Instructions for use
PAX Vacuum splints

Status: 10|2026|001

Instructions for use

PAX Vacuum splints

Hersteller: X-CEN-TEK GmbH & Co. KG
Westerburger Weg 30
26203 Wardenburg / Germany
Phone: +49 (0) 44 07 - 7 14 76 0
Fax: +49 (0) 44 07 - 7 14 76 99
Email: info@pax-bags.de
Web: www.pax-bags.com

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 products:

Product name:	**Article number:**
PAX Vacuum splint - set	157500000S
PAX Vacuum splint - forearm	155535210
PAX Vacuum splint - leg	155545210
PAX Vacuum splint - elbow	155555210
PAX Vacuum splint - rec - set	162400000S
PAX Vacuum splint - rec - arm	162025210
PAX Vacuum splint - rec - joint	162035210
PAX Vacuum splint - rec - leg	162265210
PAX Vacuum splints - Reilly - set	162310410S
PAX Vacuum splint - Reilly - ankle	162285210
PAX Vacuum splint - Reilly - leg	162295210
PAX Vacuum splint - Reilly - arm	162305210
PAX Vacuum splints TPU-FS - Reilly - set	288225210S
PAX Vacuum splint TPU-FS - Reilly - arm	288145210
PAX Vacuum splint TPU-FS - Reilly - leg	288155210
PAX Vacuum splint TPU-FS - Reilly - ankle	288165210
PAX Vacuum splint – leg – ski patrol	286285210

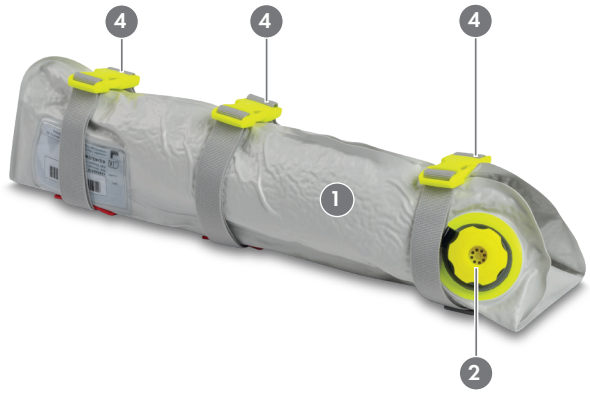
NOTE:
The simplified designation PAX Vacuum splints are used to make these instructions for use easier to read and understand. All information on handling refers equally to the products listed in the table.

Intended use

The PAX Vacuum splints are medical devices which are intended for immobilization in the event of injuries and illness.

Illustration

PAX Vacuum splint – forearm



1 Vacuum splint
2 Vacuum valve
4 Fixation straps

Illustration

PAX Vacuum splint – leg



1 Vacuum splint
2 Vacuum valve
3 Fixation straps - foot
4 Fixation straps – splint

Illustration

PAX Vacuum splint – elbow



1. Vacuum splint
2. Vacuum valve
3. Fixation straps - upper arm
4. Fixation straps - splint

Illustration

PAX Vacuum splint - rec – arm



1. Vacuum splint
2. Vacuum valve
4. Fixation straps - splint

Illustration

PAX Vacuum splint - rec - leg



1 Vacuum splint
2 Vacuum valve
4 Fixation straps - splint

Illustration

PAX Vacuum splint - rec - joint



1 Vacuum splint
2 Vacuum valve
4 Fixation straps - splint

MD Intended use

1.
Ensure that the indication for applying the vacuum splint 1 is correct.

2.
Place the vacuum splint 1 on a flat and clean surface.

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

3.
The vacuum valve 2 should be open – CHECK.

4.
If necessary, adapt the shape of the vacuum splint to the situation or lay it out flat.

5.
Distribute the EPS beads evenly. As soon as the vacuum splint is optimally prepared, close the vacuum valve 2 by turning it to the right. Then connect the suction unit to the valve.

6.
Check perfusion motor and sensory functions of the affected limb before applying the vacuum splint.

7.
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.

8.
Place the injured limb in the non-evacuated vacuum splint. Pay attention to the medical correct position and any injuries to the patient. Follow current medical guidelines for proper immobilization of the extremity.

9.
Make sure that both adjacent joints (starting from the injury) are also immobilized.
If this is not possible, consider using a vacuum mattress.

⑩
Once the vacuum splint has been optimally positioned on the patient, model it around the injured limb.

⑪
Fasten the fixation straps – foot / upper arm 3 and tighten them. Make sure that the straps are neither too tight nor too lose.

⑫
Now close the fixation straps 4 and tighten them. Make sure that the straps are not too tight, but also not too loose.

⑬
Now suck the air out of the vacuum splint while shaping it accordingly.
Tighten the fixation straps 3 & 4 again. Check that the splint and the straps are optimally positioned.

⑭
Finally, perform another check of perfusion motor and sensory functions of the affected limb.

⑮
The patient is ready for transport.

User group

The PAX Vacuum splints are medical devices which may only be used by trained personnel who have received regular training on the product. The operator and the user of the medical devices 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 splints 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 product before each use.**
- **The immobilization of the affected limb should be done in accordance with the current guidelines of the professional association.**
- **Be careful with sharp or pointed objects – these can damage the surface of the vacuum splint.**

Observe the occupational health and safety guidelines applicable to you when using the PAX Vacuum splints.

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 splints 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.

Restriction on use / contraindications

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

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 splints 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.

Accessories that can be used together with the PAX Vacuum splints

Article name:	**Article No:**
PAX Vacuum pump – Foot	273130003
PAX Vacuum pump – Hand	270890003
PAX Vacuum pump – Hand S	286320003
PAX Vacuum valve with adapter for finger tip	274270000

Medical devices that can be used in combination with the PAX Vacuum splints

The PAX Vacuum splints 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, vacuum mattress, carrying chair, 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 Vacuum splints

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 splints 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 splints 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 splints 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 splints, this medical devices must not be used and must be replaced immediately with a functional vacuum splint.

Information on possible mutual interference during examinations and treatments

The PAX Vacuum splints are 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 Vacuum splints 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 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 splints 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 splints, by means of 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

- PAX Vacuum splint - forearm
- PAX Vacuum valve with adapter for finger tip

Technical data / Performance characteristics of the product

Article number:	155535210
Length:	50 cm
Width:	32 cm
Height:	3 cm
Weight:	approx. 0,35 kg
Operating temperature:	-30°C - +70°C
Material:	PAX Flex-Tec grey MP

Technical data / Performance characteristics of the product

Registrierung DE – DMIDS:	DE/CA11/895-4259
Registrierung UK – MHRA:	2024070101372438
UMDNS:	13-689
EMDN:	V 08 04
GMDN:	35358
UDI-DI:	4260745481083

Scope of delivery

- PAX Vacuum splint - leg
- PAX Vacuum valve with adapter for finger tip

Technical data / Performance characteristics of the product

Article number:	155545210
Length:	97 cm
Width:	66 cm
Height:	5 cm
Weight:	approx. 1,05 kg
Operating temperature:	-30°C - +70°C
Material:	PAX Flex-Tec grey MP

Regulatory information on the product

Registration DE – DMIDS:	DE/CA11/895-4261
Registration UK – MHRA:	2024070101372438
UMDNS:	13-689
EMDN:	V 08 04
GMDN:	35358
UDI-DI:	42607454811106

Scope of delivery

- PAX Vacuum splint - elbow
- PAX Vacuum valve with adapter for finger tip

Technical data / Performance characteristics of the product

Article number:	155555210
Length:	69 cm
Width:	52 cm
Height:	3 cm
Weight:	approx. 0,50 kg
Operating temperature:	-30°C - +70°C
Material:	PAX Flex-Tec grey MP

Regulatory information on the product

Registration DE – DMIDS:	DE/CA11/895-4262
Registration UK – MHRA:	2024070101372438
UMDNS:	13-689
EMDN:	V 08 04
GMDN:	35358
UDI-DI:	4260745481090

Scope of delivery

- PAX Vacuum splint – leg – ski patrol
- PAX Vacuum valve with adapter for finger tip

Technical data / Performance characteristics of the product

Article number:	286285210
Length:	102 cm
Width:	69 cm
Height:	4 cm
Weight:	approx. 1,29 kg
Operating temperature:	-30°C - +70°C
Material:	PAX Flex-Tec grey MP

Regulatory information on the product

Registration DE – DMIDS:	DE/CA11/895-4261
Registration UK – MHRA:	2024070101372438
UMDNS:	13-689
EMDN:	V 08 04
GMDN:	35358
UDI-DI:	4260745481366

Scope of delivery

- PAX Vacuum splint - rec - arm
- PAX Vacuum valve with adapter for finger tip

Technical data / Performance characteristics of the product

Article number:	162025210
Length:	57 cm
Width:	47 cm
Height:	3 cm
Weight:	approx. 0,60 kg
Operating temperature:	-30°C - +70°C
Material:	PAX Flex-Tec grey MP

Regulatory information on the product

Registration DE – DMIDS:	DE/CA11/895-4275
Registration UK – MHRA:	2024070101372438
UMDNS:	13-689
EMDN:	V 08 04
GMDN:	35358
UDI-DI:	4260745481014

Scope of delivery

- PAX Vacuum splint - rec - joint
- PAX Vacuum valve with adapter for finger tip

Technical data / Performance characteristics of the product

Article number:	162035210
Length:	65 cm
Width:	46 cm
Height:	3 cm
Weight:	approx. 0,60 kg
Operating temperature:	-30°C - +70°C
Material:	PAX Flex-Tec grey MP

Regulatory information on the product

Registration DE – DMIDS:	DE/CA11/895-4273
Registration UK – MHRA:	2024070101372438
UMDNS:	13-689
EMDN:	V 08 04
GMDN:	35358
UDI-DI:	4260745481021

Scope of delivery

- PAX Vacuum splint - rec - leg
- PAX Vacuum valve with adapter for finger tip

Technical data / Performance characteristics of the product

Article number:	162265210
Length:	108 cm
Width:	66 cm
Height:	3 cm
Weight:	approx. 1,2 kg
Operating temperature:	-30°C - +70°C
Material:	PAX Flex-Tec grey MP

Regulatory information on the product

Registration DE – DMIDS:	DE/CA11/895-4274
Registration UK – MHRA:	2024070101372438
UMDNS:	13-689
EMDN:	V 08 04
GMDN:	35358
UDI-DI:	4260745481038

Scope of delivery

- PAX Vacuum splint - Reilly - ankle
- PAX Vacuum valve with adapter for finger tip

Technical data / Performance characteristics of the product

Article number:	162285210
Length:	65 cm
Width:	46 cm
Height:	3 cm
Weight:	approx. 0,51 kg
Operating temperature:	-30°C - +70°C
Material:	PAX Flex-Tec grey MP

Regulatory information on the product

Registration DE – DMIDS:	DE/CA11/895-4267
Registration UK – MHRA:	2024070101372438
UMDNS:	13-689
EMDN:	V 08 04
GMDN:	35358
UDI-DI:	4260745481076

Scope of delivery

- PAX Vacuum splint - Reilly - leg
- PAX Vacuum valve with adapter for finger tip

Technical data / Performance characteristics of the product

Article number:	162295210
Length:	107 cm
Width:	64 cm
Height:	3 cm
Weight:	approx. 1,0 kg
Operating temperature:	-30°C - +70°C
Material:	PAX Flex-Tec grey MP

Regulatory information on the product

Registration DE – DMIDS:	DE/CA11/895-4265
Registration UK – MHRA:	2024070101372438
UMDNS:	13-689
EMDN:	V 08 04
GMDN:	35358
UDI-DI:	4260745481052

Scope of delivery

- PAX Vacuum splint - Reilly - arm
- PAX Vacuum valve with adapter for finger tip

Technical data / Performance characteristics of the product

Article number:	162305210
Length:	57 cm
Width:	47 cm
Height:	3 cm
Weight:	approx. 0,53 kg
Operating temperature:	-30°C - +70°C
Material:	PAX Flex-Tec grey MP

Regulatory information on the product

Registration DE – DMIDS:	DE/CA11/895-4266
Registration UK – MHRA:	2024070101372438
UMDNS:	13-689
EMDN:	V 08 04
GMDN:	35358
UDI-DI:	4260745481069

Scope of delivery

- PAX Vacuum splint TPU-FS - Reilly - ankle
- PAX Vacuum valve with adapter for finger tip

Technical data / Performance characteristics of the product

Article number:	288165210
Length:	65 cm
Width:	46 cm
Height:	3 cm
Weight:	approx. 0,51 kg
Operating temperature:	-30°C - +70°C
Material:	PAX Flex-Tec grey MP

Regulatory information on the product

Registration DE – DMIDS:	DE/CA11/895-4267
Registration UK – MHRA:	2024110502394161
UMDNS:	13-689
EMDN:	V 08 04
GMDN:	35358
UDI-DI:	4260745481441

Scope of delivery

- PAX Vacuum splint TPU-FS - Reilly - leg
- PAX Vacuum valve with adapter for finger tip

Technical data / Performance characteristics of the product

Article number:	288155210
Length:	107 cm
Width:	64 cm
Height:	3 cm
Weight:	approx. 1,0 kg
Operating temperature:	-30°C - +70°C
Material:	PAX Flex-Tec grey MP

Regulatory information on the product

Registration DE – DMIDS:	DE/CA11/895-4265
Registration UK – MHRA:	2024110502394161
UMDNS:	13-689
EMDN:	V 08 04
GMDN:	35358
UDI-DI:	4260745481427

Scope of delivery

- PAX Vacuum splint TPU-FS - Reilly - arm
- PAX Vacuum valve with adapter for finger tip

Technical data / Performance characteristics of the product

Article number:	162305210
Length:	57 cm
Width:	47 cm
Height:	3 cm
Weight:	approx. 0,53 kg
Operating temperature:	-30°C - +70°C
Material:	PAX Flex-Tec grey MP

Regulatory information on the product

Registration DE – DMIDS:	DE/CA11/895-4266
Registration UK – MHRA:	2024110502394161
UMDNS:	13-689
EMDN:	V 08 04
GMDN:	35358
UDI-DI:	4260745481434

In addition to the individual products listed (Art. No. 155535210, 155545210, 155555210), the **PAX vacuum splint - set** includes a PAX transport bag for PAX vacuum splints, Art. No. 157490410.

In addition to the individual products listed (Art. No. 162025210, 162035210, 162265210), the **PAX vacuum splint - rec - set** includes a PAX transport bag for PAX vacuum splints, Art. No. 157490410.

In addition to the individual products listed (Art. No. 162285210, 162295210, 162305210), the **PAX vacuum splint - Reilly - set** includes a PAX transport bag for PAX vacuum splints, Art. No. 157490410.

In addition to the individual products listed (Art. No. 288145210, 288155210, 288165210), the **PAX vacuum splint TPU-FS - Reilly - set** includes a PAX transport bag for PAX vacuum splints, Art. No. 157490410.

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.

SAFTY 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:
X-CEN-TEK GmbH & Co. KG

Westerburger Weg 30
26203 Wardenburg
Germany

Phone: **+49 (0) 44 07 - 7 14 76 0**
Fax: **+49 (0) 44 07 - 7 14 76 99**

E-Mail: **info@pax-bags.de**
Web: **www.pax-bags.com**

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

MK-Med Medizintechnik AG
Industriezone Basper 33
CH-3942 Raron
CHRN-AR-200003155

UK REP

PAX – bags UK Ltd.
Merlin House, No.1 Langstone Business Park, Priory Drive
NP18 2HJ Newport - UK

Subject to technical changes

The contents of these instructions for use are protected by copyright. Any use, even in extracts, requires written permission.

X-CEN-TEK GmbH & Co. KG

Westerburger Weg 30
26203 Wardenburg
Germany

Phone: +49 (0)44 07 - 7 14 76 - 0
Fax: +49 (0)44 07 - 7 14 76 - 99
Email: info@pax-bags.de

www.pax-bags.com