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(2)



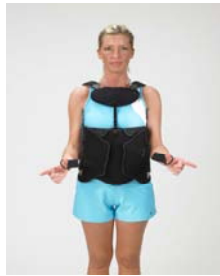
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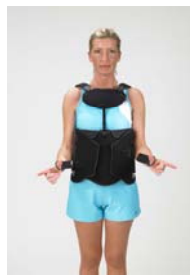
(5a)



(5b)



(6)



(7)



APPLICATION INFORMATION:

INITIAL FITTING: (To be performed by a licensed medical professional only) (Make sure to wear cotton T-shirt underneath)

- 1) While Standing, open both of the anterior/side Velcro® panels. With the shoulder straps attached and extend to maximum length, lift the TLSO over the patient's head. Lower the TLSO into position, keeping the patient's head between the two shoulder straps. Let the Anterior Panel and Posterior Panel hang over the torso. Be sure to maintain the bottom edge of the anterior panel aligned with the pubic symphysis and the posterior panel shoulder aligned between the scapular spine and mid-gluteal fold.
- 2) To adjust the shoulder straps, release and adjust the posterior Velcro® straps first. Adjust to desired length. Be sure to maintain the bottom edge of the anterior panel with the pubic symphysis and the posterior panel between the scapular spine and mid-gluteal fold. Use the anterior straps (closest to the quick release buckle) for fine-adjustments.
- 3) Now close both of the compression side panels so that they are even and comfortably snug on the Anterior panel.
- 4) Adjust the STERNAL Y-Bar while the patient is SEATED in prescribed posture. Pull up on the black release button (on top portion of Anterior panel) to release the sternal bar lock. Slide the sternal Y-bar into position, so that the top of the sternal pad fits ½" below the sternal notch. Be sure to keep the bottom edge of the Anterior Panel aligned with the "Pubic Symphysis". (If desired, the sternal strut may be locked in place by unscrewing the provided sternal lock-out screw located 2" below the release button. Remove the screw in its current location and place into the hole that is in-line with the strut).
- 5) To activate compression, grasp each of the two pull-handles, simultaneously pull both straight out in front of the torso. After the desired level of compression has been achieved, fasten the pull handles to anterior portion of the compression panels. To avoid tangling of the lacer cords, position one pull handle higher up on the side panel than the other. Adjust compression after five minutes, then re-adjusting as needed.

REMOVING TLSO

- 6) Lift and release both pull-handles on the compression panels simultaneously to relieve compression. To assist the process, push out the abdomen, allowing the handles to slide back into their original location.
- 7) Now release one side of the compression side panel and unclip the quick release buckle on the same side.

RE-APPLYING TLSO:

- 8) Place the BOA Duel back into proper position. Re-attach the quick release buckle on the shoulder strap. Close anterior panel and compression side panels as instructed in step #5 above.

CUSTOMIZING TLSO: (To be performed by a licensed medical professional only)

- 9) The rigid, anterior and posterior panels are made from thermoformable plastic, so they can be heat formed or cut to provide a custom fit.
 - a) Remove the rigid, thermoformable plastic anterior and/or posterior panels from their respective soft pockets.
 - b) Panels may be customized by thermo-forming and /or trimming.
- 10) The Sternal Bar may be bent as needed by using a stable edged of a table. Using both hands, bend the bar in a slow and controlled fashion to adjust to desired degree of offset. The stock sternal Y-bar is set at 15°.
- 11) The side compression panels can be removed and reattached at different locations to ensure a proper fit.

CLEANING INSTRUCTIONS: Separate the thermoformable panels and sternal pad cover from the device before cleaning. The plastic parts, pad, and TLSO device can be hand washed with mild soap in cold water. Rinse thoroughly, dry with towel then AIR DRY separately. If not rinsed thoroughly, soap residue may cause skin irritation and material breakdown.

WARRANTY: Breg, Inc. will repair or replace all or part of the unit and its accessories for material or workmanship defects for a period of three months from the date of sale.

For single patient use only.

Rx Only

NOTICE: WHILE EVERY EFFORT HAS BEEN MADE IN STATE-OF-THE-ART TECHNIQUES TO OBTAIN THE MAXIMUM COMPATIBILITY OF FUNCTION, STRENGTH, DURABILITY AND COMFORT, THIS DEVICE IS ONLY ONE ELEMENT IN THE OVERALL TREATMENT PROGRAM ADMINISTERED BY A MEDICAL PROFESSIONAL. THERE IS NO GUARANTEE THAT INJURY WILL BE PREVENTED THROUGH THE USE OF THIS PRODUCT.

CAUTION: FEDERAL LAW (U.S.A) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED HEALTH CARE PROFESSIONAL.

BOA Duel TLSO

BEFORE USING THE DEVICE, PLEASE READ THE FOLLOWING INSTRUCTIONS COMPLETELY AND CAREFULLY. CORRECT APPLICATION IS IMPORTANT FOR THE PROPER FUNCTIONING OF THE DEVICE.

INTENDED USE/INDICATIONS: Acute and Chronic low back pain, post-operative support, spondylolisthesis, fusion, compression fractures.

CONTRAINDICATIONS: Pregnancy and Circulation, Pulmonary, Cardiovascular or Skeletal conditions which have risk to be made worse as a result of compression and /or pressure.

WARNINGS AND PRECAUTIONS: If you experience any pain, swelling, sensation changes, or any unusual reactions while using this product, consult your medical professional immediately. If any fraying or deterioration of the cording is noticed, discontinue use.

Distributed By:



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