

ROLLER AC/AV
Roll-in trolley

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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First edition: 2001
Rev. 3: 20/05/13

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 number
	Serial Number
	Product code
	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 service@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

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, 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.
- 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".
- 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 at your disposal to plan trainings on products.
- 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 persons to help during the use of the device, because they could cause damage to the patient or to themselves.
- Regularly check the appliance, carry out the prescribed maintenance and respect the average life span, as indicated by the Manufacturer in this 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.
- 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 of any medical device.
- As a Distributor or End Users 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 goods final destination Country (including laws and norms regarding technical specifications and / or safety requirements) 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. regarding any revisions to be made by Manufacturer in order to guarantee the conformity of the product to the territory's legal specifications (including those resulting from rules and/or norms of other nature).
- 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, as specified in the relevant User Manual.
- Actively contribute to product safety checks on products 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.
- You are 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 we expressly disclaim any responsibility and/or liability for your non-compliance with the present "Regulatory provisions".



2.2 Specific warnings

- Establish a maintenance program and periodic testing, identifying a 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.
- Use only accessories/spare parts that are original or approved by Spencer Italia S.r.l., in order to carry out any operation without causing any alteration or modification to the device, otherwise we assume no responsibility for the proper functioning or damage resulting from device to the patient or the operator and warranty and will be considered void according to the compliance to the Medical Device Directive 93/42/CEE.
- Always respect the maximum capacity of the device, as indicated in this user's manual. Maximum load capacity means the total weight distributed according to the human anatomy. In determining the load of the total weight on the product, the operator must consider the weight of the patient, the equipment and the accessories. Moreover, the operator must consider that the overall dimensions of the patient do not reduce the functionality of the device.
- Never leave the patient unassisted on the device, because he may be injured.
- The device and all its components, after washing, should be allowed to dry completely before storing.
- Lubrication must be carried out after cleaning and complete drying.
- Avoid contact with sharp objects.
- Do not use the device if it is pierced, torn or frayed.
- Make sure, before lifting, that the operators have a firm grip on the device.
- Avoid pulling the device on rough surfaces.
- The device is a trolley for patients transport and cannot be used as a stationing device.
- First practice with an empty trolley in order to get used to the way in which the trolley manoeuvres.
- For the use of the device, at least two operators in suitable physical conditions are needed; they must therefore have strength, balance, coordination, and common sense and must be trained on the correct functioning of the device Spencer trolley.
- For techniques for loading particularly heavy patients, for rescue operations on steep ground or in unusual circumstances, it is recommended the presence of more operators (not just two as required under standard conditions).
- The maximum weight sustained by each rescuer must comply with requirements prescribed by the law of the Country, concerning Health and Safety at Work.
- Before each use, check the integrity of the belts and their hooks, as specified in the User's Manual. In case of malfunction or damage that may compromise the function and safety of the device, patient or operator, it is necessary to replace the belts.
- Make sure the belts are properly fastened to the frame of the stretcher.
- Always immobilize the patient, using the straps; lack of immobilization may cause serious damage.
- In order to meet the requirements of the standard UNI EN 1789, use only belts that have as anchor point the frame of the stretcher.
- To optimize patient's immobilization, is necessary to use a thorax belt secured to the frame of the stretcher in addition to the supplied ones.

- Make sure the mattress is properly secured/anchored to the frame /patient board of a trolley.
- Make sure the sheet does not interfere with the footrest and do not prevent the operator from handling of the sidebars.
- Do not operate in case the weight has not been distributed correctly.
- The sidebars may be damaged due to improper use. Keep the sidebars always raised during patient transport.
- Always grasp the structure to lift and carry the trolley and not the sidebars or polyethylene boards.
- Avoid extreme force during the loading procedure of the trolley on the ambulance. Too much force may have negative effects on the functioning of the trolley.
- Keep the trolley firmly if the patient is sitting.
- Use the trolley only as described in this user's manual.
- Do not alter or modify the trolley arbitrarily to make it fit into the ambulance: the modification may cause unforeseeable functioning and damages to the patient and operators. In any case the warranty will be lost.
- Pay a lot of attention to possible obstacles (water, ice, debris, etc.) on the route of the trolley, because they could cause loss of balance for the operator and compromise the proper functioning of the device. If you can not set the path free from obstacles, choose an alternative path.
- For gradients greater than 10 mm, the device must be raised, taking care to grasp the structure and not from the banks/platforms.
- Condensation, water, ice and accumulations of dust can affect the correct operation of the device, making it unpredictable and causing a sudden alteration of the weight that operators have to carry.
- The self-loading trolleys are certified for use with dedicated Spencer fastening systems, it is therefore forbidden the use of fasteners not approved by the Manufacturer. Fastening systems that have not been approved may alter the structural and functional characteristics of the trolleys.
- Once positioned the wheels of the loading trolley on the support surface of the ambulance, the wheels of the front leg must have a distance from the ground of at least 6 cm. Check regularly the loading height of the ambulance; if it is altered, the trolley must be immediately set up by the Manufacturer or by an authorized centre. Otherwise we assume no responsibility for the proper functioning or damage caused by the device itself.
- Improper installation of the loading platform may cause structural damage and consequent injury to the weldings of the front legs.
- Improper installation of the loading platform may cause undesired operation of the device and cause harm to the patient and to the operator.
- Replace the wheels with original parts, in case of failure to stop the device.

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

Spencer Roller trolley is destined to professional use only. The rescue operators must have the following minimum requirements:

- physical capacity for operating the device
- be able to seize the device firmly with both hands
- have strong back, arms and legs for lifting, pushing and pulling the trolley
- have a good muscular coordination

The operators must be trained in efficient, effective and safe patient transport.

This trolley requires the employment of at least two operators equipped with strength, balance, coordination and common sense.



Patient loading procedures for extremely heavy patients, operations in rough terrain and in particular situations more operators may be needed (not only two as in normal conditions).



The capacities of the various operators must be considered before determining his role in the employment of the trolley.

3. DESCRIPTION OF PRODUCT

3.1 Intended use

Roller AC and Roller AV are self loading trolleys for transport of patient to be used with the stretchers Roller S, Roller T and Roller TF, for rescue operations on road and on ambulances. The legs fold away independently, activating the dedicated commands and they open automatically during the unloading procedure. The model Roller AV has intermediate height used to make the transfer of patient easier (example: from stretcher to bed, from bed to stretcher).

The patient should not intervene on the device

3.2 Main components

n°	Description of component
1	System for attachment of cot and trolley
2	Loading trolley
3	Wheel diameter 125mm with brake
4	Complete loading trolley
5	Rear left leg
6	Rear right leg
7	Autodirectional wheel 125mm
8	Left command lever for trolley closure
9	Right command lever for trolley closure
10	Upper part of trolley
11	Front lever for adjustable height (only for AV)

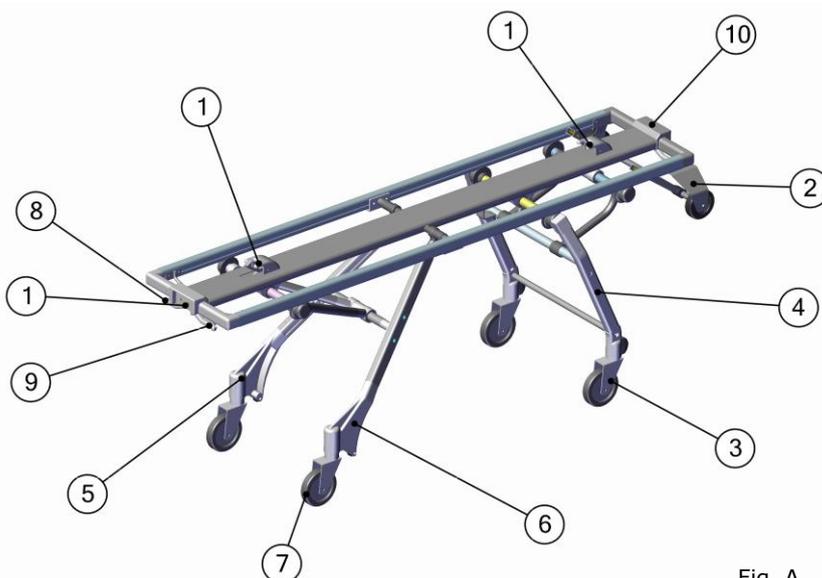


Fig. A

3.3 Models

This model could be modified, with reference to codes and/or descriptions without any previous notification.

ST40010A	Roller AC loading height 490mm
ST40012A	Roller AC loading height 620mm
ST40011A	Roller AC loading height 690mm
ST40020A	Roller AV 490mm adjustable height
ST40018A	Roller AV 620mm adjustable height
ST40019A	Roller AV 690mm adjustable height
ST40030A	Roller AV 490mm adjustable height and swivelling wheels
ST40022A	Roller AV 490mm adjustable height and swivelling wheels (length 1750mm)

3.4 Technical data

Characteristics	Technical data
Width (mm)	550
Length (mm)	1900
Weight (kg)	32
Load capacity (kg)	170

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 9001	Managing systems for quality: requirements
UNI EN ISO 13485	Medical Devices - Managing systems for quality - Requirements for regulation requirements
UNI EN 1865-1	Directives for stretchers and other patient transport equipment on ambulances
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
BS OHSAS 18001	Managing systems for safety and health at workplace

3.6 Environmental conditions

Functioning temperature: from -10 to +50 °C
 Storage temperature: from -20 to +60 °C
 Relative humidity: from 5 to 95%

4. OPERATING INSTRUCTIONS

4.1 Transport and storage

Before transporting the appliance, make sure that it is correctly packaged ensuring also that there are no risks of shocks, 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 cuts, holes, tears on the structure, including the straps
- Correct fixation of all nuts, bolts and screws
- Correct fixation of straps on the stretcher
- Correct fastening of straps on the stretcher
- State of use (moving parts, wheels, belts)
- Integrity of components
- Lubrication of moving parts
- When taking out for the first time the trolley from its box, the its legs should bend and lock properly
- Backrest and Trendelenburg of the stretcherwork the same way and lock properly
- Sidebars of the stretcher are raised and lowered properly
- State of use of wheels and breaking system
- Functioning of springs
- The trolley can easily get in the ambulance
- The emergency vehicle is equipped with a fastening system dedicated to the Spencer trolley
- There are seat belts in the stretcher for the immobilization of the patient and they are intact and functioning
- No piping or metal sheet present bends or cracks
- The backrest has no structural damages or fissures

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.

THE MEASUREMENT OF THE LOADING PLATFORM MUST BE TAKEN WITH THE AMBULANCE POSITIONED ON A UNIFORM AND PERFECTLY HORIZONTAL SURFACE AND WITH TWO OPERATORS SEATED IN THE PATIENT COMPARTMENT (SIMULATING A LOAD OF APPROXIMATELY 250 KG).

If the vehicle is equipped with pneumatic or hydraulic suspensions, the loading height adjustment must be carried out taking into account the worsening condition of use and/or the operating one provided by the vehicle builder.

Problems during use and/or safety risks associated with such system, cannot be attributed to the manufacturer.

4.2.1 Requirements of the emergency vehicle

Spencer Roller has been designed for entering and exiting the patient compartment of an ambulance. The requirements of the vehicle are:

- levelled loading platform
- sufficiently wide and long platform with no obstacles for the trolley

The front leg wheels (n° 3 paragraph 3.2), during loading/unloading, when the loading trolley is still on the emergency vehicle, must be at least 5/6 cm higher than the ground to allow correct and safe opening of the legs of the trolley.

A lack of the above mentioned measurement may cause unsafe use of the device, with damage risks for the patient, the operators or for the device.

In order to make the loading procedure easier, it is recommended to take away any edges from the border of the loading platform. The trolley must be fixed using Spencer fixing systems in a way in which any movement of the trolley will be avoided, also in difficult driving situations. Try out the loading and unloading procedures with an empty trolley before putting the trolley into regular service.

4.3 Functioning

4.3.1 Lowering the trolley

Make sure the side bars are positioned upwards; otherwise the stretcher may be damaged.

Before lowering the trolley, reach the place where to make all the following operations on/with the trolley.

Lower the trolley without patient, as follows:

- grab command handles of the Roller at the rear end "feet"
- lift the rear part "feet" of the trolley the loading trolley wheels (n° 2 paragraph 3.2) touch the ground
- keeping a firm grasp on the trolley and ready to sustain its weight, pull both command handles in order to close the legs (n° 8 e 9 paragraph 3.2)
- lower the trolley, carrying its weight, until it touches the ground

Before loading the patient, while the stretcher is on the ground, make sure the underground is stable and horizontal; unstable and non-horizontal surfaces may affect the static balance of the stretcher.

Brake the front wheels (optional) when the stretcher is on the ground and do not forget to unblock them before raising the trolley.



4.3.2 Lowering the trolley to intermediate positions (only Roller AV model)

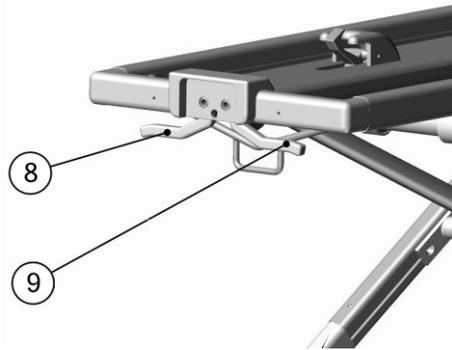


The operation must be performed by two operators.

on the respective control levers (n. 8 and 9), to obtain the release from the current position.

Operators need to predispose to support the weight of the device.

- Release the lever and accompany the trolley in its descent until reaching the next level automatically.
- Other possible levels can be reached by proceeding as described in the preceding paragraphs above.



4.3.3 Lifting the trolley and the stretcher with patient

Fix the patient on the stretcher with the dedicated belts.



The capacities of the various operators must be considered before determining his role in the employment of the stretcher.

Two operators must be positioned at the edge of the trolley, consider how many operators to employ according to the weight to lift and according to the capacities of each operator. Using an adequate lifting technique, make sure to grab the trolley firmly at both ends. Lift the trolley until the legs, front and rear, are open and completely blocked. Make also sure the underground is safe and stable

4.3.4 Lifting the trolley from middle position (only Roller AV model)

- Secure the patient to stretcher with belts supplied.
- Follow the steps described in par. 4.3.2 in the opposite order, using proper lifting technique to avoid fatigue.

4.3.5 Loading the trolley onto the ambulance

Make sure the ambulance's doors are blocked correctly in open position, in order to avoid any hindrances. Make sure the sidebars of the stretcher are blocked in upward position, otherwise the stretcher may be damaged. During the loading operation:

- push the trolley towards the rear door opening of the ambulance;
- push the trolley onto the loading platform of the ambulance until the front legs touch the edge of the ambulance (bumpers and/or platform);
- the operator must make sure both wheels of the loading trolley are placed on the loading platform (safety position) and contemporarily evacuate the distance between the wheels on the front legs and the terrain (at least 5/6 cm);
- once the front legs touch the ambulance's bumpers, the operator must pull the red handle for unlocking the front legs (n° 9 paragraph 3.2), without pushing the trolley;
- once pulled the handle, push the trolley inside the ambulance, allowing the front legs to fold and close; avoid extreme bumping of the front legs against the ambulance's bumpers and/or loading platform; legs and related mechanisms could be damaged;
- insert the trolley into the ambulance until the rear legs touch the bumpers and/or platform, then lift the trolley slightly and pull the green handle (left) unlocking the rear legs (n° 8 paragraph 3.2) and complete the loading procedure of the trolley;
- make sure the wheels of the loading trolley move into the dedicated anterior and posterior Spencer fastening systems;
- make sure the trolley is securely fixed to the Spencer fixing system.

The use of the original Spencer fixation systems is recommended in order to guarantee optimal stability in all directions. Whenever other fixation systems are used, the safety and correct functionality of the device are not granted.

4.3.6 Unloading the trolley from the ambulance

Unlock the trolley from its fixation system.

Grab the trolley at the posterior tube of the frame ("feet" side) and gently pull the trolley out of the ambulance. Make sure the trolley remains horizontal until the safety position (the rear legs block automatically in the open position): the legs will open and block automatically.

The operator must make sure the rear and front legs open up and block correctly.

Make sure the underground is stable and secure before extracting the loading trolley wheels as well.



When unloading the stretched do not grasp the footrest of the Trendelenburg board, this may cause damages to the operator, the patient or the device.

4.3.7 Coupling and uncoupling of stretcher on Roller trolley

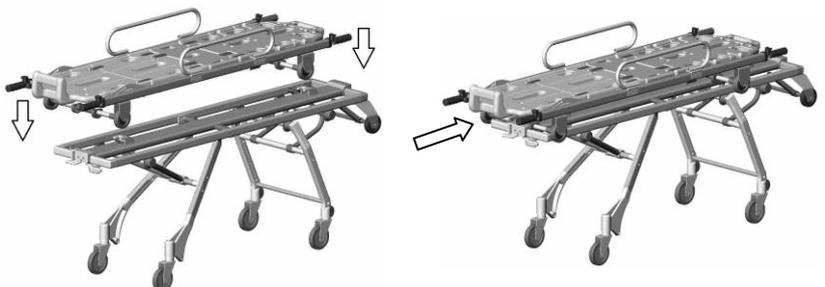
Place the stretcher on the trolley as shown.

Slide up to lock automatically.

Make sure the stretcher is firmly anchored to trolley.

- This requires at least two operators.

- To unlock, pull the release lever (n. 1 par. 3.2) and make all the steps above in the opposite order.



4.3.8 Brakes

The brake is activated by pressing the lever on the front wheels (n. 3 paragraph 3.2). To release the brake, press it on the opposite side.

4.4 Troubleshooting

PROBLEM	CAUSE	REMEDY
Pushing the trolley against the vehicle's bumper, the legs do not fold away	The lever has not been actioned or the metal cable under the trolley does not transmit the commands	Put immediately the trolley out of service and contact the service centre
During patient transport the trolley is difficult to move	The brakes are still blocked	Unblock the brakes and check the condition of the wheels
Structural damage	Improper use or operators not adequately trained	Put immediately the trolley out of service and contact the service centre
The intermediate height does not unlock after actioning the lever	Unlocking lever is damaged	Put immediately the trolley out of service and contact the service centre
The stretcher does not unlock after actioning the lever	Unlocking lever is damaged	Put immediately the trolley out of service and contact the service centre

5. MAINTENANCE AND CLEANING

5.1 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.

The board has been made out of incontaminable material, in order to increase hygiene and easy cleaning.

Clean the exposed parts with water and delicate soap then dry with a soft cloth. In order to obtain a shine effect, it is possible to use car waxes and creams.

Do not clean with high pressure water; this will damage the joints and the lubricated parts.

If the trolley is not cleaned regularly, this may cause risks in terms of cross-contamination.

We recommend the use of the polishing detergent Spencer STX 99.

Rinse thoroughly with warm water making sure that you have removed all traces of detergent, which could degrade or compromise the integrity and durability of the device. The use of high pressure water should be avoided. Water penetrates the joints and removes the oil, 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

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 the failure of cleaning may cause the risk of cross infections)
- Absence of cuts, holes, tears on the structure, including the straps
- Correct fixation of all nuts, bolts and screws
- State of use (moving parts, wheels, belts)
- Integrity of components
- Lubrication of moving parts
- When taking out for the first time the trolley from its box, the its legs should bend and lock properly
- State of use of wheels and breaking system
- Functioning of springs
- The trolley can easily get in the ambulance
- The emergency vehicle is equipped with a fastening system dedicated to the Spencer trolley
- Weldings are intact, no cracks or breaks
- No piping or metal sheet present bends or cracks

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.

The person responsible for routine maintenance can identify damaged/worn parts, but the replacement or restoration of the them can only be done by the manufacturer or or by an authorized service center.

Use only accessories/original spare parts approved by Spencer Italia S.r.l., otherwise 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.

5.2.2 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 CE branding will no longer be considered valid as it will no longer be compliant with the 93/42/CE Directive for Medical Devices and therefore there is the possibility that 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 the incorrect functioning or any damage caused by a device that has not undergone regular revision.

Legs movement systems , are components subjected to periodic replacement depending on intensity of use.

The following table shows some replacement intervals related to the number of average uses. The evaluation of needed maintenance, must be carried out by people responsible for maintenance of the device, according to this table.

The replacement is mandatory in order to ensure the safety of the product.

Intensity of use	Heavy usage (over 30 times/month)	Medium usage (less than 30 times/month)
Replacement frequency	Every 3 years	Every 5 years

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.

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.

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 repaired, or certified on expiry date by the Manufacturer or by one of the Manufacturer's Authorised Service centres, making void the guarantee and the conformity to the Medical Devices Directive 93/42/CEE.

6. ACCESSORIES AND SPARE PARTS

6.1 Accessories

ST42100A	Posterior fastener (FP) **
ST42200A	Anterior fastener (FA) **
ST40300A	Roller S stretcher
ST40021A	Roller T stretcher
ST40400A	Roller TF stretcher

**** Warning:** Doesn't meet the requirements of EN 1789 – Not suitable for use with 10G Certified Stretchers

6.2 Spare parts

ST22400A	Ø125 mm wheel
ST42110A	Ø100 mm wheel loading trolley

