

Instruction for use

VACO[®]diaped

Introduction

The VACO[®]diaped/VACO[®]ped diabetic foot system is an orthopedic treatment concept for the diabetic foot syndrome similar to a total contact cast. By utilizing a vacuum cushion (bean bag) in conjunction with a dampening insole and a rocker bottom, the product has been designed to evenly distribute the pressure underneath the foot. Thus, pressure peaks can be reduced in order to promote wound healing or to prevent wounds from occurring. The VACO[®]diaped system, featuring a lightweight but stable lattice frame structure together with the before mentioned vacuum cushion, offers cast-like stability. As a result, shear forces underneath the foot, as would normally occur when walking without cast-like protection, can be diminished. Unlike with a total contact cast, the VACO[®]diaped can be removed and reapplied instantly for wound control purposes and in order to accommodate for possible structural changes to the bone system of the foot.

These instructions provide general information regarding the handling of the VACO[®]diaped/VACO[®]ped device. Additional information, including video instructions, can be found at www.vacodiaped.com.

Product characteristics

- Rapid, pressure-free and reversible application utilizing the vacuum technology
- Easy access for wound control
- For ankle joint immobilization
- Normal walking-pattern utilizing rocker sole
- Radiolucent
- Can be worn on left or right foot, 2 sizes

Trouble shooting

Pressure areas

Repeat the application process. During the process, while the vacuum cushion is soft, adjust the content of the vacuum cushion away from the pressure point.

Vacuum cushion is too hard

Pull colored valve ring forward and move from side to side to allow air to enter.

The sole cannot be attached

Carefully bend the sole so the walking surface is bent outward and then attach to the boot. Inspect that all the connectors are secure.

Important safety instructions

Always check that the sole is firmly in place and never walk without a sole – DANGER OF SLIPPING! Do not walk without front shell being properly attached and secured by girth straps.

- It is not recommended that patients drive an automobile while wearing the VACO[®]diaped/VACO[®]ped.
- Ensure that all girth straps are securely tightened.
- Inspect the device prior to application for tears, holes or other damage, particularly after washing. If you suspect that a device is damaged, contact your OPED representative.

Sizes

EU S 35-39 **UK S** 2 1/2 - 6 **US S** Men 5-7, Women 7-9
L/M 39-46 L/M 6 1/2 - 11 L/M Men 7-13, Women 9-11+

Further information

If you have any questions, please contact your retailer or OPED directly. You may also consider visiting our webpage:

www.vacodiaped.com

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General guidelines for patients with diabetic foot syndrome treated with VACO[®]diaped/VACO[®]ped

In order to obtain best treatment results, please closely follow your physician's recommendations. In the event that the physician does not allow you to remove the VACO[®]diaped/VACO[®]ped system on your own, all necessary measures will be addressed during your office visit. Should your physician allow the removal of the VACO[®]diaped/VACO[®]ped system for personal hygiene outside the physician's office, the following guidelines should be considered:

- Pay close attention to the condition of your feet. Visually inspect your feet for changes such as skin irritations or new wounds (consider utilizing a mirror or the help of relatives/friends). Inform your physician about such changes at once!
- If relevant, apply doctor prescribed skin care products.
- When allowed foot bathing, do not exceed bathing time of 3 minutes. Carefully and thoroughly dry your feet. Pay close attention to the areas between your toes.
- Professional (medically skilled) help for pedicure is recommended.
- When walking, always wear shoes and/or your VACO[®]diaped/VACO[®]ped, even in your home.

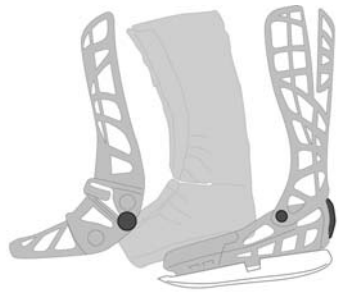
Specific recommendations regarding the use of VACO[®]diaped/VACO[®]ped

- Change and wash your liner at least every second or third day (Before washing, remove the vacuum cushion from inside the liner. Note: a second liner has been provided with the product.)
- Ensure that the vacuum cushion remains rigid; you may need to re-evacuate the air with the pump every couple of days if the liner loses some of its rigidity.
- Prior to re-applying VACO[®]diaped/VACO[®]ped: be sure to make the vacuum cushion pliable by letting air in through the valve so that it will contour to your foot properly.
- When walking, always wear your VACO[®]diaped/VACO[®]ped, even in your home.
- Always follow the treating physician's recommendations.
- After about three months of wear, the vacuum cushion will need to be replaced. Consult your foot specialist to obtain a replacement liner kit every three months.

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VACO[®]ped
diabetic foot

Application procedure I



Open valve on vacuum cushion (see also valve functions) and remove the front shell. Place foot in inner boot and close Velcro tabs. Then insert foot with inner boot in shell.

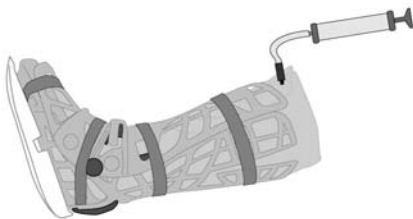
Application procedure II



Put on front shell and close straps. The recommended sequence is as shown in the diagram. For optimum adjustment, patients who are allowed weight bearing should take a few steps and then re-adjust the tension of the straps.

Application procedure III

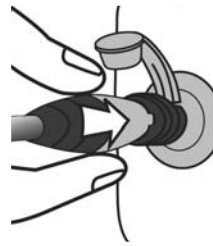
Attach the vacuum pump to the valve stem and evacuate the air. The vacuum cushion will feel hard to the touch. Remove pump and close valve cap. Check and if necessary re-adjust the tension of the straps.



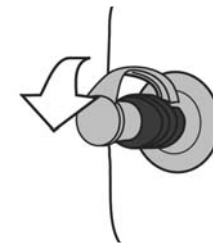
Valve functions



Bean bag becomes soft:
Pull valve rim, then bend valve gently sideways

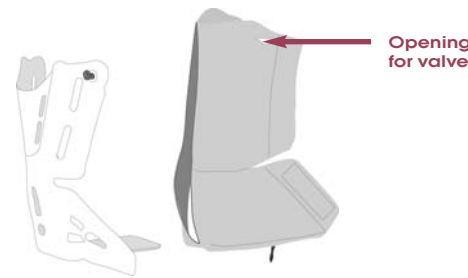


Bean bag fixed in place:
Push down the valve rim and use the pump

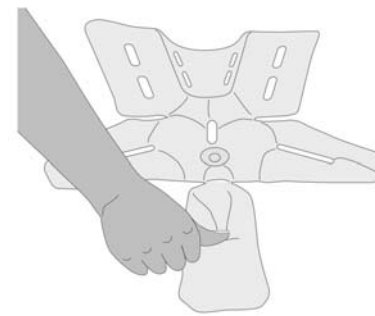


Close valve cap

Exchange of velour liner



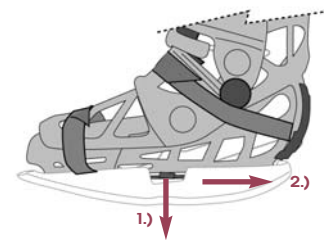
The vacuum cushion is placed inside a velour liner similar to a pillow inside a case. To get it out, open the zipper in the back and pull out the vacuum cushion.



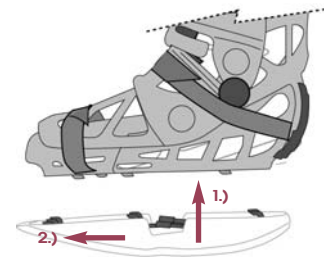
Make sure that the valve is open, place the cushions flat and evenly fill out the contents.

When getting the vacuum cushion back into the liner, please assure that all wings are inserted properly. Evacuating the vacuum cushion will make insertion easier. Close the zipper all the way.

Attaching and changing the sole



Removal: Pull down both levers at the same time to unlock (1) and then push the sole toward the back to remove (2).



Replacement: Do not depress side levers when replacing sole. Align the raised plastic barbs on the foot sole to the open slots of the boot. Push the sole forward and an audible click will be heard. Inspect that all the connectors are secured.

Insert spreader (1)



In cases of a severely swollen ankle, the spreader creates more space in the rear (dorsal) shell.

- Attach spreader (as illustrated) to the guiding line on the dorsal shell
- Press the center of the spreader inwards with both hands and assure that the spreader clicks into place

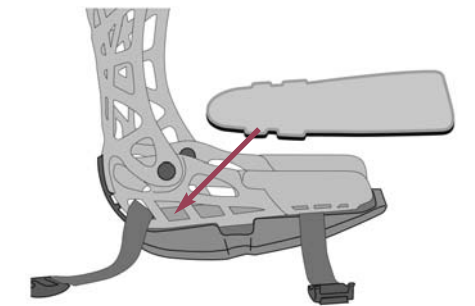
Remove spreader (2)



- Press the locking spring inwards on one side with the thumb, keeping the index and middle fingers on the outer edge of the spreader
- Repeat this procedure on the other side
- Remove spreader

Note: In the US, the ankle spreader is sold separately.

Change insole



Remove used insole.

Insert the new insole with hard, dark side face downwards in the cast. Adjust the lateral grooves of the insole with the lattice frame.

Cleaning

Rigid shell and straps

Can be washed in a dishwasher-style washing machine at up to 95°C (~200°F). Please assure that vacuum cushion, velour cloth liner and sole have been removed before. Shell system should be closed and secured with straps.

Velour cloth liner

These liners are machine washable at 60°C/140°F (please close Velcro tabs first). For hygienic reasons, each patient is given two new velour cloth covers. Velour cloth liners are intended for single-patient use.

Vacuum cushion

The cushion can be cleaned with soap and water.

Check for damage

Prior to the application, inspect the device for tears, holes, cracks and other damages. If such damages are detected, the affected piece or the entire system needs to be replaced.

Storage

In a dry, dust-free place at 5° - 25°C (41°F - 77°F)