


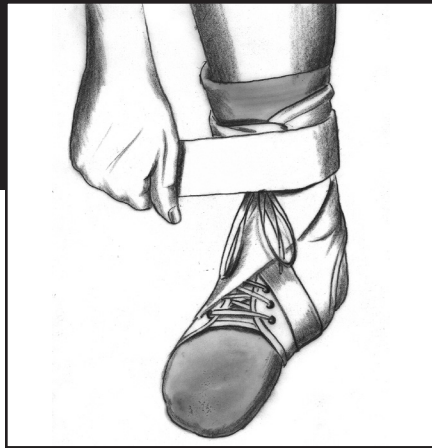





ANKLE BRACE - LACE UP DSAB

	SINGLE PATIENT USE
	NON-STERILE
	NOT MADE WITH NATURAL RUBBER LATEX
RX ONLY	FEDERAL U.S.A. LAW RESTRICTS THIS DEVICE TO SALE OR USE 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® Ankle Brace is used for acute and chronic ankle sprains, osteoarthritis and syndesmosis sprain.

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.
- Prolonged usage can result in muscle atrophy in the user. The user may require (1) a weaning period from the brace to build muscle strength (2) regular physical therapy exercises to maintain the strength of the ankle (3) a limitation on duration of use or (4) some combination of these.
- 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.
- Wear a sock underneath this brace.
- 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.

INSTRUCTIONS FOR USE

NOTE: Wear a sock underneath this brace.

-  1. Release all straps before applying. For patient's comfort, a cotton athletic sock must be worn with this brace.
-  2. Place foot into brace and lace from the bottom up securely, but comfortably. For proper fitting, apply the brace with the ankle positioned at a 90 degree angle. If desired, support stays can be removed from the brace. (Picture 1)
-  3. Apply tension to the outside strap by pulling the strap in an upward fashion. While tension is being applied, roll ankle to the inside toward the opposite leg and attach the strap to the outside of the brace. This strap should be fed through the guide on the outside of the brace to ensure proper positioning. (Picture 2)
-  4. Apply tension to the figure eight strap by pulling the strap across the top of the foot toward the inside of the ankle, around the



bottom of the foot to the outside of the ankle and back across the top of the foot to attach on the inside of the brace. (This should form a “figure eight”). Strap should not be so tight that it causes cramping or pain in the arch of the foot. If cramping occurs, the strap is too tight and should be loosened. **NOTE:** Straps may be cut off if they are too long. Apply the brace and ensure proper fit, then cut straps the desired length. (Picture 3)

5. Wrap the elasticized holding strap around the leg and secure as shown. (Picture 4)

CARE INSTRUCTIONS

Hand wash with a mild soap and let air dry completely before 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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