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Bebax Pediatric Forefoot Orthosis
Practitioner Guide
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INTRODUCTION

The Bebax Tri-Plane Pediatric Forefoot Orthosis provides a progressive and dynamic correction of congenital forefoot deformities and minimizes retractions from muscular or neurological disorders. A multi-directional hinge located distally on the orthosis adapts easily for correction of all three planes. Unlike plaster casts, the Bebax orthosis is removable to accommodate stretching and hygiene.

Product Code (Left)	Product Code (Right)	Foot Size	Length (cm)
08731L01	08731R01	1	7.5
08731L02	08731R02	2	8
08731L03	08731R03	3	8.5
08731L04	08731R04	4	9
08731L05	08731R05	5	9.5
08731L06	08731R06	6	10
08731L07	08731R07	7	10.5
08731L08	08731R08	8	11.5
08731L09	08731R09	9	12.5
08731L10	08731R10	10	13.5

LIMITATIONS

The Bebax orthosis is not intended for the treatment of clubfoot.

INSTRUCTIONS AND USE

1. Use the Allen wrench provided to loosen the two swivel joints and adjust the hind foot and forefoot in relation to one another (FIGURE 1).

Note: Adjust the forefoot position so that it is opposite of the diagnosed deformity. If the deformity in any direction is too severe, make corrections in several intervals, allowing 5–7 days between each step.

2. Use the Allen wrench to carefully tighten the swivel joints to lock the orthosis in the desired position.

FIGURE 1: Adjusting the alignment.

Note: Do not over tighten the screws. Excessive tightening can damage the joint assembly.

3. Make a slit at the toe portion of a thin cotton sock and place it on the patient's foot. The slit should be large enough to view the patient's toes.
4. Place the patient's foot into the orthosis so that the heel is firmly placed to the back of the Bebax.
5. Verify that the orthosis is properly positioned for the desired correction and for the correct foot.

Note: Left and right models are determined by the strap orientation. Straps should always fasten towards the lateral side.

6. While firmly holding the foot in place, close the straps so they are snug.
    - For smaller sizes (7.5 cm–10 cm); fasten the proximal ankle strap first followed by the distal toe strap.
    - For larger sizes (10.5 cm–13.5 cm); fasten the middle leather strap through the slit first, followed by the proximal ankle strap and then the distal toe strap.
7. Check the patient's toes for signs of excessive compression. If the toes are very blue or white, wait a few minutes to see if they return to normal color. Adjust the strap tightness if necessary.

Trulife

Caution: Only qualified professionals should adjust the orthosis. It is strongly recommended that the Allen wrench be kept at the care facility and not provided to the parents.

Caution: The Bebax is should not be worn while walking.

QUESTIONS

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Trulife has appointed Medical Device Safety Service (MDSS) of Hannover, Germany to act as our EU authorized representative. They may be contacted at:

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LIMITED WARRANTY

Trulife warrants that the Bebax Pediatric Forefoot Orthosis will be free from defects in material and workmanship for the Bebax Pediatric Forefoot Orthosis from the date of installation.

This warranty will not apply if the product has been damaged by misuse, abuse, neglect, improper care, failure to follow instructions, abnormal wear and tear, or in the event that a Bebax Pediatric Forefoot Orthosis has been modified/repaired by persons unauthorized by Trulife.

If a defect in material or workmanship is found during the warranty period, Trulife will, at Trulife's option, either repair or replace the product. If it is not possible to repair or replace the product, Trulife will be limited to refunding the purchase price.

Trulife will not be liable under any legal theory for any direct, indirect, special, incidental or consequential damages arising from the use of or inability to use this product.

The application guidelines for this Trulife product are for the use of and by certified, qualified practitioner only. Patients are not to attempt to apply or adjust the item unless expressly instructed to do so by the practitioner responsible for the prescription and/or initial fitting of the device. All patient questions should be referred to the practitioner and not to the manufacturer. The manufacturer warrants only that the enclosed product has been inspected for quality and can be effective for certain indications, but final decisions and ongoing monitoring must be made by the medical professional(s) prescribing and/or fitting the device to determine its effectiveness for an individual patient. Patient compliance is an integral part of the entire protocol and must be adhered to in order to avoid potential problems and to maximize the effectiveness of the prescribed product.

As a condition of the sale of any Trulife product, this product is restricted to a "Single Patient Use Only" by the originally fitted patient in order to protect the care provider and the patient against potentially adverse consequences of infectious disease transmission, material instability in adapting to the configuration of the original user and/or decrease in effectivity. Any express or implied warranties are voided if the product is reused or fitted to another patient. Additionally, a license of right to use under any relevant patents pertaining to the product is terminated with the cessation of use by the original patient. As with all Trulife products, this product must be prescribed and applied by a qualified practitioner to determine it meets the needs of the particular patient and accomplishes the desired results.