patient perfectly	Wrong collar selection	Replace the collar with the correct one

5 MAINTENANCE

5.1 CLEANING

All parts of the device must be cleaned and disinfected very carefully after every use, particularly attention is required for the joints between the different (moving) parts. The device must be cleaned with a 1:10 disinfectant - water solution or with water and normal soap.

Do not use aggressive chemicals or other potentially damaging substances for cleaning the device

If cleaning is not carried out regularly there may be a risk of cross infection due to the presence of secretions and/or residuals on the collar.

5.2 MAINTENANCE

5.2.1 Precautionary 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 anomalies which could compromise its integrity and correct operation, as described in paragraph 4.2.

5.2.2 Servicing 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

Transport bag for JEMS collars

QC19010C

Warning

The information contained 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.

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