User's manual

Head immobilizers and ankle immobilizers

SPENCER®

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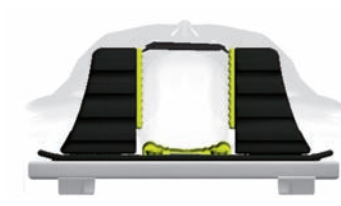

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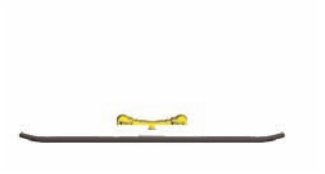

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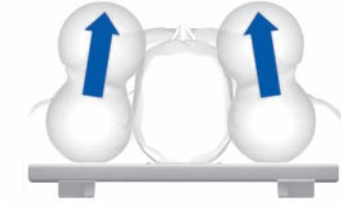

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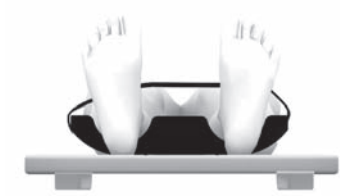

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Thank you for choosing a Spencer product

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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, 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 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
⚠ General or specific warning

See instructions for use

LOT Lot number

REF Product code

CE Product compliant with specifications of the Directive 93/42/CEE

Single use

1.4 Servicing request
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.

1.5 Demolition
Follow the current regulations.

1.6 Labelling
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.

2. WARNINGS

⚠ 2.1 General warnings

- Before carrying out any kind of operation on the appliance, 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 S.r.l. for any necessary clarifications.
- Regularly check the appliance.
- 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 injuries caused by the appliance itself.
- 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.
- 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.
- Handle with care.

⚠ 2.2 Specific warnings

- The product must be used by trained personnel only.
- 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.
- When the device is being used, the assistance of qualified staff must be guaranteed.
- The head immobiliser or ankle immobiliser should not be exposed nor get in contact with heat sources or flammable agents.
- The device must be applied to the patient by at least two operators.
- Always check the integrity of all the parts of the device before use.
- Replace the belts immediately if worn out or damaged (if present).
- Select the fixation points of the belts accurately (if present).
- Position and regulate the device so not to obstruct any operations the rescuers may need to carry out and the use of the rescue appliances.

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. PRODUCT DESCRIPTION

3.1 Intended use
The Spencer head immobiliser and ankle immobiliser have been designed to increase the stability of the cranium and the spine and likewise the distal areas of the lower limbs during movement and transport of patients on the spine board. Their function is to eliminate the results caused any movement that may occur and in any direction with a guarantee of stability even if subjected to stress by vertical components (perpendicular to the fixing board). Designed to immobilise the head or the ankles when moving a patient who has suspected spinal injuries. The Spencer head immobiliser and ankle immobiliser, if used in combination with the spine board, restraint belts and rigid cervical collar, offer efficient immobilising which permits extended transport or transport over uneven surfaces even of patients in a critical state.

3.2 Main components (fig. 1 - 2 page I)
A Nylon belts to optimise stability of device

B Side support cushions with ear holes
C Semi rigid base for application of cushions with Velcro® system
D Removable cushion for use as paediatric head immobiliser
E Restraint belts for use with spine board
F Shaped surface for restraint of the ankles

3.3 Models

SH00300A
Fix Head Advanced universal head immobiliser, orange
SH00310A
Fix Head Advanced universal head immobiliser, black
SH00201A
Spencer Contour Anatomic universal head immobiliser, yellow/black
SH00200A
Spencer Contour Anatomic universal head immobiliser, blue
SH00111C
Super Blue Compact universal head immobiliser, yellow
SH00112C
Super Blue Compact universal head immobiliser, orange
SH00117C
Super Blue Compact universal head immobiliser, green
SH00110C
Super Blue Compact universal head immobiliser, blue
SH00104C
Super Blue Compact universal head immobiliser, black
SH00240A
Tango Fix Integrated adult/paediatric head immobiliser
SH00250A
U-Fix Adult head immobiliser
SH00260A
Pedi Fix Paediatric head immobiliser
SH00262A
Pedi Go Paediatric head immobiliser, only cushions, for Baby Go and Pedi Loc spine boards
ST02605A
Pedi Roll Paediatric head immobiliser
SH00160A
751 Inflatable disposable head immobiliser
SH00130C
755 Universal disposable head immobiliser
SH00120C
756 Stabilized disposable head immobiliser
SH00150A
FXA Universal ankle immobiliser
SH00151A
FXA Pro Anatomic universal ankle immobiliser

3.4 Technical data (chart 3.4 page 4)

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.
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. During storage take care not to put heavy materials onto the device. In no way and under no circumstances should the device be considered as a work top.

⚠ 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.
Before putting the device in service make the following careful checks:
• general integrity (absence of cuts, holes, abrasions)
• general functionality
• Velcro® and belts tightness (if present)
If everything is regular, the device is ready to be used.

⚠ 4.3 Functioning

4.3.1 Application of head immobiliser Fix Head, Spencer Contour, Super Blue, Tango Fix, U-Fix, Pedi Fix (fig. 3 - 4 - 5 - 6 page II)

The product must be used by trained personnel only and must be applied to the patient by at least two operators.
Attach the device to the spine board before use using the belts supplied (E fig. 1 page I), making sure that the side of the spine board with Velcro® is topside. Check the position and the correct fixing of the belts before use with the patient. Load the patient on the spine board maintaining the correct alignment. Block the patient's head by placing the special anatomical cushions symmetrically on each side and without applying any pressure. Fix the two belts which restrain the head (A fig. 1 page I) by passing them over the anatomical cushions and uniting them with the buckles on the opposite side.
Proceed and attach the belts, adjust the tension and block them using the Velcro® system. Proceed in the same way with both belts making sure to block the chin strap first and then the forehead strap. Before transporting the patient it is necessary to proceed with the application of the special restraints for the spine board which will block the patients shoulders so as to avoid compression of the vertebrae in the neck area.

4.3.2 Double use adult/paediatric head immobiliser: Spencer Contour and Tango Fix

Spencer Contour and Tango Fix head immobilisers can be used both for adult and paediatric patients.
They have a removable cushion in the centre of the base applied with Velcro® (fig. 7 page II). If using the head immobiliser with an adult patient, the cushion must be in position in the centre between the two cushions. When in use for a paediatric patient the cushion must be removed. This will also permit the two anatomical cushions to be positioned closer and the Velcro® permits fixing in the correct position.
The Tango Fix head immobiliser is characterised by the special "U" shape of the cushions. The cushion for immobilising the paediatric patient is situated inside the main cushion. Therefore in a confined space you have both adult and paediatric head immobiliser which will permit the correct immobilising for both paediatric and adult patient (fig. 8 page II).

4.3.3 Application of the Pedi Go, Pedi Roll, 751, 755, 756 head immobiliser

The device must be applied only by trained operators. At least two operators are essential for the application.
The Pedi Go, Pedi Roll and 751 head immobilisers are extremely simple to use and to apply. When the patient is in the correct position on the spine board, maintain the correct spinal alignment and proceed to immobilise the head by positioning the cushions at the sides of the head. The Pedi Go and Pedi Roll should then be fixed to the spine board and to the patient's head using the special belts (fig. 9 page II).
The 751 head immobiliser can be fixed using 50 mm surgical tape (fig. 10 page II).
To immobilise the patient with the 755 and 756 an immobiliser base must first be placed on the spine board. Once the patient has been loaded and correctly aligned, with the patient's head positioned on the head immobiliser base proceed to block in position by lifting the extension on the sides until they are positioned on the sides of the head but do not exert any pressure. Fixing of the device should be carried out using the purpose made straps which block the device and the head in position and then maintain them in position on the spine board (fig. 11 - 12 page II).

4.3.4 Application of FXA, FXA Pro ankle immobiliser (fig. 13 - 14 page II)

The device must be applied only by trained operators. At least two operators are essential for the application. Assemble the device on the spine board before use using the purpose made belts supplied (E fig. 1 page I). Load the patient in the correct alignment. Continue to position the ankles in the hollows on the cushion. Block the ankles in a stable, correctly aligned position using the top fixing wrap (fig. 13 - 14 page II).

4.4 Troubleshooting (chart 4.4 page 4)

5. MAINTENANCE AND CLEANING

5.1 Cleaning

Failure to carry out cleaning operations can cause the risk of cross infection.
Do not use aggressive substances or solvents of any type. The device can be washed using delicate detergents or water and soap. At the end always dry the product with a soft and clean cloth. Using high pressure water will raise the risk of lesions.
Ensure you have dried the device perfectly so to avoid the presence of residual detergents, which could deteriorate or compromise the integrity and duration of the device.

5.2 Maintenance

5.2.1 Precautionary Maintenance

The person responsible for every day maintenance can only substitute the spare parts indicated on paragraph 6 "Spare Parts". All other substitutions or repairs can be carried out only by the manufacturer or by a centre authorised by the manufacturer. For any operations that are not carried out directly by the manufacturer but by an authorised centre, we have to underline that a report regarding all operations carried out must be requested. This will permit both Spencer Italia S.r.l. and the end user to keep a log book regarding the operations carried out on the device.
The device does not require programmed servicing.

5.2.2 Special servicing

⚠ **Only the manufacturer or centres with written authorisation are authorised to complete any special servicing operations.**
For any operations that are not carried out directly by the manufacturer but by an authorised centre, we have to underline that a report regarding all operations carried out must be requested. This will permit both Spencer Italia S.r.l. and the end user to keep a log book regarding the operations carried out on the device.
The device, if used as indicated in the following instruction manual, has an average life span of 5 years. The life span can be expanded only following a general revision of the product that must be carried out by the manufacturer or by a centre authorised by the manufacturer.

6. SPARE PARTS

SH00303A
Base for orange Fix Head
SH00302A
Cushion for orange Fix Head
SH00301A
Kit head/chin straps for Fix Head
SH00242A
Base for Spencer Contour, Tango Fix, U-Fix and Pedi Fix
SH00214A
Cushion for yellow/black Spencer Contour
SH00212A
Cushion for blue Spencer Contour
SH00244A
Kit head/chin straps for Spencer Contour, Super Blue, Tango Fix, U-Fix, Pedi Fix, Pedi Go and Pedi Roll
SH00243A
Base for Super Blue
SH00100C
Cushion for yellow Super Blue
SH00101C
Cushion for orange Super Blue
SH00102C
Cushion for green Super Blue
SH00108C
Cushion for blue Super Blue
SH00103C
Cushion for black Super Blue
SH00241A
Adult/paediatric cushion for Tango Fix
SH00251A
Adult cushion for U-Fix
SH00261A
Paediatric cushion for Pedi Go

3.4

Head immobilizers and ankle immobilizers	Head immobilizers						Ankle immobilizers	
	Fix Head	Spencer Contour	Super Blue	Tango Fix	Pedi Fix	Pedi Roll	FXA	FXA Pro
Code	SH00300A	SH00200A	SH00110C	SH00240A	SH00260A	ST02605A	SH00150A	SH00151A
Total weight (kg)	2,3	1,5	1	2,5	1,1	0,092	0,4	0,376
X-ray compatible	●	●	●	●	●	●	●	●
Immobilization directions	◀▶▼▲	◀▶▼▲	◀▶▼▲	◀▶▼▲	◀▶▼▲	◀▶▼	◀▶▼	◀▶▼
Floatation	●		●	●	●	●		
Compatibility with spine board	All	All	All	All	Pedi Loc / Baby Go	Pedi Loc / Baby Go	All	All
Compatibility with scoop stretcher			●					●
Fixation straps	2	2	2	2	2		1	1
Type of fixation	Velcro® / straps	Velcro® / straps	Velcro® / straps	Velcro® / straps	Velcro® / straps			
Reusable	●	●	●			●	●	●
Base								
Dimensions (mm)	375 x 10 x h275	390 x 15 x h260	384 x 21 x h290	445 x 28 x h 280	445 x 28 x h 280		345 x 120 x h90	
Weight (kg)	1,2	0,5	0,3	0,5	0,5		0,4	
Type	Semi rigid collection	Removable layer	Stuffed	Removable layer	Removable layer			
Material	Plastic compound	Expanded PE / Spentex®	Expanded PE / Spentex®	Polyethylene / rubber	Polyethylene / rubber		Closed cell expanded PE	Plastic compound
Manufacturing system	Injection	Injection	Injection	Blow moulding / injection	Blow moulding / injection	Hand made	Hand made	Injection
Colour	Orange	Blue	Blue	Black / yellow	Black / yellow	Blue	Orange	Black
Head blocks								
Dimensions (mm)	225 x 90 x h150	235 x 130 x h160	245 x 80 x h160	230 x 125 x h160	190 x 70 x h123	160x80xh80		
Weight (kg)	1,2	1	0,5	1,2	0,6	0,092		
Structure		Stuffed pillows	Stuffed pillows	Rigid with soft pillows	Rigid with soft pillows			
Material	Plastic compound	Plastic compound	Plastic compound	Polyethylene / rubber	Polyethylene / rubber	Vinyl covered expanded		
Manufacturing system	Injection	Injection	Injection	Blow moulding / injection	Blow moulding / injection	Hand made		
Auricular inspection	●	●	●	●	●	●		
Colour	Orange	Blue	Blue	Black / yellow	Black / yellow	Blue	Orange	Black
Functioning temperature (°C)	from -20 to +40	from -20 to +40	from -20 to +40	from -20 to +60	from -20 to +60	from -20 to +40	from -20 to +40	from -20 to +40
Storage temperature (°C)	from -20 to +40	from -20 to +40	from -20 to +40	from -20 to +60	from -20 to +60	from -20 to +40	from -20 to +40	from -20 to +40

4.4

PROBLEM	CAUSE	REMEDY
Excessive mobility of the head/ankles	The basis presents an excessive mobility in relation to the spine board it is strapped to	Tighten the belts at the basis around the spine board
	Loose belts	Check the correct closure and tension of the fastening belts
	Anatomic supports positioned wrong	Ensure that the hollow part of the anatomic support is in contact with the head/ankles
Lesions to the device	Wear and tear, improper use	Put immediately the device out of service and contact the service centre

CE

We declare that the appliances conform with the Directive 93/42/CEE "Medical Devices".
Si dichiara che i dispositivi sono conformi alla Direttiva 93/42/CEE "Dispositivi Medici".
Se declara que los dispositivos son conformes a la Directiva 93/42/CEE "Dispositivos Médicos".
Nous déclarons que les dispositifs sont conformes à la Directive 93/42/CEE "Dispositifs Médicaux".

ISO 9001	Quality management systems - Requirements
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 980	Graphical symbols for use in the labelling of medical devices
CEI EN ISO 14971	Medical devices - Application of risk management to 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.
Sistema di Garanzia di Qualità per la produzione ed il controllo finale dei prodotti certificato dall'organismo notificato TÜV SÜD Product Service GmbH.
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Système de Garantie de Qualité pour la production et le contrôle final des produits certifié par l'organisme TÜV SÜD Product Service GmbH.

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