SPENCER

CONTOUR	*SUPER*	*TANGO FIX*
CONTOUR HP	*SUPER HP*	*PEDI FIX*
FXA PRO	*SUPER SX*	*PEDI GO*

Manuale d'uso e Manutenzione
FERMACAPO E FERMACAVIGLIE IT

Use and Maintenance Manual
HEAD RESTRAINTS AND ANKLE RESTRAINTS EN

Benutzungs- und Wartungshandbuch
KOPFHALTER UND KNÖCHELHALTER DE

Manuel d'utilisation et d'entretien
IMMOBILISATEUR DE TÊTE ET DE CHEVILLES FR

Manual de uso y mantenimiento
INMOVILIZADOR DE CABEZA E INMOVILIZADOR DE TOBILLOS ES

Manual de Uso e Manutenção
IMOBILIZADOR DE CABEÇA E IMOBILIZADOR DE TORNOZELO PT

Εγχειρίδιο χρήσης και συντήρησης
ΑΚΙΝΗΤΟΠΟΙΗΤΗΣ ΚΕΦΑΛΗΣ ΚΑΙ ΑΣΤΡΑΓΑΛΩΝ EL

Ръководство за употреба и поддръжка
ИМОБИЛИЗАТОР ЗА ГЛАВА И ОРТЕЗА ЗА ИМОБИЛИЗАЦИЯ НА ГЛЕЗЕН BG

Manual de utilizare și întreținere
IMOBILIZATORUL PENTRU CAP ȘI SISTEMUL DE IMOBILIZARE A PICIOARELOR RO

Bruger- og vedligeholdelsesvejledning
HOVED- OG ANKELIMMOBILISATOR DA

Gebruikers- en onderhoudshandleiding
HOOFD- EN ENKELSTEUNEN NL

SPENCER ITALIA SRL – Via Provinciale n° 12
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1. MODELS

The following basic models may be subject to implementation or change without notice.

- CONTOUR
- CONTOUR HP
- FXA PRO
- SUPER
- SUPER HP
- SUPER SX
- TANGO FIX
- PEDI FIX
- PEDI GO

2. INTENDED USE

2.1 INTENDED USE AND CLINICAL BENEFITS

Head and ankle restraints are accessories for spine boards or pick-up stretchers, to be used to increase the degree of patient immobilisation.

2.2 TARGET PATIENTS

There are no particular indications related to the patient group.
The target patients are those for whom use of a spine board or pick-up stretcher is foreseen.

2.3 PATIENT SELECTION CRITERIA

The patients expected are those for whom use of a spine board or pick-up stretcher is foreseen.

2.4 CONTRAINDICATIONS AND UNWANTED SIDE EFFECTS

No particular contraindications or side effects are known with relation to use of the device, as long as it is used in accordance with the user manual.

2.5 USERS AND INSTALLERS

The intended users are rescue workers with in-depth knowledge related to the immobilisation and handling of individuals with suspected spinal trauma or who require immobilisation. The user must be able to evaluate the most suitable type of device for use on the specific patient.
These devices are not intended for lay people.
Operators must be able to provide the necessary patient care.
The product must be used only by personnel trained in the use of this product and not on other similar products.

3. REFERENCE STANDARDS

REFERENCE	DOCUMENT TITLE
EU Regulation 2017/745	EU Regulation on Medical Devices

4. INTRODUCTION

4.1 DEVICE LABELLING AND TRACEABILITY

Each device is provided with a label, placed on the device itself and/or on the packaging, which contains the Manufacturer's identification data, product, CE marking, serial number (SN) or lot number (LOT).

4.2 SYMBOLS

Symbol	Meaning	Symbol	Meaning
CE	Device in compliance with EU Regulation 2017/745	⚠	Danger – Indicates a hazardous situation that may result in a situation directly related to serious injury or death.
MD	Medical device		See the user manual
	Manufacturer	LOT	Lot number
	Date of manufacture	REF	Product code
UDI	Unique Device Identifier	Rx only	Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner (only for USA Market)

4.3 WARRANTY AND SERVICE

Spencer Italia S.r.l. guarantees that products are free from defects for a period of **one year from the date of purchase.**
Spencer Customer Service tel. +39 0521 541154, fax +39 0521 541222, e-mail **service@spencer.it**
Warranty and service conditions are available on the website http://support.spencer.it

5. WARNINGS/DANGERS

Product features

Use of the product for any purpose other than that described in the User Manual is prohibited.

- The product must not be tampered with or modified without the manufacturer's authorisation.
- Avoid contact with sharp or abrasive objects.
- Operating temperature: from -5°C to + 50°C.
- Storage temperature: -10°C to +60°C.

General warnings for medical devices

- Do not use if the device or parts of it are punctured, torn, frayed, or excessively worn.
- Do not alter or modify the device arbitrarily, as doing so could result in unpredictable operation and damage to the patient and shall void the manufacturer's warranty and release the manufacturer from all liability.
- Participate in safety checks on products placed on the market, transmitting information regarding product risks to the Manufacturer as well as to the Competent Authorities for their respective actions.

With reference to EU Regulation 2017/745, please note that public or private operators who, when exercising their activity, detect an incident involving a medical product are required to notify the Ministry of Health, within the terms and in the manner established by one or more ministerial decrees, and notify the Manufacturer. Public or private health care professionals are required to notify the Manufacturer of any other incident that may allow the adoption of measures to ensure the protection and health of patients and users.

6. SPECIFIC WARNINGS

To use the head and ankle restraints, you must also have read, understood and carefully follow all the instructions in the user manual.

- ⚠ Perform immobilisation simulations with dummies before putting the device into service.

- ⚠ Improper use may result in injury or permanent disability. Always follow the procedures and protocols approved by the relevant Emergency Medical Service.
- ⚠ These instructions provide information on the functionality and application of the device and do not address patient positioning procedures, for which it is advisable to always follow the guidelines of the relevant emergency medical service.
- To preserve the life of the device, protect it as much as possible from UV rays and adverse weather conditions.
- If the product is found to be malfunctioning, immediately use a similar device to ensure continuity of ongoing operations. Non-compliant devices must be taken out of service.
- The device must only be used by trained personnel.
- Qualified personnel must be present during use of the device.
- At least two rescuers must be present for correct application of the device.
- Operators must be able to assess the patient's injuries and decide whether the use of the device is appropriate.
- Before using the head or ankle restraints, assess the need for their application according to the clinical condition of the patient and make sure that the most suitable type of device is used.
- Operators must be able to assess the most suitable type of head restraint for use, taking into account the type of patient and the characteristics of the injuries.
- The device must not be exposed, much less come into contact with thermal sources of combustion or flammable agents.
- Always check the conditions of all parts before use.

7. RESIDUAL RISK

No residual risks, or rather risks that could arise despite compliance with all warnings in this user manual, have been identified.

8. TECHNICAL DATA AND COMPONENTS

CONTOUR / CONTOUR HP	SUPER/SUPER HP	TANGO FIX / PEDI GO
		
FXA PRO	**SUPER SX**	**PEDI FIX**
		

Cushions: Made of polyurethane foam, they immobilise the patient's head from lateral movement.
Base: Made of padded PVC, or rigid polyethylene for the HP versions, it is used for anchoring to the primary immobilisation device (e.g. spine board or pick-up stretcher). It is equipped with strap inserts for the application of cushions.
Ankle restraints: Made of rigid polyethylene, it is equipped with straps for application to the spine board as well as for fixing the ankles.

9. PROPER USE

Operators performing immobilisation must be able to select the most suitable type of head restraint.
Regardless of the type of head restraint used, make sure that there are no conditions that are not compatible with use of this device (i.e. penetrating bodies).

9.1 APPLYING THE HEAD RESTRAINT BASE TO THE SPINE BOARD

1 – Insert the upper belt into the hole provided on the spine board.

2 – Pull out the strap from the opposite side.

3 – Pass the strap through the dedicated slot.

4 – Close the strap by adhering the strap.

5 – Pass the lateral straps through the holes present on the spine board.

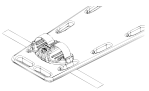
6 – Pass the straps underneath the board and insert them into the two holes on the opposite side of the board.

7 – Fix the straps on the base of the head restraint, making the strap properly adheres.

IT EN DE FR ES PT EL BG RO DA NL

The cushions can be applied after making sure that the base is properly secured, placing them on the base and having the straps adhere..
Pedi Go is not equipped with a base and therefore cushions must be applied directly on the Baby Go spine board at the strap areas.
Once the patient is positioned according to the protocols approved by your emergency medical service, attach the cushions with the chin and forehead straps provided with the headband.
If the device is to be used with paediatric patients on the **Tango Fix,** the paediatric cushions can be removed from the adult cushions, then applied as described above.

9.2 APPLYING THE SUPER SX HEAD RESTRAINT



- Carefully clean the surface of the pick-up stretcher so that no dust or oily residues are present.
- Apply the strap adhesive elements in the head rest area where the head restraint is to be applied.
- Cushions can be applied during patient positioning manoeuvres by placing them in the dedicated strap areas and attaching them to the patient by means of the chin and forehead straps.

9.3 APPLYING THE ANKLE RESTRAINTS

- After positioning the patient on the board, insert the device below the ankles so that the logo representing the feet is visible to the operator.
- Wrap the ankles with the straps, pass them through the eyelets on either side of the device and, after wrapping them around the handles, close them on themselves by adhering the strap inserts.

10. CLEANING AND MAINTENANCE

10.1 CLEANING

Failure to carry out the correct cleaning operations could increase the risk of cross-infection due to presence of body fluids and/or residues.
The operator must wear suitable personal protective equipment, such as gloves, goggles, etc. during all checking and cleaning operations.

Clean the exposed parts with water and delicate soap. Never use solvents or stain removers.
Rinse thoroughly with lukewarm water, making sure you have removed all traces of detergent, which may deteriorate or compromise conditions and durability. The use of high-pressure water should be avoided.
Allow to dry thoroughly before storing. Drying after washing or after use in a wet environment must be natural and not forced. Do not use flames or other direct heat sources.
If blood is visible, oxidise it before washing with water.

If **disinfecting**, use products that do not have a solvent or corrosive action on materials constituting the device, in addition to being classified as medical-surgical devices. Be sure to take all precautions to ensure that there is no risk of cross-infection or contamination of patients and operators.

10.2 MAINTENANCE

The device does not require a routine maintenance program, but checks must be made to verify:
- General functionality of the device.
- Cleanliness of the device (remember that the failure of cleaning may cause the risk of cross infections).
- Fulfilment of the requirements of the user manual in section Warnings and Specific Warnings.
- Fulfilment of the requirements of the manual in section on Proper use.

No periodic overhaul is foreseen for the device.

10.3 LIFE SPAN

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

11. TROUBLESHOOTING TABLE

PROBLEM	CAUSE	REMEDY
The straps do not adhere correctly	The straps are dirty	Remove any residue from the straps.
Excessive device mobility	The base is excessively mobile with respect to the spinal board to which it is attached	Tighten the fixing straps around the spine board
The device has tears or other damaged parts	Misuse or normal wear and tear	Put the device out of service immediately and replace it with a similar one

12. ACCESSORIES

There are no accessories present.

13. SPARE PARTS

CODE	DESCRIPTION	CODE	DESCRIPTION
RISH002	SET OF HEAD RESTRAINT CHIN/FOREHAND STRAPS	**RISH003**	SET OF HP HEAD RESTRAINT CHIN/FOREHAND STRAPS

14. DISPOSAL

When devices and their accessories are no longer suitable for use, they can be disposed of as normal municipal solid waste if they have not been contaminated by special agents. Otherwise, follow the regulations in force regarding disposal.

Warning

The information contained in this document is subject to change without notice and is to be intended as a commitment by Spencer Italia S.r.l. subject to change.

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