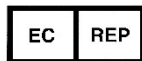


SPINAL AND SCOLIOSIS BRACING

- Boston Original
- Boston RC
- Boston Night Shift
- Boston Soft Spinal Orthosis (SSO)
- Boston 3D
- Boston Baby
- Boston Kyphosis Brace



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PRODUCT DESCRIPTION

The Spinal and Scoliosis Bracing, including Boston Original, Boston 3D, Boston Night Shift, Boston RC, Boston Baby, Boston Kyphosis Brace, and Boston Soft Spinal Orthosis (SSO), is fabricated for spinal correction in three planes, coronal, sagittal, and transverse. The corrective forces are created in conjunction with open/void areas that allow for easier breathing mechanics.

The Boston Night Shift is a nocturnal brace that takes advantage of the recumbent position. Some studies suggest that most growth occurs at night. For some curves, nighttime wear has shown to be as effective as full-time braces (more than 14 hours per day).

MATERIALS

The Spinal and Scoliosis Bracing is made from various types of metal and plastic materials. The materials include low density polyethylene, co-polymer, polypropylene, aluminum, nickel plated brass, nylon, pressure sensitive adhesive, polyethylene foam, crosslinked polyolefin foam, hook-and-loop fasteners.

INTENDED USE

The Spinal and Scoliosis Bracing is intended to treat scoliosis, kyphosis, and other spinal conditions for pediatric patients by controlling curve progression and/or improving the curve(s).

INDICATIONS FOR USE

The Spinal and Scoliosis Bracing is intended to treat scoliosis, kyphosis, and other spinal conditions for pediatric patients by controlling curve progression and/or improving the curve(s).

CLINICAL BENEFITS

The Spinal and Scoliosis Bracing is used in the non-operative management of scoliosis, kyphosis and other spinal conditions. By reducing the magnitude of the curve and improving the overall balance, while in brace, scoliotic/kyphotic curves may retain their in-brace reduction (improve), may stop progressing (stabilize), or see the rate of progression slow down there by avoiding or delaying surgery.

CONTRA-INDICATIONS

Do not use the Spinal and Scoliosis Bracing 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

- Federal Law restricts the Spinal and Scoliosis Bracing to sale by, or on the order of, a qualified physician or healthcare provider and is only to be used as prescribed.
- It is important to prevent skin irritation, such as soreness, redness, or raw skin while wearing your brace.
 - Always wear a clean, dry, and snug-fitting shirt under the brace. Be sure there are no wrinkles in your shirt under the brace by pulling it down tightly before and after putting on the brace.
 - If you notice areas of redness that do not fade after 30 minutes or are causing pain, blistering, or bruising, please consult your healthcare provider.
 - Be sure to wear your Brace tightly. A loose brace will cause chaffing and will not correct your spine well.
 - Cornstarch-based powder can help to relieve rashes and irritations.

- Avoid creams or lotions on your skin under the brace, unless recommended by a clinical care provider. Never use a brace that is damaged, broken or not functioning properly.
- Lack of compliance 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
 - Fit
- Device damage, wear, and tear would compromise the outcome as well as the use of the brace outside (not following) the intended use guidance. Improper fit and/ or lack of barrier protection (i.e clothing) between the product and intact skin may create a risk of irritation, blisters, or pressure ulcers.
- Improper clothing that is loose fitting, wrinkled, damp, or dirty may create a risk of skin irritation, soreness, redness, or raw skin.
- A loose-fitting brace may create a risk of chaffing and/ or impact device performance and outcomes. Lack of routine cleaning, leaving soil on device, may allow for microorganism growth.

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 Spinal and Scoliosis Bracing products. This information should be provided solely by 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 clinical care provider.

MRI SAFETY INFORMATION

The Spinal and Scoliosis Bracing is MR unsafe and should remain outside the MRI scanner room.

APPLYING BRACE INSTRUCTIONS

Boston Original, Boston 3D, Boston RC, Boston Baby, Boston Kyphosis Brace

1. Ensure straps are outside the brace, Velcro is folded back on itself, and buckles are turned toward the opening. (Figure A)



Figure A

2. The under shirt should be pulled down tightly to ensure there are no wrinkles before putting on your brace.
3. Open the brace and wrap it around the torso. Hold each opening of the brace with palms flat against the brace, and your fingers inside (knuckles facing each other) the brace to stabilize the orthosis when assisting the patient to don the orthosis.
4. The waist indent should rest above your hips and below your ribs. (Figure B)



Figure B

5. Fasten the straps in the most comfortable order for you. Have all straps tightened to the initial mark, and gradually work toward the goal mark. (Figure C)



Figure C

6. Confirm the opening sides in the back should be parallel with each other.

Note: If someone is helping you, your helper should hold the brace on the opposite side of the buckle while pulling on the strap. Your helper may also lift the edges of the brace to help prevent skin pinching.

Boston Night Shift

1. Apply a snug fitting shirt. Make sure there are no wrinkles.
2. While standing, open the brace wide and slip into it. Align the waist pads in the brace with your natural waist (the area between your ribs and hips). Pull your shirt down through the bottom of the brace.
3. Carefully lie down on your back; make sure that the brace remains positioned on your waist.
4. Loop the straps through the metal buckles. Tighten to the marks as indicated by your clinical care provider for appropriate tightness.

Boston Soft Spinal Orthosis (SSO)

1. With patient seated, orient top and bottom of brace and open brace. (Figure D)



Figure D

2. Help patient lie down into brace.

3. Adjust the orthosis so that the waist indentations in the orthosis align above the hips and below the lower rib.

4. The opening of the orthosis should be centered with the patient's belly button.

5. If possible, have patient bend knees, or assist with bending patient's knees to approximately 45 degrees prior to tightening straps. (Figure E)



Figure E

6. Start with the bottom strap and fasten to the tension line. Then fasten all straps to the tension line. (Figure F)



Figure F

SAMPLE WEAR SCHEDULES

Boston Original, Boston 3D, Boston RC, Boston Baby, Boston Kyphosis Brace

Over a period of three weeks, gradually increase the time per day in your brace. The break-in period allows your skin and muscles to adjust to the brace. Your clinical care provider will specify how many hours you need to wear your brace each day.

| Stage | Wear Duration Schedule | Instructions | Total Daily Wear Time |
|-------|-------------------------------|--|-------------------------------|
| 1 | 1-2 hours on | Check skin between wear | 6-8 hours total wear time |
| 2 | 3-4 hours on | Check skin between wear | 10-12 hours total wear time |
| 3 | 2 hours added each day | Begin wearing throughout the day and overnight | 14-18 hours total wear time |
| 4 | Follow the clinical care plan | Begin tightening straps to “tight marks” indicated by your orthotist | Follow the clinical care plan |

Boston Night Shift Brace

Your Boston Night Shift brace may be uncomfortable at first, this schedule is set up to allow for gradual adjustment to your brace. This allows your spine and body time to adjust together. The best way to break-in your orthosis is to simply begin wearing it. It takes approximately one week to be able to wear the brace all night. It is typical to feel sore or achy as your body adjusts to the orthosis. This will go away after a few days. Your clinical care provider will specify how many hours you need to wear your brace each day.

| Night(s) | Wear Duration Schedule | Notes |
|--------------|------------------------|---|
| Nights 1 + 2 | 2 hours before bed | N/A |
| Nights 3 + 4 | Wear while sleeping | Remove if you wake up with discomfort |
| Nights 5 + 6 | All Night | Begin to tighten as tolerated |
| Night 7 | All Night | Tighten as close as possible to lines on straps |
| Night 8 | All night | Un-Velcro the strap and pull the strap through the metal buckle to the line drawn on the strap by the clinical care provider. |

Boston Soft Spinal Orthosis (SSO)

Over a 3-week period, gradually increase the time per day in your brace. The break-in period allows your skin and muscles to adjust to the brace. Your clinical care provider will specify how many hours you need to wear your brace each day.

| Stages | Wear Duration Schedule | Instructions | Total Daily Wear Time |
|--------|-------------------------------|--|-------------------------------|
| 1 | 1-2 hours on | Check skin between wear | 6-8 hours total wear time |
| 2 | 3-4 hours on | Check skin between wear | 10-12 hours total wear time |
| 3 | 2 hours added each day | Begin wearing throughout the day and overnight | 12-18 hours total wear time |
| 4 | Follow the clinical care plan | Begin tightening straps to “tight marks” indicated by your orthotist | Follow the clinical care plan |

CLEANING INSTRUCTIONS

It is important to clean the interior of your spinal and scoliosis brace daily. If the brace has a foam liner, the foam will not absorb moisture, but perspiration will collect on it. Clean the foam with 70% Isopropyl alcohol, which will disinfect the liner and evaporate quickly. Your brace should be allowed to air dry, do not use a hair dryer or other heat source.

SAFE DISPOSAL

The Spinal and Scoliosis Bracing can be disposed of in regular trash. None of the components of the device are recyclable.

STORAGE AND HANDLING

The Spinal and Scoliosis Bracing requires 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 and other languages at <https://opsb.com/> (Regulation (EU) 207/2012). 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. and the competent authority of the EU and EEA Member State in which the user and/or patient is established.

SYMBOL LEGEND

| Symbol | Meaning | Symbol | Meaning |
|---|---|---|--|
|  | Manufacturer |  | Catalogue Number |
|  | Date of Manufacture |  | Batch Code |
|  | Single Patient Multiple Use |  | Authorized Representative in the European Community/European union |
|  | Non-Sterile |  | Authorized Representative in the United Kingdom |
|  | Consult Instructions for Use or Consult Electronic Instructions for Use |  | Importer |
|  | Prescription Device Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. |  | CE Mark Indicates medical device conformity with the provisions of this Directive to enable the device to move freely within the Community and to be put into service in accordance with their intended purpose |
|  | MR Unsafe |  | Medical Device |