

SLEEQ® FLEX

Spinal orthosis for active relief and correction of the lumbar and the thoracic spine in the sagittal plane

INSTRUCTIONS FOR USE

Purpose:

The Sleeq Flex spinal orthosis is an orthosis for active relief and correction of the lumbar and the thoracic spine in the sagittal plane. The orthosis may only be used for lower spine treatment. 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:

- · Stable, osteoporotic vertebral fractures
- · Kyphosis with poor shoulder posture
- · Spondylitis
- · Morbus Bechterew (Arthritis)

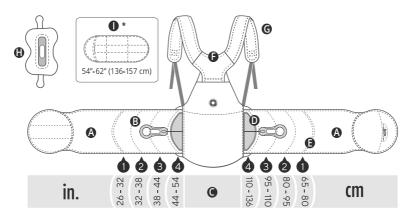
Contraindications:

- · Unstable vertebral fractures
- · 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

Side Effects:

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

1.0 BRACE COMPONENTS



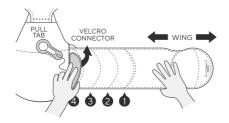
BRACE COMPONENTS

- **A** WING
- **B** PULL TAB
- © SIZING GUIDE
- **●** VELCRO® CONNECTOR
- **(B)** SIZING ARCS
- THORACARE SUPPORT
- **G** SHOULDER STRAPS
- ♠ LATERAL PANEL (2)

EXT-EXTENSION PANEL
 *(Sold Separately)

2.0 SIZING

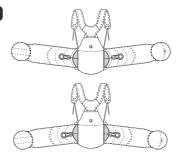
2.1



Size Determination and Adjustment

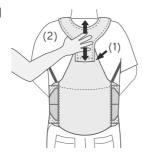
Refer to Sizing Guide **(C)** to determine wing positioning. Detach Pull Tab, lift Velcro Connnector, slide wing in or out to adjust. Press down Velcro Connector. Repeat on opposite wing panel.

2.2



Customize for waist to hip disparities: Follow procedures from section 2.1-2 to release wing. Angle wings to up or down to address disparities and pendulous abdomen.





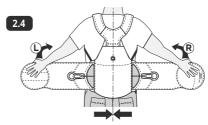
Adjust Height

With brace donned (1) Separate base of ThoraCare Support (2) Adjust upward or downward so that top center of ThoraCare support aligns at T3/scapular spine level

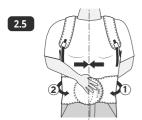
2.0 Donning/Doffing



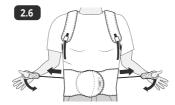
First loosen the shoulder straps, don brace over the shoulders.



Adjust "ThoraCare" strap up or down to accommodate larger patients. Position brace to desired height (T-3 / scapular spine level).



(1) Wrap left wing to align with medial line of abdomen.
(2) Wrap right wing and attach at mid-line.



Detach pull tabs and adjust compression by pulling forward and re-attaching the pull tabs to the front of the brace.

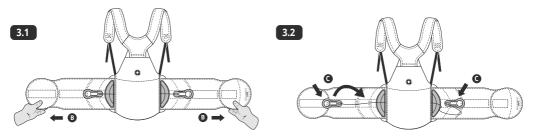


Pull downward on straps to tighten shoulder harness.

Removing Brace:

Loosen shoulder straps, detach pull tabs from front of brace and re-attach laterally. Separate wings and slide brace off over the shoulders. Reset brace.

3.0 Reset



When removing the brace, always replace Pull Tabs **①** to ready position (3.1). Lay brace on a flat surface then pull both Wings **①** outward to reset the tightening mechanism (3.2).

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.











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)

Disposal:

Dispose of in accordance with local regulations.

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.

KEEP THESE INSTRUCTION

www.thuasne.com

www.thuasne.com/global-contact







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Medical Device

Single Patient