

# ISOFORM® TLSO

## Clinician Application Instructions

BEFORE USING THE DEVICE, PLEASE READ THE INSTRUCTIONS FOR USE COMPLETELY AND CAREFULLY. CORRECT APPLICATION IS VITAL TO THE PROPER FUNCTIONING OF THE DEVICE

### SIZING:

#### Size the Brace

Begin by measuring the circumference of the patient approximately 1" (2.5cm) above the widest part of the hips. Then, match the patient's size to the sizing chart below. If patient's circumferential measurement is between sizes, select the larger brace.

SIZE	CIRCUMFERENTIAL MEASUREMENT
S/M	Less than 48" (122 cm)
L/XL	49" - 60" (125 cm - 152 cm)

**NOTE:** It is not uncommon for the patient to experience post-surgical swelling, followed by weight loss (10-20+ lbs/4.5-9.1 kg). The TLSO brace is designed with two (2) adjustable belts which can be easily sized to achieve optimal fit.

### FITTING:

#### Prepare Brace

Open both of the anterior/side hook and loop panels. Keep the shoulder straps attached and extend to maximum length. (Figure A)

### APPLICATION:

#### Step 1. Apply Brace

With patient standing, 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 front/anterior panel and back/posterior panel hang over the torso.

#### Step 2. Position Panels

Close both of the compression side panels so that they are even and comfortably snug on the Anterior Panel (Figure B).

#### Step 3. Adjust Sternal Y-Bar

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 1/2" below the sternal notch. Be sure to keep the bottom edge of the Anterior Panel aligned with the pubic symphysis (Figure C).

#### Step 4. Adjust Shoulder Straps

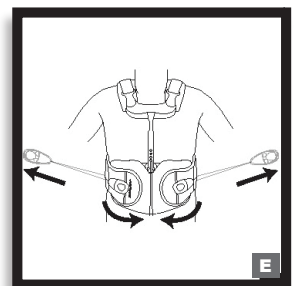
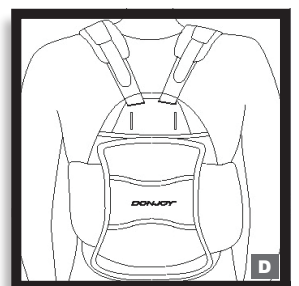
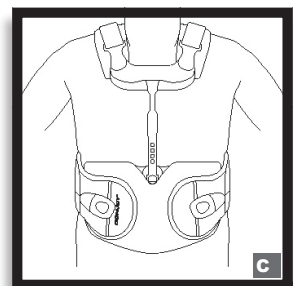
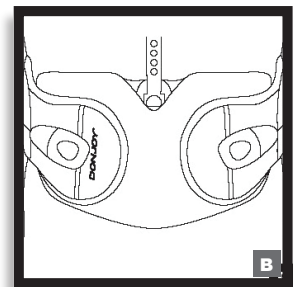
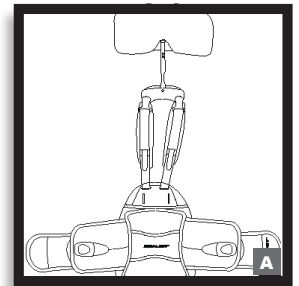
To adjust the shoulder straps, release and adjust the posterior hook and loop straps first. Adjust to desired length. Be sure to maintain the bottom edge of front panel with the pubic bone and the back panel between shoulder blades and lower back (Figure D). **Underarm shoulder strap option:** Release the posterior hook and loop from the back panel and insert into lateral strap slot. Adjust to desired length.

#### Step 5. Activate Compression

Grasp pull-handle and pull straight out from the torso. After the desired level of compression has been achieved, fasten the pull handle to anterior portion of the compression panels. Adjust compression after five minutes, then re-adjusting as needed (Figure E).

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

- **Waist Belt:** If needed, to modify the waist belt, adjust the side panels by un-hooking the hook and loop on the backpanel and moving panels more center for a smaller waist, or closer to the edge of the back panel for a larger waist.
- **Shoulder Straps:** If needed, the extra length in the straps can be trimmed with scissors.
- **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°.



## BRACE REMOVAL:

1. Release the compression handles and remove one of the shoulder straps.
2. Release one side of the side panel from front panel and slide the orthosis off the other shoulder like removing a jacket or backpack.

## HOT/COLD PACK (sold separately):

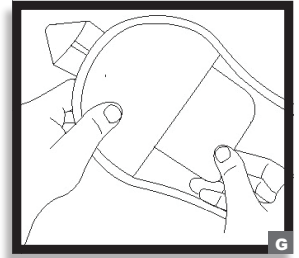
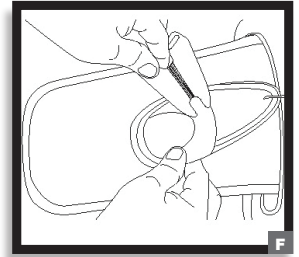
Follow instructions on hot/cold pack. Insert hot/cold pack into pocket and adhere to back panel.

## INSERT/REMOVE FRONT PANEL:

1. Open inside panel pocket. Remove semi-rigid panel. (Figure G)
2. Open inside panel pocket and insert semi-rigid panel.

## ADJUSTING PULL TAB LENGTH (OPTIONAL):

1. Remove lace spool from the pull tab pocket and wind lace around the spool to shorten the length of the pull tab. Unwind lace from the spool to lengthen the pull tab. (Figure F)
2. Insert lace spool back into pull tab pocket.



## CLEANING INSTRUCTIONS:

Separate the brace's removable REAR PANEL before cleaning. Hand wash in cold water, less than 86°F (30°C), using mild soap. Air dry.

NOTE: If not rinsed thoroughly, residual soap may cause irritation and deteriorate material.

- Do NOT iron
- Do NOT tumble dry
- Do NOT bleach.

## INTENDED USER PROFILE:

The user should be able to: Read and understand the directions, warnings and cautions.

## INTENDED USE/INDICATIONS:

The Isoform® TLSO brace is designed to support and stabilize the spine for acute pain relief through postural extension alignment and may be suitable for people with compression fractures of the thoracic spine, osteoporosis, thoracic mechanical pain and kyphosis.

**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 CAUTIONS:

If you experience any pain, swelling, sensation changes, excessive discoloration, irritation to the skin or any unusual reaction while using this product, consult your medical professional. If any distortion of the support panels, fraying or deterioration of lace cables is noticed, discontinue use. Brace is intended to be worn over clothing. Brace should be appropriately sized to the patient to ensure proper support and function. If the brace does not fit properly, it may be adjusted by a healthcare professional. Care should be taken with patients, especially the elderly, not to apply the brace too tightly, which MAY cause excessive pressure. Patients should be instructed on appropriate tensioning during ongoing use. Patient should see a healthcare professional for a replacement if a product quality issue occurs within the warranty timeframe. Brace should not be exposed to moisturizers, chemicals, or solvents, as they may affect durability.

## MATERIAL CONTENTS:

Nylon, Polyester, Polyethylene, Polyurethane, Polypropylene, Acrylic, PVC, EVA, Acetal, Aluminum, Steel, Synthetic Rubber, Glass, Calcium Carbonate

## NOT MADE WITH NATURAL RUBBER LATEX

## WARRANTY:

DJO, LLC 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. To the extent the terms of this warranty are inconsistent with local regulations, the provisions of such local regulations will apply.

## RX ONLY. INTENDED FOR SINGLE PATIENT USE.

Individual results may vary. Neither DJO, LLC nor any of its subsidiaries dispense medical advice. The contents of this document do not constitute medical, legal, or any other type of professional advice. Rather, please consult your healthcare professional for information on the courses of treatment, if any, which may be appropriate for you.

