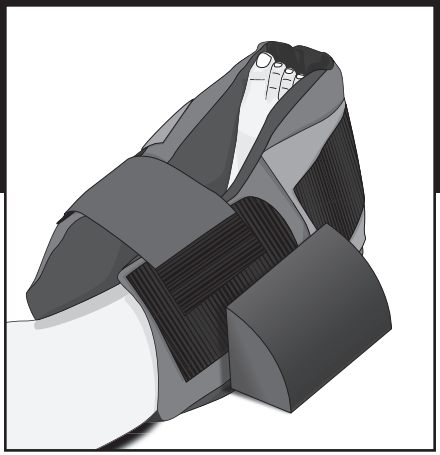
DeRoyal®

PRUVENTOR™ II HEEL OFF-LOADING DEVICE



	SINGLE PATIENT USE
NON STERILE	NON-STERILE
DRY	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 functioning of the device.
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® PRUventor™ II Heel Off-Loading Device is intended to be prescribed by a properly licensed practitioner to help prevent heel decubitus ulcers, foot drop and foot rotation.

CONTRAINDICATIONS

Severe ankle contractures; Severe spasticity.

⚠ WARNINGS

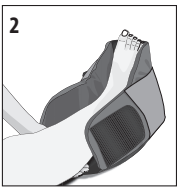
- Inspect product for damaged, missing components, or contamination prior to patient application.
- If device is used with a sequential/ intermittent compression device, be sure tubing does not interfere with off-loading of the patient's foot.
- Remove the device prior to ambulation. Do not allow patients to stand or walk while wearing the device.

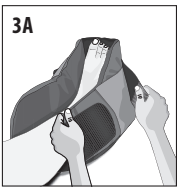
CAUTIONS

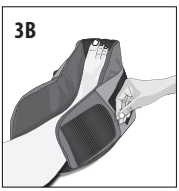
- This product is to be fitted initially by a physician (or properly licensed practitioner) who is familiar with the purpose for which it is intended. The physician or practitioner is responsible for providing wearing instructions and cautions to other healthcare practitioners or healthcare providers involved in the patient's care.
- Consult physician (or properly licensed practitioner) immediately if patient experiences sensation changes, unusual reactions, swelling or increased pain while using this device.
- Be sure to follow your facility's policies and guidelines for frequency of patient monitoring.

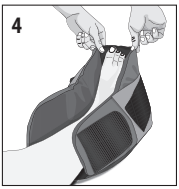
INSTRUCTIONS FOR USE

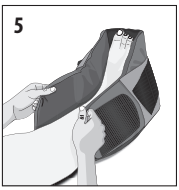
1. Open all strap closures. The DeRoyal® sew-in label should be on the outside of the boot.
2. Gently place the patient's foot into the boot, making sure the heel is placed over the heel opening.
3. Take the two foot drop straps and attach laterally to the blue loop portion.
4. With both lateral straps secured, pull both toe flap edges up vertically to help position the foot in an upright and neutral position.
5. Pull flaps on either side of the leg toward the patient to ensure the device fits securely and that the heel is suspended over the heel opening.
6. Take the preattached lower leg securement strap and apply the hook tab to the loop on the opposite side of the boot.
7. Make sure two fingers fit between the device and the patient to ensure circulation is not compromised. Hook tabs should not





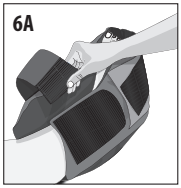


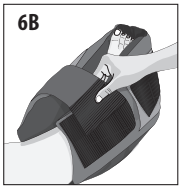


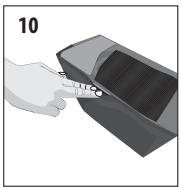


touch the patient's skin.

8. Make sure the heel is suspended. Check the bottom of the boot to ensure that nothing is touching the heel.
9. If using the optional foot securement strap, attach blue loop to blue hook on one side of the boot. Pull strap over foot and attach second piece of blue hook to the blue loop section on opposite side of the boot.
10. If the PRUventor™ II Heel Off-loading Device is used with sequential or intermittent compression devices, make sure the tubing exits through the top of the boot or through the access ports located on either side of the boot. Tubing of compression devices should not touch the patient's skin.







APPLYING THE ANTI-ROTATION WEDGE.

1. Place the anti-rotation wedge flat on the bed with hook facing the loop on the lateral side of the boot.
2. Slide the wedge to the side of the boot making sure the hook and loop are engaged.

NOTE: Perform periodic skin assessment as specified by hospital facility's policies and procedures.

SIZING
Universal: 13" Long
Bariatric: 15" Long

CALF CIRCUMFERENCE
Universal: Up to 18"
Bariatric: 18" to 24"

CLEANING AND/OR MAINTENANCE
Wipe down surface using a cloth and/or a hospital approved disinfecting wipe. Air dry completely prior to reapplication. Do not use bleach or oxidizing agents.

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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