



STERNAL PAD KIT

	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 warning 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 sternal pad kit is used for neutral sagittal alignment, hyperextension or flexion bracing using a thoracic or regular lumbar sacral orthosis. This sternal pad kit is an accessory to be used with the DeRoyal® ULTRAlign® line of braces only.

INDICATIONS

Postoperative fusion, postoperative laminectomy, postoperative discectomy (neutral sagittal alignment); compression fractures, degenerative disc disease, osteoporosis, chronic low back pain; IDET procedure (hyperextension); spondylolisthesis, spondylolysis, spinal stenosis, spinal osteoarthritis and facet syndrome (flexion).

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.
- Inspect product for damage and/or missing components before use.
- Inspect the fit of the brace 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.
- This device is for single patient use only. **DO NOT** reuse on another patient, reprocess, or sterilize. Reuse, reprocessing, or sterilization may damage the device, and may result in user or patient injury, patient infection, or patient death.



STERNAL PAD KIT CONFIGURATION & APPLICATION?

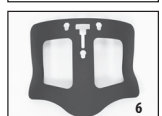
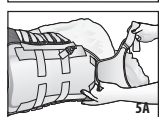
1. In positioning and shaping the Sternal Pad Kit (SPK) refer to Step #5 in the LSO/TLSO Patient Application Instructions that came with the base LSO/TLSO brace.
2. At this point, you should have predetermined the correct brace size for your patient and are ready to attach the SPK. If the brace is fastened to the patient:

- A. Loosen the pull straps that tighten the brace closure (if brace features dynamic straps) or,
- B. Pull-out the dials to release the brace tension (if the brace features the BOA® Fit System).

3. The SPK Accessory will come configured with 2 metal screws (Figure 3a) AND a triangular height adjustment mechanism (Figure 3b).
4. Remove the rigid anterior panel insert from the base LSO/TLSO brace (Figure 4a).

5. If the ridged anterior panel looks like Figure 5, use the two screws to attach and adjust the Sternal Pad Bar and discard the triangular height adjustment mechanism. If the ridged anterior panel looks like Figure 6, skip section 5, and proceed to section 6:

- A. Slide the Sternal Pad Bar into the notched section of the rigid anterior panel insert and position the anterior insert over the anterior fabric as if it were inserted inside the panel and determine the appropriate height of the Sternal Pad Bar (Figure 5a)
- B. The center of the superior edge of the Sternal Pad Bar should be 3-4” below the sternal notch.
- C. After the Sternal Pad Bar is positioned appropriately, use the two screws included to secure the sternal pad bar to the anterior plastic insert.
- D. Insert anterior plastic panel with attached sternal pad bar back into anterior panel.
- E. Place the Posterior Thoracic Extension (PTE) on the





- back of the brace via the hook and loop attachment, pull the straps over the shoulders (Figure 5e).
- F. Once the PTE is positioned, pass each strap through the chafes on the Sternal Pad and tighten. Any excess strap trimmed off.
 - G. Tighten the four pull straps or push in and turn the BOA dials that were loosened on the base brace to allow the SPK to be applied.
6. If the ridged anterior panel looks like Figure 6, use the triangular height adjustment mechanism to adjust the Sternal Pad Bar and discard the two screws:
- A. First, attach the height adjustment mechanism to the anterior panel and slide downward to click it securely in place (Figure 6a).
 - B. Slide the Sternal Pad Bar into the mechanism by pinching and holding the mechanism flanges to allow the Sternal Pad Bar to slide up and down along the mechanism attached to the panel (Figure 6b).
 - C. The center of the superior edge of the Sternal Pad Bar should be 3-4" below the sternal notch.
 - D. After the Sternal Pad Bar is positioned appropriately, release the mechanism flanges to secure the Sternal Pad Bar in place.
 - E. Insert anterior plastic panel with the attached sternal pad bar back into the anterior panel.



WARRANTY

DeRoyal® products are warranted for one hundred and 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.**

CARE INSTRUCTIONS

Remove panels from the brace and clean all soft goods by hand washing with mild soap and let air dry completely prior to reapplication. Anterior and posterior panels can be cleaned by wiping down with a disinfectant wipe.

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.



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