

# SPINAL AND SCOLIOSIS BRACING

- Boston Overlap Brace (BOB)
- Boston Body Jacket



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**R<sub>x</sub> ONLY**



**PRODUCT DESCRIPTION**

The Boston Overlap Brace (BOB) has been clinically proven effective in the treatment of spinal conditions such as spondylolysis and spondylolisthesis, as well as severe back pain, lumbar fusion and fracture.

The Boston Body Jacket is designed to immobilize the thoracic and lumbar spine after trauma or surgery. It is the ideal solution for postoperative patients and trauma situations and can help shorten hospital stays.

**MATERIALS**

The Boston Overlap Brace (BOB) and Boston Body Jacket are made from various types of metal and plastic materials. The plastic materials include low density polyethylene, Polyethylene, Modified Polyethylene or co-polymer.

**INTENDED USE AND INDICATIONS FOR USE**

The Boston Overlap Brace (BOB) and Boston Body Jacket are intended to provide trunk support, improve postural alignment, and enhance functional positioning in patients who are diagnosed with spondylolysis, spondylolisthesis, back pain, post operative lumbar fusion, lumbar fracture(s), and spinal trauma and therefore requiring spinal stabilization and pelvic control.

**CONTRAINDICATIONS**

Do not use the Boston Overlap Brace (BOB) and Boston Body Jacket in the presence of any contraindication.

Contraindications include but are not limited to:

- Material sensitivity documented or suspected.
- Inability to follow treatment protocol and care instructions.

**WARNINGS AND PRECAUTIONS**

- Federal Law restricts the Boston Overlap Brace (BOB) and Boston Body Jacket to sale by, or on the order of, a qualified physician or healthcare provider and is only to be used as prescribed.
- It is very important to prevent skin breakdown (sore, red, raw skin). The skin under the orthosis needs to adjust, especially where the orthosis applies the most pressure.
  - Bathe daily.
  - Pay special attention to the pink areas of your skin where the orthosis pressure is highest.
  - Always wear a Boston T or a snug cotton undershirt (without side seams) under your orthosis.
  - Wear your orthosis as tightly as possible. A loose orthosis may rub and cause skin breakdown.
- Contact your orthotist if any of the following issues arises:
  - Any redness or irritation that does not go away within 30 minutes after removing the orthosis.
  - Complaints of discomfort after the break-in period.
  - Worn-out straps or padding.
  - Cracks or breaks in the plastic.
  - It appears the orthosis is too small due to growth.
- Never use an orthosis that is damaged, broken or not functioning properly. Device damage, wear, and tear would compromise the outcome as well as the use of the orthosis outside the intended use.
- Components may be affected by extreme temperatures, and device breakage could occur in the environment. Monitor and discontinue to use if broken or damaged.
- Lack of adherence to the treatment plan by users based on the plan of care from the clinical care provider or improper use may impact device performance and outcomes.
  - Contributing factors may include:
    - Off label use
    - User errors
    - Product sizing incorrect
    - Poor Fit

Boston Brace International, Inc. does not provide medical treatment, advice or recommendations about the risks and benefits of medical treatment, including treatment that involves the use of the Boston Overlap Brace (BOB) and Boston Body Jacket. This information should be provided solely by the clinical care provider treating your child. If you have questions about your child's treatment, it is important for you to discuss those questions with the appropriate healthcare provider.

## MRI SAFETY INFORMATION

The Boston Overlap Brace (BOB) and Boston Body Jacket have not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Boston Overlap Brace (BOB) and Boston Body Jacket in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

## APPLYING ORTHOSIS INSTRUCTIONS

- **Boston Overlap Brace (BOB)**
  - Start from a standing or sitting position, open your orthosis and wrap loosely around the torso.
  - Lie down on your back and align waist rolls (bumps in the middle of the brace) so that they fall above your hips and below your ribs. The Boston Overlap Brace (BOB) is most effective when applied in the lying down position because lordosis is reduced in the lying down position and the orthosis can be tightened easier.
  - Tighten the middle strap first, then the bottom and top straps.
  - Getting up from a lying position. Log roll onto your side, allowing your feet to hang over the edge while using your lower arm, elbow, and opposite hand to lift your body off the surface to a sitting position.
  - Postoperative Protocol: the patient should lie on their side with hips and knees slightly flexed.
    - Gently open orthosis and slide under the patient.
    - Align waist rolls with patient's waist.
    - Rotate orthosis to ensure proper alignment.
    - Help log roll patient to their back, realign orthosis.
- **Boston Body Jacket**
  - Position brace to determine the top and bottom.
  - Separate anterior (front) and posterior (back) sections. Close the Velcro straps onto themselves to keep from tangling.
  - Begin by laying on your back, then log roll to your most comfortable side. Be sure to move your torso and hips simultaneously.
  - Adjust the back section of the brace so that the waist indentations align above your hips and below your lower rib.
  - While holding the orthosis in place, roll back onto your back. You may need to slightly readjust the posterior section.
  - Place the anterior section of the brace on your torso. This section should overlap with the posterior section. Align both sets of straps and loops.
  - Starting with the middle straps, tighten both sides of the orthosis evenly. Once the middle straps are secure, tighten the top and bottom straps in the same fashion.
  - When advised, roll onto your side allowing your feet to hang over the surface edge. Use your lower arm, elbow, and opposite hand to lift off the surface into a sitting position.



Note: Patient will generally require initial assistance in putting on the orthosis. With their clinical care team's approval, the patient may put the brace on in a standing or sitting position but must always tighten while lying on their back. The orthosis is most effective when applied in the lying down position because lordosis is reduced in the lying down position and the orthosis can be tightened easier.

## SAMPLE WEAR SCHEDULES

Unless otherwise directed, gradually increase the wear time as tolerated. A break-in period is necessary to allow the patient and the patient's skin to get used to the new orthosis. This is important even if you have used an orthosis before. The break-in schedule will vary depending on your level of involvement or any past bracing experiences. A commonly used break-in schedule is provided in the table below. At the end of the break-in period, you should be able to wear the device following your clinician's recommendations.

Stage	Wear Duration Schedule	Instructions	Total Daily Wear Time
1	2 hours on	Check skin between wear	6 hours total wear time
2	4 hours on	Check Skin between wear	12 hours total wear time
3	4 hours on	Check Skin between wear	18-23 hours total wear time

## CARING FOR YOUR SKIN

Check your skin for any irritation or redness each time you remove the orthosis. It is normal to notice some pinkness due to pressure from the plastic and straps. However, any redness should fade within 30 minutes. If redness lasts longer than 30 minutes, contact your orthotist.

## FOLLOW UP

Visits should be scheduled with your orthotist following the clinical care plan.

## CLEANING INSTRUCTIONS

Your orthosis should be cleaned daily with warm water and mild detergent, towel or air dry, and low level disinfected using 70% isopropyl alcohol. Make sure the orthosis is completely dry before putting it on. You can let it air-dry or dry it with a towel. Do not use a hair dryer or any other heat source, as heat can damage the plastic.

## SAFE DISPOSAL

The Boston Overlap Brace (BOB) and Boston Body Jacket can be disposed of in regular trash. None of the components of the devices are recyclable.

## STORAGE AND HANDLING

The Boston Overlap Brace (BOB) and Boston Body Jacket require no special handling during transport or storage.










## REUSING THE DEVICE

All parts were designed to be used by a single patient, multiuse under normal use conditions and as instructed by a clinical care provider.

## IMPORTANT STATEMENT

- Instructions for Use (IFU) manuals are available in English. To obtain a copy of the paper IFU, please call the Customer Service Group at Boston Brace International, Inc. at 1-800-262-2235.
- The manufacturer and distributor are not liable for cases of material damage or personal injury caused by incorrect handling or non-compliance with instructions. Normal use is defined as a single user following intended use.
- If a user and/or patient experiences any serious incident that has occurred in relation to the device, it should be reported to Boston Brace International, Inc.

## SYMBOL LEGEND

Symbol	Meaning	Symbol	Meaning
	Manufacturer		Catalogue Number
	Date of Manufacture		Batch Code
	Single Patient Multiple Use		Non-Sterile
	Consult Instructions for Use or Consult Electronic Instructions for Use		Prescription Device Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Medical Device		