

Improving Care. Improving Business.®

### UNIVERSAL SPINE BRACE EXTENSION PANEL

	SINGLE PATIENT USE
NON	NON-STERILE
$\overline{\mathbb{X}}$	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.

### **INTENDED USE**

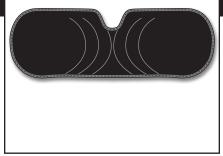
The DeRoyal<sup>®</sup> Universal Spine Brace Extension Panel is intended to be used with a DeRoyal<sup>®</sup> Universal Spine Brace for patients who exceed the recommended measurements of the brace and require additional brace circumference for proper support and application.

#### INDICATIONS

Post-operative thoracic/lumbar fusion, laminectomy, discectomy, compression fractures, degenerative disc disease, osteoporosis, single column instability, and facet syndrome for users with a waist circumference of greater than 59".

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- A physician or properly licensed practitioner (a "prescriber") who is familiar with the use and purpose of the DeRoyal Universal Spine 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.
- Inspect product for damage, missing components before use.
- Inspect the fit of the brace and extension panel on the patient to ensure fit is proper. DO NOT OVERTIGHTEN.
- Prolonged usage can result in muscle atrophy in the user.
- Consult your prescriber immediately if you experience sensation changes, unusual reactions, swelling or increased pain while using this brace.
- The Universal Spine Brace Extension Panel is only to be used with the MAXAlign<sup>®</sup> and Warrior<sup>®</sup> Spine Brace lines.



### **INSTRUCTIONS FOR USE**

# Using the Universal Extension Panel with MAXAlign® TLSO-S Brace:

- Consult the MAXAlign<sup>®</sup> Spine Brace IFU for brace sizing adjustment. Belt sizing indicators should be set at sizing zone 6 prior to application when using the Universal Extension Panel.
- Place the small loop section on the back of the extension panel on the gray hook section of the anterior panel and set aside for now.
- 3. Consult the MAXAlign® Spine Brace IFU for brace application. Once the brace has been placed under the supine patient with the belt arms spread, retrieve the appropriately sized sternal pad bar/anterior panel assembly and place just above the pubic bone.
- Place the double-sided hook piece included with the Universal Extension Panel on the inside loop section of the left anterior belt closure.
- Close the belt by attaching both belt arms to the sides of the Extension Panel. Ensure the belt arms are equally placed and continue application as per the MAXAlign<sup>®</sup> Spine Brace IFU.

## Using the Universal Extension Panel with MAXAlign® TLSO-D/LSO Brace:

- 1. Consult the MAXAlign<sup>®</sup> Spine Brace IFU for brace sizing adjustment. Belt sizing indicators should be set at sizing zone 6 prior to application using the Universal Extension Panel.
- Consult the MAXAlign<sup>®</sup> Spine Brace IFU for brace application. Once the brace has been placed under the supine patient with the belt arms spread, retrieve the Universal Extension Panel and place just above the pubic bone.
- Place the double-sided hook piece included with the Universal Extension Panel on the inside loop section of the left anterior belt closure.
- Close the belt by attaching both belt arms to the sides of the Extension Panel. Ensure the belt arms are equally placed and continue application as per the MAXAlign<sup>®</sup> Spine Brace IFU.



## Using the Universal Extension Panel with Warrior<sup>®</sup> Spine (642, 648, 650):

- 1. Consult the Warrior<sup>®</sup> Spine Brace IFU for brace sizing adjustment. Belt sizing indicators should be set at sizing zone 4 prior to application using the Universal Extension Panel.
- Consult the Warrior<sup>®</sup> Spine Brace IFU for brace application. Once the brace has been placed under the supine patient with the belt arms spread, retrieve the Universal Extension Panel and place just above the public bone.
- Place the double-sided hook piece included with the Universal Extension Panel on the inside loop section of the left anterior belt closure.
- Close the belt by attaching both belt arms to the sides of the Extension Panel. Ensure the belt arms are equally placed and continue application as per the Warrior<sup>®</sup> Spine Brace IFU.

### **CARE INSTRUCTIONS**

Clean the Universal Extension Panel by hand washing with mild soap and let air dry completely prior to reapplication.

### **STORAGE AND TRANSPORT CONDITIONS**

Ť	KEEP DRY
淡	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.** 



Improving Care. Improving Business:



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