

ISOFORM® Postural Extension

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.

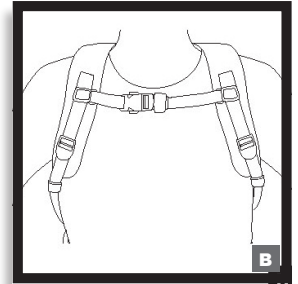
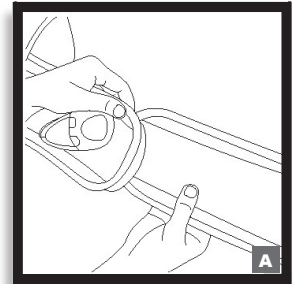
SIZE	CIRCUMFERENTIAL MEASUREMENT
S/M	Less than 48" (122 cm)
L/XL	49" - 60" (125 cm - 152 cm)

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 Postural Extension brace is designed with two (2) adjustable belts which can be easily sized to achieve optimal fit.

FITTING:

Prepare Brace

Prior to applying, un-hook both pull-handles and secure to the side of the belt. Open the belt by unhooking one hook and loop side panel from the front panel. Loosen both shoulder straps at the buckle (Figure A).



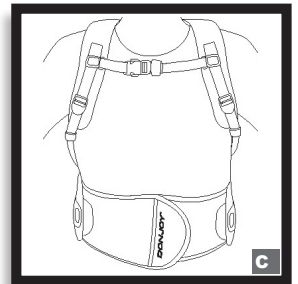
APPLICATION:

Step 1. Apply Brace

Feed one arm through the shoulder strap as if you were applying a backpack; continue with the other arm (Fig. B)

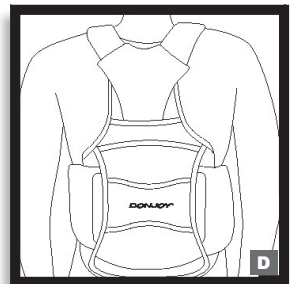
Step 2. Position Panels

Position front/anterior panel with the bottom edge aligned with the pubic bone. Secure hook and loop side panel to front panel (Figure C).



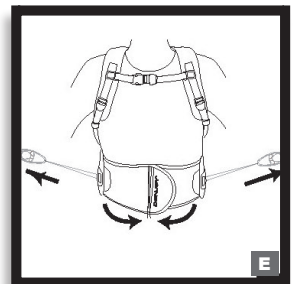
Step 3. Adjust Shoulder Strap

Adjust the shoulder strap length by pulling on the end of the strap. Be sure to maintain the bottom edge of the front panel with the pubic bone and the back panel between the shoulder blades and lower back (Figure D).



Step 4. Tighten Brace

With product in proper position, tighten brace by slipping thumbs through the holes in the pull tabs. Pull away from body. When tightened, secure the pull tabs to the loop exterior (Figure E).



Brace Removal

To Remove, release both pull-handles and one side of the belt. Slide the brace off the other shoulder like removing a backpack.

Brace Re-Application

When reapplying the brace, it is easiest to guide the belt by inserting a hand in the donning mitt pocket.

BRACE ADJUSTMENTS:

- **Waist Belt:** If needed, to modify the waist belt, adjust the side panels by un-hooking the hook and loop on the back panel 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.
- **Back Panel:** Length can be adjusted by loosening the two screws.

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.

ATTACH/REMOVE SOFTGOODS (FOR CLEANING)

Removal of soft goods: Open rear panel pouch and detach waist belt. Remove rigid rear panel from pouch.

Waist belt: Detach rear panel section by unlooping waist belt from lacing guide panel. Remove semi-rigid front panel from inside panel pocket of waist belt. Wash soft goods per instructions below. (Figure H)

Attaching soft goods- Waist belt: Reattach tall, rear panel section by looping waist belt through lacing guide panel. Open inside panel pocket of waist belt and replace semi-rigid front panel. Insert rigid rear panel into pouch. With tall, rear panel pouch open, lay waist belt on top with lacing guide facing up. Close pouch.

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 Postural Extension brace is designed to support and stabilize the spine and may be suitable for people with thoracic spine conditions such as kyphosis, osteoporosis, acute pain, mechanical back pain, compression fractures, strain and mild scoliosis.

CONTRAINDICATIONS: Pregnancy and circulation, pulmonary, cardiovascular or skeletal conditions which have risk to be made worse as a result of compression of the abdomen 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, Polyethylene, Acrylic, PVC, EVA, Acetal, Aluminum, Steel, Synthetic Rubber

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.

