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SHOULDER P.A.D. II PILLOW ABDUCTION DEVICE

| | |
|----------------|---|
| | 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

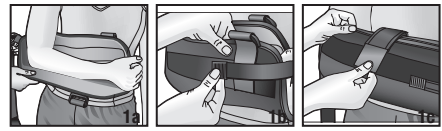
The DeRoyal® Shoulder P.A.D. II provides immobilization for surgical rotator cuff repair, anterior glenohumeral capsular joint ligament reconstructions, acute rotator cuff tendinopathy, S/P glenohumeral acromioplasty, dislocation/subluxation of G-H joint, acromioclavicular joint dislocations, bankart repairs, soft tissue repairs, and shoulder sprains and strains.

CAUTIONS

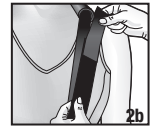
- A physician or properly licensed practitioner (a "prescriber") who is familiar with the use and purpose of this brace must fit it to the user. The prescriber has a duty to provide wearing instructions and risks related to the use of this brace to other healthcare practitioners treating the users and 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 shoulder (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 clothing 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

- Detach shoulder strap from rings at front of arm sling. Place affected arm in sling so that it rests in the fold of the sling (1a) (Rest thumb on adjustable strap for additional comfort if desired) (1b). Attach strap across top of sling for closed pouch effect (optional) (1c).



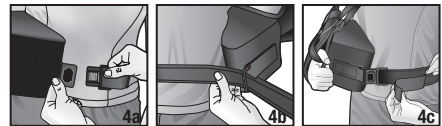
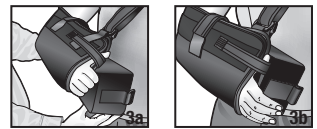
- Bring strap across the back and opposite shoulder (2a) and pull through both rings at front of sling. Secure strap end back onto sling strap (2b). Note: Depending on right or left fitting, adjust Y-tab end so that the strap secures back onto itself properly. Strap length may also be adjusted by removing Y-tab end, trimming the strap, and reapplying Y-tab end.



- Align foam pillow at waistline on affected side (3a). Attach arm sling to pillow by securing hook and loop portions together (3b).



- Detach clasp at end of pillow and place waist strap around patient (4a). Adjust length as necessary before buckling clasp back into the receiving end (4b). Pull waist strap tightly before securing Y-tab end back onto strap (4c). The position of the pillow may be adjusted by sliding the pillow forward or back along the waistline to achieve the desired external or internal rotation. If pillow can be pushed downward with pressure, the waist strap should be tightened. Stress ball included to promote proper circulation and encourage exercise.



CARE INSTRUCTIONS (IF APPLICABLE)

Hand wash arm sling and pillow cover in lukewarm water, mild detergent, air dry.



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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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