




SHOULDER IMMOBILIZER WITH WAIST STRAP

	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

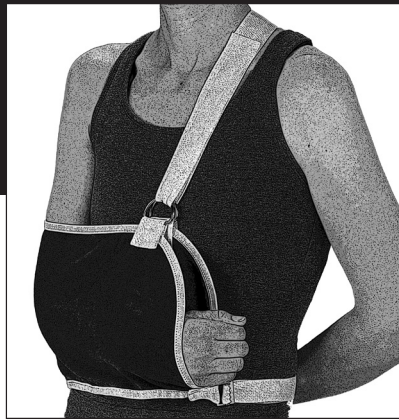
 Please read all instructions, warnings and cautions before use. Correct application is essential for proper functioning of the product. Use only on the person it was provided to by a healthcare professional and only for the use it was intended.

INTENDED USE

The DeRoyal® Shoulder Immobilizer with Waist Strap is for surgical rotator cuff repairs, anterior glenohumeral capsular reconstruction, dislocation/subluxation of G-H joint, S/P glenohumeral acromioplasty, Bankart repairs, soft tissue repairs, and shoulder sprains and strains.

CAUTIONS

- 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.
- Prolonged usage can result in muscle atrophy in the user. The user may require (1) a weaning period from the device to build muscle strength (2) regular physical therapy exercises to maintain strength (3) a limitation on duration of use or (4) some combination of these.
- Inspect device 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 you experience sensation changes, unusual reactions, swelling or increased pain while using this device. Discontinue use if pressure injuries develop.
- Wear clothing underneath this device.
- 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

1. Place the affected arm in the pocket of the sling.
2. Slide arm back in the pocket of the sling until the elbow is resting comfortably and the arm is supported by the back of the pocket of the sling.
3. If applicable, place the thumb through the thumb loop. Proper use of the thumb loop will help prevent wrist drop.
4. Wrap the shoulder strap (top strap) around the back and over the opposite shoulder.
5. a.) For products with a hook and loop closure, slide the strap through the O-ring, adjust to proper height and secure with hook and loop. b.) For products with buckle closure, thread the strap through the buckle and adjust to proper height.
6. Wrap the waist strap (located at the bottom of the sling) around the back, through the O-ring or buckle and secure.
7. Make sure the sling properly supports the arm in its resting position. Adjust straps for a secure and comfortable fit.

CLEANING INSTRUCTIONS

Hand wash with mild detergent in lukewarm water. Air dry prior to wearing.

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 one hundred twenty (120) 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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