



HEAT AND MOLD INSERT USED WITH LUMBAR SACRAL SUPPORTS

	SINGLE PATIENT USE
	NON-STERILE
	MEDICAL DEVICE
	NOT MADE WITH NATURAL RUBBER LATEX
RX ONLY	FEDERAL U.S.A. LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR PROPERLY LICENSED PRACTITIONER.

IMPORTANT INFORMATION

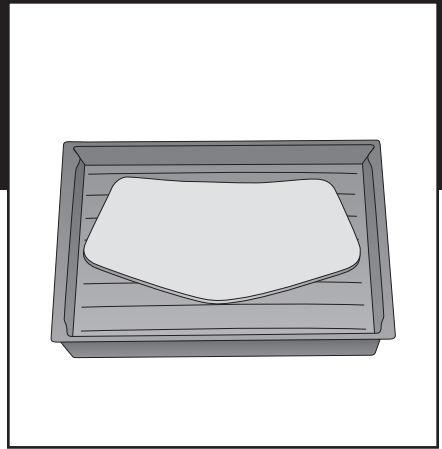
Please read all instructions, warnings and cautions before use. Correct application is essential for proper product function and to reduce the risk of injury or re-injury inherent with the use of any brace. Use only on the person it was provided to by a healthcare professional and only for the use it was intended.

INTENDED USE

The DeRoyal® Heat and Mold Insert used with Lumbar Sacral Support is used to provide support to the lumbar region of the lower back.

CAUTIONS

- A physician or properly licensed practitioner (a "prescriber") who is familiar with the use and purpose of this brace must fit it to the user. The prescriber has a duty to provide wearing instructions and risks related to the use of this brace to other healthcare practitioners treating the users and the users themselves, including duration of use. The instructions provided in this sheet do not supersede hospital protocol or direct orders of the prescriber. Use only as directed.
- Inspect brace for damaged or missing components before use.
- Discontinue use and consult your prescriber if the brace or its components break or become damaged.
- Inspect the fit of the brace on the patient to ensure fit is proper. **DO NOT OVERTIGHTEN.** Check regularly to ensure circulation is not compromised.
- Consult your prescriber immediately if you experience sensation changes, unusual reactions, swelling or increased pain while using this brace. Discontinue use if pressure injuries develop.




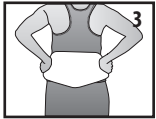
- Take special care if the user is diabetic or has poor circulation. These users may have decreased skin sensitivity and are at greater risk for poor peripheral circulation and pressure injuries.

SIZING

Measure waist circumference to determine proper size.

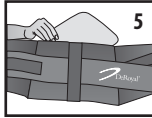
Small	24"-28"
Medium	32"-38"
Large	40"-46"
Extra Large	48"-54"

DIRECTIONS FOR MOLDABLE INSERT

- Preheat warming tray for approximately 3 minutes. May be used with the hydrocollator. Optimal warming temperature (for warming tray and hydrocollator) is approximately 160° F. Place insert on tray (foam side up) and leave until pliable (approximately 1-1 1/2 minutes). **NOTE:** Insert only needs to be soft enough to conform to the contour of the lower back.
- With patient standing upright and feet together, place the softened insert against the patient's back (foam side in). Make sure the bottom of the insert is approximately 1" below the top of the gluteal crease and level. Press the insert firmly against the patient's back. 
- Bring the patient's hands back so that they press the outer ends of the insert firmly against the body and gently against the coccyx. 
- Massage the insert up and down against the spine until the insert becomes rigid. Remove to allow additional



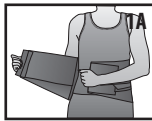
- setting time.
5. Place insert in support, foam side toward patient, making sure the insert is all the way in the pocket.



Secure pocket to prevent the insert from moving upward. **NOTE:** Heat and mold insert can be used with DeRoyal NE7741-1x product series

BACK SUPPORT APPLICATION

1. With support insert in proper position, have patient center the support in middle of back and wrap around body by grasping ends and stretching evenly. Bring left side to stomach (holding firmly) and then fasten the right side on top.



2. The patient should grasp the ends of the tension straps by bringing the left side first and then attaching the right on top. **NOTE:** Support should be snug, but comfortable.



INSTRUCTIONS

Hand wash with mild soap and let air dry completely, prior to reapplication.

STORAGE AND TRANSPORT CONDITIONS

	KEEP DRY
	KEEP AWAY FROM SUNLIGHT

In addition to the competent authority in the country where the patient resides, serious incidents must be reported to DeRoyal Industries, Inc.

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.**



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