

FOOT/ANKLE WRAP, (OPEN HEEL), UNFILLED, SINGLE PATIENT USE

Re-Order Part Number: **OP9BANKLMR3-U-CTN** (Non-Sterile)/**OP9BANKLMR3-S** (Sterile)



Figure 1

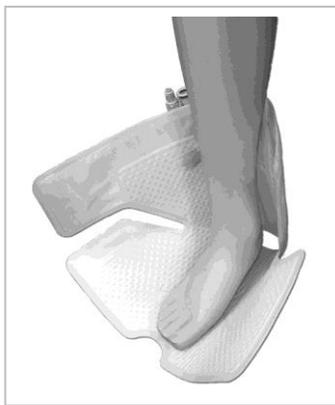


Figure 2

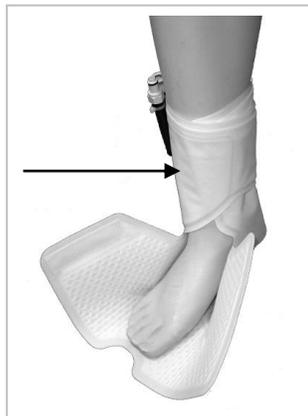


Figure 3



Figure 4

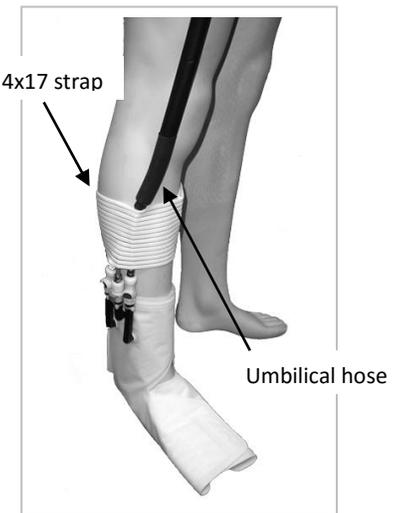


Figure 5

Patents: www.thermotekusa.com/patents

WARNING STATEMENT:

INTENDED USE: Disposable therapy wraps are designed for single patient use only and may only be used on the same patient for length of treatment.

WARNING: DO NOT REUSE OR REPROCESS TO USE ON MORE THAN ONE PATIENT. Per FDA, 21CFR Part 820, this product has not been validated for reprocessing or reuse.

APPLICATION INSTRUCTIONS:

- ❄ Position the therapy wrap fluid side up and place foot onto designated area as shown in Figure 1.
- ❄ Fold wrap around foot as shown in Figure 2. Apply upper flaps (around ankle area) around leg and secure with Velcro edge as shown in Figure 3.
- ❄ Apply flaps around foot area to the top of the foot and secure with Velcro edge as shown in Figure 4.
- ❄ Connect the umbilical hose to the therapy wrap (Figure 5). The quick disconnects will make a “click” sound indicating a secure connection.
- ❄ Fold one end of the Velcro strap over onto itself. Start with this end and apply strap snugly around the leg (just above the wrap) securing the hose to the leg as shown in Figure 5.





PRIMING THE WRAP:

- ❄ Fill the unit with fluid.
- ❄ Connect the wrap to the unit. Insert the two male fittings on the wrap into the female fittings on the unit.
- ❄ Turn ON the unit.
- ❄ Fluid should appear in the clear tubes of the wrap. If fluid does not appear, stop and start the unit until fluid is visible.
- ❄ Check the fluid in the unit while the unit is running. Add fluid if reservoir appears low. For larger wraps this will need to be repeated several times.
- ❄ Run the unit until the air bubbles in the clear tubes of the wrap are minimal or not visible.
- ❄ Please refer to the appropriate user manual for detailed instructions.

RECOMMENDED STORAGE PROTOCOL:

- Store between 50-80°F (ambient)
- Rotate stock to use older inventory first (FIFO)

WARNINGS/CAUTIONS:

- ⚠ Carefully read user instructions and warnings prior to operation.
- ⚠ A licensed healthcare practitioner must select the correct temperature setting. Patients vary in sensitivity to cold. A regular check of the temperature must be made once it has been established for the patient. Caution should be taken during prolonged use, for children, diabetics, incapacitated patients, and those with decreased skin sensitivity or poor circulation.
- ⚠ Due to individual differences in sensitivity and susceptibility to cold, patient's skin should be frequently observed. Follow instructions of your physician for length, frequency and duration of treatment.
- ⚠ Prolonged exposure to cold has a potential to cause injury to tissue. Please consult your medical practitioner for therapy setting, duration and frequency of treatment. There is a potential for cold injury even when providing cooling within the prescribed treatment.
- ⚠ If unusual swelling, skin discoloration or discomfort occurs, immediately discontinue use of the VascuTherm unit and consult a healthcare professional.
- ⚠ These products are to be fitted initially by a healthcare professional that is familiar with the purpose for which they are used. The healthcare professional is responsible for providing wearing instructions and precautions to other healthcare professionals, care providers involved in the patient's care, and the patient. If unusual swelling, skin discoloration or discomfort occurs, use should be discontinued and a healthcare professional consulted.
- ⚠ A therapy wrap with therapy unit should be used in a medical facility or clinical environment with direct healthcare provider supervision. If the prescribing healthcare practitioner determines it is appropriate for a patient to use the therapy wrap at home, the healthcare practitioner must provide the patient with adequate and appropriate instructions for use of the device. Further, the healthcare practitioner must monitor the patient's use of the device to assure appropriate use of the device and appropriate application of therapy.
- ⚠ Do not wrap the therapy wrap so tightly as to restrict blood or fluid flow. Do not use pins to secure the therapy wrap or hoses.
- ⚠ Therapy wraps are available in sterile and non-sterile; non-sterile therapy wraps should not be directly applied to an open wound. Do not use wrap directly over breached skin.
- ⚠ Do not attempt to sterilize a non-sterilized wrap or re-sterilize a sterilized wrap by any means.
- ⚠ Dressings used under the therapy wrap should be applied lightly.
- ⚠ This product should not be used during the inflammatory phlebitis process or during episodes of pulmonary embolism, congestive heart failure, pulmonary edema, suspected deep vein thrombosis, acute inflammations of the veins (thrombophlebitis), decompensated cardiac insufficiency, arterial dysregulation, erysipelas, deep acute venal thrombosis (phlebothrombosis), carcinoma and carcinoma metastasis in the affected extremity, decompensated hypertonia, acute inflammatory skin diseases, infection, venous or arterial occlusive disease or in any instances where increased venous and lymphatic return is undesirable. Use with caution on an extremity which is not sensitive to pain. Individuals with extremely low blood pressure should check with their doctor before using ThermoTek products.
- ⚠ Cold therapy should not be used by patients with Raynaud's Disease, poor peripheral circulation, diabetes, decreased skin sensitivity or hypersensitivity to cold.
- ⚠ Do not allow the therapy wrap or hoses to contact sharp objects.
- ⚠ All therapies using compression must be turned OFF when the unit is not in use or the wrap is removed from the patient for prolonged periods or for repositioning of the wrap.
- ⚠ Do not use wraps near open flame.
- ⚠ Do not smoke while therapy wraps are in use.
- ⚠ Clean exposed surfaces of the therapy wrap with either a mild anti-bacterial soap and water solution or an isopropyl alcohol and water solution. Do not use bleach on therapy wraps. Disposable therapy wraps are designed for single patient use only and may be used on the same patient for the length of treatment.

WARRANTY:

ThermoTek warrants to the immediate purchaser from ThermoTek, or an immediate purchaser of an unused wrap from an authorized distributor of ThermoTek products, that ThermoTek single patient use wraps will be free from defects in workmanship and material under normal use for only the first use of the wrap or for a duration of six months from the date of shipment.

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