

User's manual

NECK YORK CERVICAL COLLARS



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 Product Service GMBH

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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		
1	WARNING	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 5411 -Fax 0039 0521 541222 - email:info@spencer.it or write to Spencer Italia Srl - Strada Cavi, 7 - 43034 Collecchio (Parma) ITALY. In the case of any doubts as to the correct interpretation of the instructions, please contact Spencer Italia Sr.I. for any necessary clarifications.

1.5 DEMOLITION

Follow the current regulations.

1.6 LABELS

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

SPENCE	R®		
SPENCER ITALIA S.r.I Strada Cavi, 7 43044 Collecchio (PR) ITALY tel. +39 0521 541111 fax +39 0521 541222	REF	œ	LOT

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 SrI, 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 func tioning and a long life.
- In the case of any abnormalities or damage to the appliance, which could jeopardize the functioning and 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.
- The right size of the collar is extremely important. A collar that is too large or too small will not immobilize correctly and may cause severe damages to the patient.
- For application of the collar, the patient's head must be aligned in neutral position.
- Protect the collar from dirt, dust and humidity.
- 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.

2.3 CONTRAINDICATIONS AND SIDE EFFECTS

The appliance, if used by personnel who are familiar with First Aid procedures, does not present particular contraindications or side effects.

3 DESCRIPTION OF PRODUCT

3.1 INTENDED USE

Cervical collars are very common devices in emergency operations. These devices represent a quick, safe and efficient solution for the immobilization of the patient's neck in case of trauma. Besides, the NEC YORK, thanks to the mono-valve structure and the various sizes available, presents an ele vated employment ductility. It is equipped with a frontal hole for tracheostomy treatment.

In order to speed up emergency operations and to simplify the identification of the collar's size, different models and sizes are colour-coded; every colour represents size and specific characteristics of the collar. The materials used for the device and high-quality polymers, for example X-ray compatible, low-density polyethylene has been used.

3.1.MODELS

SIZE	Α	в	с	COLOR	CODE
INFANT	17"	13/4"	23/4"	PINK	QC19001C
PEDIATRIC	17"	2"	3"	ACQUA	QC19002C
NECKLESS	22"	21/2"	31/4"	PURPLE	QC19020C
SHORT	22"	3"	33/4"	BLUE	QC19021C
REGULAR	22"	4"	41/2"	ORANGE	QC19022C



3.2 MAIN COMPONENTS

The cervical collar is composed of:

- printed polyethylene
- closed-cell moulded expanded foam
- nylon rivets
- identifying labels
- Velcro® closure
- 3.3 TECHNICAL DATA

CHARACTERISTICS

Mono-valve	Material		Connection between materials
	Structure	Covering	-
Х	HDPE	Carrying structure in moulded polyethyle- ne.Volara® foam, crossed closed-cell polyethylene, flexible, with integral surface in order to avoid absorption of liquids and odours and to simplify washing	Rivet

Fixed closures in nylon with adjustable straps (Velcro®), light, X-ray compatible , easy to wash. Flatten for easy stocking.

3.4 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 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 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.

4.3 FUNCTIONING

Before using the device, it must be carefully chosen by trained and competent personnel, selecting the right model according to the patient's age and characteristics. A simple method could be the measurement of vertical distance between chin and shoulder using the operator's fingers. Once chosen the right size, assemble the device correctly in order to render it completely functional. Move the patient very carefully, keeping the rachis aligned with the head.



Curve front portion of collar and shape chin piece by pushing rivet into position.

Slide back under patient's neck and ad just for proper fit.



Position front part of coller under chin to patient's comfort.



Press Fastening-System with buttomhole and hook closuree to fit.

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 immedia tely and contact the customer service centre.
Wearing out of the Velcro® straps	Use	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 MAINTENCANCE

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.

5.2 MAINTENCANCE

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

BAG FOR COLLAR SET

QC19010C

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.

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