

Manuale d'Uso e Manutenzione SPENCER 402 / SPENCER 406 / SPENCER 407 IT Sedie da evacuazione



Si dichiara che il dispositivo è conforme al Regolamento UE 2017/745

Sistema di Garanzia di Qualità per la produzione ed il controllo finale dei prodotti certificato dall'organismo notificato TÜV SÜD Product Service GmbH

User's Manual SPENCER 402 / SPENCER 406 / SPENCER 407 EN Evacuation chairs



The device is in compliance with the Regulation UE 2017/745

Guarantee of Quality system for the production and the final control of the products certified by the notifying body TÜV SÜD Product Service GmbH



INDICE / CONTENTS

IT

1. INFORMAZIONI GENERALI	4
1.1 SCOPO E CONTENUTO	4
1.2 CONSERVAZIONE DEL MANUALE D'USO E MANUTENZIONE	4
1.3 SIMBOLI UTILIZZATI	4
1.4 RICHIESTA DI ASSISTENZA	4
1.5 SMALTIMENTO	4
1.6 ETICHETTATURA	4
2. AVVERTENZE	4
2.1 AVVERTENZE GENERALI	4
2.2 AVVERTENZE SPECIFICHE	5
2.3 CONTROINDICAZIONI ED EFFETTI COLLATERALI	5
2.4 REQUISITI FISICI DEGLI OPERATORI	5
3. DESCRIZIONE DEL PRODOTTO	5
3.1 DESTINAZIONE D'USO	5
3.2 COMPONENTI PRINCIPALI	6
3.3 MODELLI	6
3.4 DATI TECNICI	6
3.5 STANDARD DI RIFERIMENTO	7
3.6 CONDIZIONI AMBIENTALI	7
4. ISTRUZIONI OPERATIVE	7
4.1 TRASPORTO E STOCCAGGIO	7
4.2 PREPARAZIONE	7
4.3 FUNZIONAMENTO	7
4.3.1 APERTURA DEL DISPOSITIVO	7
4.3.2 CHIUSURA DEL DISPOSITIVO	8
4.3.3 TRASPORTO PAZIENTI SU SCALE	8
4.3.4 TRASPORTO PAZIENTI SU SCALE (SPENCER 402)	8
5. TABELLA GESTIONE GUASTI	8
6. MANUTENZIONE E PULIZIA	9
6.1 PULIZIA	9
6.2 MANUTENZIONE	9
6.2.1 MANUTENZIONE ORDINARIA	9
6.2.2 REVISIONE PERIODICA	9
6.2.3 TEMPO DI VITA	9
6.2.4 MANUTENZIONE STRAORDINARIA	9
7. ACCESSORI E RICAMBI	10
7.1 ACCESSORI	10
7.2 RICAMBI	10
ALLEGATO A – REGISTRO DELLA FORMAZIONE	10
ALLEGATO B – REGISTRO DELLA MANUTENZIONE	11

EN

1. GENERAL INFORMATION	12
1.1 AIM AND CONTENTS	12
1.2 CONSERVATION OF THE INSTRUCTION MANUAL	12
1.3 SYMBOLS USED	12
1.4 SERVICING REQUESTS	12
1.5 DEMOLITION	12
1.6 LABELLING	12
2. WARNINGS	12
2.1 GENERAL WARNINGS	12
2.2 SPECIFIC WARNINGS	13
2.3 CONTRAINDICATIONS AND SIDE EFFECTS	13
2.4 PHYSICAL REQUIREMENTS OF THE OPERATORS	13
3. PRODUCT DESCRIPTION	13
3.1 INTENDED USE	13
3.2 MAIN COMPONENTS	14
3.3 MODELS	14
3.4 TECHNICAL DATA	14
3.5 REFERENCE STANDARD	15
3.6 ENVIRONMENTAL CONDITIONS	15
4. OPERATING INSTRUCTIONS	15
4.1 TRANSPORT AND STORAGE	15
4.2 PREPARATION	15
4.3 FUNCTIONING	15
4.3.1 OPENING THE DEVICE	15
4.3.2 CLOSING THE DEVICE	16
4.3.3 PATIENT TRANSPORT ON STAIRWAYS	16
4.3.4 PATIENT TRANSPORT ON STAIRWAYS (SPENCER 402)	16
5. TROUBLESHOOTING	16
6. MAINTENANCE AND CLEANING	17
6.1 CLEANING	17
6.2 MAINTENANCE	17
6.2.1 PRECAUTIONARY MAINTENANCE	17
6.2.2 PERIODIC MAINTENANCE	17
6.2.3 LIFE SPAN	17
6.2.4 SPECIAL SERVICING	17
7. ACCESSORIES AND SPARE PART	18
7.1 ACCESSORIES	18
7.2 SPARE PARTS	18
ATTACHMENT A – TRAINING REGISTER	18
ATTACHMENT B – MAINTENANCE REGISTER	19

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	Symbol	Meaning
	Device in compliance with regulation UE 2017/745		Warning
	Medical Device		Read user manual
	Manufacturer		Product code
	Date of manufacture		Serial number
	Unique Device Identification		

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@spencerit or write to Spencer Italia S.r.l. – Via Provinciale, 12 – 43038 Sala Baganza (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.
- 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 Regulation UE 2017/745, 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.
- 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 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.
- 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 Regulation UE 2017/745.
- Always respect the maximum load capacity indicated in this User Manual. Maximum load capacity means the total weight distributed according to human anatomy. In determining the total weight of the load on the product, the operator must consider the weight of the patient, equipment and accessories. In addition, the operator must check that the size of the patient does 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.
- The lubrication should be done after cleaning and drying.
- 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 immobilization and transport of the patient.
- Follow the procedures approved by the Emergency Medical Services for recovery and transport of the patient.
- Avoid contact with sharp objects.
- Do not use the device if it is pierced, torn, frayed or excessively worn.
- Before lifting, make sure that the operators have a firm grip on the device.
- Avoid using the device on rough surfaces.
- Do not lift by crane or other mechanical lifts.
- This device is a chair for patient transport and it can't be used as a device for seat.
- Use the device first without patient to make sure that you have become familiar with it.
- The use of the device requires at least two operators in appropriate physical condition, they must therefore be equipped with strength, balance, coordination, common sense and should be trained on the proper functioning of the device.
- In case of particularly heavy patients, for working on steep terrain or under unusual or special circumstances it is recommended to have more operators (not just two as required under standard conditions).
- The maximum weight taken by each rescuer must comply with requirements prescribed by the laws of the Country, Occupational Health and Safety at Work.
- Before each use always check the integrity of the belts and their hooks, as specified in the User's Manual. In case of malfunctioning or damage that could compromise the functionality and safety of the device, the patient or the operator, you need to replace the belts.
- Always immobilize the patient, using the straps supplied by the manufacturer, since the lack of immobilization can cause serious damage.
- Do not move the chair if the weight is not correctly distributed.
- Keep the chair firmly if the patient is sitting there.
- Use the chair only as described in this User's Manual.
- Pay maximum attention to any obstacles (water, ice, debris, etc.) on the track, as they may cause loss of balance of the operator and compromise the proper functioning of the device. If the way cannot be freed, choose an alternative track.
- Condensation, water, ice and accumulations of dust can affect the correct functioning of the device, making it unpredictable and causing a sudden alteration of the weight that operators have to bear.
- The chairs are certified when used with dedicated Spencer fasteners, so it is strictly forbidden to use fastening systems not approved by the Manufacturer. Fastening systems which have not been approved may alter the structural and functional characteristics of the device.
- Replace the wheels with original parts, in case of failure to block the device
- **The device should only be used to transport the patient in a sitting position, from where the rescue was performed to the ambulance. It is therefore not permitted to use the transport chair open inside the emergency vehicles, even if equipped with suitable fastening systems.**

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 Spencer 402, Spencer 406 and Spencer 407 chairs are for professional use only. Operators using the device must possess the following minimum requirements:

- physical capacity for using the device.
- be able to grab the device firmly with both hands
- have robust back, arms and legs for lifting, pushing and pulling the evacuation chair
- have a good muscular coordination

Every operator has to be trained in safe and efficient patient transport techniques..

 Loading techniques, in case of extremely heavy patients, uneven terrains or unusual situations, may require more than the usual two operators.

 **Before deciding the roles of the operators during the use of the device, their capabilities must be evaluated.**

3. PRODUCT DESCRIPTION

3.1 INTENDED USE

Folding transport chairs are devices to be used to move and bring a patient into a sitting position in the ambulance, but not to be used for transporting the patient inside the ambulance. They must not be used for parking.

INTENDED USERS

The intended users are people trained in first aid procedures and the use of medical equipment in an EMS environment.

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Among the possible users are also contemplated the fitters of emergency vehicles who can handle the product before putting it into service or during any maintenance of the vehicle on which the chair is installed.

PATIENTS

The expected patients are those with temporary motor difficulties.

There are no known contraindications or side effects resulting from the use of the device, as long as it is used in accordance with the user manual.

3.2 MAIN COMPONENTS

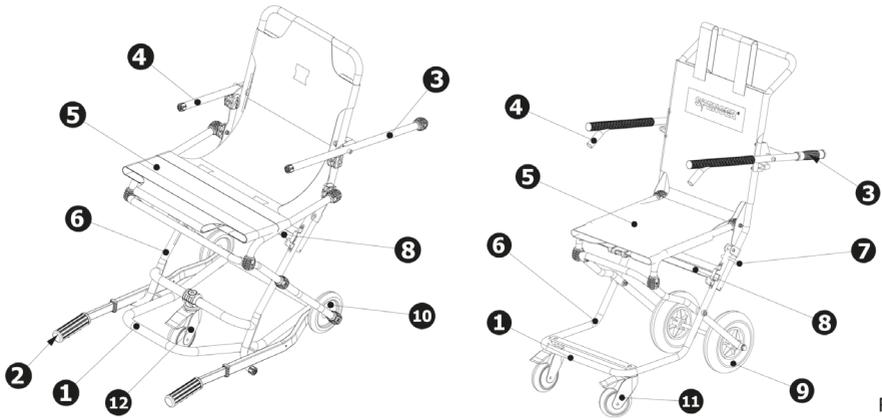


Fig.A

N°	MAIN COMPONENTS	MATERIALS	402	402/3	406	406 B	407	407 B
1	Front footrest	Steel	•	•	•	•	•	•
2	Front telescopic handles	Aluminium	•	•				
3	Rear handles	Steel	•	•				
4	Armrests	Steel	•	•		•	•	
5	Cover sheet	PVC	•	•	•	•	•	•
6	Frame	Steel	•	•	•	•	•	•
7	Safety mechanism against accidental closure	Steel			•	•	•	•
8	Opening/closure system	Steel	•	•	•	•	•	•
9	Rear wheel Ø 200 mm	Rubber coated polyurethane			•	•	•	•
10	Rear wheel Ø 125 mm	Polypropylene	•	•				
11	Front pivoting wheel with brake Ø 100 mm	Polypropylene					•	•
12	Front pivoting wheel Ø 100 mm, autodirectional	Polypropylene	•	•				

3.3 MODELS

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

ST00403B	Spencer 402/2 – Space saving foldable chair with two wheels
ST00402B	Spencer 402/3 – Space saving foldable chair with three wheels
ST00406A	Spencer 406 – Compact evacuation chair
ST20406A	Spencer 406/B - Compact evacuation chair with armrests
ST00407A	Spencer 407 – Evacuation chair with four wheels
ST40407A	Spencer 407/B – Evacuation chair with four wheels with armrests

3.4 TECHNICAL DATA

CARACTERISTICS	402	402/3	406	406 B	407	407 B
Length (mm)	520	520	410	410	410	410
Length open (mm)	630	680	840	810	810	810
Length open handles (mm)	1020	1040	–	870	–	840
Height open (mm)	860	860	930	930	970	970
Height closed (mm)	610	610	770	770	770	770
Width closed (mm)	160	160	220	220	300	300
Weight (kg)	9,2	9,5	10	11,6	10,8	12,4
Maximum load capacity (kg)	150	150	150	150	150	150

3.5 REFERENCE STANDARD

REFERENCE	DOCUMENT TITLE
Regulation 2017/745/UE	European Regulation of the european parliament and of the council of 5 April 2017 on medical devices
UNI EN 1865-1	Directives for stretchers and other patient transport equipment on ambulances
UNI EN 1789	Medical vehicles and their equipment - Ambulances

3.6 Environmental conditions

Functioning temperature: from -15 to +50 °C

Storage temperature: from -20 to +60 °C

Relative humidity: from 5 to 90 %

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

4.2 PREPARATION

On receipt of the product:

- Remove the packaging and display the material so that all components are visible.
- Check that all the components/pieces on the accompanying list are present.

The appliance must be checked before every use so as to reveal any working abnormalities and/or damage caused by transport and/or storage. Therefore, before using the device, 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
- Proper closure of screws and bolts
- Correct fixation of the straps
- Correct tightening of the straps
- Status of wear (moving parts, wheels, straps, covers, belts)
- Integrity of sewing and covers
- Integrity of components
- Integrity of handles (Are they worn? Are the sewing intact?)
- Lubrication of the moving parts
- Status of wear of wheels and braking system
- Functionality of springs
- The emergency vehicle is equipped with a Spencer fastening system dedicated to the device
- The seat belts for the immobilization of the patient are present, intact and are working
- The weldings are intact, without cracks or damages
- No pipe or metal plate has bent or cracked

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 FUNCTIONING

4.3.1 Opening the device

1. Put the device in vertical position.
2. Hold the head side of the frame with the right hand and grab the seat with the left hand, opening up the chair, pushing the two ends to the outside, until the automatic lock of the movement mechanism.
3. Convey the safety system fall into its seat (Spencer 406, 406 B, 407, 407/B).
4. Release the brake of the front wheels acting on the red pedal (Spencer 407, 407/B).

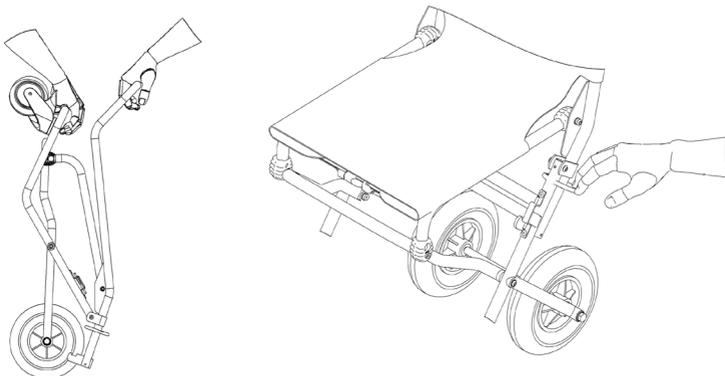


Fig. B

4.3.2 Closing the device

1. Block, with their brakes, the pivoting wheels 100 mm Ø after turning them towards the inside (Spencer 407, 407 B).
2. Unplug the safety system by grabbing the rings and lifting them up in a static position.
3. Unlock the chair in the closed position by pulling the movement mechanism bar and grip, at the same time, the head side of the frame by pushing inward, until the complete closure of the chair.

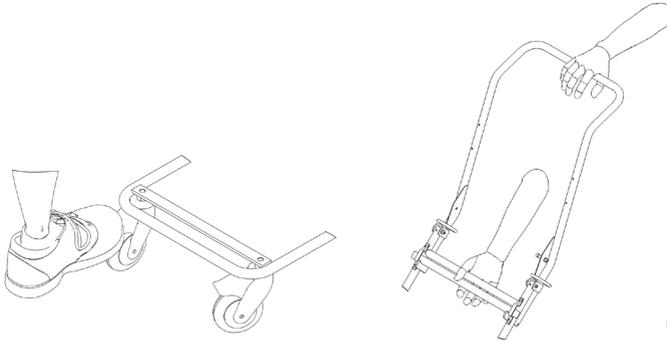


Fig. C

4.3.3 Patient transport on stairways

1. Apply the procedure described in paragraph 4.3.1.
2. Keep the chair in a stable arrangement grabbing the back to accommodate the patient, take care during this operation that the wheels or footrest, depending on the model, stick to the ground.
3. Ensure the patient to the device with the dedicated seat belts.
4. The operator must position himself on the back of the chair and grab the frame at the head side.
5. Another operator must be positioned in front of the chair, facing the patient and grasp the frame at the front.
6. Using adequate lifting techniques, the operators must simultaneously lift the chair and start transport.

 For this type of transport the presence of a third operator is recommended in order to guide the other two.

4.3.4 Patient transport on stairways (Spencer 402)

1. Apply the procedure described in paragraph 4.3.1.
2. Keep the chair in a stable arrangement grabbing the back to accommodate the patient, take care during this operation that the wheels or footrest, depending on the model, stick to the ground.
3. Ensure the patient to the device with the dedicated seat belts.
4. The operator must position himself on the back of the chair and grab the transport handles.
5. Another operator must be positioned in front of the chair, facing the patient and grasp the rubber part of the telescopic handles, the handles come outside their place by pulling them.
6. Using adequate lifting techniques, the operators must simultaneously lift the chair and start transport.

 For this type of transport the presence of a third operator is recommended in order to guide the other two.

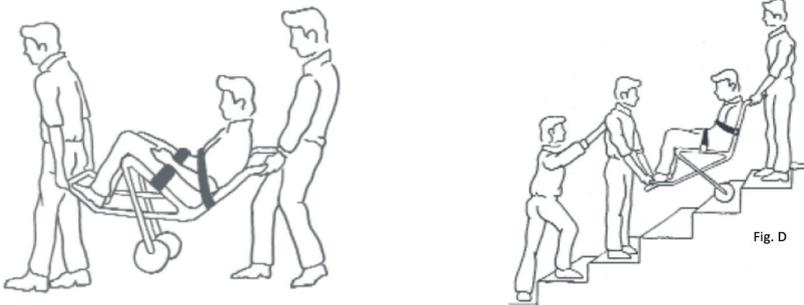


Fig. D

5. TROUBLESHOOTING

PROBLEM	CAUSE	REMEDY
The device does not unblock from open or closed position during the opening or closing procedure	The functional geometry has been compromised or damaged; the safety systems have not been removed	Try complete lubrication and check if the problem has been solved; if not, take immediately the device out of service and contact the service center
Difficulties extracting and inserting the telescopic handles (402/2, 402/3)	Presence of foreign bodies in the slide or breakage in aluminium part	Clean accurately; if this does not solve the problem, do not use the device for upstairs transport and contact the service center
Structural damage	Improper use or untrained personnel	Take the device immediately out of service and contact the service center

6. MAINTENANCE AND CLEANING

6.1 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 influences are treated superficially and/or painted in order to obtain better resistance. Clean the exposed parts with delicate soap and a sponge and dry with a soft cloth. In order to obtain a shiny finish of the frame parts, use shiny creams and waxes for vehicles. We advise the use of the polishing detergent Spencer STX 99. Do not use high-pressure water. It may penetrate joints and eliminate lubricants, increasing the risk of corrosion of components. Rinse carefully with warm water to remove all traces of detergents. Failure to do so could compromise the product and its life span. The device must be left to dry completely before storage. To dry the product after washing, or if used in a humid atmosphere, do not use direct sources of heat or flame.

6.2 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 Regulation UE 2017/745, 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.

6.2.1 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 Regulation UE 2017/745 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.

Check ups to be performed before and after every use, and at least every six months, are as follow:

- 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
- Proper closure of screws and bolts
- Correct fixation of the straps
- Correct tightening of the straps
- Status of wear (moving parts, wheels, straps, covers, belts)
- Integrity of sewing and covers
- Integrity of components
- Integrity of handles (Are they worn? Are the sewing intact?)
- Lubrication of the moving parts
- Status of wear of wheels and braking system
- Functionality of springs
- The emergency vehicle is equipped with a Spencer fastening system dedicated to the device
- The seat belts for the immobilization of the patient are present, intact and are working
- The weldings are intact, without cracks or damages
- No pipe or metal plate has bent or cracked

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 Regulation UE 2017/745.

The person responsible for precautionary maintenance can identify any damaged / worn parts, but the replacement or restoration of the same can be done only by the manufacturer or authorized service center. For other activities of repair / replacement contact the manufacturer or an authorized by the latter.



Use only components/spare parts and/or original accessories or approved by Spencer Italia S.r.l., in order to perform any operation without causing any alteration, modification to the device, otherwise we assume no responsibility for the proper functioning or damage caused by the device on the patient or operator and void the warranty and making void the compliance with the Regulation UE 2017/745.

6.2.2 Periodic maintenance

The device must be subjected to annual revisions to verify the proper operation and compliance with the safety requirements guaranteed by the Manufacturer when the device is placed on the market. The revisions must be made by the Manufacturer, who uses specialized internal and external technicians and is authorized by the Manufacturer himself. In the absence of such annual revisions, the device must be **SECRETED UNTIL REPAIRING**, otherwise it must be **DISPOSED OF AND IT MUST BE GIVEN COMMUNICATION TO THE MANUFACTURER**. For any operations that are not carried out directly by the Manufacturer but by an authorized 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.

6.2.3 Life span

The device, if used as described in this user manual, has an average life span of 5 years from the date of purchase, which can be extended following annual revisions.

The life span can be extended, based on manufacturer's or on authorized service center evaluation, if the safety requirements of the device are still guaranteed.

In the absence of such extensions, the device must be **DISPOSED AND IT MUST BE COMMUNICATED TO THE MANUFACTURER**.

Belts, fabric seat and backrest shall be replaced **every two years**.

Spencer Italia S.r.l. disclaims any responsibility for incorrect operation or for any damage caused by the use of devices not revised by the Manufacturer or authorized service center, or that have exceeded the maximum permissible life span.

6.2.4 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 the operations carried out on the device.

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