

CARE INSTRUCTIONS

Remove inserts from front and back panels. Hand wash in cool water with a mild liquid soap. Do not use strong detergents or bleaches as both may be detrimental to the elastic. Thoroughly rinse and blot excess water from support with a clean towel. Carefully stretch support into its normal shape and lay flat to dry. Ironing or automatic dryers will deteriorate elastic.

WARRANTY

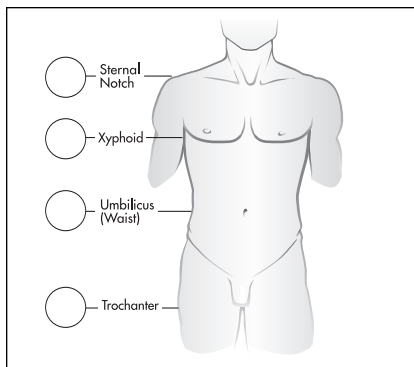
DeRoyal products are warranted for ninety (90) days from the date of shipment from DeRoyal as to product quality and workmanship. DEROYAL'S written warranties are given in lieu of any implied warranties, including warranties of merchantability or fitness for a particular purpose.



Manufacturer
DeRoyal
200 DeBusk Lane, Powell, TN 37849 U.S.A.
888.938.7828
865.938.7828

Authorized Representative
DeRoyal Europe, Ltd.
Virginia Road, Kells, County Meath Ireland
353.46.9280100

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SIZING CHART

| | Small | Medium | Large | X-Large | XX-Large |
|--------------------|-----------|-----------|-----------|-----------|-----------|
| Non-tapered | | | | | |
| Xyphoid | 31" – 35" | 34" – 38" | 37" – 41" | 38" – 45" | 45" – 53" |
| Waist | 31" – 35" | 32" – 38" | 35" – 41" | 38" – 45" | 45" – 53" |
| Trochanter | 31" – 35" | 34" – 39" | 38" – 42" | 38" – 45" | 45" – 53" |
| Tapered | | | | | |
| Xyphoid | 25" – 31" | 28" – 35" | 32" – 38" | 35" – 42" | 40" – 46" |
| Waist | 25" – 31" | 29" – 36" | 32" – 38" | 36" – 42" | 39" – 47" |
| Trochanter | 27" – 33" | 32" – 38" | 35" – 41" | 38" – 46" | 43" – 49" |



DeRoyal Ultralign® + LSO/TLSO

RX Only

For Single Patient Use Only



IMPORTANT INFORMATION

Please read all instructions before use.

INTENDED USE

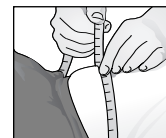
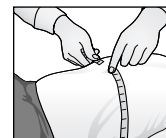
Used for neutral sagittal alignment, hyperextension or flexion bracing using a thoracic or regular lumbar sacral orthosis with dorsal lumbar extension straps or sternal pad kit. Tapered and non-tapered versions to ensure proper fit.

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).

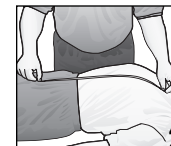
PRECAUTIONS

- This product is to be fitted initially by a physician (or properly licensed practitioner) who is familiar with the purpose for which they are responsible. The physician or practitioner is responsible for providing wearing instructions and precautions to other healthcare practitioners, care providers involved in the patients' care and the patient.
- Consult your physician (or properly licensed practitioner) immediately if you experience sensation changes, unusual reactions, swelling or prolonged pain while using this product.
- Follow the instructions of your physician (or properly licensed practitioner) for length and duration of use.



anatomical locations)

- 1" below the tip of the breast bone (xyphoid process)
- Around the waist (umbilicus)
- Around the greater trochanter or fullest contour of the buttocks
- For a TLSO using a Sternal Pad, a sternal notch to symphysis pubis measurement is necessary.



To Position the Posterior Panel under the Back, the Patient must have Assistance Rolling from Supine to Side-Lying.

- The first step is to place a draw sheet under the patient while they are still lying supine. Fold a sheet to a width of 3 to 3 1/2 feet and slide it under the patient's lower back and hips. The width of the sheet should extend from mid torso to just below the buttocks.
- To roll the patient to their right side, straighten the right leg while keeping the left knee bent to a 90° angle. Place the right arm overhead (elbow straight) by the right ear. Place the left hand on the abdomen.
- Instruct the patient to maintain their position while the draw sheet is used to turn them on their side. The patient's shoulders should move with the hips to prevent rotation of the spine during transfer.

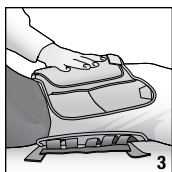
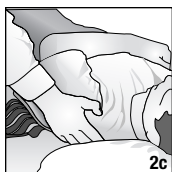
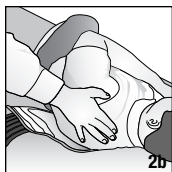
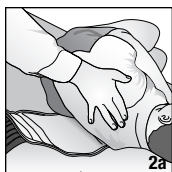
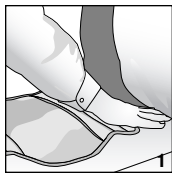




- To turn the patient onto their right side, reach across the patient and grasp the draw sheet located on the left side of the patient. On the count of three, pull the draw sheet toward you rotating the patient to their right side. Pull the draw sheet slowly, monitoring the patient for comfort and preventing any rotation of the spine from occurring. Position one or two pillows between the patient's knees while they are in the side-lying position.

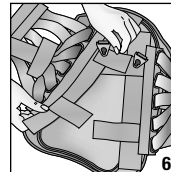
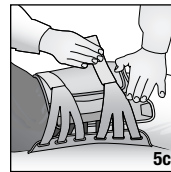
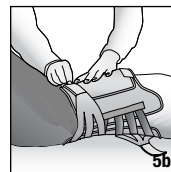
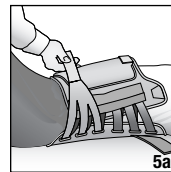
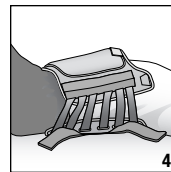
Patient Application Instructions for the LSO/TLSO

- Tuck or slide the closure under the low back so that it can be retrieved on the other side. The inferior (lower) portion of the posterior panel should be positioned just above the coccyx and the superior (top) portion below the inferior angle of the scapula. (If using a TLSO, the superior portion will be below the spine of the scapula).
- Next, the patient needs to be rolled back into the supine position. Do this by folding their arm comfortably in front of their chest. Assist the patient by placing your hand under their shoulder blade and guide them into position, keeping their knees bent and their hips parallel with their shoulders. Remove the pillow(s) from between the patient's knees and place aside.
- Lay the side closure attachment straps out to each side of the posterior panel. Gently flatten the patient's back (posterior pelvic tilt) against the posterior panel while keeping the knees comfortably bent (flexed). Place the anterior (front) panel in the proper position 1" above the pubic bone.
- Secure the slide closure attachments by applying the strips first on the left side, then on the right. Make sure the side closure attachments are symmetrical to one another and are equal distance from the center so



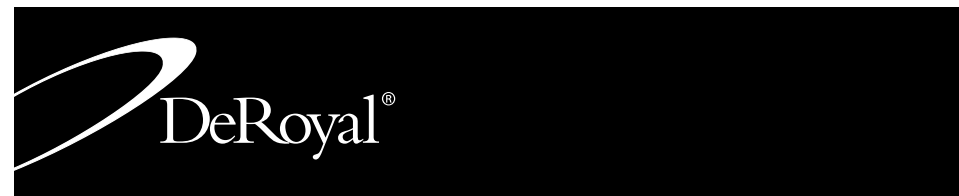
the panel is not turned or rotated. The side closure securing system should contour to the shape of the patient's anatomy.

- Beginning with the lower two straps, pull each strap forward at the same time to tighten the brace evenly. Repeat the steps with the top two straps. After insuring that the anterior panel is in the correct position, you can repeat the strap tightening procedure while applying mild downward pressure on the panel. It is easier to secure a snug fit if bottom straps are pulled and attached in a "V" shape and top straps are pulled straight across the anterior panel. The most compression is achieved if straps are pulled away from the brace and then back to the anterior panel for closure, rather than all the pull being toward the brace before attaching the dynamic strap to anterior panel.
- If straps overlap significantly or do not meet evenly when adjusted from both sides, adjust closure system from the posterior section. **Hint:** for female patients or patients with larger hip development, the closures can be vectored to be wider at the bottom to gain a better fit.



To Position the Patient from their Back to Side-Lying to Sitting.

- Keeping the patient's legs together, gently bend their knees, monitoring the patient for pain. Flex the knees to a right angle or approximately 90°.
- Position the patient's arm, extended overhead with the elbow straight on the side on which they will be turned. Instruct



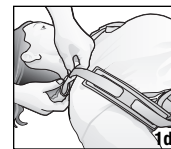
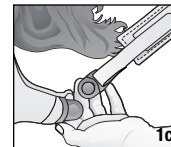
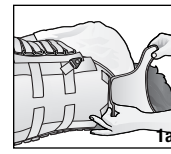
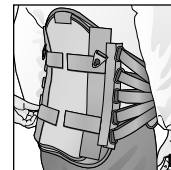
the patient to assist you as you transition him/her from a side-lying to a seated position. Instruct them to push with the down side elbow as you maintain their posture and assist them in lowering their legs to the floor. The shoulder must be maintained over the hips as the patient is being repositioned, preventing side-bending or rotation of the spine.

- Assist the patient by placing one hand under the down side shoulder and one hand just behind the bend in the knees. On the count of three, simultaneously lift upwards on the shoulder and support the lower legs as they are lowered to the floor. The goal is to keep the shoulders squarely over the pelvis as the patient is being transferred.



Confirm Orthosis Positioning

- Re-check the positioning of the anterior and posterior panels, making sure the orthosis is in a midline position with the spine and that it has not migrated upwards or downwards.



TLSO Options

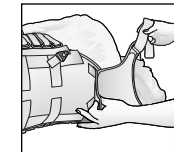
1. Dorsal Lumbar Extension (DLE) Application

In using the Dorsal Lumbar Extension, refer back to the LSO/TLSO Patient Application Instructions to Step #2. Before rolling patient in supine position, secure the DLE as shown in Figure 1a. Next, bring the DLE strap and pad over the top shoulder and back under the axilla and clip it to the mating piece on the posterior section. See Figure 1b. On the opposite side, release the click and close buckle, Figure 1c. Make sure to place the strap and pad where they can be retrieved after the patient is rolled back into the supine position. Then retrieve the strap and pad and engage

the click and close buckle so that the spine is not experiencing an axial load. The patient should always be in the supine position when tightening the Velcro® straps. Achieve a snug fit as seen in Figure 1d.

2. Posterior Thoracic Extension (PTE) Application

In using the Posterior Thoracic Extension, refer back to the LSO/TLSO Patient Application Instruction Manual to Step 2. Before rolling patient into a supine position, secure the PTE as shown in Figure 2. A unique feature of the PTE is its ability to extend past the spine of the scapula. However, the base of the curve should not extend past C7-T1. Once positioned make sure you can retrieve straps before rolling patient back into supine position.



3. Sternal Pad Kit (SPK) Application

In positioning and shaping the Sternal Pad refer to Step #5 in the LSO/TLSO Patient Application Instructions. At this point, you should have predetermined the correct orthosis size for your patient and are ready to attach the SPK. The first step is to loosen the 4 pull straps that tighten the closure. Remove the anterior insert as seen in Figure 3a and slide the Sternal Pad Bar into the notched section of the anterior insert. Position the anterior insert over the anterior fabric as if it were inserted inside the panel, Figure 3b. Next, determine the length of the Sternal Pad Bar. The center of the superior edge of the Sternal Pad Bar should be 1-2" below the sternal notch. See Figure 3c. After proper length is determined, use the two screws included to secure the sternal pad bar to the anterior plastic insert. Insert anterior plastic with attached sternal pad bar back into anterior panel. Place the PTE straps over the shoulders, pass through chafe, and attach back onto the removable hook on both sides as shown in Figure 3d. Once the PTE is positioned, tighten the four pull straps that were loosened to allow the SPK to be applied. The PTE straps should also be tightened and any excess strap trimmed off.

