USER MANUAL

SCALEO MEDICAL

Radiolucent flat stretcher and

Intensive care stretcher

CE MADE IN FRANCE

Content

Warnings and safety instructions

Stretchers are medical devices and should be installed, used and serviced by trained personnel only.

The stretchers are designed and manufactured so they can be used to transfer patients of up to 240 kg (S1921002) or of up to 300 kg (S1921001, S8311302 & S8311301). It is important to check the maximum load of your stretcher before use.

The maximum load of the combination hoist + stretcher is the lowest value of the two maximum loads.

Before using the stretcher with a patient lifter, it is important to check the user manual of the patient lifter to be sure that the hoist and its accessories (weighing systems ...) are compatible with the use of a stretcher. If not, or if the documentation is not present, do not use the stretcher with this hoist, and contact the manufacturer or the distributor to get more information.

The stretcher must be serviced only with original spare parts.

SCALEO Medical stretchers have been designed specifically for the 4-point suspensions of the SCALEO Medical patient lifters.

If you use the stretcher with a hoist of another manufacturer, make sure before use that the suspension is compatible, and demand proofs of compatibility, including the results of tests made under the EN 10535 standard. SCALEO Medical is not responsible of accidents when using other hoists without precaution.

The SCALEO Medical Stretchers are radiolucent and contain only nonmagnetic metal parts (aluminum, stainless steel screws). However, the use of the stretcher with medical imaging like computed tomography (CT) magnetic resonance imaging (MRI) is NOT claimed by SCALEO Medical.

Packaging elements (plastic, polystyrene wrappings etc.) must not be left within reach of children as they can be potentially harmful.

Make sure the stretcher and the hoist have a transfer capacity adapted to the patient's weight.

Patient lifters must NEVER be used to transfer, lift or transport people over slopes. They must be used only for short distance transfers and are not intended to replace wheelchairs or other types of transport devices.

Make sure before any transfer that you have enough space on both sides of bed, shower trolley... to pass half stretcher.

Transfers of patients with a stretcher should preferably be done by three caregivers: two for the implementation of the stretcher and patient monitoring, and one for handling the lifter.

If the stretcher is used with an agitated patient, it is recommended to secure the patient with slings in order to avoid the patient from falling. Patient slings can be ordered as an option.

SCALEO Medical stretchers can be used to carry the patient: spaces between the slings may be used as handles.

It is recommended that the stretcher be used with a fixed-suspension lifter, where the suspension is capable of rotating 360° around an axis.

Symbols and pictograms

The symbols used in this manual are:

This symbol indicates instructions and safety information when injuries may occur if warnings are ignored or partially followed. It is important to carefully follow the advice and warnings.

This symbol indicates important information regarding the use of the equipment. Failure to follow this information may result in damage or malfunction of the equipment.

This symbol indicates important and useful information. This information will help the user and optimize the use of the material. It will simplify routine operations and provide solutions to complex operations.

Symbols used in labels:

Symbol	Meaning
	Manufacturer
	Date of manufacturing
	Device reference
	Batch number
	Maximum load
	Medical device

Symbol	Meaning
	Read user manual for instruction
	Sense of use : feet side
	In accordance with the applicable European Regulations
	Warning : read user manual for instruction

General information – Radiolucent flat stretcher

You have recently purchased a Radio transparent stretcher.
We would like to thank you for the trust you have placed in our company.

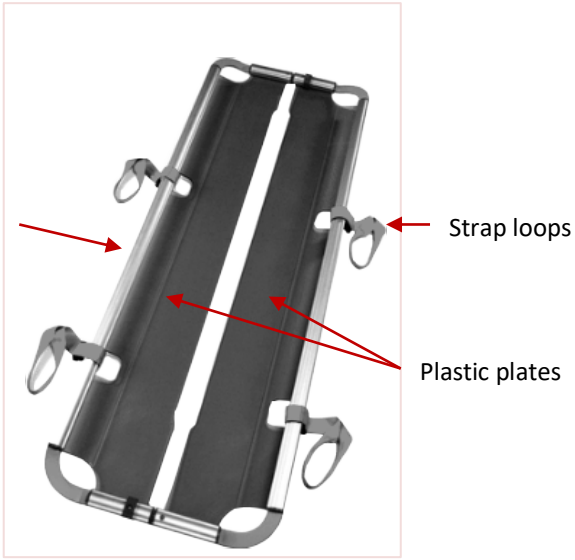
This user manual contains important safety instructions and information concerning the use of the stretchers. Carefully read the manual before using the equipment: all the functions and safety measures have to be familiar to the user.

This manual is relating to the following devices:

- Radiolucent stretcher, maximum load 300 kg ref: S19 21 001
- Radiolucent stretcher, maximum load 240 kg ref: S19 21 002

The stretchers are delivered in a cardboard box containing:

- A Radiolucent stretcher divided in two parts.
- A set of four straps loops, ref: S82 99 003.
- This user manual



Intended use

The Radiolucent flat stretcher is intended to lift and transfer patients of up to 240 kg or 300 kg, depending on the model, when the lying position must be maintained during all the transfer operation.

They are designed to meet the requirements of the most specialized cares, such as severe burn victims and of the resuscitation, cardiology, pulmonology, radiology, neurology, nephrology and operating theater services, including spinal operation, anesthesia, heart surgery, digestive surgery and trauma.

Contraindications

The Radiolucent stretcher should NOT be used:

- With patients weighting more than the maximum load.
- To lift or carry objects.
- To perform transfers in sitting position.
- With a lifter that is not compatible

Assembly and commissioning instructions – Radiolucent flat stretcher

Instructions for assembly

Before assembling the stretcher, please ensure the packaging is not damaged before unpacking. If that is the case, immediately notify in written the forwarder and to contact SCALEO Medical.

If a component is missing or deteriorated, do not assemble and use the device: contact your distributor or SCALEO Medical.

Using the stretcher requires a good experience of patient transfer, and some training for assembly/disassembly operations.

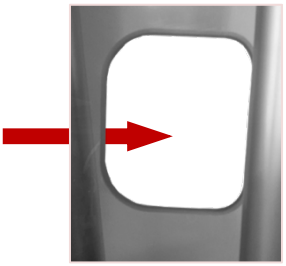
Unpacking, assembling and disassembling the stretcher requires two people.

Installing the strap loops reference S8299003

Strap loops are used to hang the stretcher on the suspension of the patient lifter.

Before use, it is mandatory to check that the four loops are in good condition and to install them properly for a safe use of the stretcher.

1. Locate the slot of the loops.



2. Slide the loop in the slot, black part first.

3. Slide the loop end in the black loop.

4. Pull the end of the loop to insure a good mounting.

5. Repeat the operation with the three other loops.

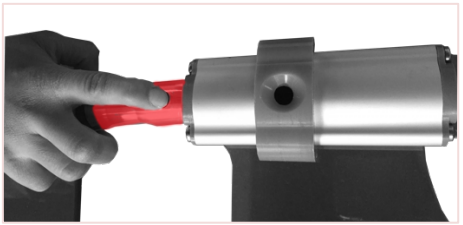
Mounting and locking the stretcher

The locking system allows a secure assembly of the two halves of the stretcher.
The locking system cannot be unlocked or disassembled once the stretcher is hanging on the hoist spreader bar.

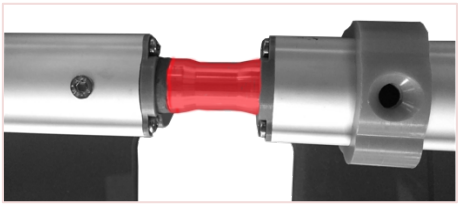
1. Unpack the stretcher, remove all the protection parts.
2. Lay down the parts of the stretcher on a flat area in order to facilitate the assembly.
3. The two operators position the two halves face to face: refer to the labels indicating the foot end.
4. Lock the two parts of the stretcher as follows:

a. Position the male part face to the female part

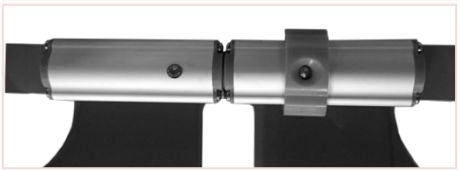
b. Press the lock pin and insert the male part, so that the pin is blocked in its housing.



The safety ring prevents the accidental unlocking of the stretcher



c. The system is locked



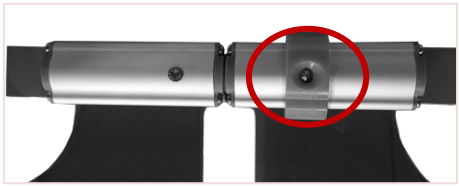
Locking is automatic: a "click" sound accompanies the lock; the locking ball must be visible through the locking ring.

Disassembly and storage

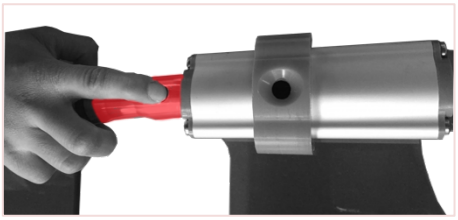
Disassembly

Lay down the stretcher on a flat area in order to facilitate the disassembly.
The two operators position face to face at each end of the stretcher.

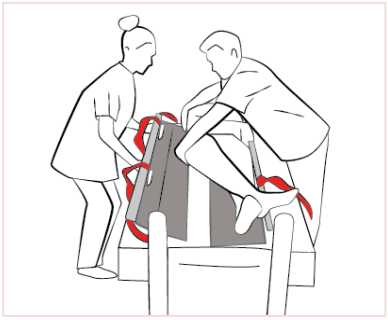
1. Press the pin through the locking ring to unlock the locking system.



2. Unlock the system: slide the male part out the female part. Remove the male part of the stretcher first.



3. The patient may be lateralized to facilitate uncoupling.



Storage

If the stretcher is assembled:

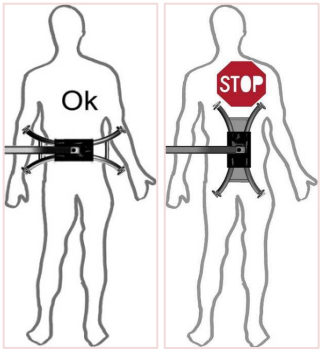
1. Set the two loops at the upper corners of the stretcher.
2. Place the assembly against a wall.

If the stretcher is disassembled, attach the two parts to the hoist suspension.

These modes of storage facilitate access to the stretcher, save space, simplify cleaning and disinfection procedures and ensure a safe storage of the stretcher.

Instructions for use – Radiolucent flat stretcher

The spreader bar must always be positioned above the patient as shown:



In all cases: hang the four loops of the stretcher to the four hooks of the spreader bar. Make sure before transferring the patient that the four loops are in position: gently lift the stretcher and make sure all four straps are in tension.

Radiolucent stretchers are used mainly to transfer patients whose lying position must be maintained during all the transfer operation:

- Transferring a lying patient from a bed to a stretcher.
- Lifting a patient from the floor to a bed or a stretcher.

Three maneuvers must be therefore mastered by the nursing staff:

1. Transferring the lying patient to the Radiolucent stretcher,
2. Lifting the patient lying on the floor,
3. Transferring the patient from the radiolucent stretcher to the bed, the shower trolley or other horizontal support.

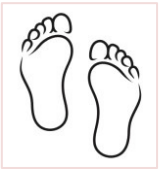
Place a pillow under the patient's head to protect the head against possible shocks during the transfer.

During the operations done around the patient, make sure that you do not to damage any cables, hanging tubes or devices connected to the patient.

Transfers of patients with a stretcher must be performed by trained personnel in the handling and transfer of patients with reduced mobility: lateralization, patient transfer must be made in accordance with safety rules and specific ergonomics.

Stretchers should be used in accordance with a direction: balancing the stretcher and therefore the patient safety are optimized when the stretcher is used properly.

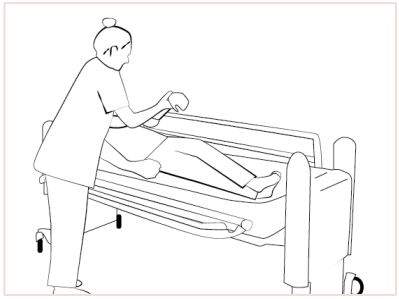
The direction of use is very simple: a label clearly indicates the side "feet" of the litter:



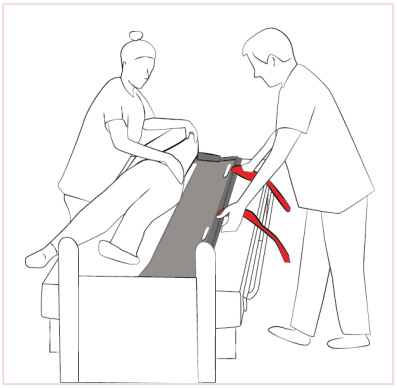
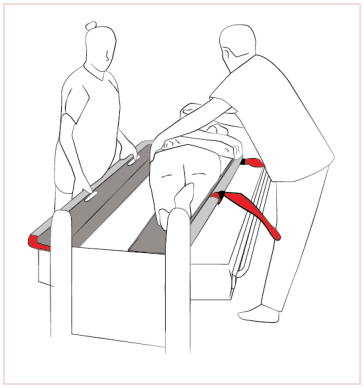
Transferring a patient to the Radiolucent stretcher

Depending on the condition of the patient, it is also possible to lateralize the patient with a hospital sheet following good practices of gestures and postures.

1. If the lateralization is possible (a medical advice is mandatory) lateralize the patient: position a patient's leg above the other, the corresponding arm over the other arm, then rotate the patient.

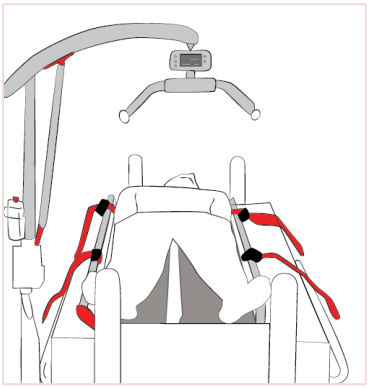
2. Slide the two half-stretcher under the patient, one after the other and lock the two parts together. To facilitate the transfer phase, the first caregiver maintains the patient in a supine position while the other caregiver slips the half-stretcher under him.

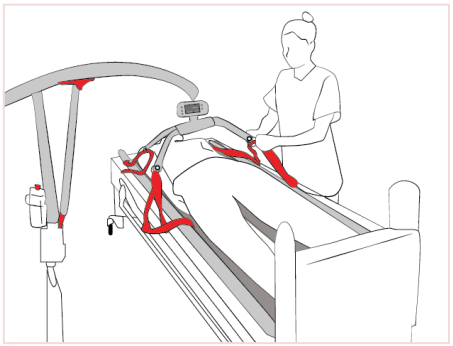



3. Lay the patient on his back and have a pillow under his head for a better comfort.

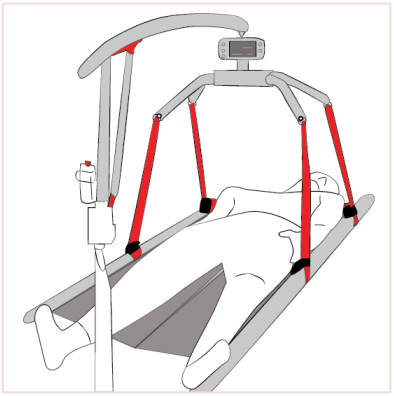
It is mandatory to refer to the user manual of the hoist for precautions of use during transfer operations.

4. Bring the hoist near to the patient and center the spreader bar above the patient (see above). Move the spreader bar down to a distance sufficient so you can hang the loops. Attach the four loops to the spread bar like shown above.





5. Slowly lift the patient a few inches making sure that the patient is properly installed in the stretcher and that the straps are properly positioned into the hooks of the spreader bar, and they are tense.



The patient can now be transferred.

Lifting a patient from the floor

Because in this case the patient has fallen and may have been hurt, and especially if the patient is unconscious, the patient must always be examined by a physician or a first aid personnel before attempting to move him.

In some cases, caregivers will not be able to lift the patient: trained first aid personnel will have to intervene with specialized equipment.

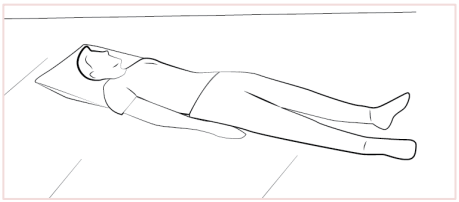
1- Put the patient on the back if his position is different and place a pillow under his head for comfort during the transfer.

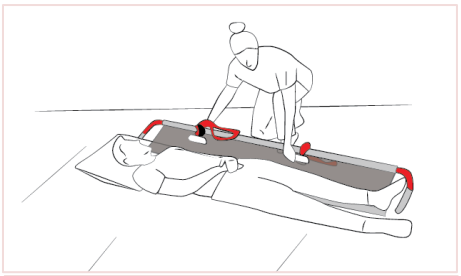
2- Slide a half of the stretcher under the patient, and if necessary lateralize him.

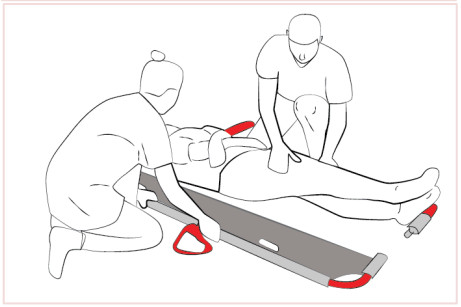
3- Slide the other half of the stretcher under the patient until it reaches the first half. The second caregiver may maintain the patient in a lateral position to facilitate the assembly of the stretcher.

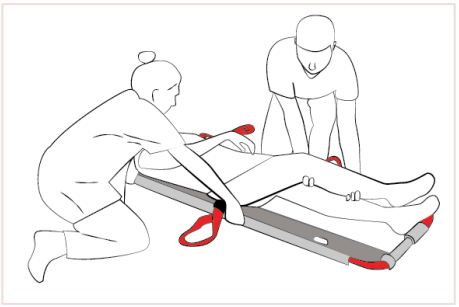
4- Lock the stretcher.

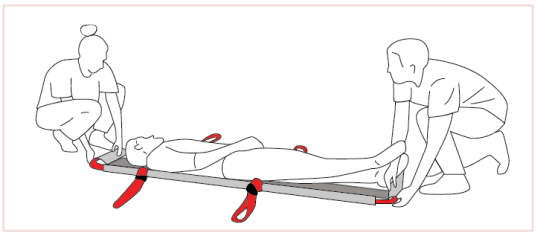
5- Bring back to patient to a lying position









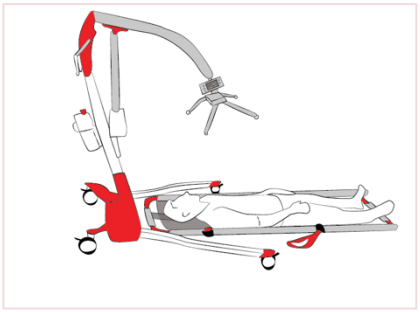


Lifting a patient using a lifter with a mobile or fix suspension

Always refer to the user manual of the hoist for safety measures to be taken.
Use exclusively the SCALEO lifter with the SCALEO accessories.

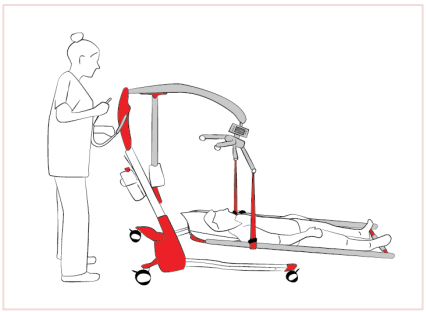
When used with a mobile suspension it is recommended to use the stretcher assisted by at least two caregivers: one person will manipulate the hoist, the other should stay with the patient to insure the stability of the stretcher.

1. Move the hoist above the patient.



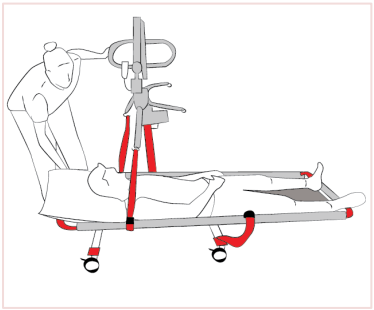
2. Hang two loops of the stretcher to the spreader bar.

3. Lift the stretcher at the head of the patient so as to pass the leg of the hoist under the stretcher.

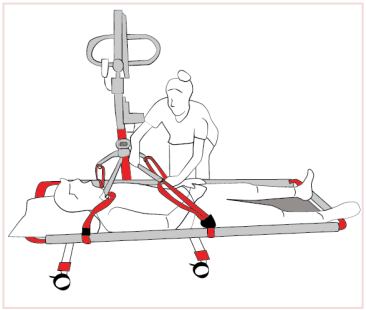


4. Verify the proper arrangement of straps in the spreader bar hooks. Perform a rotation of the hoist as soon as the legs can be slid under the stretcher.

5. Rotate the hoist until the stretcher rests on the legs of the hoist.



6. If necessary correct the position of the stretcher on the legs of the hoist, then hang the two remaining loops to the spreader bar.



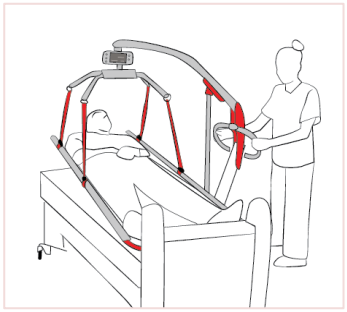
7. Slowly lift the patient a few inches making sure that the patient is properly installed in the stretcher and that the straps are properly installed into the hooks of the spreader bar and are tense. The patient can now be transferred.

Transferring the patient from the Radiolucent stretcher

Once the patient has been transferred, it is necessary to lay it down to the support: bed, shower trolley, examination table, etc.

Prior to the transfer, make sure:

- ***That the bed, the shower trolley... has enough space under its base to allow manipulation of the hoist without any risk.***
- ***That you have enough space around the patient to manipulate half-stretchers once the patient has been laid on the support.***
- ***That the brakes the shower trolley, bed... are blocked so that the support is stable and there is no risk of inadvertent movement.***



1- Bring the hoist above the destination support and lower the arm until the stretcher lies on the destination support and the loops are loosed.
Make sure that the patient is in a proper position.

2- Make sure the patient is in the correct position.

3- Remove the loops from the spreader bar; take out the hoist from the room in order to have more freedom of movement around the patient.

4- Unlock the stretcher.

5- Break off the two halves of the stretcher.

6- Put the patient in a supine position, as it will be easier to remove the half-stretcher one after the other. Place your hands at the openings for better grip and slide half-stretchers.

If necessary, lateralize the patient alternately on both sides to remove the half-stretchers, then turn the patient on his back or in any position that secured his physiological condition and/or devices he could be connected.

General information – Intensive care stretcher

You just bought an intensive care stretcher with supple sling and we would like to thank you for your confidence.

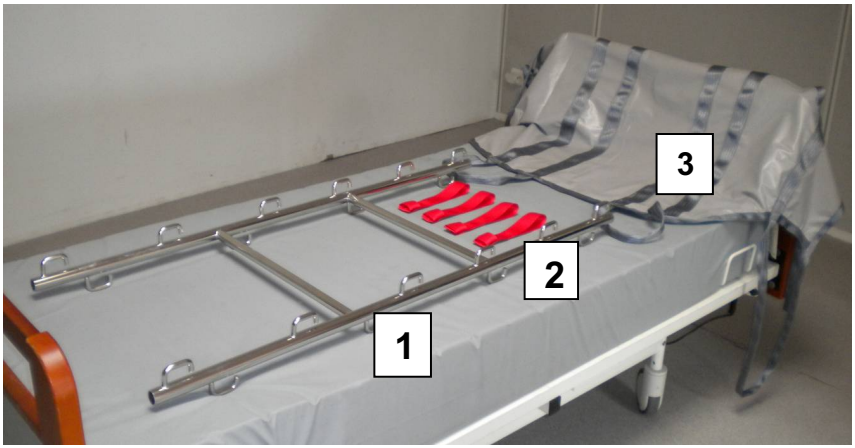
Our stretcher are made to fulfil your needs for treatments and more specifically intensive care, resuscitation, cardiology, anaesthetic, cardiac surgery, digestive, traumatology, pneumonology, radiology, neurology, nephrology…

The materials of the stretcher are chosen to limit the risks of infection.

The stretcher is made of a stainless-steel rigid frame and supple vinyl sling to adapt perfectly the stretcher to the patient morphology.

The stretcher is delivered in a box containing:

- 1 frame made of stainless steel (1)
- 4 loops (2)
- 1 supple sling (3) or 4 supple slings, depending on the variant,
- 1 User Manual (unrepresented)



Packaging elements (plastic, polystyrene, wrappings, etc.) must not be left within reach of children as they can be potentially harmful.

Contraindications

- Use of functions without notice, by a patient or a nurse
- Use with a patient weighting more than 300kg
- Out-door use
- Use of the lifter on a sloping ground with or without patient
- Moving on a non adapted surface, fitted carpet or carpet
- Washing of the slings in a washing machine
- Use of torn or damaged slings/loops
- In an usual way wrong installation, use, maintenance explained in this manual

Injuries or damages can be caused if :

- ***The instruction for use are not respected***
- ***A regular maintenance is not performed***
- ***The maximum safety weight capacity is exceeded.***

Concerning the combination between different devices: the user has the responsibility to verify that the different devices (lifters, suspension, weighing instruments, slings, and stretcher) are compatible and that the final combination of devices is safe for the patient and the nurse.

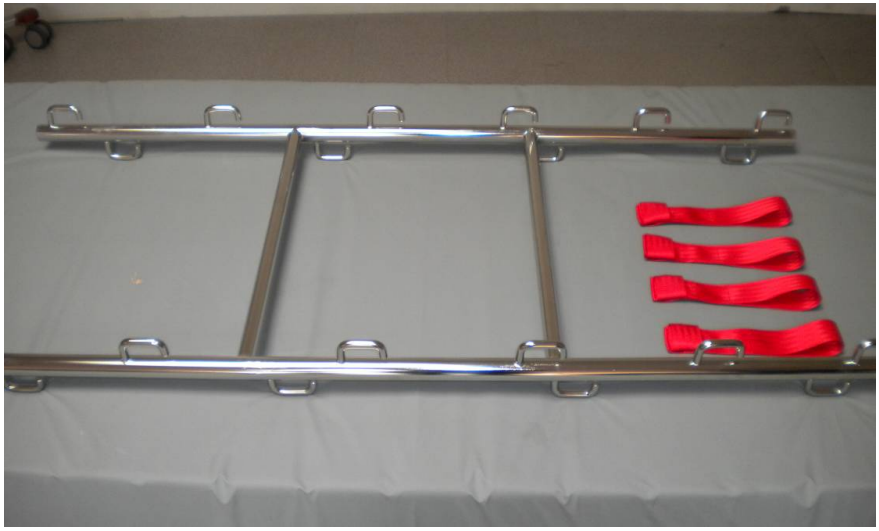
Assembly and commissioning instructions – Intensive care stretcher

Before the first use, the stretcher must be prepared.

Each time the stretcher will be disassembled for disinfection purposes, this operation will have to be done again.

Put down the steel frame as shown below:

- 6 hooks facing up
- 4 hooks under in order to hang up the slings loops

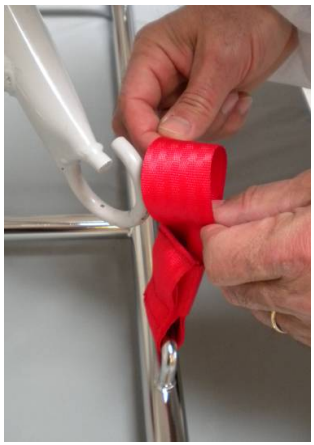


Prepare the 4 attach loops: slide the sling extremity in the loop to get a closed loop.

Repeat this operation for the 4 loops.

Position the lifter above the stretcher frame and hang the 4 loops to the hooks of the stretcher to the closest hook of the suspension.

Be careful when fixing the loops to avoid any risk of detaching the loops from the steel hooks.



Wrong assembly : the loop can detach: WARNING

Good Assembly : the loop will not detach

<u>Final result</u>: the stretcher frame is aligned on the suspension.

Using a lifter with a fixed suspension will help to keep the stretcher in a horizontal position while transferring the patient.

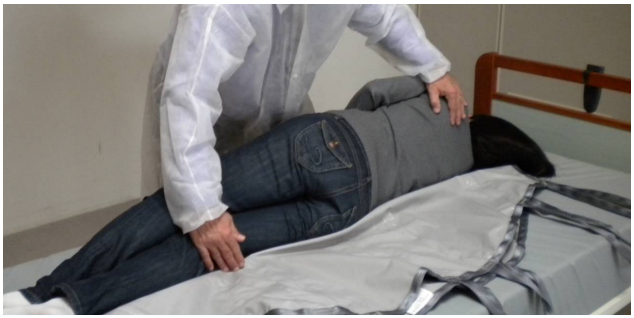
Before any use with a patient, try a lift cycle without any load to verify the security of the assembly.

Instructions for use – Intensive care stretcher

The patient must be handled with care, regarding his clinical condition. The nurse must handle the patient following good practices, to avoid any injuries or work-related musculoskeletal disorders (MSDs).

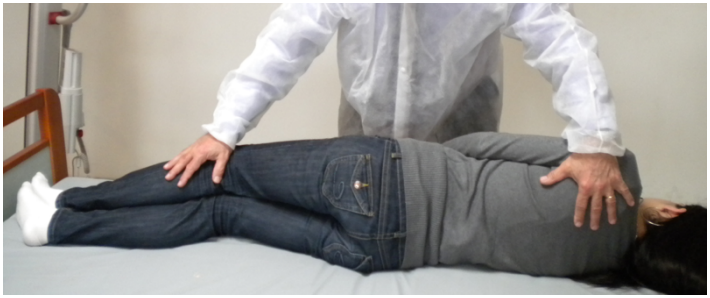
Before any transfer, be sure that the stretcher and the lifter are adapted to the patient, his pathology and particularly that his weight doesn't exceed the maximum capacities of the stretcher and the lifter . A sudden rupture of the equipment could cause important injuries.

Put the patient in the position showed below (similar to a recovery position).

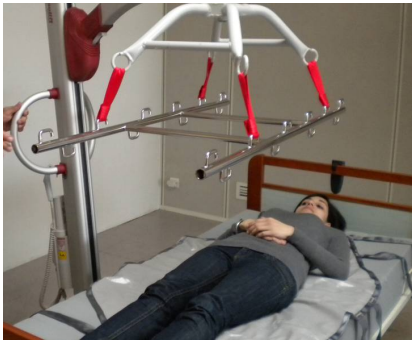


Fold the sling in two and position it as shown on the picture below and slide it under the patient. Be sure that the sling is not upside down.

Then position the patient lying down on his back and be sure the sling is correctly placed as shown on the picture below.

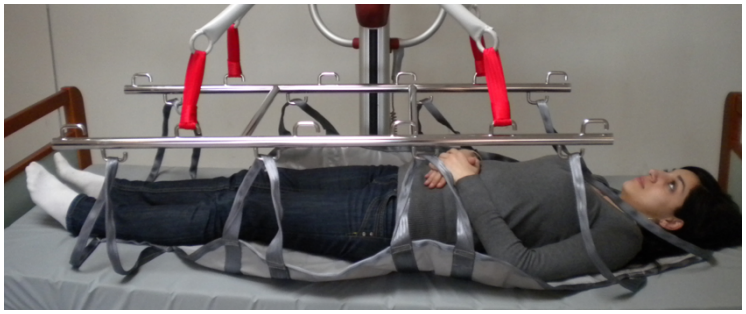


Be sure that the loops are under and not facing the patient.



Bring the lifter right above the patient, so that it's placed just above his centre of gravity. (approximately at the pelvis).

Fixe the 8 sling loops to the steel frame hooks.



Before any transfer, be sure that all the loops are correctly fixed and the patient's head is correctly held in the sling

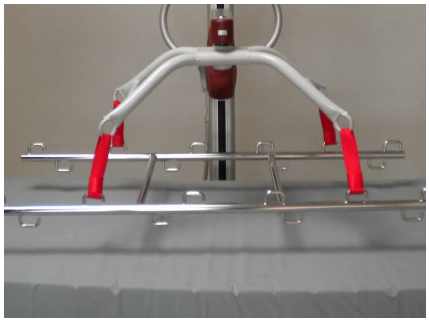
Lift the stretcher while holding the patient head to be sure of its position on the stretcher.

Finally the patient can be transferred in total security.

Depending on the suspension model used, a wrong installation could cause an imbalance and a risk of injuries.

To avoid this risk, please follow the instructions below.

The imbalance of the stretcher can be caused by different elements as a wrong lining up of the lifter on the centre of gravity of the patient: in this case re adjust the lining up. The centre of gravity of the patient is situated around his navel, but its exact location can vary depending on morphology of the patient.



Or a wrong installation of the patient in the stretcher: replace the patient or change the position by wrapping the straps around the frame.

Cleaning, disinfecting and periodic inspection

The following program for cleaning and disinfection has been established in compliance with the "Guide to good practices for disinfection of medical devices" edited by the French council of public HEALTH.

DEVICE CLASSIFICATION: Not critical
INFECTUOUS HAZARD: low risk
LEVEL OF TREATMENT REQUIRED: Low-level disinfection

Have always your disinfection process validated before proceeding.

General guidelines

- Discard after use any equipment or disposable medical device.
- Always respect the general hygiene and safety precautions (gloves, goggles, protective apron and mask if necessary) when handling equipment contaminated with body fluids and before contact with disinfectants.
- Disinfect your hands after removing the gloves.
- Always perform the cleaning and disinfecting from top to bottom.
- Respect the expiration dates of products.
- Follow the recommended dilutions.
- Never mix different cleaning or disinfection products.
- In case of contact with eyes, swallowed... refer to safety data sheet of the manufacturer of the product and notify a physician or poison control center.

Recommended procedures for the cleaning and disinfection

- The multiple-use devices should be thoroughly cleaned and/or disinfected at least once a month if they are used by a single patient.
- The multiple-use devices should be systematically and thoroughly cleaned and disinfected between patients if they are used by multiple patients to avoid cross infection.

1. **Prepare the equipment for disinfection**

Purpose: This facilitates cleaning, lower the level of contamination, and protect the staff and the environment.

2. **Cleaning:**

Purpose: Eliminate dirt.

- Use gloves for this operation.
- Use preferably a non-abrasive type accessory: a soft cloth or soft bristle brush if necessary. Do not use aggressive accessory that may damage the surfaces of the structure and facilitate the onset of corrosion.
- Use non-abrasive cleaning products.
- Perform the dilution of detergent in warm water in the proportions given by the detergent manufacturer.
- After cleaning, rinse with warm water and a sponge.
- Dry surfaces after rinse.

3. **Disinfection:**

Purpose: To destroy or inactivate micro-organisms.

- Use gloves for this operation.
- Apply a disinfectant with a carrier moistened with a disinfectant solution.
- Rinse thoroughly with water and a sponge.

4. **Drying:**

Purpose: Protect equipment from contamination once disinfected.

- Wipe the equipment with a dry, lint-free clean.

5. **Storage:**

Purpose: To maintain the cleanliness of the cleaned and disinfected devices.

- Store equipment and medical devices, once retired, in clean places, raised above ground and protected from dust, moisture, heat, sunlight and risk of deterioration of packaging's (tears, staples, ...)

Product that should be avoided for cleaning and disinfecting:

- Peracetic acid at concentrations > 10%,
- Organic solvents like halogenated hydrocarbons / aromatic or acetone,
- Products with a pH> 8 and <5,
- Products containing corrosive or caustic substances.

Recommended products for cleaning and disinfecting (examples)

- Argos spray 750 ml Argos 1861.
- Neodisher® Dekonta, Neoform MED AF, Neoform MED FF, Neoform MED Spray.
- SEPTOTAL S-911.
- Surfanios.
- Axiol.

In the case of use of a specialized product, we strongly advise to adhere to the protocol recommended by the manufacturer.

The vinyl slings must be disinfected only by pulverization or immersion in a disinfectant solution, a rinsing up to 30° maximum is only to perform to eliminate the disinfectant product.

Before any use and after disinfection, an inspection of the slings is very important in a minimum base of 2 times a year, in accordance with the B annexe of the EN ISO 10535 standard. The aim is to prevent or detect malfunction which could cause injuries to the patient or the nurse.

The sling life expectancy depends on the frequency of use and on the disinfection protocol. A sling used every day and well-kept can last five years.

Periodic inspection

The aim of the periodic inspection is to control safety and maintenance issues on equipment that is being used. This inspection must be done regularly every year so as to prevent malfunctions that could harm the patients or users – according to annex B of the EN ISO 10535 standard and recommendations from Health authorities.

The periodical inspection must be performed by a trained technician knowing the model.
If the technician detects a defect, he must inform the user and have the device put in quarantine for maintenance before use.

- Check the label's visibility
- Check very carefully the worn state and eventually damages on: fabric, seams and suspension loops.
- If any of those in not conformed, don't use the sling.
- A broken accessory could cause serious injuries to the patient.

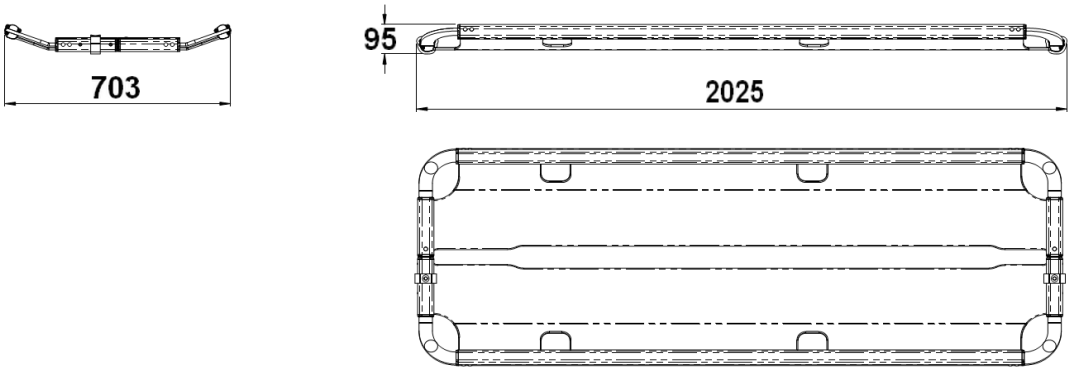
It is highly recommended to keep all the recordings of the supervision in case of other problems.

Technical specifications

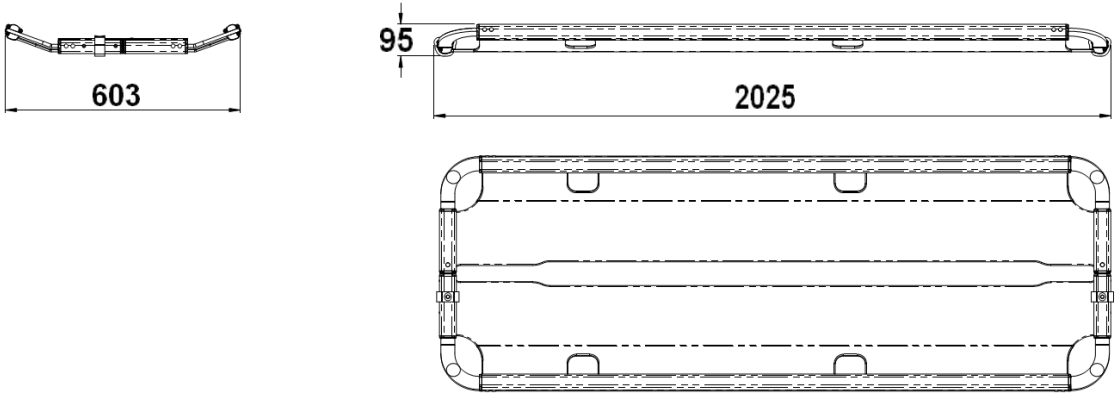
All our devices are designed and manufactured in France under the ISO 13485 Quality management system.

All dimensions are expressed in mm.

Radiolucent flat stretcher in two parts for 300 kg, ref. S1921001



Radiolucent flat stretcher in two parts for 240 kg, ref. S1921002



Technical specification Radiolucent flat stretcher:

	S19 21 001	S19 21 002
Maximum safety load	300 kg	240kg
Weight	20 kg	16 kg
Standard	EN ISO 10535	
Materials	• Metal parts: anodized aluminum, painted aluminum l, all screws are in stainless steel. • Plastic parts: HD polyethylene • Plates: polycarbonate	

Technical specification Intensive care stretcher:

	S83 11 302	S83 11 301
Maximum safety load	300 kg	
Weight	total weight: 7kg weight of the supple sling: 290g	
Frame dimensions	Length: 125cm Width: 52cm	
Supple sling dimensions	Length: 160cm Width: 90cm	
Materials	Frame : stainless steel Sling : PVC coated polyester 70g/m² Loops : polyester, 2650 daN resistant	
Fire resistance	M2 according to the NF P 92503 standard	

Terms of warranty

The Radiolucent flat stretcher is warranted for two (2) years.
The Intensive care stretcher is warranted one (1) year.

- Any intervention contrary to this manual will entirely void the warranty.
- Any abnormal use or non-compliant usage will result in the cancellation of the warranty.
- Any modifications to the device will render the warranty void.
- Any technical intervention made by non-qualified personnel or a non-authorized distributor will render the warranty void.

Liability

SCALEO Medical assumes no liability for any injury or harm and consequences thereof directly or indirectly caused to operators, patients, or any third party in the following cases:

- Non-compliance of the instructions and recommendations supplied within the present user manual.
- Using un-adapted spare parts.
- Assembling, adjusting and repairing carried out by non-qualified personnel or a non-authorized distributor.
- Abnormal use of the equipment, negligence, accident, human error, or maintenance and cleaning with non-adapted products
- REGULAR PREVENTIVE AND ANNUAL MAINTENANCE IS NOT CARRIED OUT in accordance with the annex B of the EN ISO 10535 standard, and the advices and instructions presented in this manual.

All statements and technical information contained in this manual are based on our knowledge and experience on patient transfer.
We reserve the right to change these instructions or to make technical changes to the equipment.

EU Declaration of conformity

SCALEO MEDICAL

EU Declaration of Conformity
Déclaration UE de conformité

Manufacturer / Fabricant

SCALEO Medical
107 rue Dassin, Parc 2000, 34080 Montpellier, France

(SRN): FR-MF-000002929

We hereby declare under our sole responsibility that the following product(s)
Déclarons sous notre entière responsabilité que le(s) produit(s) suivant(s) :

Intensive care and Radiolucent stretchers in annex 1
Civières de soins intensifs et civières radio transparentes en annexe 1
Base UDI-DI : 3664844STRS19

Class I, rule 1 according to appendix VIII of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL,
Classe I, règle 1 suivant l'annexe VIII du RÈGLEMENT (UE) 2017/745 DU PARLEMENT EUROPÉEN ET DU CONSEIL,

Are compliant with the the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL and amendments concerning medical devices and the French Public Health code by compliance to the Harmonized European standards EN 10535 : 2007,

Sont conformes au RÈGLEMENT (UE) 2017/745 DU PARLEMENT EUROPÉEN ET DU CONSEIL, relatif aux dispositifs médicaux et à ses amendements, et au Code de la Santé Publique par conformité aux normes harmonisées européennes EN 10535 : 2007,

Montpellier, March, 13, 2023
Montpellier, le 13 Mars 2023

Michel MALGOUYRES
Président

DOQA292 - EU Declaration of Conformity Stretchers - 20230313 1 / 2

SCALEO MEDICAL

EU Declaration of Conformity
Déclaration UE de conformité

ANNEX 1

Reference	Description	Class	UDI-DI
S8311301	Intensive care stainless steel stretcher one-part sling – without slings	Class I	3664844001790
S8311302	Intensive care stainless steel stretcher 4 vinyl slings – without slings	Class I	3664844001806
S1921001	Radiolucent flat stretcher in 2 parts for 300 kg – without straps	Class I	3664844001776
S1921002	Radiolucent flat stretcher in 2 parts for 240 kg – without straps	Class I	3664844001783

Contact information

The information and advice provided in this User manual are also intended to inform you of the importance of paying attention to safety measures and the necessity of regular maintenance.

Any serious incident related to the device must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

This is a matter of responsibility for your establishment, and a question of safety for your patients and staff.

Please do not hesitate to contact us if you require electrical diagrams, lists of components, descriptions and/or any information that could be useful for your qualified technicians.

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