



# **Instructions for use**

## **PAX Carrying Sheet XXL 400 kg**

Article number: 101820201





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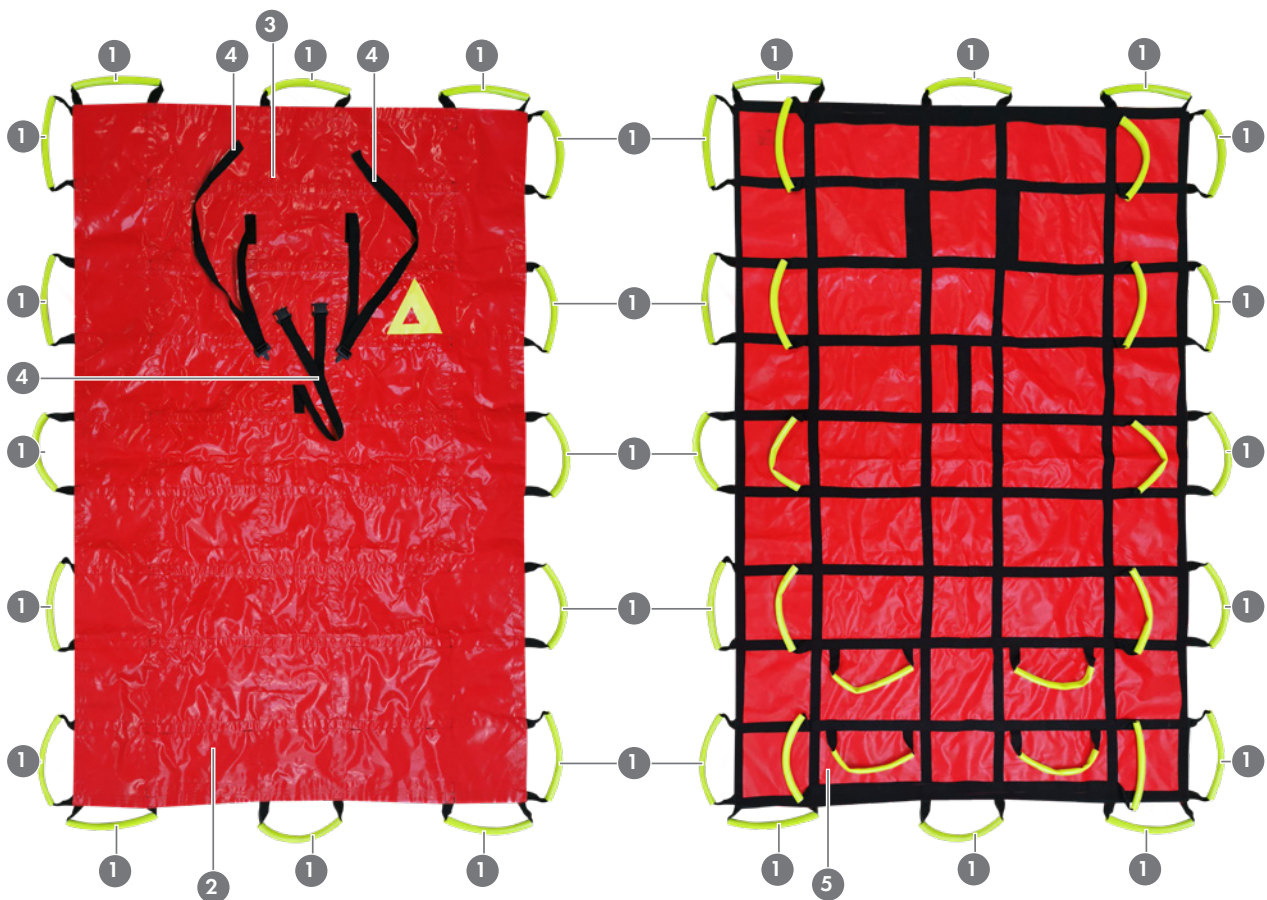
For the safe use of this product, please read and follow this instruction manual before first use. These instructions for use apply to the following product.

Product name : PAX Carrying Sheet XXL 400 kg  
Article number : 101820201

## Intended use

The PAX Carrying Sheet XXL 400 kg is a carrying sheet according to EN 1865-1. It is intended for the transportation of injured and / or sick persons.

## Illustration



- |                                 |                             |                             |
|---------------------------------|-----------------------------|-----------------------------|
| ① Handles                       | ③ Carrying sheet - head end | ⑤ Carrying sheet - backside |
| ② Carrying sheet - patient side | ④ Fixation straps           |                             |



## **MD** Intended use

①.

Place the carrying sheet on a flat and clean surface and spread it out completely.  
The backside with the straps (5) should be facing downwards.



### **CAUTION:**

**Pointed and sharp objects (e.g., broken glass, sharps stones, etc.) can damage the surface of the carrying sheet.**

②.

If possible, prepare the patient for transfer to the carrying sheet.

③.

Place the patient in the desired position on the carrying sheet.  
Ensure that the carrying sheet is smooth and free of folds underneath the patient.  
Pay attention to the medically correct position and any injuries of the patient.  
Follow the current medical guidelines for the correct positioning and repositioning of the patient.

④.

If possible, use all handles ① of the carrying sheet to ensure that the patient can be transported gently and in an axially correct manner.

⑤.

The patient is ready to be transported on the carrying sheet.

## **User group**

The PAX Carrying Sheet XXL 400 kg is a medical device which may only be used by trained personnel who have received regular training on the product.

The operator and the user of the medical device are responsible for providing instruction.

The type and indication of application is based on the current, generally recognized medical guidelines and recommendations of the relevant professional associations.

If the product is classified by the operator as a self-explanatory product for the group of intended users, this must be documented by the operator in a suitable form (e.g. risk analysis).

A general classification of the product as self-explanatory by the manufacturer is not possible, as this always depends on the intended user group.



**When using the PAX Carrying Sheet XXL 400 kg following handling conditions must be particularly observed:**

- Treat open wounds or skin areas that are not intact according to the current recommendations for aseptic wound treatment and cover them with sterile dressings.
- Check the integrity of the handles and patient lying surface before each use.
- Additional securing of the patient during transportation in a vehicle with the respective restraint system of the patient stretcher.



**Make sure that the handles are evenly distributed.  
The patient's weight must be evenly distributed on the PAX Carrying Sheet XXL 400 kg**



**Observe the occupational health and safety guidelines applicable to you when using the PAX Carrying Sheet XXL 400 kg**

The product is intended for multiple use after proper reprocessing.

It can be used in a temperature range of -30°C - +70°C.

## Intended patient group

- Adolescents and adults
- Children and schoolchildren
- Product is not gender-specific

## Use in children, pregnant or breastfeeding women

The use of the PAX Carrying Sheet XXL 400 kg in these patient groups does not require any special precautions. For the specific treatment the therapy recommendations of the relevant expert associations must be observed, particularly regarding the positioning of pregnant women.



## Restriction on use / contraindications

Patients who need to be immobilised for treatment must not be carried or transported using the PAX Carrying Sheet XXL 400 kg.  
In this case, immobilisation should be carried out using an appropriate transport device.

The product is intended for use in patients up to a maximum body weight of 400kg.

## Unwanted side effects when using the medical device

No undesirable side effects are to be expected, if the product is used as intended.



### SAFETY NOTE

**The product has no life-sustaining or life-supporting effects.  
The product may only be used in a proper and undamaged condition.**

## Actions in the event of product malfunction or changes in performance

If the PAX Carrying Sheet XXL 400 kg shows signs of damage, it must be replaced by an intact sheet.  
Contact the manufacturer before continuing to use the damaged carrying sheet.

## Medical devices that can be used together with the PAX Carrying Sheet XXL 400 kg

The PAX Carrying Sheet XXL 400 kg can be combined with all medical devices approved for patient transport or patient positioning when used as intended. Examples are given below: Stretcher, scoop stretcher, vacuum mattress, spine board, helicopter stretcher, hospital bed, X-ray table, A&E stretcher, etc. (List is not exhaustive – in case of questionable combination possibilities, please contact the manufacturer).

## Notes on restrictions when combining medical devices and accessories for medical devices with the PAX Carrying Sheet XXL 400 kg

If the product is used as intended, no restrictions are to be expected when combining it with medical devices and accessories for medical devices.

## Instructions for proper installation of the medical device before use

Before first use, take the PAX Carrying Sheet XXL 400 kg out of the packaging box and remove the protective cover.



## Notes on special treatment / preparation of the medical device before use

The PAX Carrying Sheet XXL 400 kg must be reprocessed according to the instructions under Reprocessing – Cleaning and care / disinfection before the first and all subsequent uses on the patient.

## Checking the safe and operational condition of the medical device

Immediately before using the PAX Carrying Sheet XXL 400 kg it must be visually inspected to ensure that it is in perfect technical and hygienic condition.

Damaged products must be replaced immediately. This applies in particular to properly reconditioned devices.



**As an immediate measure in the event of suspected or obvious damage to the PAX Carrying Sheet XXL 400 kg this medical device must not be used and must be replaced immediately with a functional carrying sheet.**

## Information on possible mutual interference during examinations and treatments

The PAX Carrying Sheet XXL 400 kg is permeable for X-rays and non-magnetic and can therefore be left on the patient during an X-ray examination / computer tomography / magnetic resonance imaging.

However, interactions during these procedures may lead to reduced diagnostic accuracy and the presence of artifacts.

When performing EEG, ECG or ultrasound examinations, no mutual interference is to be expected if the device is used as intended.

## Maintenance actions

Maintenance actions include, in particular, inspections and servicing that are necessary to ensure the continued safe and proper operation of the medical devices.

## Inspection and maintenance

The PAX Carrying Sheet XXL 400 kg must be checked regularly for damage and function.

Further maintenance and servicing actions by the operator or user are not intended by the manufacturer.

## Repair and maintenance

The repair of medical devices includes in particular the repair to restore functionality.

For reasons of product liability and safety, repair and maintenance work may only be carried out by authorized specialist companies using original spare parts.

Please contact our customer service department if repairs or maintenance work needs to be carried out.



## Reusability

The product can be reused if function is maintained, and the material is undamaged.  
Before reuse, the user must ensure that the product is in proper condition.  
Only products in perfect technical and hygienic condition may be used again.  
If there are indications of material wear or material fatigue, the product must not be reused.

## Reprocessing – cleaning and care

The PAX Carrying Sheet XXL 400 kg can be pre-cleaned with water and a soap solution.  
Extreme mechanical cleaning, which can lead to damage to the surface material, should be avoided.

## Reprocessing - disinfection

Disinfection of the PAX Carrying Sheet XXL 400 kg, by means of a surface wipe disinfection is possible with commercially available disinfectants of the substance classes alcohols, aldehydes and amines.  
The use of other classes of substances may result in irreversible damage to the surface and material, and therefore may affect the performance and safety of the product.  
Do not use solvents! For questions regarding the applicability of special disinfectants, please contact the manufacturer.

### SCOPE OF DELIVERY

**Product name:** PAX Carrying Sheet XXL 400 kg  
**Article number :** 101820201

## Technical specifications of the product

The PAX Carrying Sheet XXL 400 kg complies with the requirements of EN 1865-1 for carrying sheets.

## Technical data / Performance characteristics of the product:

Length:	240 cm
Width:	160 cm
Height:	1 cm
Weight:	approx. 6,6 kg
Maximum load:	400 kg
Operating temperature:	-30°C - +70°C
Material:	PAX-Plan
Color:	Red



## Regulatory information on the product:

Registrierung DE – DMIDS:	DE/CA11/837-3885
Registrierung UK – MHRA:	2024072901378085
UMDNS:	15-693
EMDN:	n.a.
GMDN:	13818
UDI-DI:	4260745482158

## Storage

The product can be stored in the rescue vehicle within a temperature range of -30°C - +70°C.  
For long- term storage, room temperature is recommended to protect the material.

## Shelf life

The shelf life is not limited if the product is used as intended, remains functional and is in perfect hygienic condition.

## Information on proper disposal of the medical device and its accessories

After proper disinfection, the medical device can be disposed of as residual waste.  
Please observe your local regulations for the disposal of medical waste and residual waste.

- Disposal must comply with the respective national legal regulations.
- Please ask your city / municipal administration about local waste disposal companies.

## Information on proper disposal of the packaging

- The product packaging can be recycled.
- The metal parts can be recycled as scrap metal.
- Plastic parts can be sent for plastic recycling.
- Disposal must be carried out in accordance with the respective national legal regulations.
- Please ask the city / municipal administration about local waste disposal companies.





## Warranty

The manufacturer provides a warranty for this product in accordance with legal provisions.

This covers material and manufacturing defects.

Excluded from this are wearing parts and components / assemblies that are subject to normal wear and tear as well as damage resulting from excessive strain, improper use, damage caused by force or unauthorized modification / repair.

In the event of a warranty claim, please contact the manufacturer.



### SAFETY NOTE

**Any serious incident that has occurred in relation to the device must be reported immediately to the manufacturer and the competent authority of the Member State in which the user and / or patient is established.**



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**This product is compliant with the  
Essential Requirements of Annex I  
of EC Regulation 2017/745  
for medical devices / MDR**

**CH**

**REP**

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**UK**

**REP**

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Subject to technical changes

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