



THUASNE

SLEEQ[®] MAX

Premium Post-Op/Post-Injury TLSO

INSTRUCTIONS FOR USE

PURPOSE:

Spinal orthosis for active relief and correction of the lumbar and the thoracic spine in the sagittal plane. This device is intended only for the treatment of the indications listed and for patients whose measurements correspond to the sizing table.

PROPERTIES:

- Pulley system for individual power transmission
- Pliable material
- Reinforcing elements in the abdominal area

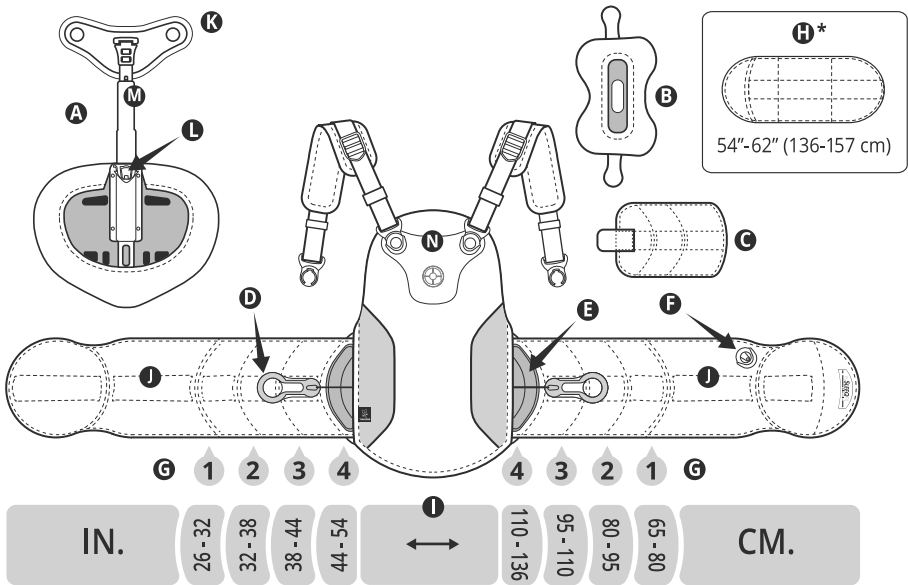
INDICATIONS:

Sagittal/coronal/transverse plane motion restriction; stable vertebral fracture; 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:

- Do not use the product if the diagnosis has not been confirmed
- Do not use in the event of known allergy to any of the components
- Do not apply the product in direct contact with broken skin
- Pregnancy
- Persons with circulatory, cardiovascular or other conditions where increased abdominal pressure would be of concern

1.0 BRACE COMPONENTS



BRACE COMPONENTS

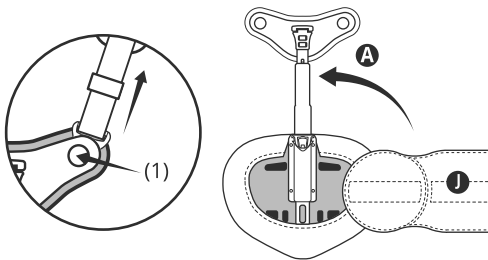
- A** ANTERIOR PANEL ASSEMBLY
- B** LATERAL PANEL (2)
- C** WING SHELL (2)
- D** PULL TAB

- E** VELCRO® CONNECTOR
- F** STRAP CLIP
- G** SIZING ARCS
- H** EXT. EXTENSION PANEL
**(Sold Separately)*
- I** SIZING GUIDE

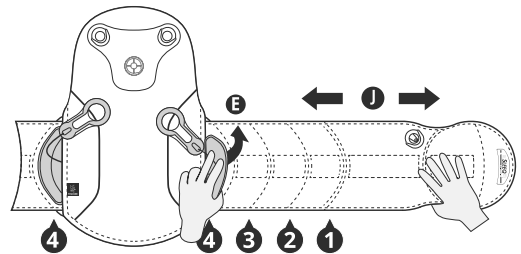
- J** WING
- K** STERNAL PLATE
- L** STERNAL BAR CLIP
- M** STERNAL BAR
- N** STRAP ANCHOR

2.0 SIZING

2.1 PREPARE TO FIT: Push button (1) Remove anterior panel **A**.

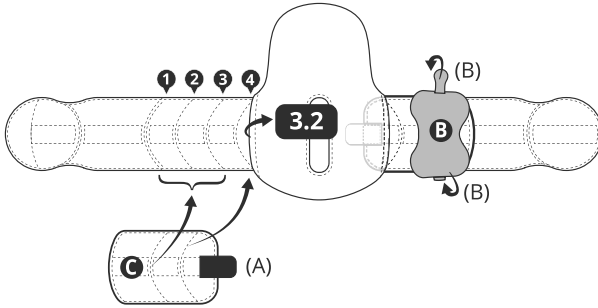


2.2 ADJUST CIRCUMFERENCE: Measure waist and see Sizing Guide (1.0).

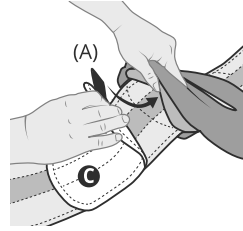


3.0 ATTACH WING SHELLS & LATERAL PANELS

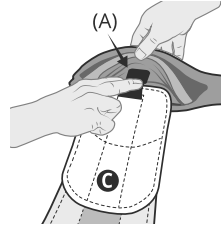
- 3.1** ALIGN wing shell **C** sew line Arcs to sew line Arcs on wing. **Note:** For size (4) use posterior Arc near Velcro tab **(A)**.



- 3.2** TUCK wing shell **C** inside back panel.



- 3.3** SECURE tab **(A)** to wing inside back panel. - Repeat on opposite side.

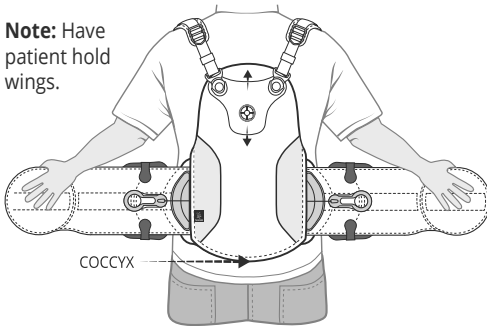


- 3.4** ALIGN Lateral Panel **(B)**. Attach by folding over both tabs **(B)**.

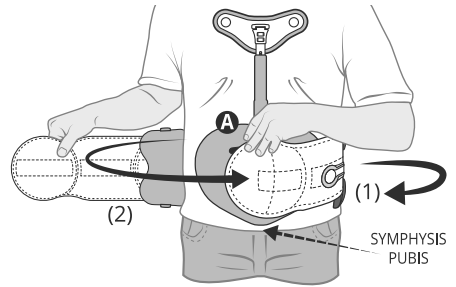
4.0 ADJUST AND FIT

- 4.1** POSITION brace at coccyx level.

Note: Have patient hold wings.



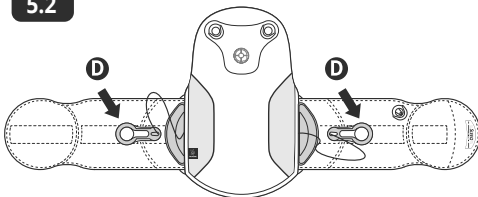
- 4.2** POSITION Anterior Panel **(A)**. Wrap wing **(1)** and attach to anterior panel. Wrap wing **(2)** and secure.



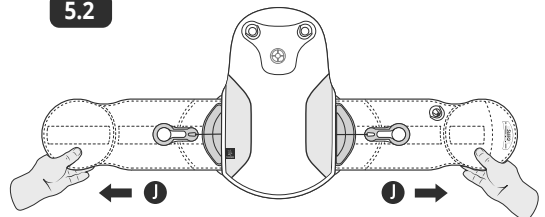
5.0 Reset

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

- 5.2**



- 5.2**



5.0 ADJUST AND FIT (Continued)

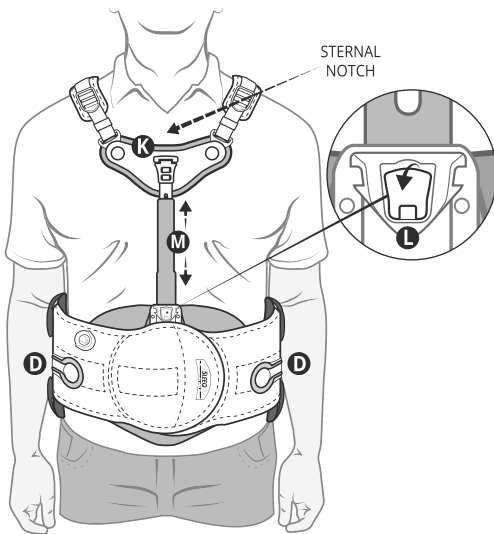
5.3 TIGHTEN BRACE: Move pull-tabs **D** anteriorly and re-attach.

5.4 STERNAL BAR: Open sternal bar clip **L** to adjust height, then close clip to lock.

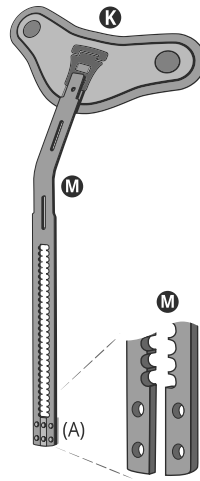
Sternal plate **K** is 1 to 2" (25-50cm) below Sternal Notch when standing and 1/2" (23cm) below when seated.

Sternal bar **M** can be bent to achieve proper fit with bending irons or over the edge of a table.

Note: Only bend Sternal Bar above toothed area.



5.3 REMOVING OR REPLACING STERNAL BAR (with available Short Bar option)



- Remove anterior panel from wing.
- Release sternal bar clip **L** and lower bar.
- Remove retainer clip **(A)** by pushing through bar while bending bar away from panel.
- Pull bar **M** up to remove from bar slot.
- Replace bar, or (optional Short Bar) into bar slot and replace retainer clip **(A)**.

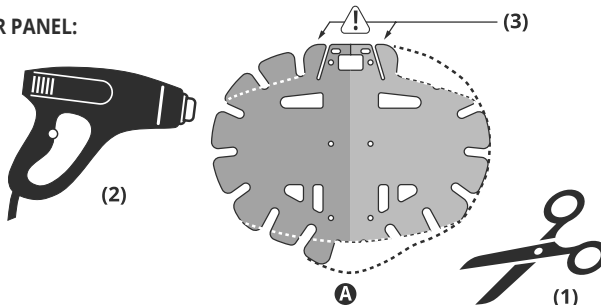
Note:
Clip **(A)** must be replaced on the panel side of bar.

6.0 Modifications

The Back Panel, Anterior Panel **A** (shown), Lateral Panels and Wing Shells can be trimmed with scissors **(1)** and heat modified **(2)** to adjust lordosis, add scapula reliefs or create flares. The steel Sternal Bar **M** can be bent to match anatomical contours and the wings can be attached to the Velcro® Connectors at up to 5 degree angles up or down to accommodate various waist to hip ratios.

CAUTION: Do not trim top center tabs **(3)** on anterior panel.

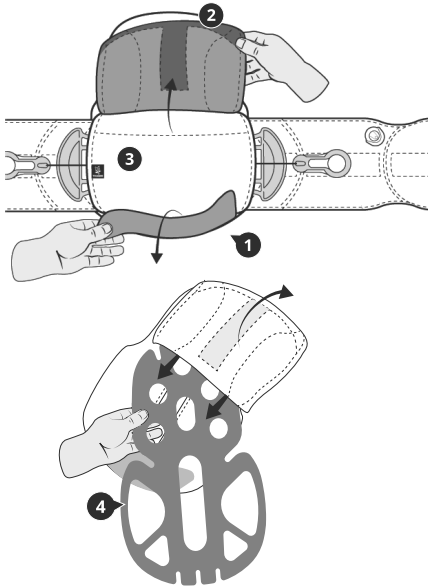
6.1 ANTERIOR PANEL:



6.0 Modifications (Continued)

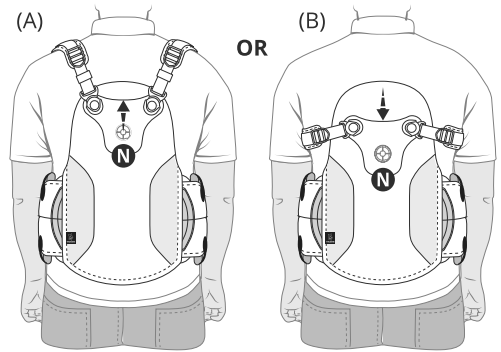
6.2 BACK PANEL REMOVAL FOR MODIFICATION:

(1) Open cover at the base of the back panel. (2) Lift cover. (3) Remove the LSO assembly. (4) Remove plastic panel.



6.3 ADJUST FOR OVER THE SHOULDER OR UNDER AXILLA STRAPPING OPTION

Detach Strap Anchor (N) and reposition up for over the shoulder (A) or down for under axilla strap placement (B).



SIDE EFFECTS:

This device can cause skin reactions (redness, itching, burns, blisters...) or wounds of various degrees of severity.

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.

PRECAUTIONS:

Follow the advice of the professional who prescribed or supplied the product. Consult your professional if discomfort occurs. Store at room temperature, preferably in its original packaging. For hygiene and performance reasons, do not re-use the product for another patient. Any serious incident that occurs in connection with the product must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient are/is domiciled.

CARE:

Do not use any cleaning agents, conditioners or aggressive products (containing chlorine). Squeeze out the water thoroughly. Dry away from any heat sources.



MATERIAL COMPOSITION:

Nylon, Polyester, Polypropylene, synthetic rubber (latex-free), neoprene, stainless steel, brass, aluminum.

DISPOSAL:

Dispose of in accordance with local regulations.

KEEP THIS INSTRUCTION LEAFLET.

Limited Warranty:

Thuasne USA will repair or replace all or part of the unit and its accessories for material or workmanship defects for a period of six months from the date of sale.

www.thuasne.com

www.thuasne.com/global-contact



4615 Shepard Street, Bakersfield, CA 93313, USA
800.432.3466 • ThuasneUSA.com



Medical Device



Single Patient