



English

Please read the user manual and safety advice before using VACOped. You will find a readable instruction manual on our VACOped homepage.

Put the lower leg and foot orthosis for immobilisation of the joints in defined, adjustable positions, and for mobilisation in definable ranges of movement.

Safety information

The product is intended only for use on a single patient.

VACOped is not designed for dynamic stresses such as jumping and fast walking, if you do this with VACOped fitted, check your device immediately for damage, if the VACOped is damaged, it can impair your safety.

Never wear the product over open wounds and only wear it after prior medical instruction.

The patient may only change the position of the device after consultation with the physician responsible for their care.

If excessive pain, numbness or sensation changes occur, or if unusual reactions or an unpleasant feeling are experienced while wearing the device, please contact your doctor or orthopaedic technician without delay.

This orthosis has been developed for the indications listed and can be damaged by unintended or inappropriate use, by activities such as sport, falls or other accidents, and by liquids.

When used in combination with another medical product, consult your doctor.

Only spare and/or replacement parts approved by OPED GmbH should be used.

Please note the Road Traffic Act applicable in your country.

Not made from natural rubber latex.

Check that the sole fits securely - otherwise there is a risk of slipping!

Sole: When the toe section is fully extended, the gait may be modified or restricted.

The small spheres in the vacuum cushion can slide around. We therefore recommend opening the valve every two to three days, smoothing any collections of small spheres and then restoring the vacuum.

Storage: The valve flap must always be closed!

The valve ring must be pushed downwards and the valve flap closed (Figure 1 + Figure 2).

This product is intended to be used for no more than 4 months.

How to put the orthosis on (instruction video can be found at app.oped.de)

Fitting the VACOped

Put the various parts (details can be found in "Value functions") to allow air to flow in (Figure 3). If the small spheres in the liner (Figure 4) have grouped together, stroke them smooth. Place your foot in the fabric liner (Figure 4) and position it with the upper shell (Figure 5). Then close the strap (Figure 6). Press the valve ring (Figure 7) onto the lower shell, bottom: attach the lower shell and close the strap by hand and then fit the upper shell (Figure 8). When fitting the upper shell, ensure that the valve is not kinked. The upper shell should not be positioned over or over the heel.

Adjusting and securing the orthosis

Before you start fitting the liner there is a cushion containing thousands of small spheres (Figure 9) which adapt perfectly to the anatomy and any swelling of your ankle joint. Pressure-sensitive areas and swellings can be relieved through the large number of small spheres. To ensure that the spheres do not slide around inside the cushion, the air is extracted via the valve using a suction pump, creating a vacuum (Figure 10).

Value functions

The valve ring opens the vacuum cushion:

Push the valve ring upwards and move it to the side to allow air to flow in (Figure 3). Then slide the valve ring back to its original position.

Close the vacuum / hardens the vacuum cushion:

Push the valve ring downwards. Attach the suction pump and squeeze it (approx. 3-5 seconds). The valve ring pump removes air from the cushion and creates a vacuum. This fixes the adapted fit in place (Figure 11). To finish, close the valve cap (Figure 12).

Closing the valve cap

Push the valve ring downwards and close the valve cap. This sets the vacuum (Figure 12).

Changing the cushion liner

Note: The cushion liner does not contain a cushion! When changing the liner, the cushion must be removed from the used liner and inserted into the new one! Open the rear zip fastener all the way and remove the vacuum cushion from the used liner. The spheres in the cushion will redistribute themselves (see Value functions). Establish the vacuum (see Value functions), place the vacuum cushion in the new liner and slide the valve through the liner. A second cover is not included in the box in all countries. If the supplied package does not include a second cover, this must be ordered separately from OPED.

Angle adjustment

Delivery condition: Neutral zero position ("0° ± 0") (Figure 19)

There are two possible uses:

1st option: Fixed ankle (fixed setting): The upper and lower adapter screws are not separated.

2nd option: Limited freedom of movement (ROM setting): For use as soon as possible after surgery. The angle of the upper and lower adapter screws determines the extent of the ankle joint's range of movement (ROM).

The range of movement can be changed in 5° increments from 15° of dorsal extension (lifting of the toes) to 30° of plantar flexion (equinus position = toes inclined).

Note: The use of a range of movement (ROM) is the decision of the doctor / physiotherapist.

Scale on the product

Corresponds in degrees

		Ranges of movement (ROM)
3	+30°	
	+25°	
2	+20°	
	+15°	
1	+10°	
	+5°	
0	0°	Neutral - zero position
	-5°	
1	-10°	Dorsal extension, starting from the neutral - zero position
	-15°	

Changing the angle setting

Upper: Turn the screw for plantar flexion (equinus position = toes inclined) lower: adapter screw and stop for dorsal extension (lifting of the toes).

Remove the key from the holder (Figure 21) and insert it into the screw. Turn the key horizontally (Figure 23). Lift the screw and push it into the desired position (Figure 25). Turn the key vertically (Figure 25). Repeat the steps above if necessary with the other screw.

Note on treating Achilles tendon injuries in the equinus position: With a fixed angle setting between +15° and +30°, please use the wedge sole (Figure 22). If the wedge sole isn't included in the package, it has to be ordered separately from OPED.

Fitting and changing the sole

Removing the sole

Push both release buttons simultaneously (Figure 13).

Fitting the sole

Push the VACOped straight and centred on the sole before pushing it against the sole (your will hear two clicks) (Figure 14).

Adjusting the sole length

Remove the sole (see Fitting the sole) and push the unlocking button. Pull the toe section to the desired length (Figure 15).

Adjusting the calf circumference

Push the buckle out of the lower shell (Figure 16). Push the buckle to the desired position. Position A = large calf circumference, Position B = small calf circumference (Figure 17). Push the buckle into the required hole (Figure 18). Repeat the process on the opposite side.

Patient information

Pressure points / problem solving

Remove the orthosis from your foot. Pull the valve ring to allow air to flow into the cushion. Spread the cushion filling evenly at the pressure point. Re-fit the orthosis (see How to put the orthosis on). Check if there are enough small spheres in the cushion between the pressure point and the outer lower shell.

Showering / washing

You can shower / enter water with the product if your doctor has given you permission to do so.

Sleeping

Before you go to sleep, place a towel, such as a hand towel, underneath the device so that the bed sheets are not damaged.

Product characteristics

Sizes

The product can be worn on the left or right.

Recommendation: At a time interface between the Small/Medium and Medium/Large versions, supply a smaller VACOped size if possible.

Small **Medium** **Large**

EUR 35 - 40 40 - 45 45 - 50

UK 2 ½ - 6 ½ 6 ½ - 10 ½ 10 ½ - 14

US (M) 3 ½ - 7 ½ 7 ½ - 11 ½ 11 ½ - 15

US (F) 4 ½ - 8 ½ 8 ½ - 12 ½ 12 ½ - 16

Indications

• Ankle joint fractures

• Metatarsal fractures

• Achilles tendon ruptures

• Calcaneal fractures

• None known

Cleaning and maintenance

Cleaning instructions for patients:

• Lower shell: Dismantle at 60 °C

• Straps: Washing machine at 60 °C

• Terry liners: Washing machine at the Terry liner before washing it. Close the zip and Velcro fasteners again for washing.

• Cool Liner: Remove the vacuum cushion from the Cool Liner before washing it. Close the zip and Velcro fasteners again for washing.

• Vacuum cushion: Surface disinfection

Accessories

If this accessory is not included in the scope of delivery, it can be ordered from OPED GmbH.

• Wedge sole for treating Achilles tendon injuries

• Positioning support/anti-rotation bar

• Dorsum Pad

• Click Disk

Technical data/parameters

Materials used:

High density polyurethane (PP): Liners (PU foam); Cushion sleeve (PVC): Filler material (EPS spheres); Strap (PP fabric); Sole (EVA); Upper shell (EVA/PP). All parts and components are latex-free.

Note: Not made from natural rubber latex.

Transport conditions / storage conditions / disposal

Storage: Store in a dry and clean hygienic place and protect from direct sunlight.

Germany/Switzerland: The medical device is a rental product and must be returned to OPED.

Other countries: Please dispose of the medical device in residual/household waste.

Warranty

The warranty complies with statutory regulations. The terms and conditions of OPED GmbH also apply, where permissible.

In the event of complaints relating to the product, such as damage or problems with the product, please contact the relevant distributor or service centre, who will refer the complaint to the responsible authorities of the member state. Serious events are defined in Article 2 (6) of Directive (EU) 2017/745 (MDR).

Your OPED Team

Customer service: 0800 11 11 11 11 | info@oped.de | www.oped.de

Product registration: www.amed.de | www.amed.de | www.amed.de

CE marking: www.amed.de | www.amed.de | www.amed.de

Medical device classification: IIa

Medical device identifier: 00000000000000000000000000000000

Classification code: 00000000000000000000000000000000

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