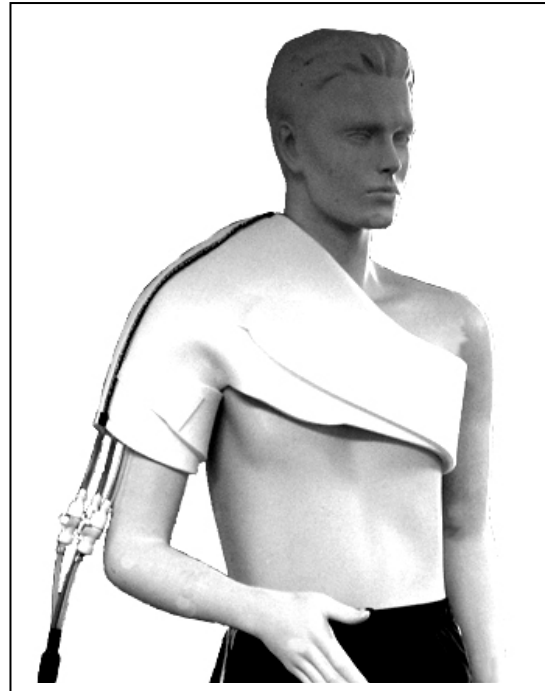




MEDIUM SHOULDER WRAP w/ HARNESS (SINGLE PATIENT USE)



0P8DLFKNBL3



Therapy Wraps are intended for single patient use only.

Application Instructions:

Contents: (1) **Large Butterfly Wrap, Single Patient Use** (0P8DLFKNBL3), (1) **Harness, Shoulder Wrap** (0P8DSHLDHR), (1) **Insert, Medium Shoulder Wrap w/ Harness (Single Patient Use)** (0P1DMSWHAD)

- Preset the arm Velcro loosely and insert arm. The long strap of the harness should be positioned on the patients back so that it can be pulled up to the chest area.
- Position the center of the therapy wrap with harness over the shoulder area as shown.
- Apply the second Velcro piece to the longer strap end and pull up to the chest. The smaller strap can be tucked under the larger strap. Secure Velcro.
- Tighten the arm strap to secure.
- Once sized and fitted, the excess length of the strap can be cut to fit patient.
- Connect the umbilical hose to the therapy wrap. The connectors will make a “click” sound to indicate a secure connection.
- Re-Order Part Number: **0P9BMSWHMR3**
0P9BMSWHMR3-S (Sterile)

Wraps are packaged for right shoulder use. For left shoulder application turn the harness inside out and re-apply black Velcro squares. Attach wrap fabric side down to attach to the Velcro. Apply to patient as described above.



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.

Warranty Information: ThermoTek Single Patient Use Products

ThermoTek, Inc. warrants the single patient use product in accordance with the following terms: *Full Replacement:* Single patient use products manufactured or supplied by ThermoTek shall be free from defects in material and workmanship upon receipt of the product and for the initial use of the product. ThermoTek shall replace the product, at no charge to the customer, if in the reasonable judgment of ThermoTek the product is found to have material or workmanship faults.

The product must be returned to an authorized ThermoTek Service Center for warranted evaluation. The buyer shall pay for the expense of returning the product to the authorized ThermoTek Service Center for warranty service. Return products must be in the ThermoTek approved box and packing material to ensure safe transport. ThermoTek will pay for the expense of returning the product back to the buyer. The buyer shall be responsible and may be assessed a fee for testing if no defects are found with the ThermoTek product.

In the event that the product or any portion thereof is not installed or used in accordance with the manufacturer's Operating Instructions, any and all warranties either expressed or implied shall be and are hereby voided. Only upon the proper installation and use of the items shall this warranty apply. This warranty does not cover any product that has been subject to misuse, neglect or accident. This warranty does not cover any product that has been altered or modified so as to change its intended use. In addition, this warranty does not extend to the use of fluids which are either incompatible with the unit or adversely affect its operation, performance, or durability.

Because ThermoTek, Inc. constantly provides our customers with the latest technology, we reserve the right to change or improve the design of any product without assuming any obligation to modify any product previously manufactured.

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