



Osteoporosis Spinal Orthosis

Single Patient Use Only

Rx Only

IMPORTANT INFORMATION

Please read all instructions, warnings and precautions before use. Correct application is essential for proper functioning of product.

INTENDED USE

The DeRoyal® Osteoporosis Spinal Orthosis is intended to provide trunk support in the sagittal plane for the treatment of hyperkyphosis and osteoporosis related spine deformities.

PRECAUTIONS

This product is to be fitted 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 or healthcare providers involved in the patient's care as well as the patient. Consult your physician (or properly licensed practitioner) immediately if you experience sensation changes, unusual reactions, swelling or increased pain while using this product. Follow the instructions of your physician (or properly licensed practitioner) for length and duration of use.

INSTRUCTIONS FOR USE

Product Preparation

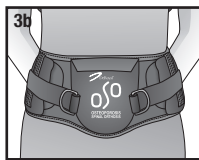
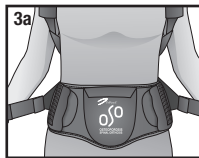
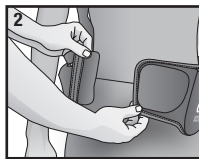
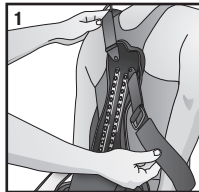
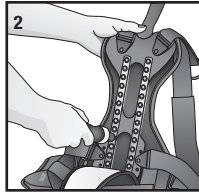
1. Unattach one side of the side closure attachment from the anterior panel and loosen both of the shoulder straps.
2. Open the flap on the posterior panel. Using the tool provided, or



other 1/8" hex tool, ensure that all adjustment screws on the Noble Hinge™ (posterior panel) are slightly loosened and in the disengaged position.

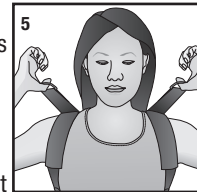
Product Application

1. Patient should be standing for product application. Insert arms through the shoulder straps, one arm at a time, similar to a backpack or jacket application.
2. Secure the side closure attachment by applying the hook strip to the anterior panel. Ensure the side closure attachments are symmetrical to one another and are equal distance from the center.
3. At each side of the orthosis the patient will find dynamic pull straps. Instruct the patient to pull each strap forward at the same time to tighten the brace evenly and to prevent any torque to the lumbar spine. Once a comfortable level of compression is achieved, secure the pull straps on the anterior panel of the orthosis.



4. To ensure proper placement, the anterior panel should sit directly above the symphysis pubis. The posterior panel should sit directly above the sacrococcygeal junction and extend to the scapular spine. Readjust as needed.

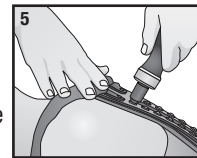
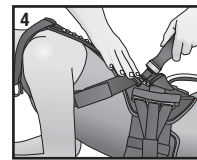
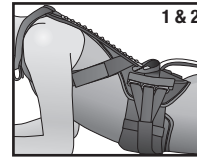
5. Instruct the patient to tighten the shoulder straps by grabbing the D-rings located at their shoulders and pulling forward and down.



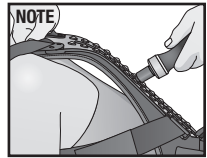
6. Once a comfortable amount of compression is achieved, secure the straps on the shoulder pads.

Adjusting the Noble Hinge™

1. To make the proper adjustments to the Noble Hinge™ (posterior panel), position the patient into a prone position (on stomach) on a fitting table.
 2. Ensure posterior flap is open to expose the Noble Hinge™.
 3. Apply slight pressure to the hinge in the lumbar region to ensure the hinge follows the patient's spinal curvature.
 4. Using the hex tool, tighten the adjustment screws on both sides in the lumbar region. When tightening, begin with the bottom screws and work up the spine. As screws are tightened moving up the spine, the area below will be locked into place.
 5. Continue following the curvature of the spine over the thoracic region, tightening the adjustment screws on both sides to the top of the posterior panel.
- Note:** A "preload" can also be achieved by leaving a 1/2" – 1" gap between the



patient and the posterior panel from the apex of the kyphotic angle and above. This is achieved by placing a hand under the top of the orthosis while tightening the adjustment screws in this region.

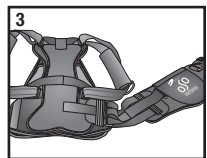
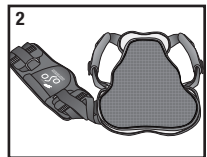
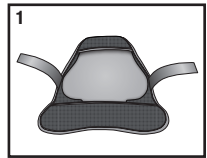


6. Once the orthosis has been locked into the correct position, close the posterior flap and assist the patient into a supine position. Knees should be comfortably bent or flexed and hips should be parallel to the shoulders.
7. Ensure that the anterior panel is in the correct position then have the patient repeat the strap tightening procedure for the side closures and shoulder straps.
8. Assist the patient into a standing position and check for a proper fit.

ADDITIONAL OPTIONS AND ADJUSTMENTS

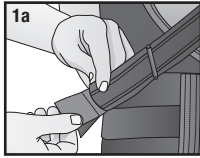
Applying the Flexible Posterior Panel

1. For additional support and comfort, the preformed flexible panel can be added to the posterior panel.
2. While the patient is not wearing the orthosis, align the flexible panel flush to the bottom edge of the posterior panel and centered.
3. Place the two pieces of hook around the frame of the posterior panel and attach to the posterior flap to secure.
4. Reapply the orthosis to the patient and check for a proper fit.

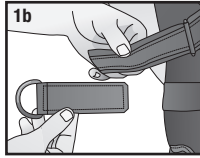


Strapping Adjustments

1. An additional strapping configuration can be obtained by switching out the Y-tabs on the shoulder straps with the provided D-ring Y-tabs.

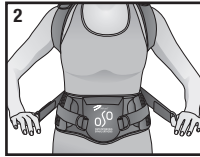


2. The patient can then tighten the shoulder straps from the lower portion by grabbing the D-rings and pulling the straps down and forward, and attaching them to the anterior panel.

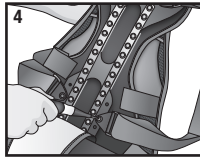


If choosing this option, ensure proper fit before trimming straps.

3. The length of the shoulder straps can also be adjusted. To adjust, remove the Y-tab, trim excess material and reapply Y-tab.



4. If the patient feels any discomfort under their arms from the shoulder strapping, the lower attachment point of the shoulder straps can also be adjusted. Choose one of three positions for the most appropriate fit. Loosen the screw and move the components to the desired location and retighten screw. Repeat on opposite side.



CARE INSTRUCTIONS

Remove Noble Hinge™, anterior insert and flexible posterior panel. Hand wash, lukewarm water, mild detergent, air dry.

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.

SIZING CHART

| Size | Waist Circumference | Short | Regular | Tall |
|--------|---------------------|-----------|-------------|-----------|
| | | < 5'7" | 5'5" - 6'1" | > 6' |
| Small | 26"-34" | OPB3333-S | OPB3333-R | OPB3333-T |
| Medium | 34"-41" | OPB3433-S | OPB3433-R | OPB3433-T |
| Large | 41"-48" | OPB3533-S | OPB3533-R | OPB3533-T |