

Care Instructions:



Warnings

- Carefully read use/care instructions and warnings prior to use.
- If increased pain, swelling, sensation changes, or any adverse reactions are experienced while using this product, immediately consult your medical professional.
- For single patient use only.

LIMITED WARRANTY

Thuasne USA warrants to the original purchaser that this product is free from defects in materials and workmanship. Normal wear and tear during the use of a product is not considered a defect. This Limited Warranty is effective from the date of delivery to the original purchaser for up to 6 months.

This warranty does not apply if this product;

- (1) has been altered in any way;
- (2) was not purchased from Thuasne USA or one of its authorized distributors;
- (3) is not used in accordance with Thuasne USA's Instructions for Use (IFU).

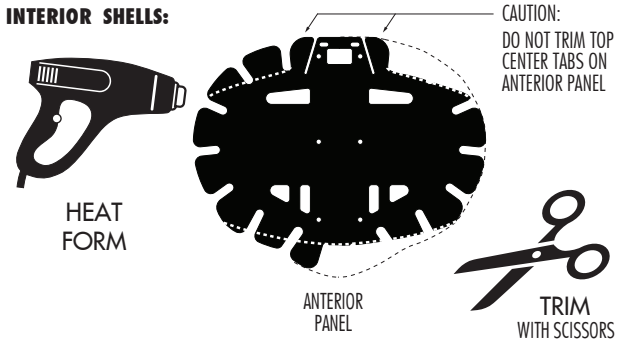
Under this Limited Warranty Thuasne USA's sole obligation shall be to repair or replace the defective product or associated part(s) at no charge. This Limited Warranty does not cover damage as a result of mishandling, accidents, improper use or alteration of the product. This warranty is in place of all other warranties, either express or implied, including but not limited to warranties of merchantability or fitness for a particular purpose. Thuasne USA shall not be liable under this or any implied warranty for any personal injury, property damage, or special, incidental, or consequential damages arising out of, related, or incidental to the use of the product even if Thuasne USA has been informed of the prospect of such possible loss or damage, unless state law otherwise prohibits this exclusion. User should seek advice from their healthcare provider immediately if user encounters any kind of adverse reaction related to the use of this product. User should consult with their healthcare provider with any questions or concerns relating to the proper use of this product for their specific medical condition. **IMPORTANT-** Read all Instructions for Use (IFU) and any other associated materials to ensure proper use.

4.0 MODIFICATIONS

The rigid back panel, anterior panel, lateral panels and wing shells can be trimmed and heat modified to adjust lordosis, add scapula reliefs or create flares. The steel upright can be bent to match anatomical contours and the wings can be attached to the Crescent Connectors at up to 5 degree angles up or down to accommodate various waist to hip ratios.

4.1

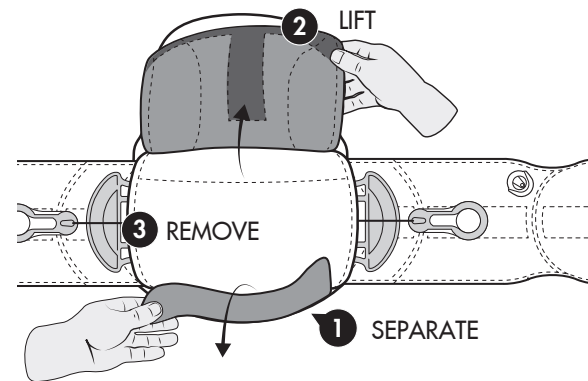
INTERIOR SHELLS:



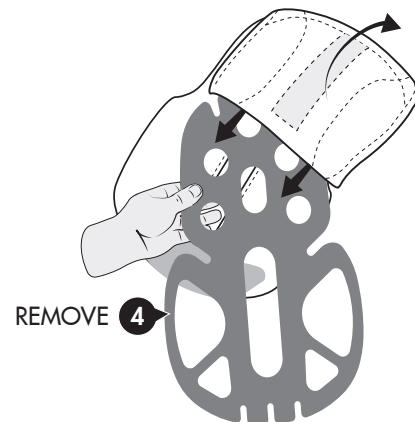
4.2

BACK PANEL REMOVAL FOR MODIFICATION:

Separate the cover at the base of the back panel (1). Lift cover (2). Remove the LSO assembly (3).



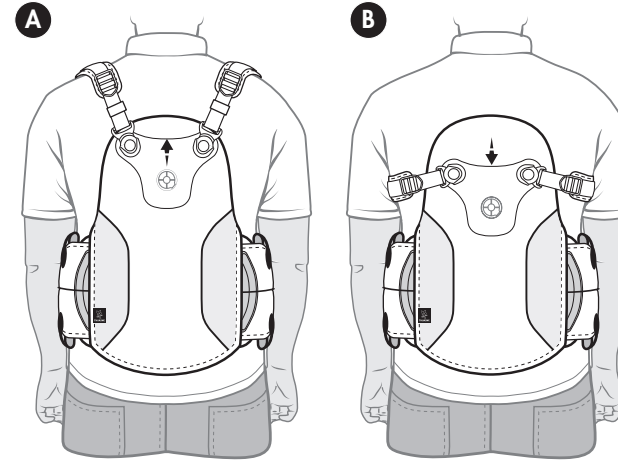
Remove plastic panel from material sleeve (4).



4.3

ADJUST FOR UNDER AXILLA STRAPPING OPTION

The posterior clip attachment piece can be detached and repositioned to accommodate proper positioning for over the shoulder strap placement (A) or the under axilla strapping option (B).

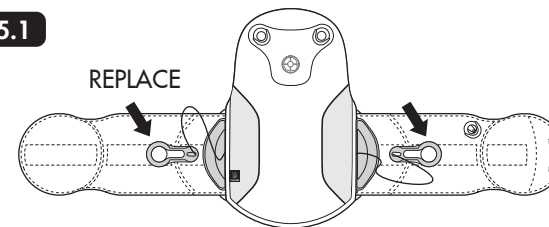


(Also see Section 3.4 for anterior view)

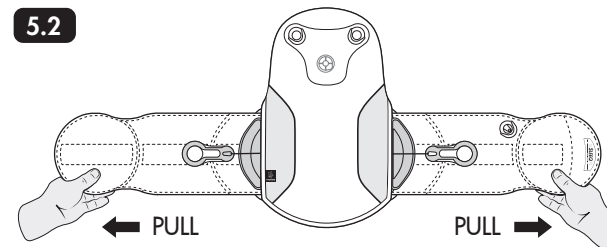
5.0 RESET

When removing the brace, always replace Pull Tabs to ready position (5.1) Lay brace on a flat surface then pull each Wing outward to reset the tightening mechanism (5.2).

5.1



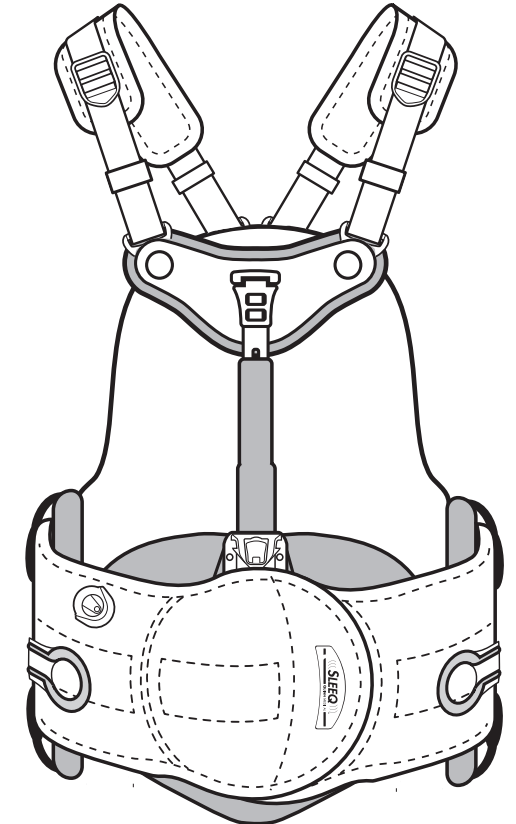
5.2



(((SLEEQ)))
spinal • therapy • system

INSTRUCTIONS FOR USE

SLEEQ MAX™ TLSO



Premium Post-Op/Post-Injury TLSO
PDAC Approved L0464

THUASNE



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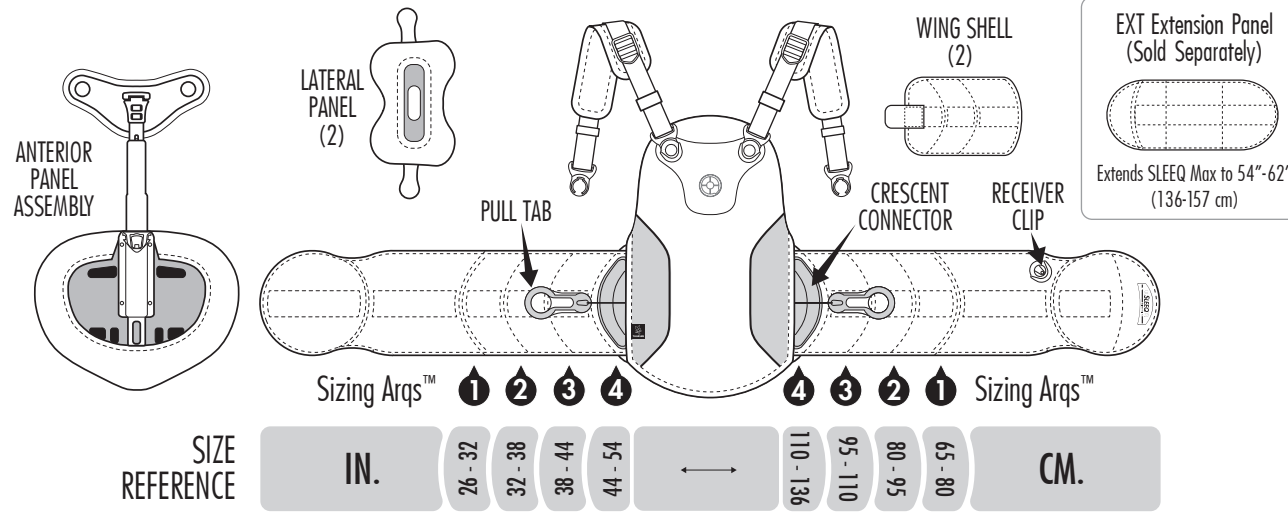
SLEEQ MAX™ TLSO

Indications:

Sagittal/coronal/transverse plane motion restriction; increased intracavitary pressure to reduce spine & disc loading; mechanical or discogenic thoracic/lumbar & extremity pain; post-operative spinal stabilization/fusion; degenerative disc disease; post-injury to facilitate healing; spondylolysis; spinal stenosis; spondylolisthesis; spondylosis; laminectomy; discectomy; facet syndrome; spinal muscle weakness; arthritis; low back sprains and strains; prophylactic back support.

Contraindications:

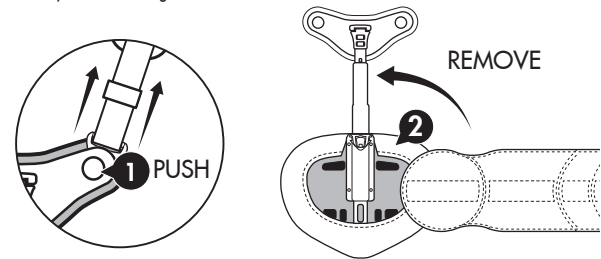
- SLEEQ braces are contraindicated for women who are pregnant.
- SLEEQ braces are contraindicated for persons with circulatory, pulmonary, cardiovascular or other conditions where increased abdominal pressure would be of concern.



1.0 SIZING

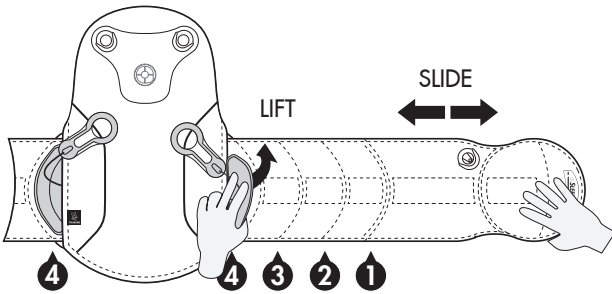
1.1

Prepare to Fit: Unclip straps (1) from sternal plate and remove anterior panel assembly (2) from wing.



1.2

Adjust Circumference: Measure waist circumference and reference size chart above for proper alignment.

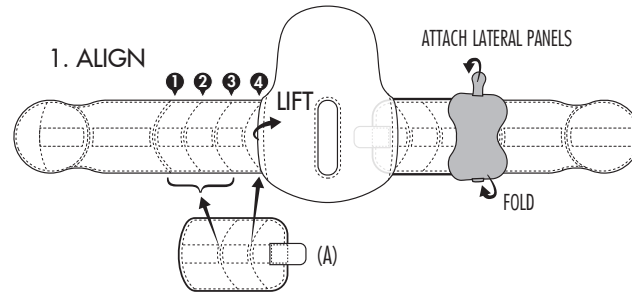


Move right wing in or out and align Crescent Connector to appropriate Sizing Arq. Repeat on left wing.

2.0 ATTACH WING SHELLS & LATERAL PANELS

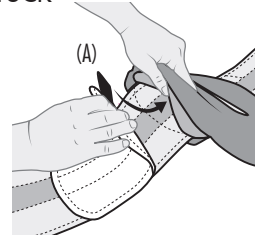
2.1

- **ALIGN** wing shell on wing with sew line Arq on shell aligned to sew line Arc on wing where crescent connector is attached from step 1.2 (see arrows below).

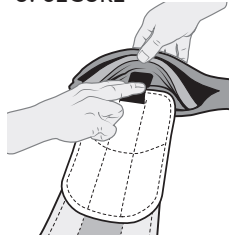


Note: For sizes 1, 2, 3, use center Arq on wing shell, and for size 4 use posterior Arq near Velcro tab (A).

2. TUCK



3. SECURE



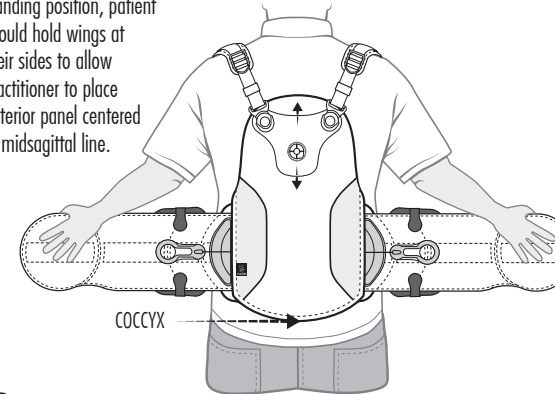
- Attach wing shell Velcro to inside of wing and secure Velcro tab (A) at inner end of wing inside back panel.
- **TUCK** and attach wing shell inside back panel as shown above.
- **SECURE** Velcro tab (A) to inner end of wing inside back panel.
- Repeat on other side.

3.0 ADJUST & FIT

3.1

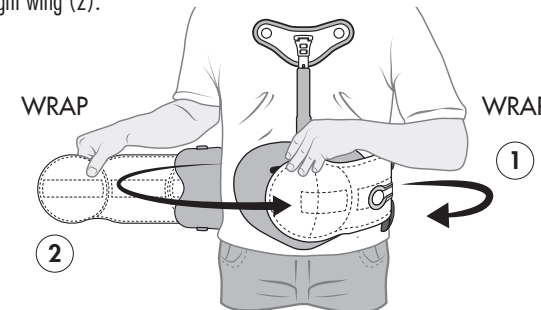
- Position the brace with lower edge of back panel at coccyx level.

Note: When fitting in standing position, patient should hold wings at their sides to allow practitioner to place anterior panel centered at midsagittal line.



3.2

- Position the anterior panel with lower edge just above symphysis pubis level.
- Wrap the left wing (1) and attach to Velcro on the anterior panel, then wrap right wing (2).



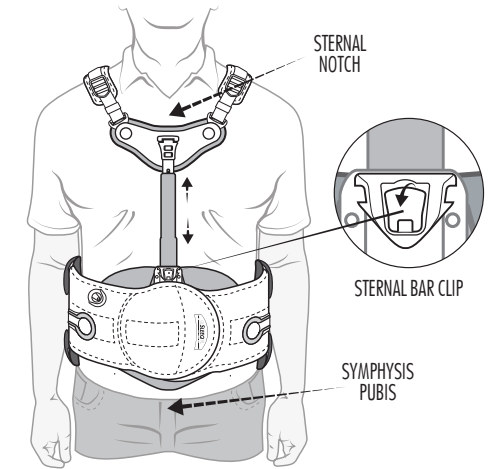
3.3

Tighten brace: Detach pull-tabs, pull out & away from the body then re-attach anywhere onto the wings. (See section 5.0 for resetting the tightening mechanism)

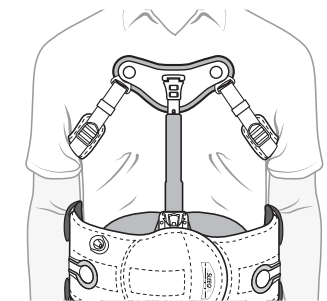
3.4

Sternal Bar: Open sternal bar clip to telescope sternal bar to desired height, then close clip to lock in place.

- Standard practice is to have sternal plate 1 to 2" below sternal notch when standing and 1/2" below when seated or supine.
- If there is a gap between sternal pad and chest or there is too much pressure on the chest, the sternal bar can be bent to achieve proper positioning with bending irons or over the edge of a table. **Note:** Bend sternal bar above toothed area.



UNDER AXILLA STRAPPING OPTION



(Also see MODIFICATIONS section 4.3)

- Attach strap clips into sternal plate and adjust straps so that strap padding is centered on the anatomy.
- The strap ends should be tucked into the anterior strap clips and posterior strap loops. Strap ends can also be cut and heat sealed.



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