

TEMPERATURE THERAPY PROTOCOLS

Treatment Period:	Frequency/Duration:	Type of Barrier:	Inspect Skin Every:	Inspection Method:
Day: Through Day:				
Day: Through Day:				
Day: Through Day:				

DeRoyal Industries, Inc. | 200 DeBusk Lane | Powell, TN 37849 USA | 800.DEROYAL | 865.938.7828 | deroyal.com

Instructions for Use

RX Only  Single Patient Use Only

Temperature Therapy Blankets



Improving Care. Improving Business.®

INDICATIONS FOR USE – WHEN TO USE TEMPERATURE THERAPY

Cold Therapy. Use of cold therapy is intended to be prescribed by a properly licensed practitioner to temporarily reduce pain and swelling resulting from injury to or surgery to areas such as the shoulder, knee and back.

Hot Therapy. Use of hot therapy is intended to be prescribed by a properly licensed practitioner to temporarily increase blood circulation and lessen muscle soreness or stiffness during rehabilitation.

Product Availability: Therapy blankets are available in both sterile and non-sterile versions. Not intended to be sterilized by user.

Any other uses of this product are not recommended.

Ask your doctor whether you can use compression or mild exercise to ensure adequate blood flow to the affected area before, during and/or after use of temperature therapy.

DO NOT use until you have completely read these *Instructions for Use*.

SAFETY ALERT FOR HEALTHCARE PROVIDERS! TEMPERATURE THERAPY CAN CAUSE THERMAL INJURY, INCLUDING SERIOUS HEAT OR COLD-INDUCED INJURIES, IF NOT PROPERLY PRESCRIBED. DO NOT prescribe temperature therapy if you have not read and understood all unit and therapy blanket warnings, contraindications and the *Instructions for Use* or if you do not feel you are appropriately trained on the use of temperature therapy. **ALWAYS** consider the individual patient's medical history in comparison to the warnings and contraindications prior to prescribing temperature therapy. **ALWAYS** provide the patient with specific written instructions on the (1) frequency and duration of use during individual therapy sessions, (2) mandatory use of a skin barrier, (3) correct therapy blanket application, (4) methods and frequency of skin inspection, (5) total length of treatment and, when appropriate, (6) use of compression or mild exercise to ensure adequate

blood flow before, during and/or after use of temperature therapy. **ALWAYS** review your patient-specific instructions and all product information with the patient. **IMMEDIATELY DISCONTINUE** use of temperature therapy if your patient experiences, at the treatment site, any change in skin condition or appearance, including burning, numbness, tingling, discoloration, itching, blisters, welts, irritation; temporary loss of normal motor function; or increased pain, redness or swelling.

SAFETY ALERT FOR PATIENTS! TEMPERATURE THERAPY CAN CAUSE THERMAL INJURY, INCLUDING SERIOUS HEAT OR COLD-INDUCED INJURIES. DO NOT use temperature therapy without a prescription from your healthcare provider. **DO NOT** use temperature therapy if you have not read and understood all unit and therapy blanket warnings, contraindications and the *Instructions for Use* or if you do not feel you are appropriately trained on the use of temperature therapy. **DO NOT** use temperature therapy if your healthcare provider has not provided you with specific written instructions on (1) how long and how often to use temperature therapy during individual therapy sessions, (2) mandatory use of a wrap to serve as a barrier between the skin and therapy blanket, (3) correct therapy blanket application, (4) how and when to inspect skin, and (5) total length of treatment with the unit. **DO NOT** use temperature therapy if you do not understand the instructions or product information provided by your healthcare provider. **DO NOT** use temperature therapy if you are not able to inspect the condition of your skin underneath the therapy blanket on at least an hourly basis or as otherwise recommended by your healthcare provider. **IMMEDIATELY DISCONTINUE** use of temperature therapy and **CONTACT YOUR HEALTHCARE PROVIDER** if you experience, at the treatment site, any change in skin condition or appearance, including burning, numbness, tingling, discoloration, itching, blisters, welts, irritation; temporary loss of normal motor function; or increased pain, redness or swelling.

CONTRAINDICATIONS – WHEN NOT TO USE COLD THERAPY

DO NOT use cold therapy on patients with any of the following contraindications:

- History of cold injury, frostbite or adverse reactions to cold therapy.
- Incoherent due to sedation, anesthesia, coma or sleep.
- Decreased skin sensitivity or localized circulation or wound healing problems, including those caused by multiple surgical procedures.
- Circulatory syndromes due to Raynaud's disease, Buerger's disease, peripheral vascular disease, vasopastic disorders, or hypercoagulable clotting disorders.
- Hand/wrist or foot/ankle surgery exhibiting polyneuropathy.
- Hypersensitivity to cold.
- Children 12 and under.
- Local tissue infection.
- Diabetes.

If you have any of the above contraindications, ask your healthcare provider for alternate treatments.

CONTRAINDICATIONS – WHEN NOT TO USE HOT THERAPY

DO NOT use hot therapy on patients with any of the following contraindications:

- History of heat injury or adverse reactions to hot therapy.
- Incoherent due to sedation, anesthesia, coma or sleep.
- Decreased skin sensitivity or localized circulation or wound healing problems.
- Arteriosclerosis or atherosclerosis.
- Abdomen of women who are pregnant.
- Localized malignancy in treatment area.
- Hypersensitivity to heat.
- Local tissue infection, swelling or inflammation.

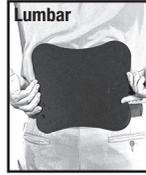
If you have any of the above contraindications, ask your healthcare provider for alternate treatments.

PRECAUTIONS

- Condensation on therapy blankets and couplings may occur when in use depending on the air temperature and temperature at the treatment site. This is normal; however, **DO NOT** continue use if skin barrier becomes moist. Change to dry barrier as necessary.
- Product should not be used if sterile packaging is damaged or opened or if shelf-life has expired.

Instructions for Use

1. Place blanket on affected extremity with the felt side facing away from the skin. **NOTE:** With the exception of the ankle and lumbar blankets, tubes should face downward.
2. Pull straps around the affected extremity and securely attach the hook and loop closures for a snug comfortable fit. **NOTE:** Not all blankets are packaged with straps. An elastic bandage or DeRoyal foam wrap can also be used.
3. Re-adjust as necessary.
4. Initiate therapy as described in 'Instructions for Use' included in temperature therapy unit.



WARRANTY

DEROYAL PRODUCTS ARE WARRANTED FOR NINETY (90) DAYS FROM THE DATE OF SHIPMENT FROM DEROYAL AS TO PRODUCT QUALITY AND WORKMANSHIP. DEROYAL'S WRITTEN WARRANTIES ARE GIVEN IN LIEU OF ANY IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

TROUBLESHOOTING

Problem	Solution
No water flow to therapy blanket.	Check for hose kinks or folds in therapy blanket.

! WARNINGS

- Read and understand all unit and therapy blanket warnings, contraindications, precautions and the *Instructions for Use* prior to using temperature therapy.
- Can cause thermal injury, including serious heat or cold-induced injury. **IMMEDIATELY DISCONTINUE** and **CONTACT YOUR HEALTHCARE PROVIDER** if you experience, at the treatment site, any change in skin condition or appearance, including burning, numbness, tingling, discoloration, itching, blisters, welts, irritation; temporary loss of normal motor function; or increased pain, redness or swelling.
- This therapy blanket is prescription (Rx) only. **DO NOT** use this therapy blanket without a prescription from a properly licensed practitioner. Use of temperature therapy without a prescription or failure to follow or understand the prescription may result in serious injury, including frostbite and tissue necrosis.
- **DO NOT** use if you are not able to inspect the condition of the skin underneath the therapy blanket on at least an hourly basis. However, due to individual differences in sensitivity and susceptibility to cold and hot temperatures, **ALWAYS** observe the treatment area as recommended by your healthcare provider.
- **DO NOT** apply therapy blanket underneath a fiberglass or plaster cast or other dressing, wrapping or bracing that would prevent the patient from checking the skin under the therapy blanket.
- **DO NOT** let any part of the therapy blanket touch the skin or an open wound. **ALWAYS** use a barrier between the skin and the therapy blanket. If a sterile dressing has been applied to the treatment site that does not completely cover the skin under the therapy blanket, use an additional barrier. Use of a barrier with a non-sterile blanket does not prevent possible contamination. Application of the therapy blanket directly on the skin may result in serious injury, including frostbite and tissue necrosis.
- **ALWAYS** check for moisture on the barrier between the skin and the therapy blanket. Because moisture on the barrier may create colder temperatures on the skin and result in serious injury, immediately discontinue use if moisture is present on the barrier. Change to dry barrier as necessary.
- **DO NOT** use a therapy blanket that is damaged or is leaking water as this may result in serious injury, including infection and tissue necrosis. **ALWAYS** check for a secure connection between the unit and therapy blanket. **ALWAYS** check for any leaks at the start of every individual therapy session.
- **DO NOT** use this therapy blanket with any unit other than a DeRoyal brand unit.
- **ALWAYS** follow the healthcare provider's directions for (1) how long and how often to use during individual therapy sessions, (2) mandatory use of a wrap to serve as a barrier between the skin and therapy blanket, (3) correct therapy blanket application, (4) how and when to inspect skin, and (5) total length of treatment. Failure to follow or understand the directions may result in serious injury, including frostbite and tissue necrosis.
- This therapy blanket is intended for single-patient use. Secondary use can cause serious injury, including infection.
- **DO NOT** use in the presence of flammable anesthetics or other flammable materials. Such use may result in serious injury due to the risk of explosion.
- No modifications of this equipment allowed.
- Cables and hoses may cause strangulation hazard. Keep out of reach of children.



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