



## ELBOW IMMOBILIZER

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

### IMPORTANT INFORMATION

Please read all instructions, warnings and cautions before use. Correct application is essential for proper functioning of the product. Use only on the person it was provided to by a healthcare professional and only for the use it was intended.

### INTENDED USE

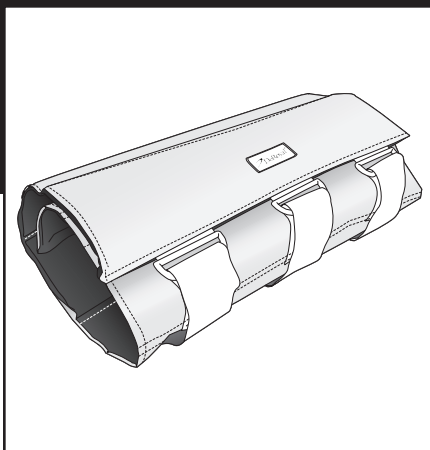
The DeRoyal® Elbow Immobilizer is intended to be prescribed by a properly licensed practitioner to help prevent patients from disturbing medical treatment.

### CONTRAINDICATIONS

**DO NOT** use on a patient who is or may become highly aggressive or agitated.

### WARNINGS

- A physician or properly licensed practitioner (a "prescriber") who is familiar with the use and purpose of this device must fit it to the user. The prescriber has a duty to provide wearing instructions and risks related to the use of this device 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 a medical professional.
- Inspect product for damaged or missing components before use.
- Discontinue use and consult your prescriber if the device or its components break or become damaged.
- Inspect the fit of the device on the patient to ensure fit is proper. **DO NOT OVERTIGHTEN.** Check regularly to ensure circulation is not compromised.
- Consult your prescriber immediately if the patient experiences sensation changes,



unusual reactions, swelling or increased pain while using this device. 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.
- Avoid using if an I.V. insertion site could be compromised.
- **DO NOT** allow patient to ingest product material.

### INSTRUCTIONS FOR USE

1. Reference sizing chart to ensure correct size for patient.
2. Open immobilizer by releasing hook-and-loop straps.
3. Place the immobilizer under the patient's arm with the opening oriented toward the inside of the arm. Adjust the immobilizer to the desired position on the arm, ensuring that the elbow is centered lengthwise. (A)
4. Starting with the strap-side, wrap around the patient's arm. (B)
5. Starting with the strap closest to the shoulder, secure the immobilizer by threading the hook-and-loop strap through the plastic buckles and attaching back onto itself. (C) Repeat with other straps. (D)
6. **NOTE: DO NOT OVERTIGHTEN.** Two fingers should fit between the device and the patient to ensure circulation is not compromised.



#### SIZING

PART NUMBER	SIZE	DIMENSIONS
M8035-I	Infant	3" L x 4" W
M8035-P	Pediatric	7" L x 7" W
M8035-C	Child	10" L x 12" W
M8035-S	Small	11" L x 14" W
M8035-M	Medium	13" L x 18" W
M8035-L	Large	10" L x 25" W

#### CLEANING AND/OR MAINTENANCE

Wipe down exterior with a damp cloth or hospital-approved disinfectant. Dry completely prior to use. If the interior is soiled, the product is damaged, or cleaning is insufficient, replace immobilizer with a new one.

#### 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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