

CE Class I Medical Device, compliant with the Medical device directive 93/42/EEC

Warning

The information contained in this manual is subject to change without notice.

The Diagrams are inserted only for reference and may vary slightly from the actual device.

Spencer Italia S.r.l. assumes no responsibility for any errors contained herein or for damage, accidents or consequences connected with the supply, performance or use of this manual.

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Warning

The information contained in this document could be modified without any warning and is not to be intended as a commitment on behalf of Spencer Italia S.r.l. Spencer products are exported to many countries and the same identical regulations are not always valid. For this reason there could be differences between the description here described and the product actually delivered. Spencer continually strives to reach the perfection of all items sold. We therefore hope you will understand if we reserve the right, at any time, to modify the shape, equipment, lay-out or technical aspects that are herein described.

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1. MODELS

The standard following models can undergo change, revision and implementation without any notice.

- F400 – 20G FASTENER FOR CHAIRS
- F400A – 20G FASTENER FOR AVIO CHAIRS

2. INTENDED USE

Spencer F400 and F400-A are fasteners to be used with transport chairs 420/425/450/455 20g certified. F400-A is the version designed for AVIO series. The device should be installed inside the ambulance and its purpose is to keep the chair in place in folded position. The patient should not intervene on the device.

3. REFERENCE STANDARD

As a distributor or end user of products manufactured and/or marketed by Spencer Italia S.r.l. you are strictly required to have basic knowledge of any legal requirements applying to the devices contained in this supply that are in power in the goods final destination Country (including laws and norms regarding technical specifications and/or safety requirements) and therefore you are strictly required to have the necessary knowledge to guarantee all aspects regarding the total conformity of the products to the regulations in the relevant territory.

| REFERENCE | DOCUMENT TITLE |
|-------------|--|
| UNI EN 1789 | Medical vehicles and their equipment - Road ambulances |

4. INTRODUCTION

4.1 USE OF THE MANUAL

This manual is intended to provide the health care operator with the all the necessary information for its safe and appropriate use as well as adequate maintenance of the device.

Note: The manual is an integral part of the device. It must be kept for the duration of the device and must accompany the device in case of change of ownership or destination. If the operating instructions received relate to products not received, you must immediately contact the manufacturer before use.

The Spencer product manuals can be downloaded from the website or can be requested by <http://support.spencer.it> or by contacting the manufacturer. Exceptions are items whose essentiality for reasonable and predictable use is such as to make it unnecessary to prepare instructions in addition to the following warnings and directions on the label.

Regardless of the level of experience gained in the past with similar devices, it is recommended that you carefully read this manual before installing, operating or using the product or any maintenance

4.2 LABELLING AND TRACKING CONTROL OF THE DEVICE

Each device has got an identification label positioned on the device itself and/or on its box, which includes identification data about the manufacturer, the product, the CE mark, the serial number (SN) or lot number (LOT).
It must never be removed or covered.

In case of damage or loss, request a duplicate from the manufacturer. Failure to do so will interrupt the validity of the guarantee as the device can no longer be traced.

The Directive 93/42/EEC requires manufacturers and distributors of medical devices to keep track of the device location. If the device was in a different location to the address where it was sent or to where it had been sold, donated, lost, stolen, exported, or destroyed, permanently removed from use, or if the device had not been delivered directly from Spencer Italia S.r.l., register your device at <http://service.spencer.it> or inform the customer (see § 4.4).

4.3 SYMBOLS

| Symbol | Meaning |
|---|---|
|  | General or specific warnings |
|  | See instructions for use |
|  | Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner (only for U.S. market) |
|  | Product code |
|  | Serial Number |
|  | The product is compliant with the requirements of Directive 93/42/EEC |

4.4 WARRANTY AND SUPPORT

Spencer Italia S.r.l. guarantees that products are without defects for a period of **one year from the date of purchase**.

For any information regarding the correct interpretation of the instruction manual, the use, maintenance, installation and restore of the product, contact the Spencer customer care service ph. +39.0521.541111, fax +39.0521.541222, e-mail service@spencer.it, or visit <http://www.spencer.it/en/contact> to find the nearest service centre for assistance.

In order to facilitate the assistance service, please always indicate the lot number (LOT) or serial number (SN) shown on the label applied on the box or on the device.

Conditions for warranty and assistance can be viewed on <http://support.spencer.it>.

Note: Record and store; these instructions, lot (LOT) or serial number (SN) if any, date and place of purchase, date of first use, date servicing, user names and comments

5. WARNINGS

The warnings, notes and other important safety information are indicated in this section and are clearly visible throughout the entire manual.



At least every 6 months, is important to verify if updated User Manuals are available or there is any change involving your product. This information is freely available on the website <http://support.spencer.it> in the section “User manuals” and “Product Updates”.

User training

*Note: 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. **Best instructions are continuous practice under tight surveillance of fully qualified and trained staff.***

- Regardless of the level of experience gained previously with similar devices, it is recommended that you carefully read this manual before installing, operating or using the product or carrying out any maintenance. If in doubt, contact Spencer Italia S.r.l. to obtain the necessary clarifications.
- The product must be used by trained personnel only, having attended specific training for this device and not for similar products.
- The suitability of the user to use the product may be attested by the records of training, where the names of those trained, of the trainers, dates and place are indicated. **This register which certifies the eligibility of the operators to use the Spencer device must 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. In the absence of such documentation, sanctions will be applied.**
- Do not allow any untrained person to help during the use of the device, because they could cause damage to the patient or to themselves.
- The product should be operated only by personnel trained in the use of this product and not in others similar.

Note: Spencer Italia S.r.l. is always at your disposal to organise product training.

Installers training

The installation of the device must be carried out only by qualified and trained staff authorized by Spencer Italia S.r.l. Timing and procedures for conducting training courses shall be agreed between the customer and our Commercial offices.

Product functionality

Use of the device in anyway other than described in this manual is forbidden.

- 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 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.
- 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.
- During use, position and adjust the device taking care not to cause any obstruction to rescuers and or any other rescue equipment.
- 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, when applicable.
- **The warranty seals, where present, must not be removed;** in such case, the manufacturer will no longer recognize the product warranty and will accept no responsibility in case of incorrect operation or damage caused by the product itself.
- Avoid contact with sharp objects
- The installation of the device must be carried out only by qualified and trained staff authorized by Spencer Italia S.r.l. Timing and procedures for conducting training courses shall be agreed between the customer and our Commercial offices.
- Operating temperature: from -10°C to + 50°C

Storage

- The device should not be exposed to or come into contact with any source of combustion or inflammable agents. Store in a cool, dry, dark place and do not expose to direct sun.
- Do not store the device underneath any heavy objects which could cause structural damage.
- Store and transport the device in its original packaging. Failure to do so makes the warranty void.
- Storage temperature: from -20°C to +60°C

Maintenance/cleaning

Spencer Italia S.r.l. disclaims any liability for any damage, direct or indirect, which is a result of improper use of the product and replacement parts and / or otherwise of any repairs made by an entity other than the authorized Spencer service centres; this will also invalidate the warranty.

- The operator must always wear adequate personal protection such as gloves and mask etc. during all checking, maintenance and cleaning procedures.
- Establish a maintenance program and periodic testing, identifying an employee responsible for overseeing. 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.
- **The frequency of inspection is determined by factors such as legal requirements, the type of use, frequency of use, environmental conditions during use and storage.**
- Spencer Italia S.r.l. disclaims any liability for any damage, direct or indirect, that is the result of incorrect repairs or use of products made by Spencer Italia S.r.l. Repairs must necessarily be carried out by an authorized Spencer Italia service centre, which in using original spare parts will provide a quality repair service in strict accordance with the technical specifications given by the manufacturer. Spencer Italia S.r.l. disclaims any liability for any damage, direct or indirect, which is a result of improper use of spare parts and/or otherwise of any repairs made by an entity other than the Spencer service centres authorized to repair or make substitutions on this product and parts and/or otherwise of any repairs made by an entity other than the Spencer service centres authorized to do so; the warranty will also be invalidated.
- Use only original components, spare parts and or accessories, approved by Spencer Italia S.r.l., in order to carry out any operation without causing any alteration or modification to the device.
- 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.
- All maintenance and revision must be recorded and documented with the corresponding report for technical assistance; documentation shall be maintained for at least 10 years from the end of life and must be made available to the competent authorities and/or the manufacturer if requested.
- The cleaning schedule for reusable products must be performed in accordance with the directions provided by the manufacturer in the user manual, in order to avoid the risk of cross-infection due to the presence of secretions and/or residuals.
- The device and all its components, after washing, should be allowed to dry completely before storing.

Regulatory requirements

As a distributor or end user of products manufactured and/or marketed by Spencer Italia S.r.l., you are strictly required to have a basic knowledge of any legal requirements applying to the devices contained in this supply that are in power in the final destination Country (including laws and norms regarding technical specifications and/or safety requirements) of the goods and therefore you are also strictly required to have the necessary knowledge to guarantee all aspects regarding the total conformity of the products to the regulations in the relevant territory.

- Promptly notify Spencer Italia S.r.l. (already during the first product enquiry) when requesting in details regarding any revisions to be made by manufacturer in order to guarantee the conformity of the products to the territory's legal specifications (including those resulting from rules and/or norms of other kind).
- Act, with all due care and diligence, and contribute to ensure conformity to general safety requirements of all devices marketed in the territory, by providing final users with all necessary information for carrying out periodical checks on their devices, exactly as specified in the relevant user's manual.
- **Actively contribute to safety checks on product** sold, by communicating any relevant risk analysis information both to the manufacturer and to any competent authorities so that the necessary action can be promptly taken.
- The distributor or final user is aware that in the event of any failure to conform to the above mentioned requirements you will be deemed fully responsible for all damages that might occur. Therefore Spencer Italia S.r.l. expressly disclaims any responsibility and/or liability for your non-compliance with the present regulatory provisions.

General warnings for medical devices

The user must carefully read not only these general warnings, but also those listed below.

- It is not foreseen that the use of the device is prolonged beyond the time necessary for recovery operation described in the intended use and in this manual.
- When the device is being used, the assistance of qualified staff must be guaranteed and at least two operators must be present.
- Follow the procedures and protocols approved by the internal organization.
- The activities of disinfection and sterilization should be carried out in accordance with the parameters given in the validated cycle as specified in the technical standards.
- 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 concerning Medical Devices, we remind both public and private operators, , That in the exercise of their activity detect an accident involving a medical product are required to notify the Ministry of Health, under the terms and in the manner established by the relative ministerial decrees and also to the manufacturer. Health care providers whether public or private are required to communicate to the manufacturer, any other inconvenience that may allow for the adoption of measures to ensure the protection and health of patients and users

6. SPECIFIC WARNINGS

For the use of fasteners F400 and F400-A, the user must have read, understood and follow carefully all the instructions described in this manual.

- Do not use if the device or its parts are pierced, torn, frayed or excessively worn out.
- Read carefully the user manual of the transport chair being used in order to perform its opening and closing procedures with confidence.
- Do not use the device in combination with other equipment not expressly approved by the manufacturer.
- Do not use drying machines.
- Before each use, check the integrity of the device as specified in the user's manual. In case of malfunction or damage that may compromise the functioning and safety of the device, patient or operator, it is necessary to put the device out of service and contact the manufacturer.
- Do not alter or modify the device arbitrarily: the modification may cause unforeseeable functioning and damage to the patient or operators. In any case the warranty will be void and the manufacturer relieved from any liability.
- When closing the device, make sure nothing interferes with locking mechanisms. Carelessness during this operation could lead to crush injuries.
- Before the installation make sure that the Vehicle satisfies all the requirements described in this manual
- The installation must be carried out in accordance with the manufacturer's instructions.
- Do not remove the chair from the fastener if the vehicle is running.
- Ensure that the locking system is always properly and fully inserted and that the chair is properly fitted on the fastener.
- There should be no foreign objects between the chair and the fastener
- In order to limit risks of injuries, make sure the footrest and telescopic handles of the chair are in closed position when the chair is placed on the fastener.
- Verify the proper tightening of screws as prescribed in this user manual.
- When placing the chair on the fastener, pay attention to the placement of the hands. Improper placing can lead to crushing injuries.
- Avoid excessive force when placing the chair on the fastener: unnecessary force can cause damage to the devices impairing their functionality and affecting adversely the rescue operations.
- Improper installation of the fastener lead to serious injuries for vehicle's occupants.

6.1 PHYSICAL REQUIREMENTS OF OPERATORS

The fasteners F400 and F400A are devices intended for professional use only. Do not allow untrained persons to help operators during use of the product, as this may cause injury to themselves or to other people.

Users should be able to lift and handle safely the chair in order to guarantee a safe coupling with the fastener.

Installers must be able to perform the installation as required by the manufacturer ensuring that the surfaces are suitable for a safe installation.

The ability of all operators must be considered before determining their role in the use of the device.

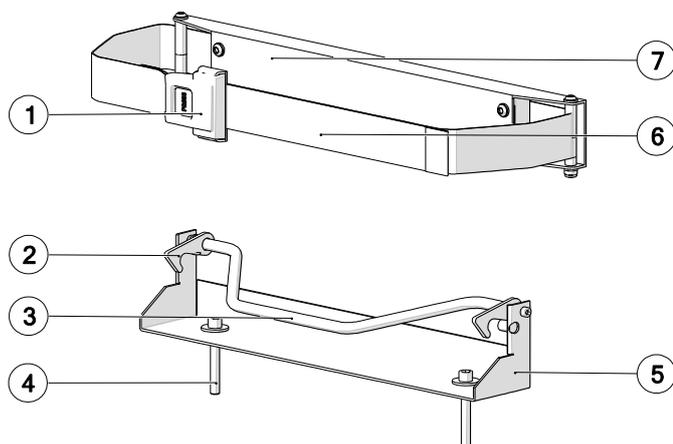
7. RESIDUAL RISK

The residual risks listed below have been identified exclusively in reference to the intended use of the device.

- The use by untrained personnel may result in injury to the patient, rescuer or others.
- Inadequate disinfection procedures may involve cross-infection risks
- Procedure di disinfezione non adeguata, possono comportare rischi di infezioni crociate.
- Interventions on the device by untrained personnel, can cause the disconnection of the locking system with consequent risks for all occupants of the vehicle. Make sure that no unauthorized person intervene in any way on the device.
- Failure to close the telescopic handles or the footrest, can cause injury caused by unexpected bulk. Make sure that all elements of the chair are in closed position when is placed on the fastener
- The presence of foreign objects between the fastener and the chair can cause an improper fixation with consequent risks for vehicle's occupants
- The use of the fastener with devices not approved by the manufacturer, does not guarantee their proper fixation with consequent risks for patient and operators.
- Failure to comply with warnings given to operators, can cause crushing risks related to the mechanisms of the device.
- Failure to respect the life span established by the manufacturer and the periodic revisions described in this manual, can result in serious damage for patient and operators linked to the use of a product that does not comply with the safety requirements established by the manufacturer
- **Failure to read and understand the instructions of F400 and F400A, can have consequences for the patient and operators.**

8. TECHNICAL DATA AND COMPONENTS

Note: Spencer Italia S.r.l. reserves the right to make changes to specifications without prior notice.



| N° | Description | Material |
|----|--------------------------------|----------|
| 1 | Quick release buckle | Metal |
| 2 | Hooks for chair fixation | Steel |
| 3 | Chair unlocking pedal | Steel |
| 4 | Fixation screws (Not included) | Steel |
| 5 | Fixation base | Steel |
| 6 | Belt for upper fixation | PP |
| 7 | Top part | Steel |

| Features | |
|--|-----------------|
| Top part dimensions (WxDxH) | 480x30x60 ± 5mm |
| Lower part dimensions (WxDxH) | 401x72x80 ± 5mm |
| Avio model top part dimensions (WxDxH) | 420x30x60 ± 5mm |
| Avio model lower part dimensions (WxDxH) | 335x72x80 ± 5mm |
| Weight F400 | 1,9 ± 0,1 kg |
| Weight F400-A | 1,6 ± 0,1 kg |

| COMPATIBILITY TABLE | |
|---------------------|--|
| FASTENER | CHAIR CODE |
| F400 | ST26420C/ ST26425C/ ST27425C/ ST36450C/ ST36455C/ ST46450C/ ST46455C |
| F400-A | ST31450C/ ST31451C/ ST31452C |

9. INSTALLATION AND STURT-UP

Before the first use verify that:

- The packaging is intact and has protected the device during transport
- Check that are present all the components included in the accompanying list.
- Functionality of the device according to the user manual
- The ambulance has installation surfaces suitable to ensure the compliance with the requirements of the EN 1789 standard, and allow the installation of the device without interfere with the access to other ambulance equipment.
- **Upper and lower part of the fastener cannot be separated for use other than those described in this user manual.**



Do not modify for any reason any part or component of the device as this may cause injury to the patient and/or rescuers.



If conditions mentioned above are not satisfied, the device cannot be considered secure, safe use is compromised and it is a possible cause of injury for patient and operators and can cause damage to the device.

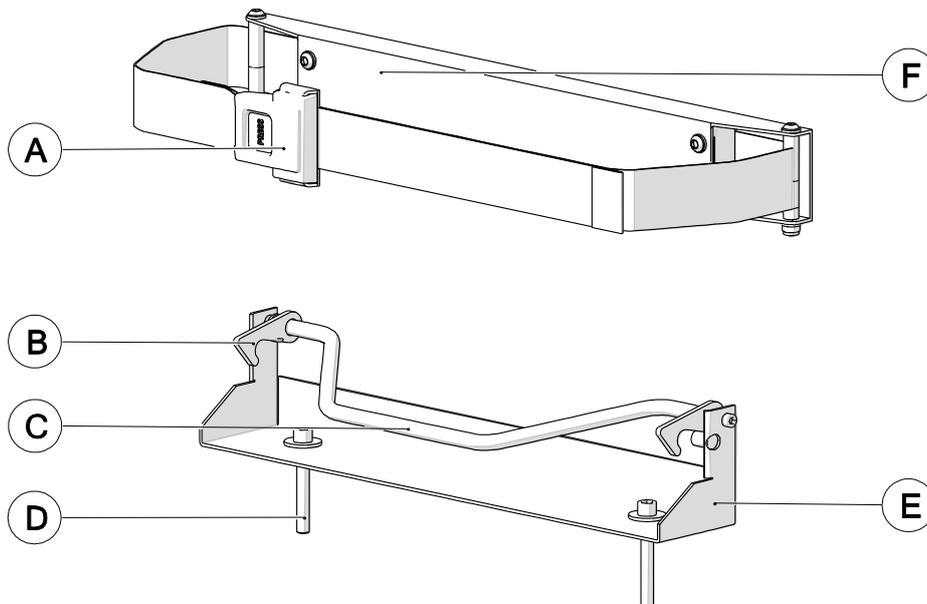
Practice in non-operative condition before the regular start-up.

For instructions on use after start-up, follow the operations described on paragraph 12.

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

Do not alter or modify in any way the appliance; any such interference could cause malfunctions and injury to the patient and/or rescuer. Moreover the manufacturer will no longer recognize the product warranty and will accept no responsibility.

10. FUNCTIONAL CHARACTERISTICS



| Element | Description | Function |
|---------|-----------------------------------|---|
| A | Upper fixation belt | Equipped with quick-release buckle, it holds the upper part of the chair |
| B | Hooks for chair fixation | Are the components that, by engaging with the dedicated elements installed on the chair, hold the lower part of the chair |
| C | Chair unlocking pedal | If operated, it raises the latching hooks allowing to release the lower part of the chair |
| D | Fixation screws (Not supplied) | To be used for floor installation of the fastener |
| E | Fixation base | Structural part of the base of the fastener. |
| F | Top part | Structural part of the upper part of the fastener. Inside there is a reel that pulls the belt |

11. INSTRUCTION FOR USE

11.1 Medical vehicle requirements

The fastener is designed for installation inside the sanitary compartment of an ambulance.

For its installation, it is necessary that the emergency vehicle is equipped with suitable surfaces to hold safely the assembly consisting of fastener and chair. The emergency vehicle should meet the following requirements:

- installation surfaces large enough to accommodate the fastener and the chair without obstacles.
- installation surfaces perpendicular to each other and perfectly leveled.
- Installation surfaces able to withstand deceleration/accelerations as specified in the EN 1789 standard. The surfaces on which the device is installed, must be equipped with backplates able to withstand the stresses to which the fastener could be subject during use. Backplates are not supplied by the manufacturer.



Failure to comply with these requirements or an improper installation could seriously affect safety for patient and operators.

11.2 Installation

For a proper installation of the fastener, is necessary that the installation surfaces are perpendicular to each other and leveled in all of the fastener and chair support zones. Failure to comply with these requirements may result in alteration of the geometries of the device resulting in non-compliance with the design specifications.



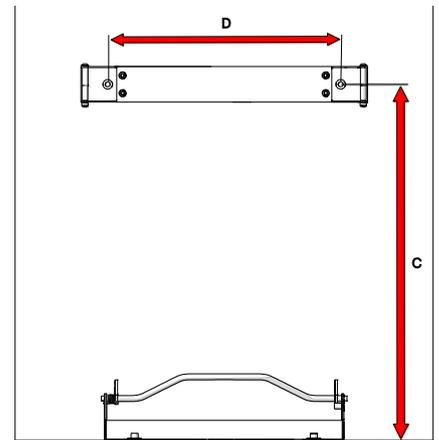
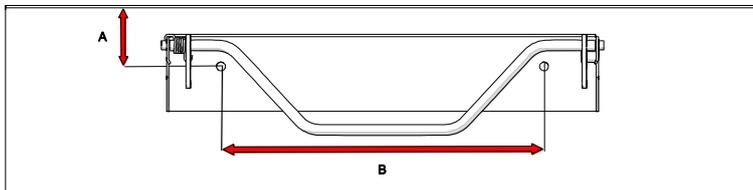
Upper and lower part of the fastener cannot be separated for use other than those described in this user manual.

The lower part of the fastener has two holes intended for installation on floor, the upper one has other two holes intended for wall installation.



Before drilling the holes, is necessary to verify that no part or element or device inside the vehicle could be compromised or damaged during this stage. Pay special attention to ensure the integrity and possibility of intervention on circuits and electrical components, structural parts and gas pipelines.

For this purpose, the images below show the drilling quotes to be used for installation. Is necessary to respect the distance from the wall, otherwise the placing of the chair on the fastener could be impossible..



Drilling quotes:

| | F400 | F400-A |
|---|-------------|-------------|
| A | 56/60 mm | 56/60 mm |
| B | 300 mm | 234 mm |
| C | 630 ± 15 mm | 630 ± 15 mm |
| D | 390 mm | 234 mm |

Drill holes ø8mm using the fastener as a drilling template.

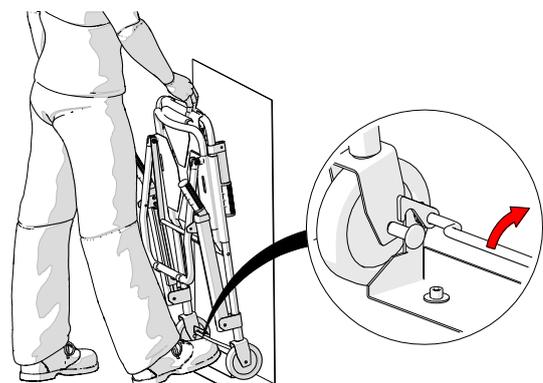
Carry out the installation fixing the base by means of two TCEI screws M8, resistance class 8.8 and washers ø8x24x2mm. For the upper part, use two screws TCEI M8, resistance class 10.9 and washers ø8mm. On the opposite side of the wall, use a back plate (not supplied) and fix with nuts M8.

If the device is to be mounted in niches or is near other devices, it is essential to ensure a free access to the chair and to the fastener. It is therefore necessary to consider the overall dimensions of the chair in use once it is placed on the fastener.

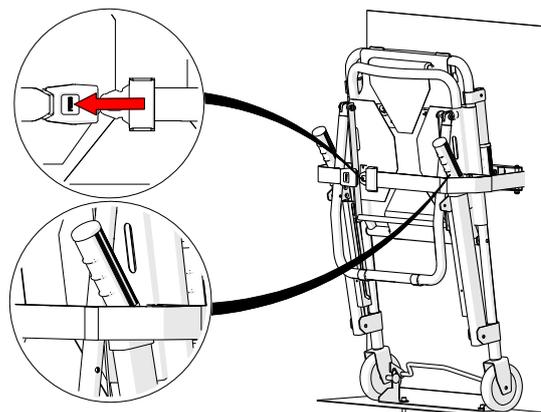
11.3 Use

Fixation of the chair

- Bring the chair in closed position near the fastener tilting it slightly and with front handles facing toward you.
- Once the chair is near the fastener, lift the chair unlocking pedal with the foot and push the chair in the direction of the fastener until the pins of the wheels are below the latching hooks.



- Release the pedal and verify that the hooks have properly locked the lower part of the chair.
- Push the upper part of the chair until it comes in contact with the wall.
- Fasten the belt being careful to keep the chair handles inside and verifying that they are tight enough to prevent movements of the chair.
- Verify that the chair is safely fastened by performing repeated traction movements.



Removing the chair from the fastener

- Loose the belt
- With the foot lift the unlocking pedal on the lower part of the fastener until the pins of the wheels are unlocked and is possible to move the chair.
- Pull the chair to your body and release the pedal

12. CLEANING AND MAINTENANCE

12.1 CLEANING

Failure to carry out the correct cleaning routine could increase the risk of cross infection, due to presence of body fluids and/or residuals. The operator must always wear adequate personal protection such as gloves and mask, etc. during all checking and cleaning procedures.

The exposed metal parts are usually treated and/or painted in order to increase their resistance to external agents. Clean the exposed parts with water and a delicate soap; **never use solvents or stain removers.**

Rinse thoroughly with warm water making sure that you have removed all traces of detergent, which could ruin or compromise the integrity and durability of the device. **The use of high pressure water should be avoided** because water penetrates in the joints removing the lubricant and creating the risk of corrosion of components. Allow the device 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.

If the device needs to be **disinfected**, use products that do not have corrosive or solvent action on the materials of which the device is made. Be sure to take every precaution to ensure that there is no risk of cross-infection or contamination for patients and / or operators.

To maintain the polished appearance of the frame parts we recommend the use of Spencer STX 99 polish cleaner or in alternative creme or wax normally used for polishing car bodywork

12.2 PRECAUTIONARY MAINTENANCE

Establish a maintenance programme and periodic testing routine and identify an employee responsible for this. The person to whom the ordinary maintenance of the device is entrusted must ensure that the basic requirements foreseen by the manufacturer in following paragraphs are inspected.

All maintenance and periodic servicing activities must be registered and kept together with the servicing reports. These documents have 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.

Routine maintenance of the device must be carried out by operators in possession of specific qualifications, trained and experienced in the use and maintenance of the device. Such training must be recorded and maintained for at least 10 years from the end of life of the product and shall be made available to the competent authorities and / or the Manufacturer upon request.

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

Checks to be carried out before and after each use and at deadline indicated above, are as follows:

- General functionality of the device
- Cleanliness of the device (remember that the failure to clean could be the cause of cross infections)
- Correct fixation of all nuts, bolts and screws
- Absence of cuts, holes, tears on the structure
- None of the tubes or any other part present bends or cracks
- Check the functionality of latching hooks and functionality of springs.
- Check the integrity of the belt of the upper part of the fastener and the proper operation of the quick release buckle.
- The coupling between the fastener and the chair takes place properly and is safe.

The inspection frequency is determined by factors such as local 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 this manual and verify functionality before and after each use. Spencer Italia S.r.l. declines any responsibility for the improper functioning or injury caused to the patient or user by the use of devices that have not been subjected to a routine maintenance programme which will void the warranty and the compliance to the Medical Device Directive 93/42/CEE.

Use only accessories/original spare parts approved by Spencer Italia S.r.l. Failing to do so, we will accept no responsibility for the incorrect functioning and/or damage caused by the use of any device which has not been repaired, or certified on expiry date by the manufacturer or by one of the manufacturer's authorised service centres. Warranty will be considered void in compliance with the Medical Device Directive 93/42/EEC.

12.3 PERIODIC MAINTENANCE

The device must be serviced by the manufacturer or by an authorised centre, every year.

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

12.4 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 operations carried out on the device.

The end user is authorised to replace only the spare parts indicated in the paragraph 15.

12.5 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. If, for any reason, is not possible to trace the purchase date, the life span starts from the manufacturing date.

The life span of the device is of 5 years from the date of purchase and 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 ACCORDING TO THE PROCEDURES SPECIFIED IN PARAGRAPH 16 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 been serviced by the manufacturer or authorized center, or of any device for which the life span is expired

13. TROUBLESHOOTING

| PROBLEM | CAUSE | SOLUTION |
|---|--|---|
| The device is installed but it doesn't fit properly on installation surfaces | The device has not been properly installed | Check that drilling quotes are correct, that the fastener was used as a drilling template and that during installation no deformation has occurred. |
| | Support surfaces do not meet the requirements established by the manufacturer | Put immediately the device out of service and verify that the installation surfaces are suitable for a safe and adequate installation of the fastener |
| The base or other components of the fastener are damaged | Components have been damaged during installation | Put immediately the device out of service and contact the service centre |
| | Normal use and arising wear has caused damage to the components | |
| Is not possible to fix the chair on the fastener | The chair in use is not suitable for the fastener | Contact the manufacturer or a service center to verify the compatibility of your device. |
| | The chair is not facing the right way | Check the proper orientation of the chair. For proper placing on the fastener, the front wheels of the chair must be facing the operator |
| | The springs are damaged or the mechanisms, or pin of the wheels are damaged and/or worn | Put immediately the device out of service and contact the service centre |
| It is not possible to push the chair against the wall once the chair is placed on the fastener. | The chair is not facing the right way | Follow instructions of par. 11.3 |
| | Foreign objects are present between the chair and the fastener | Remove foreign objects |
| The coupling between the chair and the fastener is not stable | Fixation screws are not tight enough or coupling components are worn generating gaps that are not within the tolerances foreseen by the manufacturer | Put immediately the device out of service and verify the integrity of components and the proper installation |
| The belt of the upper part of the fastener is not tight enough or is blocked | The reel doesn't work properly | Put immediately the device out of service, contact the manufacturer and provide to purchase the spare part. |

14. ACCESSORIES

There are no accessories for this device

15. SPARE PARTS

| | |
|-----------------|------------------------------------|
| RIST047D | F400 FASTENER FOR CHAIR TOP PART |
| RIST048D | F400 FASTENER FOR CHAIR LOW PART |
| RIST049D | F400 A FASTENER FOR CHAIR TOP PART |
| RIST050D | F400 A FASTENER FOR CHAIR LOW PART |

16. DEMOLITION

When the device is no longer suitable for use, if they haven't been contaminated by any particular agents, they can be disposed of as normal solid waste. Otherwise follow the current regulations for demolition.