# INSTRUCTIONS FOR USE

# Boston Band Orthosis


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NON STERILE

Rx ONLY



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**ENGLISH**

**PRODUCT DESCRIPTION**
The Boston Band is a cranial remolding orthosis (CRO) used to treat abnormally shaped craniums in infants three to eighteen months of age. This condition is clinically known as Positional or Deformational Plagiocephaly. The orthosis contains the protruding aspects of the cranium in a static equilibrium while guiding the growth of the flattened areas of the skull into the created spaces to improve proportion and symmetry. The Boston Band is only available if prescribed by a healthcare provider. The device is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

The Boston Band is a patient matched orthosis from a cast or scan of the infant's head. The mold, either plaster from a cast, or foam, carved from the scan, is modified and prepared for fabrication according to the instructions provided by the treating practitioner using plaster/CAD modification techniques. Each orthosis is composed of an outer shell of thermoformable plastic, a single layer of ½ inch (13mm) or 5-6 layers of ⅛ inch (3mm), or a combination of 1-2 layers of ¼ inch (6mm) with ⅛ inch layers of hypoallergenic polyethylene foam and a strap for securing the orthosis. It has a top and side opening. Optimum fit and alignment is insured and monitored by their healthcare provider.

**MATERIALS**
The Boston Band orthosis is made from plastic, foam, metal, and glue.

**INTENDED USE**
The Boston Band is designed to treat infants with abnormally shaped craniums from age three to eighteen months. It is available by prescription only. The most common head deformities are positional plagiocephaly, brachycephaly, and scaphocephaly. However, due to new surgical techniques for infants with craniosynostosis, post-surgical plagiocephaly, brachycephaly, and scaphocephaly are a growing patient group.

**INDICATIONS FOR USE**
The Boston Band is intended for medical purposes to passively hold prominent cranial regions of an infant's skull in order to improve cranial proportion and symmetry in infants from three to eighteen months of age, with nonsynostotic positional plagiocephaly, including infants with plagiocephalic, brachycephalic and scaphocephalic patterned head shapes. The device is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

**CONTRA-INDICATIONS**
This device is not for use on infants with:
- Craniosynostosis
- Uncontrolled hydrocephalus

**WARNINGS AND PRECAUTIONS**
- Evaluate head circumference measurements and neurological status at intervals appropriate to the infant’s age and rate of growth.
- Describe to caregiver steps that should be taken to reduce the potential restrictions of cranial growth and possible impairments to brain growth and development.
- The healthcare provider and caregiver must evaluate the patient’s skin at frequent intervals.
- If the positional plagiocephaly is associated with torticollis, the torticollis is recommended to be treated. Evaluate the device’s structural integrity and fit with care.
- It is important to prevent skin irritation, such as soreness, redness, or raw skin while wearing the Boston Band.
    - Consult your healthcare provider immediately if there is an area of deep red color that does not fade within 30 minutes.
    - If the child is perspiring excessively while wearing the helmet, cornstarch-based powder may be used lightly to help wick away moisture. A small amount dusted inside the helmet is all that is needed.

  - Hydrocortisone cream may be applied to areas or irritation after bathing.
  - Gentle shampoos may be used to help with itching.
- Lack of compliance by caregivers based on the plan of care from the healthcare provider or improper use may impact device performance and outcomes.
  - Contributing factors may include:
    - Off label use
    - User errors
    - Product sizing
    - Product Fit
    - Strap tightening
    - Device slipping
- Device damage, wear, and tear would compromise the outcome as well as the use of the helmet outside (not following) the intended use guidance.
- Lack of routine cleaning 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 Boston Band helmet. This information should be provided solely by healthcare 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.

**POSSIBLE ADVERSE EFFECTS**
This device may cause skin irritation or breakdown.

**MRI SAFETY INFORMATION**
The Boston Band has 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 Band 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.

**HEALTHCARE PROVIDER INSTRUCTIONS**
To monitor the child's progress and to make necessary adjustments to the Boston Band, regularly scheduled follow up appointments are necessary. These appointments should be scheduled every two to three weeks. If problems arise between appointments, the patients should be seen as soon as possible to resolve the matter quickly and to be sure the orthosis is fitting properly. At each appointment, ask specifically how many hours per day the child is wearing the orthosis, emphasize the importance of wearing the orthosis 23 hours a day to maximize the effectiveness of the orthosis.

At each appointment, the following should occur:
1. **Low (flat areas):** Taking an aerial view of the child's head while the orthosis is on, make sure there is room for the head to grow into. Remove layers of foam as necessary so the head will grow in the correct direction.
2. **Protruding Areas:** As symmetry improves, make sure there is total contact over the protruding areas to help correct growth. Make sure skin integrity is maintained by inspecting the skin (with the helmet off) to see if too much pressure is occurring in this area. If so, remove desired number of layers necessary in that specific area.
3. **General Fit:** Assess the overall fitting of the orthosis. Make sure it is "sitting" well, and not rotating. The areas that should be relieved are in the correct position, and the areas that should be in contact are not subjected to too much pressure.
4. **Skin Inspection:** Remove the helmet and inspect the skin for irritations and or pressure points. Adjust as necessary.
5. **Measurements**: Head circumference, medial/lateral, anterior/posterior, left anterior to right posterior, and right anterior to left posterior are recorded at each visit
6. **Ventilation**: ⅜ inch (10mm) air holes may be drilled into the helmet to assist in checking total contact as well as assisting in dissipating heat. Be sure the holes are cleaned out with a cotton swab as powder may clog the hole. After initially drilling the hole, be sure to check for any plastic artifacts they may not have cleared the hole when drilling. Remove these plastic shavings and discard appropriately.
7. **Discontinuing/end of treatment**: All measurements must be recorded. If photos were taken at initial treatment, repeat the photos and maintain in the patient's chart. If a second Boston Band is requested, refer the family back

to the healthcare provider for a new prescription.

**PRACTITIONER INSTRUCTIONS FOR TROUBLESHOOTING AND SKIN CHECKS**

1. During the first few days of wear, the patient is weaning into the orthosis. They should be out of the Boston Band for 30-minute breaks between wearing times. Skin checks need to be performed during the 30-minute break. If there are areas of bright red skin, that do not go away with in 30 minutes, the caregiver will contact the healthcare provider. As wear time is low at this stage of treatment, review fitting procedure and actual wear time with the caregiver. If the problem does not resolve after review of wear schedule and fitting, an appointment is to set for adjustments.
2. Foam liner material should be removed from the Boston Band in the area of the increased pressure causing the reddened skin. Remove one ⅛ inch (3mm) section at a time.
3. Helmets that "spin" or rotate on the patient's head will need an extra ⅛ inch (3mm) to ¼ inch (6mm) of foam added to suboccipital area to provide a better purchase for the helmet. Care is taken to make sure the suboccipital area has total contact. Check the skin after 20 minutes of wear for reddened areas. Remove liner in the area of reddened skin if needed.
4. 70% Rubbing alcohol is used to clean the inside of the helmet. This helps reduce odors from developing inside the helmet.
5. "Cradle cap" may develop, appearing as white flaking skin areas. No adjustments to the helmet are necessary. Recommend the caregiver contact the pediatrician and follow their instruction.
6. Rashes may develop on children wearing the Boston Band. If the rash follows the outline of the helmet, discontinue until the rash goes away. Review cleaning instructions of using 70% rubbing alcohol. If the child is perspiring excessively while wearing the helmet, a cornstarch-based powder may be used lightly to help wick away moisture. A small amount dusted inside the helmet is all that is needed. Instruct the caregiver that hydrocortisone cream may be applied to the area after bathing. Gentle shampoos may help with itching.
7. To be effective in helping growth in the proper locations, and limiting undesirable growth, the orthosis is recommended to be worn 23 hours per day. The only time the child should be not wearing the Boston Band is when bathing, swimming, has a cold or fever, or under direct orders from the treating healthcare provider. In the event the 23-hour protocol is not followed, recasting maybe necessary.
8. Boston Band cranial remolding helmets fit to hydrocephalic children with shunts need to be very closely monitored. Check the skin after the initial 30 minutes of wear. Have the infant assume several positions that will occur during a normal day. During the skin check, If there appears to be any areas of redness (including light pinkness), remove ⅛ inch (3mm) layers of foam in the area of concern. Reapply the helmet and repeat the process until the skin maintains its normal appearance.

**CAREGIVER INSTRUCTIONS**

1. Your child has been provided with a Boston Band Orthosis to treat their positional plagiocephaly or misshapen head. Follow the instructions to ease both you and your baby's adjustment to wearing the device. Your baby will eventually wear the orthosis 23 hours per day. Follow the provided wearing in schedule to gradually increase wear time:

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Day 1** | ON<br>1 Hour | OFF<br>30 Minutes | ON<br>2 Hours | OFF<br>30 Minutes | ON<br>3 Hours | OFF<br>30 Minutes | OFF<br>Sleep |
| **Day 2** | ON<br>4 Hours | | OFF<br>30 Minutes | ON<br>5 Hours | | OFF<br>30 Minutes | OPTIONAL<br>Sleep |
| **Day 3** | AM Check | ON<br>6 Hours | OFF<br>30 Minutes | ON<br>6 Hours | | PM Check | ON<br>Sleep |
| **Day 4** | AM Check | ON<br>All Day | | | | PM Check | ON<br>Sleep |

2. The wear duration schedule is followed throughout the day. By the fourth day, full-time wear should be achieved; the helmet is only removed during bath time and/or pool time for up to a total of one hour per day. If the helmet gets wet, simply dry with a washcloth. Make sure the orthosis is completely dry before reapplying to your child's head. If your child has been given stretching exercises, remove the Boston Band, perform exercises, and reapply the helmet once the exercises are complete.
3. Check your child's skin each time the helmet is removed. If there is an area of deep red color that does not fade within 30 minutes, contact your healthcare provider immediately. This may indicate an adjustment is needed. Keep the helmet off until the area returns to your child's normal color. If the area is noted again in the same spot, keep the

helmet off until you have seen the healthcare provider. In the event of a skin breakdown, contact the healthcare provider immediately and leave the helmet off.

4. It is not uncommon for your child to perspire excessively during the first few days of wear. Remove the helmet and dry both the helmet and the child's head. Once dry reapply the orthosis. In the event a heat rash appears, (mostly at the base of the skull), hydrocortisone cream may be applied to the area after bathing. This is an over-the-counter skin cream. Gentle shampoos may help with itching.
5. Remove and clean the orthosis each day with 70% rubbing alcohol. Use a washcloth with the 70% rubbing alcohol on it to rub the inside and outside of the Boston Band. Set the orthosis aside and be sure it is completely dry before reapplying. Your child's head should be shampooed daily. If swimming, shampoo your child's head to remove sunscreen and chlorine. Once both head and helmet are dry, the orthosis can be reapplied.
6. Make sure all childcare providers are familiar with how to care, apply, and remove the Boston Band. Review all fitting and care instructions with them.
7. To be effective in helping growth in the proper locations, and limiting undesirable growth, it is recommended that the orthosis be worn for 23 hours per day. The only time your child should be not wearing the Boston Band is when bathing, swimming, has a cold or fever, or under direct orders from the treating healthcare provider. In the event the 23-hour protocol is not followed, recasting maybe necessary.

**CLEANING INSTRUCTIONS**

It is important to clean the interior of the Boston Band helmet daily. Remove and clean the orthosis with 70% rubbing alcohol. Use a washcloth with the 70% rubbing alcohol on it to rub the inside and outside of the Boston Band. The helmet should be allowed to air dry, do not use a hair dryer or other heat source. Be sure it is completely dry before reapplying.

**SAFE DISPOSAL**

The Boston Band helmet can be disposed of in regular trash. None of the components of the device are recyclable.

**STORAGE AND HANDLING**

The Boston Band helmet requires no special handling during transport or storage.

**REUSING THE DEVICE**

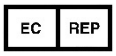
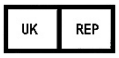
All parts were designed to be used by a single patient, multiuse under normal use conditions and as instructed by a healthcare provider.

**IMPORTANT STATEMENT**

- Instructions for Use (IFU) manuals are available in English and other languages at https://opsb.com/. 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.

# INSTRUCTIONS FOR USE

**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<br>Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. |  | CE Mark<br>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 |
| | |  | Medical Device |



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