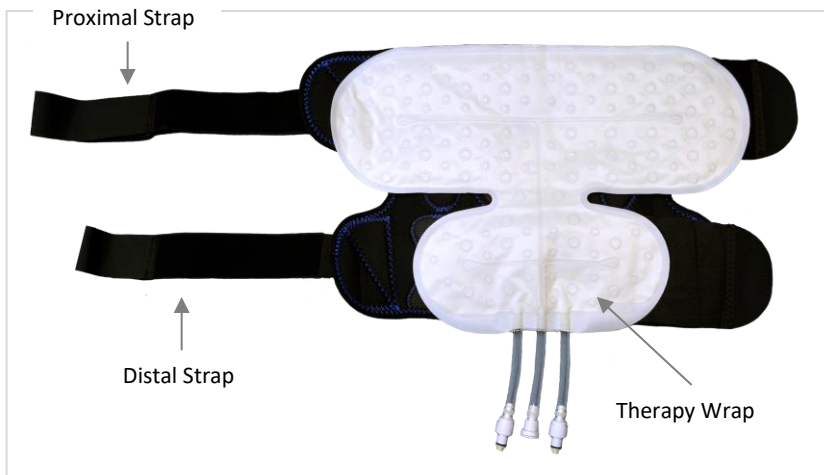


BRACETEK KNEE ROM, 13" – LARGE

WARNING/CAUTION

- ⚠ Prolonged exposure to cold has a potential to cause injury to tissue. There is a potential for cold injury even when providing cooling within the prescribed treatment. Please consult your medical practitioner for therapy setting, duration and frequency of treatment.
- ⚠ If unusual swelling, irritation, skin discoloration or discomfort occurs, immediately discontinue use of the VascuTherm unit and consult your healthcare professional.
- ⚠ For more information and warnings/cautions, please consult the User Manual. If the User Manual is not provided, please contact the provider or ThermoTek, Inc (972.874.4949 or 214.502.8800)



Re-Order Part Number: OP9BRMLX13-L

**Therapy wraps are intended for single patient use only.*

Pre-Op Instructions:

- Remove the BraceTek Knee ROM from the bag and undo the two (2) distal and proximal straps. It is recommended to fold the hook tab ends back to the straps to eliminate straps possibly sticking to themselves during application of the brace.
- Release the hinge cover and set the desired range of motion prior to brace application. The hinge is pre-set to full range of motion.
- Open the BraceTek ROM brace by releasing the hook and loop closures on the brace. The white ThermoTek standard or large therapy wrap is installed inside the brace with the connections on the distal end of the brace.
- Place the brace over the patient's leg for attachment.
- Distal and proximal oversize strap closure extensions are attached inside the brace to accommodate thick surgical dressings. Remove and discard if not required.
- Close the distal and proximal closures on the BraceTek ROM and secure the 2 distal and proximal straps, beginning with the distal strap.

Post-Op Instructions:

- To convert the BraceTek ROM brace to a conventional wrap around rehab brace, remove the white therapy wrap from the brace and the two (2) distal and proximal hook pieces that adhered the white therapy wrap to the brace. Remove and discard the 2 distal and proximal oversize strap closure extensions if they were used with thick surgical dressings.
- Flex one of the hinges to the maximum degree and remove it from the hinge pockets. Turn the hinge upside down and re-insert into the hinge pockets while flexed to the maximum degree. Repeat for the other hinge on the opposite side of the brace.
- Apply the BraceTek ROM with the wide opening now to the front of the knee.

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.

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.
- ⚠ Do not overtighten the brace, adjust as necessary.
- ⚠ 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 and brace 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 Information: [ThermoTek Single Patient Use Wraps:](#)

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

Patents: www.thermotekusa.com/patents

Instructional video link: <https://www.youtube.com/user/thermotekinc>

