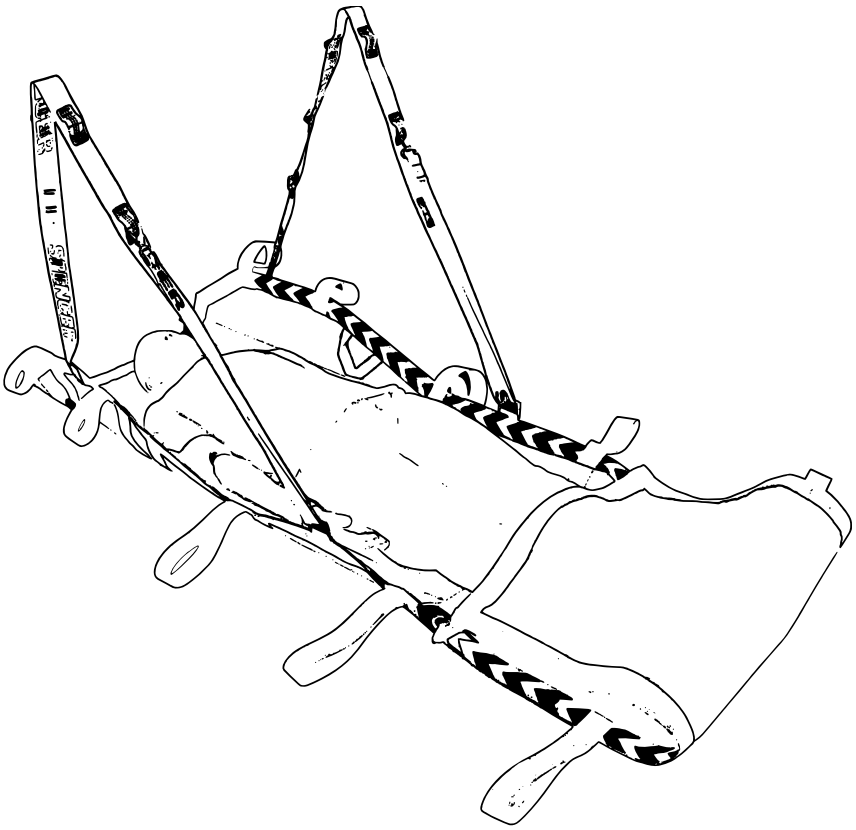
User manual

WOW

Carrying sheet



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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Quality System EN ISO 9001 – EN ISO 13485

INDEX

1. MODELS

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

- WOW – CARRYING SHEET 10 HANDLES
- WOW – CARRYING SHEET 10 HANDLES WITH FOOTREST

2. INTENDED USE

The carrying sheet WOW, is a device intended for recovery and transport from the rescue place to the primary stretcher or for trasnfers to the bed of patients not affected by spinal injuries. The transport can be performed with lying or sitting patient in accordance with its clinical condition.

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.

STANDARD	DOCUMENT TITLE
UNI EN 1865-1	Patient handling equipment used in road ambulances - Part 1: Specification for general stretcher systems and patient handling equipment

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 SYMBOLI

Symbol	Meaning
	General or specific warnings
	See instructions for use
LOT	Lot Number
REF	Product code
CE	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://it.spencer.it/contatti 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.

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. **Instructions are continually being updated and are under tight surveillance of fully qualified staff with adequate technical formation.

- 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.

Product functionality

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

- Before each use, the perfect operating state of the device must be thoroughly 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 for any malfunctions or injuries caused by the appliance itself will be denied; 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.
- For devices intended for the transport of patients, always respect the maximum load 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 total loading weight of 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.
- For devices intended for the transport of patients, make sure, before lifting, that operators have appropriate physical condition as indicated in the manual.
- **The maximum weight supported by each rescuer must comply with the requirements prescribed by the law of the land, in the field of Health and Safety at Work.**
- **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
- Temperatura di utilizzo: da 0°C a + 40°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.
- Temperatura di stoccaggio: da 0°C a +40°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 the first responders to the complete their operation and the subsequent stages of transport to the nearest rescue point.
  - When the device is being used, the assistance of qualified staff must be guaranteed and at least three 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 the *Carrying sheet WOW*, the user must have read, understood and follow carefully all the instructions described in this manual

- Follow the procedures approved by the Emergency Medical Service for the immobilization and transport of patients.
- Follow the procedures approved by the Emergency Medical Service for the positioning and transport of patients.
- Do not use if the device or its parts are pierced, torn, frayed or excessively worn out.
- Before use, ensure that all operators have a firm grip on the device.
- Avoid pulling the device on rough surfaces.
- Do not lift by crane or other mechanical lifters.
- Do not use drying machines.
- Do not use the device with other equipment not expressly approved by the manufacturer
- Practice with an empty carrying sheet and with a simulated load in order to become familiar with the manoeuvres is recommended.
- For patient loading techniques, for particularly heavy patients, for working on uneven ground or in special and unusual circumstances, the presence of more operators is recommended (not only 3 as required in standard conditions).
- Before moving the patient, operators must be coordinated in order to make liftings and synchronized movements.
- 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 replace the damaged parts.
- **The use of the carrying sheet is not recommended if heart or respiratory problems are present.** Ensure that the doctor has carried out needed primary evaluations.
- Make sure that the device does not interfere with any moving/locking system or levers of the main stretcher.
- Do not operate in case the weight has not been distributed correctly.
- Before moving the patient with the device, inform him about the maneuvers that will be carried out.
- Before lifting, it is recommended that operators have the feet placed in a wide position; this will increase their stability.
- No equipment, device or operators should pass above the patient.
- Avoid excessive force when lifting the device; unnecessary force when lifting the device, could cause injury to the patient or damage the product and may adversely affect rescue operations.
- During stair transport, make sure the patient is looking in the moving direction.
- **Have a firm grip on the device when the patient is moved.**

- Great attention must be paid to any possible obstacles (water, ice, debris, etc.) on the route of the stretcher/chair, because they could cause loss of balance of the operator and compromise the proper functioning of the device. If the path cannot be freed of obstacles, choose an alternative route.
- Condensation, water, ice and dust accumulation can affect the correct functioning of the device, making it unpredictable and causing a sudden change in weight that operators have to sustain.

- 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
- Before starting loading procedures on the device, remove patient's glasses or unstable dentures.
- The device is not suitable in case of spinal injuries or when the use of a rigid device is suggested or required.
- Lift the device without excessive force but firmly. Any uncertainties during lifting, could cause collisions of the patient's head against the ground.
- When handling the device with patient, pay attention to maintain adequate ground clearance because the device does not protect the patient against potential shocks.
- **Do not use the devie inside or near MRI machinery or equipment.**
- **The device, also the version equipped with footrest, must not be used for the transport of patient in vertical position.**

6.1 PHYSICAL REQUIREMENTS OF OPERATORS

The carrying sheet WOW is a device intended for professional use only. Each operator must be trained to transport patients safely and efficiently. Do not allow untrained persons to help operators during use of the product, as this may cause injury to themselves or to other people.

The operators that use the device must have the physical ability to use it and good muscle coordination, as well as presenting a strong back, arms and legs to raise and support and be able to grasp the device firmly with both hands.

Operators must be able to provide the necessary assistance to the patient.

Users should be able to lift and handle safely the weight of the device and the patient as well as any other equipment used with the device .

During loading procedures of extremely heavy patients, operations on rough terrain or in particular circumstances, the presence of more operators may be needed (not only 3 as required in normal conditions)

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

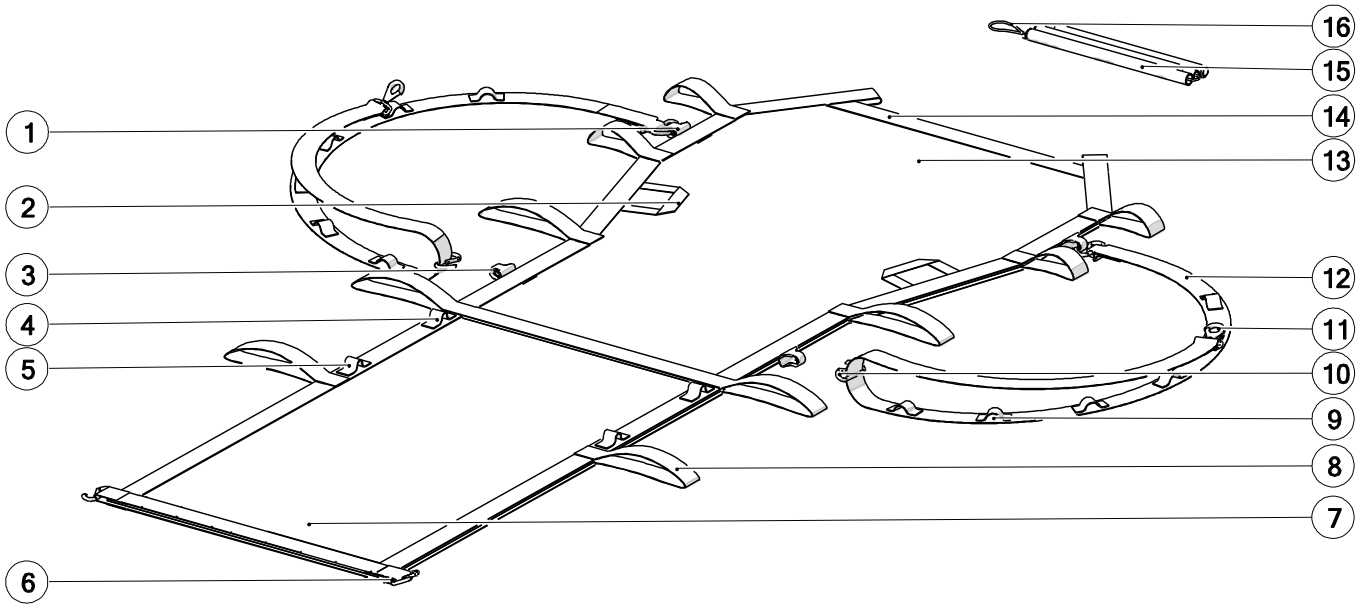
7. RESIDUAL RISK

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.
- Use of the device by a non-adequate number of operators, can cause serious harm to the patient and have consequences on the operators.
- The use of the device with patients having spinal injury, fractures of the pelvis, respiratory and/or cardiovascular problems, can seriously affect patient's clinical condition. Make sure that the responsible doctor has made necessary primary clinical evaluations.
- The use of products having a solvent action on the materials used for the construction of the device, may compromise its integrity with consequent risks for the patient.
- The use of the device in magnetic resonance imaging, may have serious consequences for the patient.
- Improper use of shoulder straps can cause injury to operators and could have consequences for the patient.
- Improper use of internal rods, can lead to operator and patient injuries
- Failure to perform checks and periodic maintenance of the device, can lead to serious consequences for patient and operators.
- Uncertainties during transport or inadequate ground clearance, could cause harms to the patient caused by impacts. Obstacles along the way should be carefully considered.
- **Failure to read and understand the instructions of this device, 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	Upper loop for shoulder strap attachment	Polyester
2	Patient handles	Polyester
3	Lower loop for shoulder strap attachment	Polyester
4	Upper loop for footrest (If present)	Polyester
5	Lower loop for footrest (if present)	Polyester
6	Footrest carabiner (if present)	Aluminium
7	Sheet fabric	PVC
8	Handles	Polyester
9	Loops for shoulder straps adjustment	Polyester
10	Carabiner for shoulder strap attachment	Aluminium
11	Shoulder strap length adjustment carabiner	Nickel plated brass
12	Shoulder strap tape	Polyester
13	Pocket for accessory storage	/
14	Holes for rods insertion	/
15	Rod	Aluminium
16	Elastic rope	Polyester

Feature	Value	
Device	WOW	WOW W/FOOTREST
Length	1870 mm	2560 mm
Upper part width	960 mm	
Lower part width	700 mm	
Storage dimensions[(1)]	500x600x150 mm	
One rod folded dimensions	74x450x30 mm	
N° of handles	10	
Tapes width	50 mm	
Upper handles length	160 mm	
Lower handles length	260 mm	
Rod length	1210 mm	
Shoulder straps adjustments	6	
Loading capacity [(2)]	150 kg	
Weight	4,2 Kg	4,7 Kg

(1) The dimension is referred to the wrapped sheet. It is indicative, since the device can be folded in many ways.

(2) Maximum load capacity means the total weight distributed according to the human anatomy. In determining the total load of the weight on the product, the operator must consider the weight of the patient, the equipment and the accessories.

Note: Indicated technical data are subject to tolerances of ±10mm and ± 20 g

9. INSTALLATION AND START-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
- Absence of cuts, holes, tears on the structure

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.

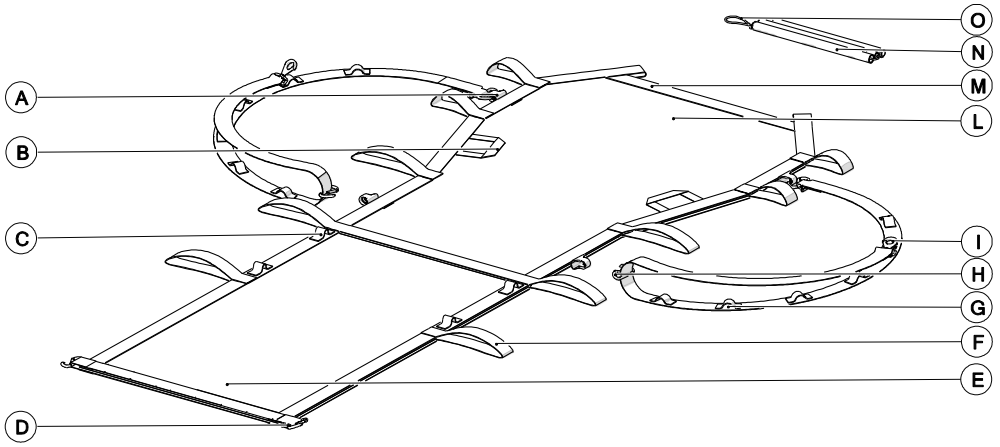
Practice with a device without patient before the regular start-up.

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	Loops for shoulder strap attachment	They are used to attach the shoulder straps. Their integrity must be carefully checked
B	Patient handles	Red coloured, are used by the patient increasing safety and stability
C	Loops for footrest	If present, they allow to maintain folded the footrest, increasing patient's longitudinal stability. Two positions are available.
D	Footrest carabiner	They allow to hook the footrest to the dedicated loops
E	Sheet fabric	It is the main component of the device and its perfect integrity and cleanliness must always be ensured
F	Handles	Used to lift the patient, they cross the whole device improving the load distribution and increasing the resistance of the device
G	Loops for shoulder straps adjustment	They are integrated on each shoulder strap and allow 6 adjustment positions to be chosen according to the operator stature
H	Carabiner for shoulder strap attachment	To be used both on upper and lower side of the shoulder strap, allow to attach and detach the shoulder strap from the loops placed on the sheet.
I	Shoulder strap length adjustment carabiner	Allows to adjust the length of the shoulder strap by placing the carabiner in the different loops. Each position corresponds to an increase of about 5cm of operator stature.
L	Pocket for accessory storage	It can be used to store the rods and the shoulder straps when the device is not used, or to insert a pillow or a padding during use to increase patient comfort. The closure can be done quickly thanks to the two integrated magnets.
M	Holes for rods insertion	Areas of the sheet used to keep in place the rods.
N	Rods	They consist of 3 parts made of aluminum. Once inserted in the dedicated housings of the sheet, they improve patient support increasing longitudinal rigidity of the sheet. The rods can be inserted for 2/3 as described later, allowing to carry the patient in sitting position
O	Elastic rope	Holds together the 3 parts of each rod. Its elasticity, allows to fold the 3 parts. In its terminal part there is a loop to make the extraction from the sheet easier.

11. INSTRUCTIONS FOR USE

Before transferring, lifting or transporting the patient, primary medical evaluations have to be performed. Once the diagnosis has been assured, it is preferable (if possible) to suggest to the patient that he actively collaborates during transfer onto the chair, and to make sure the patient is fully aware of all risks. Before loading the patient, place the device near the patient; always maintain the safety belts fastened during the manoeuvres.

11.1 PLACING THE PATIENT

Note: The procedures described below, are intended to illustrate a possible method of use of the product. For the use of the device, follow the guidelines approved by your local authorities.

Pull out the rods and the shoulder straps from the pocket.
Spread the device near the patient with the side with yellow and black pattern facing up, and the widest part at the patient's head.
Fold the device in half lengthwise.
The upper half so obtained, must be folded again on itself, exposing again the part with the yellow-black pattern.
Push the device near the patient, until the folded part is as close as possible to the patient lying supine.
The operator at the folded side of the sheet, helps the patient to rotate on its side, thus facing his back to the sheet.
The operator on the opposite side pushes the device under the patient, aligning its median line with the patient's spine.
Bring back the patient in supine position and rotate him on the other side. The other operator takes the handles and pulls until the device is fully extended.
Bring back the patient in supine position.

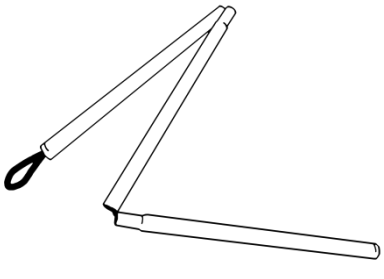
If necessary, the log roll manoeuvre can be done with already inserted rods.

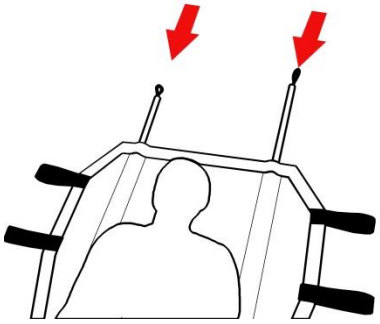
11.2 ROD INSERTION

Open each rod by straightening it and introducing the narrow end of each section inside the next section until they are completely in contact each other.

Be careful when opening the rods: Danger of crushing

Insert the rods inside the holes at the top of the sheet. To lift the patient in lying position, the rods must be fully inserted.
If the device is used in narrow spaces, the rods can also be inserted through the holes placed immediately below the transversal black tape located at the middle of the sheet and visible on its patient side.





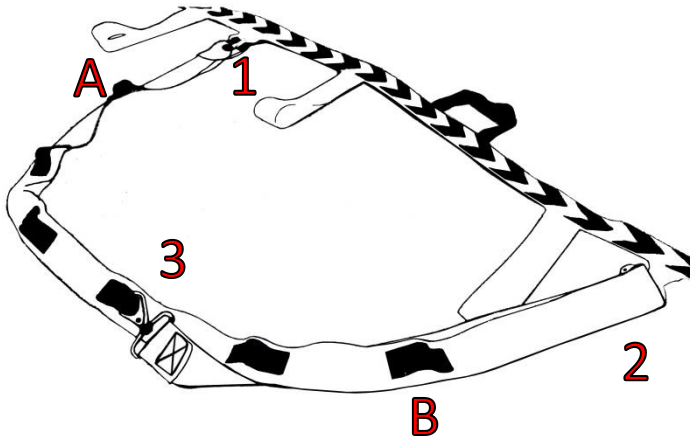
11.3 SHOULDER STRAP APPLICATION AND ADJUSTMENT

the supplied shoulder straps help to decrease the rescuer's fatigue by distributing the load even on the shoulder.

1- The shoulder strap has an end in which is integrated a small carabiner (n°11 par.8), and a free one. Apply to the free part one of the supplied carabiners and insert it into de lower loop for shoulder strap attachment (n° 3 par. 8 and n.1 in the image).

2- Insert the tape of the shoulder strap in the second carabiner and secure it to the upper loop placed at a distance of about 85cm from the lower one (n.2 in the image)

3- Then use the carabiner integrated in the strap to secure the shoulder strap in closed position by choosing the slot suitable for your stature (n°3 in the image).



The shoulder strap can be adjusted in 6 positions by varying the loop on which the terminal carabiner is attached.
In the image, with the letter "A" is identified the loop intended for operators with lower stature. With the letter "B", is identified the loop suitable for operators with higher stature. Each intermediate position, correspond to a variation of operator's height of about 5cm.

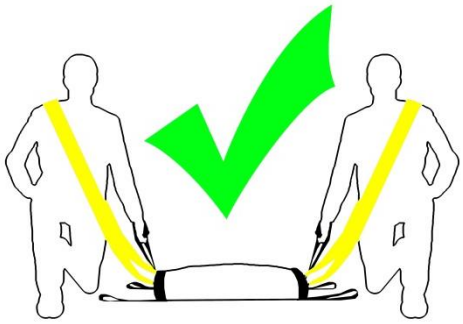
11.4 USE OF THE FOOTREST (if present)

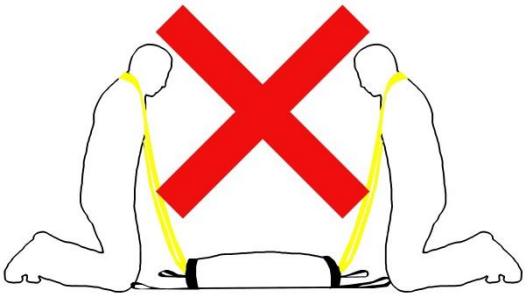
The footrest is a component of the device intended to limit the longitudinal movements of the patient. After the correct positioning of the patient has been verified, fold the bottom end of the sheet over his legs.
Then hook the carabiners of the footrest to the upper or lower loop placed at the sides of the sheet (n° 4 and 5 par.8). Choose the suitable loop according to the patient's stature.

11.5 LIFTING THE PATIENT IN SUPINE POSITION

Subsequently to the operations described above, it is possible to carry out the lifting of the patient.
The number of operators has to be proportionate to the weight to be lifted in accordance with the workplace safety standards.

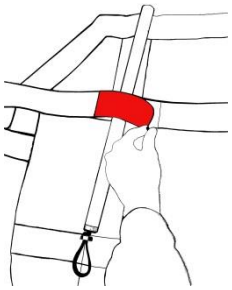
Two operators will place at the sides of the sheet facing the patient's feet and will place the shoulder straps over the shoulder at the opposite side of the patient, thus distributing the weight on the entire spine.
Warning: Do not place the shoulder strap around the neck. Such load, can lead to injuries to operators





Ask the patient to grab the red handles placed near his shoulder by crossing his arms. In this way the patient will be more protected against operator's movements, will be more stable during transport increasing his safety.
Remaining operators, will grab the handles of the sheet more appropriate to the type of transport and, after being synchronized each other, will lift the patient.

11.6 LIFTING THE PATIENT IN SITTING POSITION



The device, in addition to the transport in supine position, allows also the transport in sitting position. This is suitable in confined spaced and makes easier the device handling.

For this type of transport, the internal rods must be inserted only for 2/3 inside the sheet. The remaining part must be maintained outside and folded on the back side of the device. The rod can be secured in place using the red tapes placed on the backside of the sheet.

To ensure a better distribution of the load and to prevent stress damage, it is essential to support the weight even using the handles (not only the shoulder straps).
The operator can choose which handles to use according to its height with the aim to minimize fatigue.
It is recommended to grasp always the handle placed at the middle of the sheet (at the narrowing point of the device). During transport in sitting position, the load is focused on this point.

11.7 POCKET FOR ACCESSORIES

The device is equipped with a pocket that can be opened from the top of the sheet. It is closed by means of two magnets.
Inside the pocket is possible to place a pillow or blanket during transport in order to increase patient's comfort. After use, is possible to store the folded rods and the shoulder straps, ensuring an easy retrieval of the accessories and a low storage space.

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.

After the patient has been transferred on the main stretcher or the bed, carry out cleaning of the device and all its parts.
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.

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.

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)
- Proper working of carabiners and rods
- Absence of cuts, holes, tears on the structure, including the straps
- Integrity of handles and shoulder straps

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

Planned interventions by the manufacturer or authorized centre are not required, but it is prescribed to make cleaning and checking indicated in the specific sections "Cleaning" and "Precautionary Maintenance".

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.

12.5 LIFE SPAN

The device, if used as indicated in the instruction manual, has an average life span of 2 years.

The user or the organization that allows the use of device beyond the expiration of the average life span established by the manufacturer, assumes the responsibility for any direct and(or indirect damages arising from the use of the product relieving the manufacturer from any liability.

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 by the manufacturer or by one of the manufacturer's authorised service centres and will consider void both the guarantee and the conformity to the Medical Devices Directive 93/42/CEE

13. TROUBLESHOOTING

PROBLEM	CAUSE	SOLUTION
The fabric is torn	Wear or improper use	Put the device immediately out of service and replace it
Carabiners don’t work properly	The carabiner is deformed	Put the device immediately out of service and replace the carabiners with the spare ones indicated in the spare parts paragraph
	The internal spring is broken	
The 3 sections of the rods cannot be coupled	The elastic rope is damaged	Put the device immediately out of service and replace the rods
	One or more sections are damaged	
The sheet cannot bear the weight of the patient	The sheet is damaged	Put immediately the device out of service and contact the service centre
The handles have broken parts, are not properly sewn or are damaged	Wear or improper use	Put immediately the device out of service and contact the service centre

14. ACCESSORIES

There are no accessories for this device

15. SPARE PARTS

RIQM001C COUPLE OF BLACK ALUMINIUM CARABINERS
RIQM002C COUPLE INTERNAL RODS FOR WOW
RIQM003C COUPLE OF COMPLETE SHOULDER STRAPS FOR WOW

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.