Instructions for use

PAX Vacuum mattress - I-Mat - handles

Article number: 155165210

Stand: 12|2024

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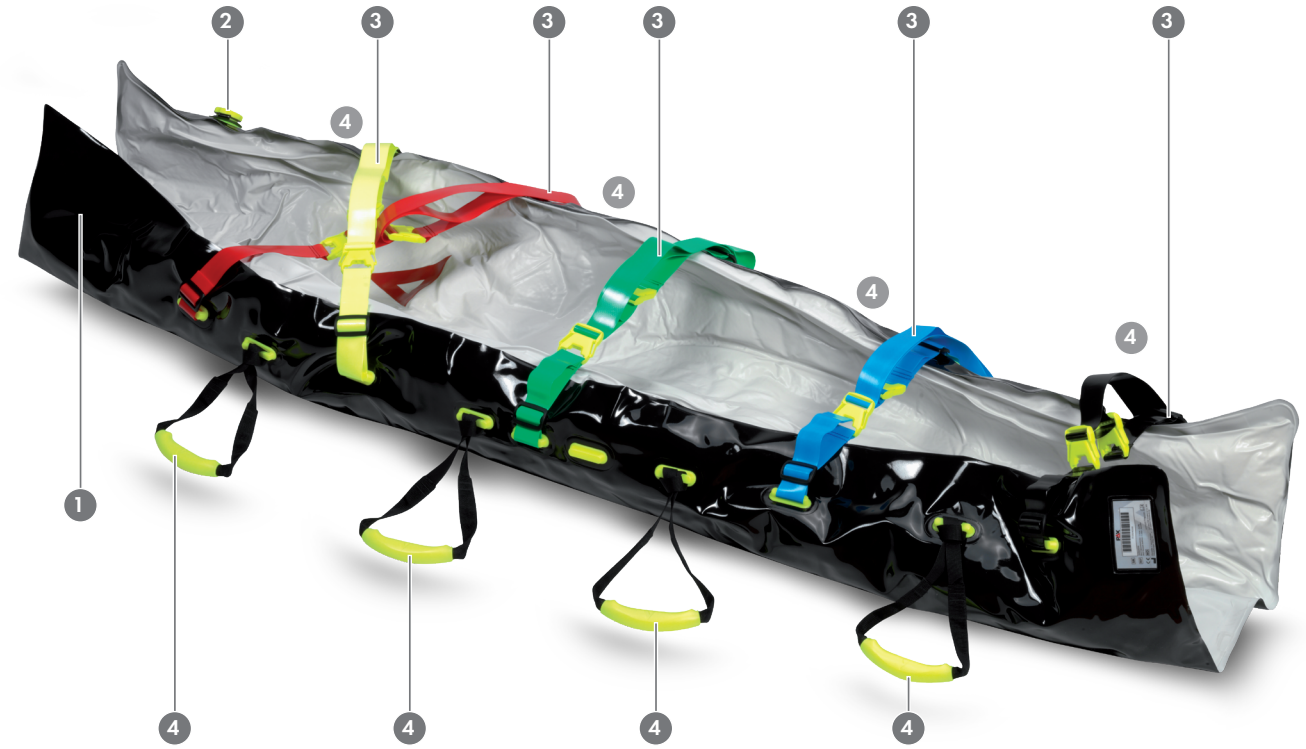
For the safe use of this product, please read and follow this instruction manual before first use.
These instructions for use apply to the following product

Product name: PAX Vacuum mattress – I-Mat - handles
Article number: 155165210

Intended use

The PAX Vacuum mattress - I-Mat - handles is a vacuum mattress in accordance with EN 1865-1.
The product is intended for immobilization in the event of injuries and illness.

Illustration



1 Vacuum mattress
2 Vacuum valve
3 Fixation straps
4 Handles

MD Intended use

1.
Place the vacuum mattress on a flat and clean surface.

CAUTION:
Pointed and sharp objects (e.g., broken glass, sharps stones, etc.) can damage the surface of the vacuum mattress.

2.
The vacuum valve 2 should be open – CHECK.

3.
If necessary, adapt the shape of the vacuum mattress
to the situation or lay it out flat.

4.
Distribute the EPS beads evenly.
As soon as the vacuum mattress is optimally prepared,
close the vacuum valve 2 by turning it to the right.
Then connect the suction unit to the valve.

5.
Place the patient in the desired position.
Make sure the patient is placed in a medical correct position and
be mindful of any injuries.
Follow current medical guidelines for proper repositioning
and positioning of the patient.

6.
Once the patient is correctly positioned on the vacuum mattress,
shape it around the patient so that the patient is stable and comfortable.
Make sure the vacuum mattress fills the space between the patient's legs.
Please note that you should not mold the vacuum mattress over the head
or under the feet!
This could exert unwanted pressure on the spine.

7.

Fasten the fixation straps 3 according to the color code and tighten them.
Make sure that the straps are neither too tight nor too loose.

8.

Now suck the air out of the vacuum mattress while shaping it accordingly.
Tighten the fixation straps 3 again.
Check that the mattress and the straps are optimally positioned.
The patient should be stable and comfortable.

9.

The patient is ready for transport.

User group

The PAX Vacuum mattress - I-Mat - handles 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 Vacuum mattress - I-Mat - handles 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.**
- **The patient should be repositioned using an appropriate repositioning aid (e.g scoop stretcher) in accordance with the current guidelines of the professional association.**
- **Check the integrity of the fixation straps, handles and lying surface before each use.**
- **Be careful with sharp or pointed objects – these can damage the surface of the vacuum mattress.**
- **Additional securing of the patient including the vacuum mattress 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 Vacuum mattress - I-Mat - handles**

**Observe the occupational health and safety guidelines applicable to you
when using the PAX Vacuum mattress – I-Mat - handles**

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

- Adults and adolescents
- Children and schoolchildren
- Patients who need to be immobilized for treatment of their injury or illness
- Product is not gender-specific

Use in children, pregnant or breastfeeding women

The use of the PAX Vacuum mattress - I-Mat - handles 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

Vacuum mattresses are not suitable for permanent immobilization.
When using vacuum mattresses on unconscious or semi-conscious patients, pressure may be exerted at certain points, the patient does not notice.
Accordingly, the user must check the positioning during transportation.

The product is intended for use in patients up to a maximum body weight of 150 kg.

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 Vacuum mattress - I-Mat - handles unexpectedly draws in air, check the product for any damage (e.g. pinpricks). Minor damage can be repaired with the PAX Repair Patch Vacuum (Art. No. 157510000).
Instructions for proper use can be found on our website. In the event of more extensive damage, please contact the manufacturer.

In addition, check if the valve is properly closed during use – an incorrectly closed valve can lead to air being drawn into the vacuum product.
In case of valve damage, contact the manufacturer.

Medical devices that can be used in combination with the PAX Vacuum mattress - I-Mat – handles

The PAX Vacuum mattress - I-Mat – handles 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, rescue sheet, 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).

Accessories that can be used together with the PAX Vacuum mattress - I-Mat - handles

Product name:	**PAX Vacuum pump – Foot**
Article number:	**273130003**
Product name:	**PAX Vacuum pump – Hand**
Article number:	**270890003**
Product name:	**PAX Vacuum pump – Hand S**
Article number:	**286320003**
Product name:	**PAX Fixation Strap Set - Vacuum mattress**
Article number:	**157004200**
Product name:	**PAX Fixation Strap Set TPU – Vacuum mattress**
Article number:	**283643000**
Product name:	**PAX Vacuum valve with adapter for finger tip**
Article number:	**274270000**

Notes on restrictions when combining medical devices and accessories for medical devices with the PAX Vacuum mattress - I-Mat - handles

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 Vacuum mattress - I-Mat - handles out of the packaging box and remove the protective cover. All fixation straps are pre-assembled at the factory.

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

The PAX Vacuum mattress - I-Mat - handles 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 Vacuum mattress – I-Mat - handles, 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 action in the event of suspected or obvious damage to the PAX Vacuum mattress – I-Mat - handles, this medical device must not be used and must be replaced immediately with a functional vacuum mattress.

Information on possible mutual interference during examinations and treatments

The PAX Vacuum mattress - I-Mat - handles is permeable for X-rays and non-magnetic and ca therefore be left under 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 Vacuum mattress - I-Mat - handles must be checked regularly for damage and function. Damaged components and accessories must be replaced with original spare parts in accordance with the manufacturer's instructions.
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.
Minor damage can be repaired with the PAX Repair Patch Vacuum (Art. No. 157510000).
You can find instructions on the correct application on our website.

For reasons of product liability and safety, more extensive 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 Vacuum mattress - I-Mat - handles 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 Vacuum mattress - I-Mat - handles, 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.

The product is not intended for sterilization.

Scope of delivery

Product name:	**PAX Vacuum mattress - I-Mat - handles + Transport bag**
Product name:	**PAX Vacuum valve with adapter for finger tip**

Technical specifications of the product

The PAX Vacuum mattress - I-Mat - handles complies with the requirements of EN 1865-1 for vacuum mattresses.

Technical data / Performance characteristics of the product:

Product name:	PAX Vacuum mattress - I-Mat - handles
Article number:	155165210
Length:	200 cm
Width:	80 cm
Height:	8 cm
Weight:	approx. 6,20 kg
Dimensions packed:	75 x 13 x 70 cm
Maximum load:	150 kg
Operating temperature:	-30°C - +70°C
Material:	Upper side: PAX Flex-Tec gray MP Bottom side: PAX Tec-Plus black MP

Regulatory information on the product:

Registration DE – DMIDS:	DE/CA11/895-4263
Registration UK – MHRA:	2024070101372507
UMDNS:	12-479
EMDN:	V 08 04
GMDN:	35185
UDI-DI:	426074548 1 11 3

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.

MANUFACTURER:
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CE MD LATEX NON STERILE

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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CHRN-AR-200003155

UK REP

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