




BraceTek LSO (Lumbar-Sacral Orthosis), ONEF1T

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).

The BraceTek LSO is a unique one piece brace that immobilizes the wearer from the sacrococcygeal junction to above the T9 vertebra. The brace is easy for individuals to put on, adjust and weighs 20 ounces. This comfortable light weight brace encourages compliance with treatment protocols.

The BraceTek LSO has a single layer of soft moisture-wicking material and anatomically designed posterior support panel with cutout to make the brace thinner, lighter, cooler and less bulky. The center cutout also reduces direct pressure on the spine—ideal for a post-operative patient or those receiving injections. As the patient pulls on the adjustable closure system, the already anatomically shaped posterior panel will mold to the patient's back regardless of their degree of lordosis. The LSO brace provides intracavitary pressure to reduce load on the intervertebral discs. The unique strapping system also provides hydrostatic lift to help hold the weight of the abdomen thus reducing lower back pain. The end result is greater patient compliance. The LSO also comes with available Cinch panel to replace existing panel as healing occurs and pain is reduced.

INDICATIONS:

- Spondylosis
- Spondylolisthesis
- Herniated Discs
- Mechanical Lower and Mid-Back Pain
- Chronic and Acute Strains
- Degenerative Disc Disease
- Bulging Discs
- Post-Surgical Stabilization
- Spinal Stenosis



Patents: www.thermotekusa.com/patents

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

Assembled in Mexico

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Re-Order Part Number: 0P9BLSBxBK

WRAP IS NOT PRE-FILLED. PLEASE SEE PRIMING INSTRUCTIONS ON PAGE 4.

APPLICATION INSTRUCTIONS:



1. Orient and apply the therapy wrap to the brace as shown. The tubes should be to the right (single tube at the top, two tubes at the bottom).



2. Stretch brace out fully across patient's back and align brace in center of back.



3. Overlap front panels of belt and secure hook and loop materials. Brace should be snug but comfortable.



4. Pull bilateral tension strings until desired level of support is achieved.



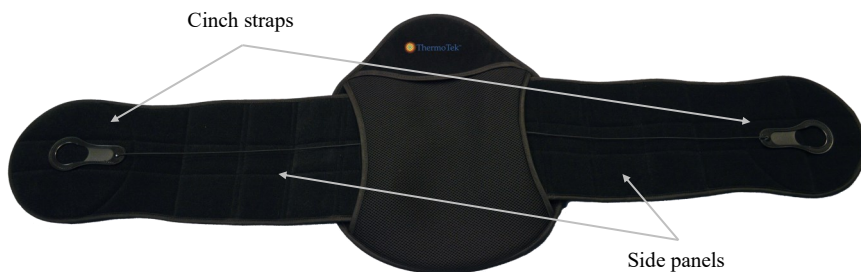
5. Secure tension strings with hook side facing down.



6. Check the patient to ensure that fully fitted LSO is secure and comfortable.

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To EXTEND THE BRACE: If the brace strap needs to be extended, follow the steps below:



1. Orient the brace as shown.



2. Remove the cinch strap from the side panel to be extended and release the side panel from the hook and loop wing as shown.



3. Flip the side panel over as shown, move the attached hook and loop piece and fold the panel to the desired length.



4. Side panel folded to desired length.



5. Replace the side panel and secure with the hook and loop wing. Replace the cinch strap to the side panel. Repeat these steps for the opposite side so that both panels are the same length.

OPTIONAL EXTENDER PANELS:



Extender Panels (hook side shown above)



1. Remove the side panel as instructed above. Place the hook side of one extender panel onto the end of the side panel and press to secure. Replace the side panel into the back pad and secure with hook and loop wing. Repeat on opposite side so that both panels are the same length.

PRIMING THE WRAP: When filling the wrap, place the wrap and hose at the level of the unit or below the unit.



WARNINGS/CAUTIONS:

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.

- ◇ 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.
- ◇ If swelling increases and pain, numbness, skin irritation occurs, discontinue use. Contact medical provider immediately. This product is only a support device, not to prevent injuries or prevent recurrence of injuries.
- ◇ 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.



BETTER THAN ICE™

Warranty Information: **ThermoTek Single Patient Use Wraps:**

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

OneFit Brace Warranty: Warranted to be free of material or workmanship defects for 5 years.