



INSTRUCTIONS FOR USE

VasoPress[®] DVT System Latex Free NON-STERILE

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Caution: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

The VasoPress garment is recommended for use in patients for whom external compression therapy is indicated to reduce the incidence of deep vein thrombosis and resulting pulmonary embolism due to the presence of risk factors for thrombosis formation.

DEVICE DESCRIPTION

The VasoPress DVT System consists of an inflatable garment that may be fitted to a patient's foot and/or leg and a pneumatic compressor or pump that provides pressure to the desired area. When the sleeve compresses, the patient's veins collapse, forcing blood to flow. When pressure is reduced, the sleeve deflates, allowing the veins to fill with blood. The cycle is then repeated.

Devices subject to this IFU document include:

Type of Garment	Model #
Foot Regular	VP520
Foot Large	VP520L
Calf Small	VP501P
Calf Medium	VP501M
Calf Large	VP501L
Calf X-Large	VP501B
Thigh Small	VP530P
Thigh Medium	VP530M
Thigh Large	VP530L
Thigh X-Large	VP530B



CONTRAINDICATIONS

1. Pulmonary edema.
2. Severe congestive heart failure.
3. Severe arteriosclerosis or other ischemic vascular disease.
4. Extreme deformity of the limb.
5. Phlebitis or any known or suspected deep vein thrombosis.
6. Any localized condition where the placement of the garment would interfere with such as untreated, infected wounds, gangrene, recent skin grafts or dermatitis.
7. The physician should review the patient's medical status and use this device in accordance with his/her best understanding of their patient's needs and current condition.

WARNINGS AND PRECAUTIONS

1. The pump connections should be checked to make sure they are securely locked and that the garment has been properly applied with the tubing at the ankle/foot.
2. If the patient experiences leg/foot pain tingling or numbness remove the garment.
3. If the compression is discontinued for 30 minutes or longer in a patient considered at risk of developing venous complications perform a noninvasive evaluation for deep vein thrombosis before resuming compression therapy.
4. Never apply or remove the garments while inflated as this may cause damage to the garments.

GENERAL INSTRUCTIONS AND INFORMATION

Verify product receipt and ensure that the owner's name is appropriate on the label. Inspect package and product for signs of damage.

1. Plug the air pump into an appropriate electrical outlet. **DO NOT SWITCH THE PUMP ON AT THIS TIME.**
2. Remove the garments from the bag. The garments may be used on either leg/foot.
3. **CALF:** Unfold the garments and position the panel labeled "**THIS SECTION BEHIND THE CALF**" behind the belly of the patient's calf. The end where the tubing is located should be placed at the ankle. Snugly wrap the garment around the patient's calf and make sure the inflation bladder is directly behind the patient's calf section, then secure with the tabs. The garment should fit securely but not tightly around all parts of the patient's leg.

THIGH: Unfold the garments and position the panel labeled "**THIS SECTION BEHIND THE KNEE**" behind the patient's knee (popliteal fossa). The end where the tubing is located should be placed at the ankle. Snugly wrap the garment around the patient's calf and thigh. Make sure the inflatable bladder is directly behind the patient's calf section first. Secure with the tabs around the calf first then repeat for the tabs in the thigh section. The garment should fit securely but not tightly around all parts of the patient's leg.

FOOT: Unfold the garment and position the connector on the bottom of the foot near the toes. Wrap the side of the foot with the flap that does not have the Velcro closure over the top of the foot, hold this flap in place and firmly pull the flap with the Velcro closure over the foot and secure the Velcro closure. Snugly tighten the “tongue” of the garment around the patient’s heel while making sure the inflatable bladder is directly under the patient’s arch section, then secure with the Velcro tab. The garment should fit securely around all parts of the patient’s foot. Check for proper fit by trying to slide your fingers between the ball of the foot and the garment. If you can easily slide your fingers down the garment, it is not wrapped tight enough; re-wrap the foot to ensure a firm wrap.

4. Repeat the process for the other leg/foot.
Note: If only one garment is to be used, simply leave the unused air outlet on the pump free (no tubing attached).
5. Air tubing is required to connect the garment to the pump and is provided separately. Attach the garments to the air tubing using the white snap lock connectors. Each tube has a male end connector at one end and a female end connector at the other. The female end (large white connector) will fit to the male end (small white connector) that is on the garment. Make certain that a “click” sound is heard to ensure a solid connection.
6. Attach the other end(s) of the air tubing (male end) to the large white female connectors(s) on the pump. Make certain that a click is heard with each snap lock connection. If you need to disconnect the tubing, press the silver colored tab on the large white (female) connector and pull apart.
7. Set the pump pressure to 40mm Hg (LEG) or maximum pressure (Foot) unless otherwise specified/ordered by a physician.
8. Press the on/off switch to turn on pump.

NOTE: DO NOT DISCARD the air tubing hose with the garments.

REPROCESSING OF THIS PRODUCT

Reprocessing these garments will maximize device usage and minimize environmental impact. SterilMed is an FDA regulated reprocessor and utilizes validated procedures to reprocess these DVT compression garments. Please contact your SterilMed Customer Service Associate for more information.

Instructions for Use can be found at www.sterilmed.com. Further questions or concerns by the health practitioner can be addressed directly by contacting your SterilMed Customer Service Associate at 1-888-541-0078.

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