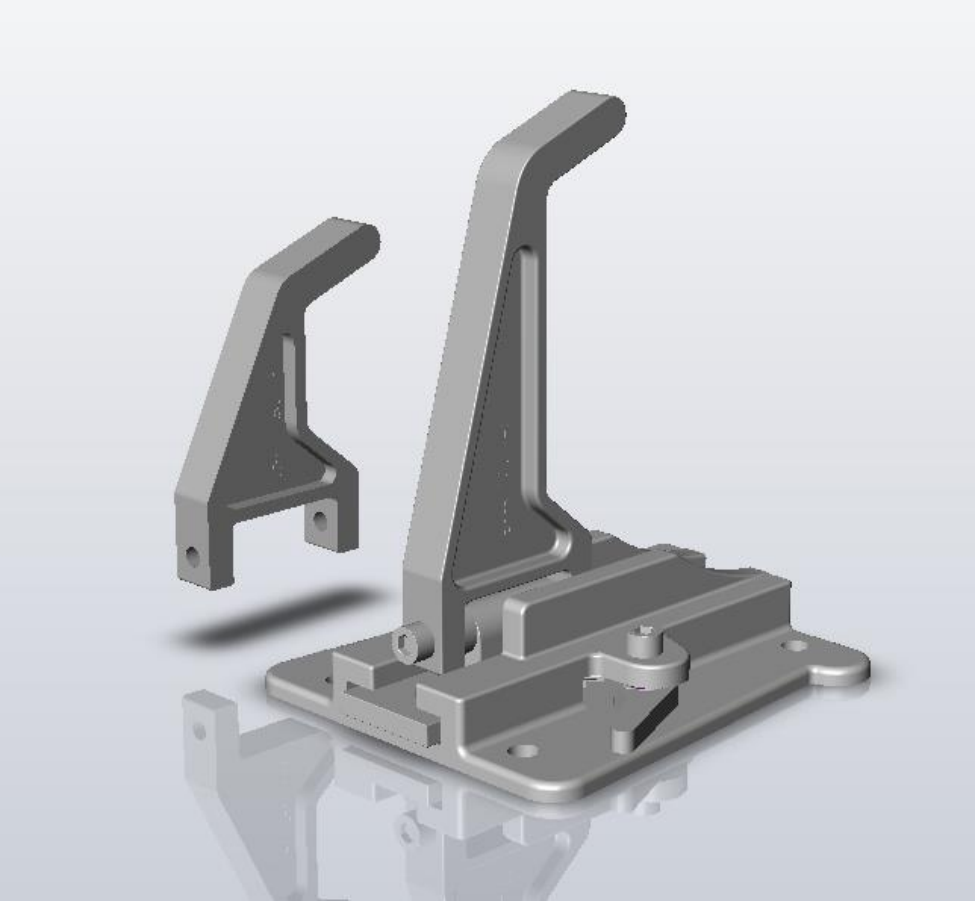
User's Manual

FP
Posterior fixation for stretchers



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 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	Lot number
SN	Serial number
REF	Product code
CE	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, serian number (SN) or 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

- Establish a maintenance program and periodic testing, identifying an reference employee. The person to whom the ordinary maintenance of the device is entrusted must ensure the basic requirements foreseen by the Manufacturer in the user's manual.
- 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.
- The device and all its components, after washing, should be allowed to dry completely before storing.

- The device has seals. If they have been removed or tampered with the Manufacturer declines any responsibility for the product and for its correct functioning and for any consequent damage that may occur to the device.
- Follow the procedures approved by the Emergency Medical Services for recovery and transport of the patient.
- Avoid contact with sharp objects.
- Avoid excessive force when loading a stretchers: an excessive force may cause damage and can adversely influence operations.
- Accumulations of dust can impair correct device operation.
- An inadequate installation of loading plan may cause undesired functioning of the device and harm patient and user

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.

2.4 Physical requirements of the operators

The fastening system is a device designed exclusively for professional use. Since this is an essential accessory for the fixation of the stretcher in the ambulance, it is necessary that operators who use it have the following minimum requirements:

- physical ability to use the device
- ability to grasp the device it firmly with both hands
- have strong back, arms and legs to raise and support
- have good muscle coordination

Each operator must be trained to transport patients safely and efficiently.
Techniques for loading the patient, especially heavy patients, for work on steep ground or in unusual circumstances require the presence of several operators (not just 2 as expected in standard conditions).

The capacity of each operator must be evaluated before the definition of the roles of rescuers in the use of the device.

3. DESCRIPTION OF PRODUCT

3.1 Intended use

The fixation system Spencer FP is designed as a posterior anchor for Spencer stretchers. It is designed only to limit forward, backwards and sideways movement of the stretcher within an emergency vehicle under normal transport conditions.

3.2 Main components

7. Base
8. Adjustable slide
9. Low fixation lever
10. High fixation lever
11. Unlock lever of the slide
12. Special lever

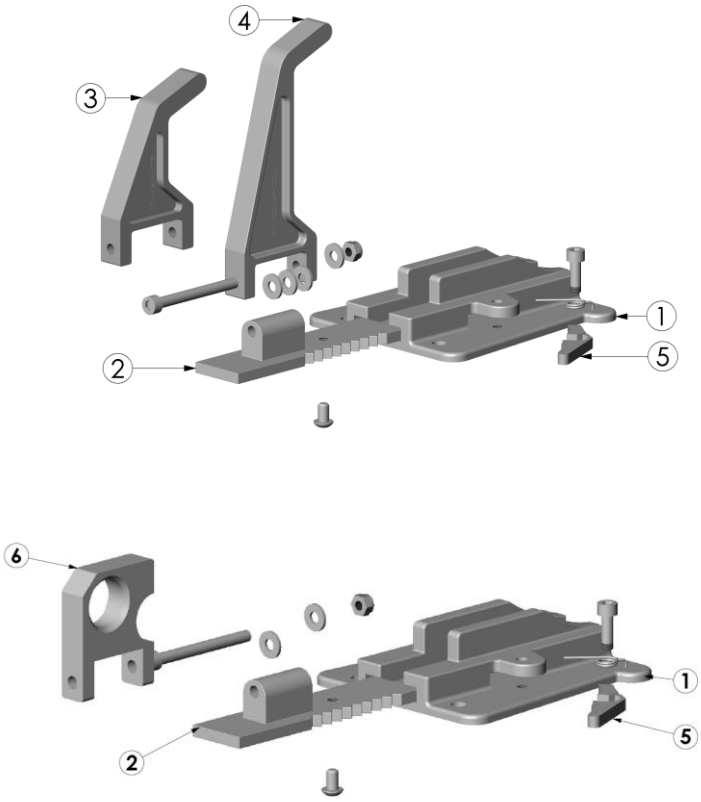

Fig. A

3.3 Models

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

ST42100A FP POSTERIOR FIXATION FOR SELF LOADING STRETCHERS AND ENDURO
ST42105A FP POSTERIOR FIXATION FOR 506/ROLLER S/TF STRETCHERS WITH SPECIAL LEVER

3.4 Technical data

Length	131 mm
Width reclined	193 mm (high lever); 145 mm (low lever); 116mm (special lever)
Width blocked	116 mm
Height reclined	35 mm
Height blocked	162 mm (high lever); 115 mm (low lever); 82mm (special lever)
Weight	1,35 kg (high lever); 1.3 kg (low lever); 1.2 kg (special lever)
Material	Stainless steel and carbon steel

3.5 Reference standards

Reference	**Title of document**
MDD 93/42/CEE	European Directive about Medical Devices
MDD 2007/47/CEE	Modifications to 90/385/CEE Directive about active implants, Directive 93/42/CEE about medical devices and Directive 98/8/CE about the introduction of biocides onto the market
Legislative Decree 24/02/1997, n. 46	Application of the 93/42/CEE Directive about Medical Devices
Legislative Decree 25/01/2010, n. 35	Modifications and additions to the 20/02/97 Decree n. 46
UNI EN ISO 9000	Managing systems for quality: basis and vocabulary
UNI EN ISO 14971	Application of risks managing to medical devices
UNI CEI EN 980	Graphic symbols used for medical devices labelling
UNI CEI EN 1041	Information supplied by the medical devices manufacturer
CEI EN 62366	Medical Devices - Application of the utilisation characteristics of engineering to medical devices
MEDDEV 2.4/1a-b	Guideline for the classification of medical devices
NB-MED 2.5.1 /Rec 5	Technical Documentation
MEDDEV 2.7.1	Clinical Data
MEDDEV 2.12/1	Medical Devices vigilance system
UNI EN 14155	Clinical evaluation of the medical devices for human beings - Part 2: Clinical evaluation plans

3.6 Environmental conditions

Functioning temperature: from -20 to +60 °C
Storage temperature: from -20 to +60 °C
Relative humidity: from 5 to 85 %

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 structure
- Proper closure of screws and bolts
- Status of wear (moving parts, wheels)
- Integrity of components
- Functionality of springs
- Make sure that pressing the lever, unlocks the moving slide

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 Requirement of the emergency vehicle

Spencer FA is designed to be installed in the sanitary compartment of an ambulance. The vehicle must meet the following requirements:

- Leveled floor
- Floor and wide enough to easy accommodate the fixation system
- To ensure the correct use of the fastening system, it is recommended to install it on an emergency vehicle that has the necessary characteristics required
- Presence of a anterior fixation system Spencer FA

4.4 Functioning

4.4.1 Fixation of the system to ambulance platform

1 Place the fixation system on the ambulance, where it is required to be fixed.

Fix the posterior fastener only after having already fixed the anterior fastner.

2 Use the fixation system as a guide for making the hole, highlighting the holes to achieve on the floor. It is necessary to make four holes.

Ceck the necessary space for allowing the fixation lever of the fastener to slide, as to allow a correct fixation of the stretcher.

3 Fix the set made by using the screws TCEI M8, large band lock washer Ø 8 and low screw nut M8 (fixation screws are not supplied).

4.4.2 Positioning the stretcher on the fixation system

1 Position the fastener lever as in fig. B.
2 Load the stretcher inside the emergency vehicle following the indication of the local authorities for EMS service operation.
3 Lift the fastener lever perpendiculary to the ambulance platform and take it completely forward till the front part dedicated to the stretcher as in fig. C.
4 Double check the stability and security of attachment.

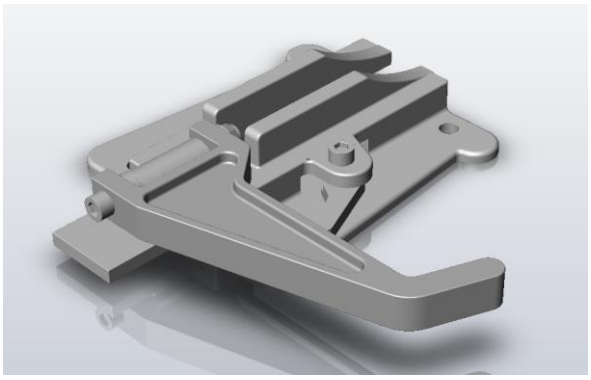

Fig. B

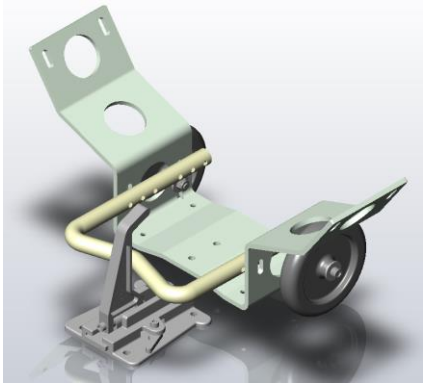

Fig. C

4.4.3 Sbloccaggio della barella dal fermo

1 Push down the release lever, and pull the fixing lever latch.
2 Place the fixing lever as in fig. A
3 At this point you can remove the stretcher from the ambulance following the indication of the local authorities for EMS service operation.

4.4 Troubleshooting

PROBLEM	CAUSE	RIMEDY	RESIDUAL RISK
Unlock lever is not functioning	The lever hasn't been activated	Push down the release lever	None
	The spring can be damaged	Immediately put the device out of service and contact the service centre	None
	The lever is broken	Immediately put the device out of service and contact the service centre	None
Damages to the structure	Improper use	Immediately put the device out of service and contact the service centre	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.

The metal parts exposed to external agents undergo surface treatment and/or painting in order to obtain better resistance. Wash exposed parts with warm water and mild soap, never use solvents or stain removers. In case of any disinfecting procedures do not use solvents wih corrosive action on the materials constituting the device. To get the brilliance of the chassis parts creams or waxes are recommended that are used for polishing the cars.
We also recommend the use of polish cleaner Spencer STX 99.
Rinse thoroughly with warm water making sure that you have removed all traces of detergent, which may deteriorate or compromise the integrity and durability of the device. The use of high

pressure water should be avoided. The water penetrates the joints and it removes the grease, creating the risk of corrosion of components. Allow to dry thoroughly before storing.
Drying after washing or after use in wet environments must be natural and not forced, do not use flames or other sources of direct heat.

5.2 Maintenance

Establish a maintenance program and periodic testing, identifying an reference employee. The person who carries out the maintenance of the appliance has to guarantee the basic requirements indicated by the Manufacturer in the following paragraphs.

All maintenance activities, both precautionary and special, must be registered on documents including technical reports about operations. This register has to be kept for a period of at least 10 years after the disposal of the device itself. This register will be made available to the Competent Authorities and/or Manufacturer if requested.

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.

5.2.1 Precautionary maintenance

The person who carries out the precautionary maintenance of the appliance (user in person, Manufacturer/supplier or a third party) 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.
- The use of components/replacement parts/accessories that are either original or approved by the supplier, in such a way that each operation causes no alteration or modification to the appliance.
- 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.

During all checking, maintenance and cleaning procedures, 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 as follows:

- General functionality of the device
- Cleanliness of the device (remember that failure of the cleaning operation may cause the risk of cross infections)
- Proper tightening of screws and bolts
- Integrity of all components

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.

5.2.2 Periodic maintenance

If the correct revision is not carried out, the device MUST BE PUT OUT OF SERVICE, because the CE branding will no longer be considered valid and consequently it is no longer compliant with the safety standards declared by the manufacturer at time of purchase.
Spencer Italia S.r.l. will take no responsibility for the incorrect functioning or any damage caused by a device that has not undergone regular revision.
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.

5.2.3 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

5.2.4 Life span

The device, if used as indicated in the instruction manual, has an average life span of 5 years starting from the purchase date.
The life span of the device can be extended for up to another 5 years following the annual revision.
General revisions must be carried out by the manufacturer or by a centre authorized by the manufacture. **If such annual revisions are not carried out, the device MUST BE DISPOSED AND THIS EVENT MUST BE NOTIFIED TO THE MANUFACTURER**.
Spencer Italia S.r.l. will accept no responsibility for the incorrect functioning and/or damage caused by the use of any device which has not

6. ACCESSORIES AND SPARE PARTS

6.1 Accessories

There aren't any accessories or spare parts for this item.

6.2 Spare parts

ST42012A Fixation lever FP h 144 mm galvanized white
ST42014A Fixation lever FP h 97 mm galvanized white

ATTACHMENT A – TRAINING REGISTER

The product must be used by trained personnel only, having attended specific training for this device and not for similar products.

Keep this document at least 10 years from the end of life of the device.

Operator's name	Training date		Training method (user's manual, during service, former class, etc)	Trainer
	Basic training	Advanced training		

ATTACHMENT B – MAINTENANCE REGISTER

Keep this document at least 10 years from the end of life of the device.

Perform the required maintenance and to respect the life span of the device, as indicated by the Manufacturer in the User's Manual.

Code and description of the device	
Purchase date	
Lot (LOT)	
Bought by	

SERVICE DATE	KIND OF SERVICE (Maintenance/ check/ extension of life span)	OPERATIONS MADE ON THE DEVICE	RESULT	PERSON IN CHARGE OF SERVICE (operator/authorized centre/ manufacturer)