



PACESETTER™ AIR WALKER

	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 warnings and instructions 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.

INTENDED USE

The DeRoyal® Pacesetter™ Air Walker is intended for grade 2 and 3 ankle sprains, stable fractures of tibia, fibula, talus and tarsus, post operative immobilization (soft tissue reconstructions and open reduction internal fixation), and metatarsal fractures.

CAUTIONS

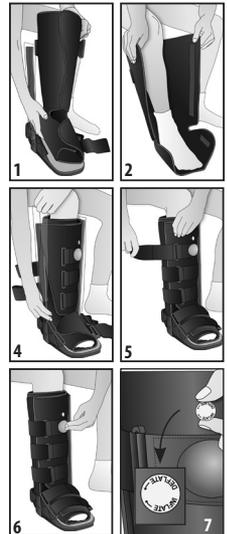
- A physician or properly licensed practitioner (a "prescriber") who is familiar with the use and purpose of this brace must fit it to the user. The prescriber has a duty to provide wearing instructions and risks related to the use of this brace to other healthcare practitioners treating the users and 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 by medical professional.
- 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 foot/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.
- Take special care if the user is diabetic or has poor circulation as these users may have decreased skin sensitivity and are at greater risk for poor peripheral circulation and pressure injuries.

INSTRUCTIONS FOR USE

NOTE: A sock should be worn with this boot.

1. Release hook and loop straps and remove inner liner/wrap from walker.
2. With patient seated, position foot and lower leg into liner/wrap making sure that the heel is positioned at the back of the liner/wrap. Secure liner/wrap around foot and lower leg by fastening the hook and loop closures making sure the liner/wrap is snug, but comfortable.
3. Insert foot and lower leg into walker.
4. Carefully center the uprights on the medial and lateral sides of the ankle to ensure a comfortable fit and proper support. Remove covers from uprights. Use attached hook to secure the upright to the liner/wrap.
5. Fasten hook and loop straps,





beginning from the bottom and working your way up the leg.

- To inflate the air bladder and increase compression, turn the air valve clockwise until secure. Press the air bulb at the top of the liner/wrap until desired compression is achieved (see image 6). To deflate the air bladder, turn the air valve counterclockwise (see image 7). Adjust compression as needed for a snug, but comfortable fit.

CARE INSTRUCTIONS

Liner may be hand washed in lukewarm water with a mild detergent and air dried prior to wearing. Plastic/metal portions of uprights may be wiped with an antibacterial wipe.

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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