



DEROYAL® SHOULDER P.A.D. IV 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 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 P.A.D. IV 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/strains.

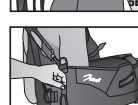
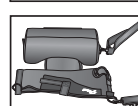
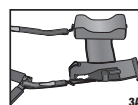
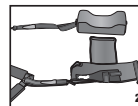
CAUTIONS

- 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 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 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 as these users may have decreased skin sensitivity and are at greater risk for poor peripheral circulation and pressure injuries.



INSTRUCTIONS FOR USE CONFIGURATION


- Abduction device is initially configured to fit the patient’s right shoulder. To configure for the left shoulder, release the waist strap from the front (black) buckle clasp on the P.A.D. (Positioned Abduction Device). Remove the P.A.D. by releasing the flap from the sling via the hook strip at the top of the P.A.D. and sling (Picture 1).
- Roll the P.A.D. away from the sling and remove the P.A.D. from the hook strip (Picture 2).
- Flip the sling over for left side configuration and ensure the pad flap is fully extended out from the bottom of the sling.
- With the inside curve of the P.A.D. facing upward and the flat side on the table, attach the flap to the center top edge of the P.A.D. (back side). **NOTE:** side closest to sling via the hook strip on the P.A.D. flap (Picture 3A). Roll the P.A.D. toward the sling and attach the exposed side of the hook strip on the flap to the loop on the sling (Picture 3B). Ensure there is no exposed hook material between the P.A.D. and sling.




APPLICATION

- Release the shoulder strap from the front (gray) buckle clasp where the D-ring attaches to the front cuff of the sling (Picture 4A). Release the waist strap from the front (black) buckle clasp on the P.A.D. (Picture 4B).
- Release the forearm strap to completely open the sling.
- Align the P.A.D. around the patient’s waistline on the affected side (Picture 5a). Place affected arm in the sling and place the patients hand under the thumb strap so it rests comfortably in the fold of the sling (Picture 5B). **NOTE:** Ensure all open wounds are covered before applying device.
- Ensure patient’s elbow is positioned as far back in the sling as possible for best fit and comfort (Picture 6). Tighten the thumb strap, if needed, so the patient’s thumb rests comfortably.

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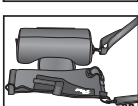
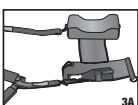
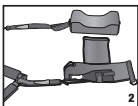
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- Ensure patient’s elbow is positioned as far back in the sling as possible for best fit and comfort (Picture 6). Tighten the thumb strap, if needed, so the patient’s thumb rests comfortably.

5. To adjust the sling length, roll the cuff at the front of the sling until the sling is aligned with the first joint of the patient's pinky finger (Picture 7).
6. Reattach the forearm strap to close and secure the sling.
7. Bring the shoulder strap across the patient's back and place the non-affected arm through the strap that is in the shape of a circle (Picture 8A), making sure one cushion is positioned on top of the shoulder and one cushion is positioned under the arm (Picture 8B). **NOTE:** Shoulder strap cushion should be positioned evenly over the patient's non-affected shoulder for comfort.
8. Reconnect the front (gray) buckle clasp to the D-ring (gray) attached to the sling cuff. **NOTE:** For patients who are not able to use buckle clasp, remove strap from buckle clasp and feed strap through D-ring.
9. The front, circle (shoulder) and back straps can be adjusted by lengthening or shortening the hook ends of the straps. **NOTE:** All strap lengths can be trimmed. To trim the straps, remove Y-tab from the end of the strap, trim the strap to desired length, and reapply Y-tab.
10. Apply the waist strap by bringing the strap around the patient's waist and reconnecting the front (black) buckle clasp to the D-ring (black) on the P.A.D. (Picture 9). Tighten the waist strap for proper fit. **NOTE:** If the waist strap is too long, remove Y-tab and trim strap to desired length and reapply Y-tab. **NOTE:** The position of the P.A.D. may be adjusted by sliding along the waistline to achieve the desired external or internal rotation. Exercise ball is included to promote proper circulation and encourage exercise.



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

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.**

Manufacturer

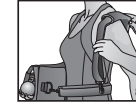
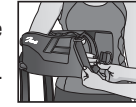
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