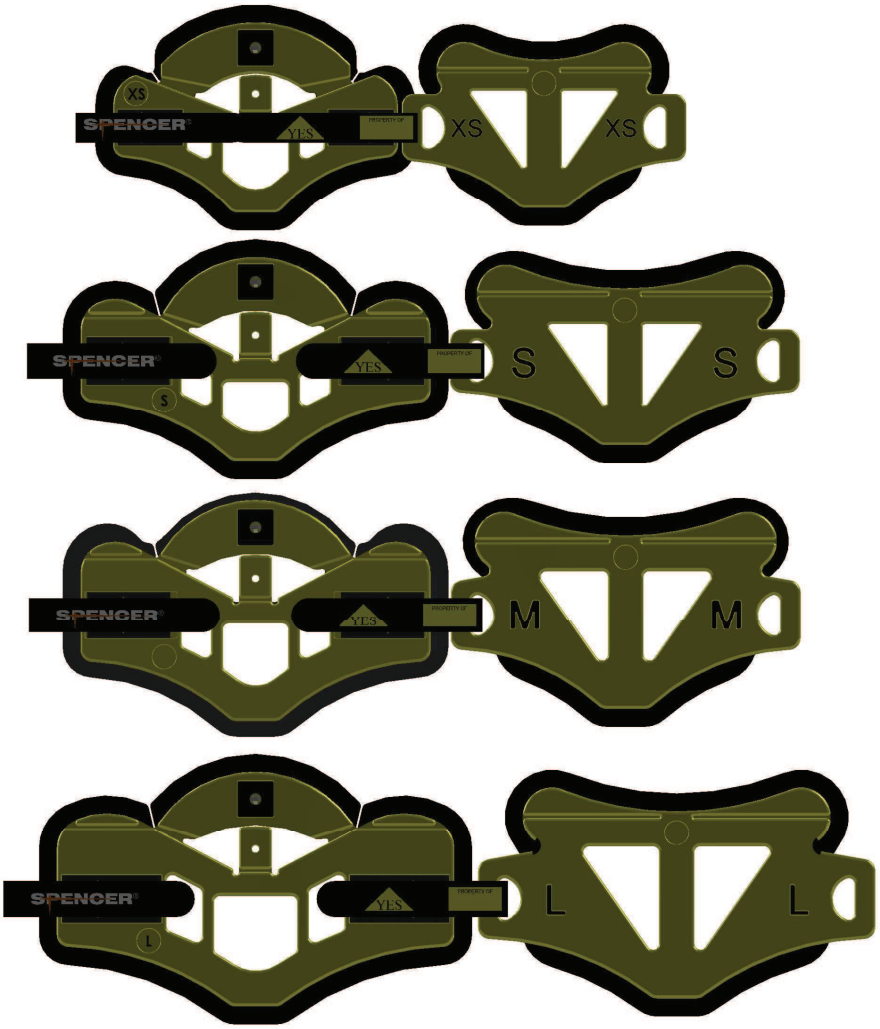
User's Manual

YES
Cervical collar



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 number
	Product code
	The product is compliant with the specifications of the Directive 93/42/CEE

1.4 Servicing requests

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 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 or communicate the serial number (SN) or lot number (LOT) shown on the label applied on the box or on the device.

1.5 Demolition

Follow the current regulations.
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.
- 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 available for conducting 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 themselves.
- Perform the required maintenance and to respect the life span of the device, as indicated by the Manufacturer in the 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.
- Never leave an unassisted patient. The presence of at least one operator is essential at all times when the medical device is in use.
- 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.

2.2 Specific warnings

- This product has been designed and tested to be used for a single patient andis not recommended for use for more than one patient.
- The device and all its components, after washing, should be allowed to dry completely before storing.
- Follow the procedures approved by the Emergency Medical Services for immobilization and transport of the patient.
- Do not machine wash.
- Avoid contact with sharp objects.
- Do not use if the device is punctured, torn, frayed or excessively worn.

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.

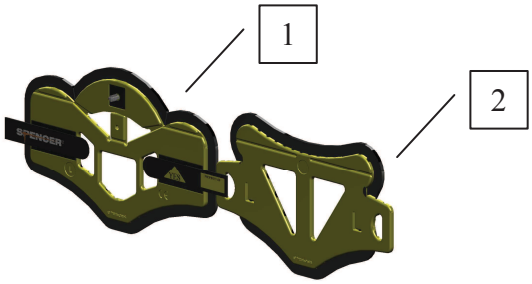
3. DESCRIPTION OF PRODUCT

3.1 Intended use

YES cervical collars are devices intended for use in first aid and emergencysituations. These devices are identified as a solution for the immobilization of the cervical spine in traumatic patients.

3.2 Main components

1. Anterior part
2. Rear part



3.3 Models

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

QC30100A	YES Yellow Emengency Super cervical collar size XS
QC30101A	YES Yellow Emengency Super cervical collar size S
QC30102A	YES Yellow Emengency Super cervical collar size M
QC30103A	YES Yellow Emengency Super cervical collar size L

3.4 Technical data

	YES size XS	YES size S	YES size M	YES size L
Anterior part				
Lenght (mm)	270	325	325	365
Height (mm)	139	168	180	192
Widht of the straps (mm)	25	30	30	30
Rear part				
Lenght (mm)	240	295	295	335
Height (mm)	170	179	194	207
Weight (g)	120	130	160	190
Material	Eva and closed cells PE	Eva and closed cells PE	Eva and closed cells PE	Eva and closed cells PE

3.5 Environmental conditions

Functioning temperature: from -5 to +40 °C - Storage temperature: from -10 to +50 °C - Relative humidity: from 5 to 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, 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.

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.

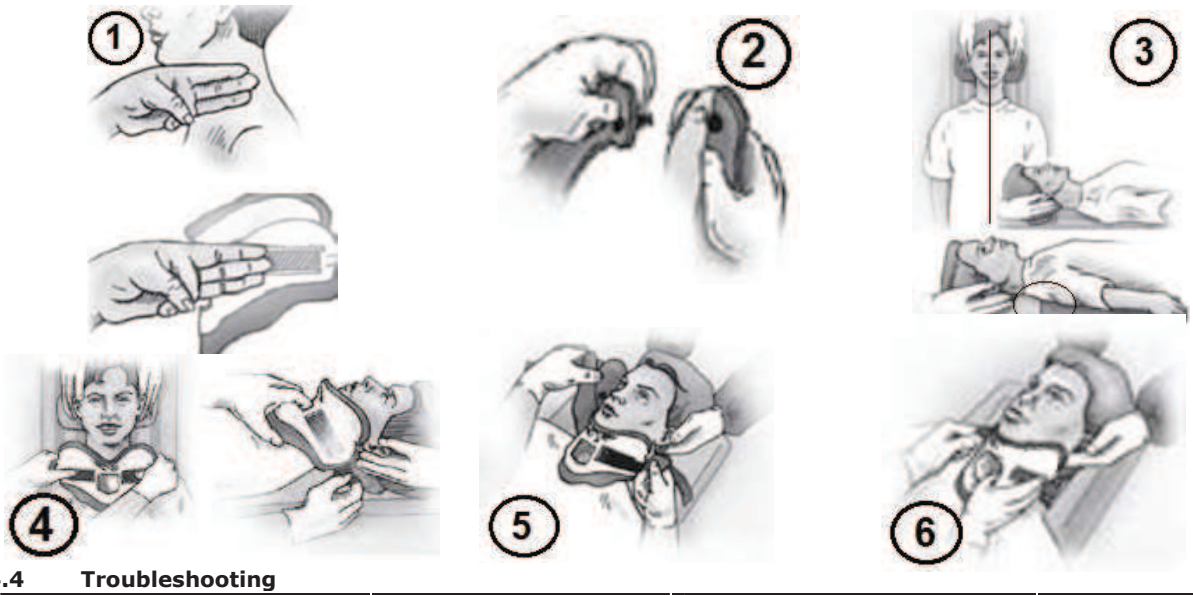
The appliance must be checked before every use so as to reveal any working abnormalities and/or damage caused by transport and/or storage. In particular, check:

- General functionality of the device
- Cleanliness of the device (remember that the failure of cleaning may cause the risk of cross infections)
- Absence of no cuts, holes, tears on the whole structure, including the straps

If the conditions above are met, the device may be considered ready for use, otherwise you must immediately remove the device from service and contact the Manufacturer.

4.3 Functioning

1. Choose the right size according to the body shape. Quick check of the size: measure with your fingers the vertical distance between the chin and shoulder.
2. Join the front element with the chin support by inserting the locking black pin through the hole.
3. Take precautions for the cervical vertebrae. Always keep the patient's head in natural alignment with the body (neutral position). For children up to 12 years, respect the correct height under the thorax to compensate the occipital prominence.
4. Apply the front element of the collar lifting it for supporting the chin.
5. Apply the rear element symmetrically.
6. Tighten the straps.
7. Check the size to make sure that the collar is not too small or too large.



4.4 Troubleshooting

PROBLEM	CAUSE	REMEDY	RESIDUAL RISK
Unsewing of Velcro parts	Improper use or worn	Put the device out of service	None
Breaking of the structural part	Improper use	Put the device out of service	None

5. MAINTENANCE AND CEANING

5.1 Cleaning

Failure to carry out cleaning operations may involve the risk of cross infection due to the presence of secretions and/or residuals.

The operator must always wear adequate personal protection such as gloves and mask etc. during all checking and cleaning procedures.

To clean the collar, use a disinfectant solution diluted in water in a ratio of 1:10.

5.2 Maintenance

5.2.1 Precautionary maintenance and periodic 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.
- 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.
- The operator must wear adequate personal protection such as gloves, mask, glasses etc.

Checks to be carried out before and after each use, and at least every 3 months, are indicated on paragraph 4.2.

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. Spencer Italia S.r.l. declines any responsibility for the proper functioning or damages caused to the patient or user by the use of devices not subject to routine maintenance, warranty and will void the compliance to the Medical Device Directive 93/42/CEE.

The device does not require periodic review of the planned interventions by the Manufacturer or an authorized centre.

5.2.2 Special servicing and average life span

Il dispositivo, se danneggiato, non può essere riparato, ma deve essere messo fuori servizio. Il dispositivo, se utilizzato come riportato nelle seguenti istruzioni, ha un tempo di vita medio di 3 anni. Spencer Italia S.r.l. declina ogni responsabilità sul funzionamento corretto o su eventuali danni provocati dall'utilizzo di dispositivi oltre il termine indicato dal Fabbricante.

6 ACCESSORIES

JM00300A Collar Bag 2 Transport bag for two-pieces cervical collars

There aren't any spare parts for this item.