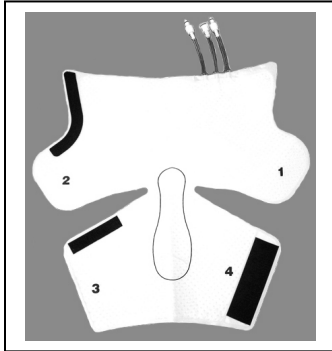


**FOOT/ANKLE, ELBOW WRAP (HALF-LEG, NON-SEGMENTAL),
SINGLE PATIENT USE**

Re-Order Part Number: 0P9BFTAKMR3 (Non-Sterile), 0P9BFTAKMR3-S (Sterile)



Wrap, Foot/Ankle, SPU



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, 21 CFR Part 820, this product has not been validated for reprocessing or reuse.

APPLICATION INSTRUCTIONS:

For Foot/Ankle Wrap Application:

- Position the therapy wrap fluid side up and place foot onto designated area as shown.
- Notice the flap areas of the wrap are numbered. Apply flaps 1 and 2 around the leg as shown and secure with Velcro edge.
- Apply flaps 3 and 4 to the top of the foot and secure with Velcro edge as shown.
- Connect the umbilical hose to the therapy wrap. The quick disconnects will make a “click” sound indicating a secure connection. Fold one end of the 4”W x 17”L 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.

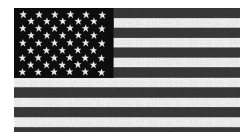
For Elbow Wrap Application:

- Rest the elbow onto the fluid side of the therapy wrap with the ports oriented toward the hand.
- Pull section 3 (see above) around the upper arm and secure with the Velcro edge of section 4.
- Pull section 1 around the upper arm and secure with the Velcro edge of section 2.
- Connect the umbilical hose to the therapy wrap. The quick disconnects will make a “click” sound, indicating a secure connection.

CAUTION: Fluid can diffuse from wrap and condense inside plastic bag. This may cause insert to get wet and form mold inside the package. ThermoTek will not warrant wraps for mold formation after 30 days from the date of purchase. To prevent wrap deterioration, ThermoTek makes the following recommendations:

Recommended Storage Protocol:

- Store between 50-80°F (ambient)
- Rotate stock to use older inventory first (FIFO)
- Do not store in a manner that blocks air vent holes in bag
- Fluid may evaporate in the wrap within 30 days if stored at 80°F or higher
- Fluid may freeze in the wrap if stored at 32°F or lower and damage the wrap.





PRECAUTIONS:

- Carefully read user instructions and warnings prior to operation.
- 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 directly over breached skin. 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.
- 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.
- 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 cold therapy.
- 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 attempt to sterilize a non-sterilized wrap or re-sterilize a sterilized wrap by any means.
- Do not use wraps near open flame.
- Do not smoke while therapy wraps are in use.
- Disposable therapy wraps are designed for single patient use only and may be used on the same patient for the length of the treatment.
- 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.
- Do not allow the therapy wrap or hoses to contact sharp objects.
- Dressings used under the therapy wrap should be applied lightly.
- Wraps should not be left open (off of the patient) and inflated to a "balloon" or "ball" state for extended periods of time.
- 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.

WARRANTY INFORMATION: **ThermoTek Single Patient Use Products:**

For Warranty Information, please see the applicable Therapy System Operators Manual.