ASPREX Fact Sheet

Club foot brace

Brace designed to modify the structural and functional characteristics of the neuromuscular system of the ankle and foot; it may be custom manufactured to meet the individual functional requirements or prefabricated and adjustable to fit the individual user. It has two differentiated parts: a) a couple of ankle foot orthoses (AFO) or shoes, and b) a bar. The AFOs or shoes are designed to control the inversion or forefoot adductus and achieve a neutral dorsiflexion of the foot; the shoes may be made of strong leather or other strong fabric and may be reinforced with a straight medial border; different shoe closures such as Velcro, straps or shoelaces can be used; the toes should not be covered by the brace: it is an open toed shoe; the heel cup needs to have an inspection on the medial side; foam mold for the inside of the shoe can make it more tolerable and better fit; the shoes may be detachable or not from the bar.

The bar is designed to position the feet horizontally at the desired angle in the sagittal plane; it should be as long as the distance between the child´s shoulders and should be bent to allow 10-15 degrees of dorsiflexion; the bar can be extensible to be lengthened over time as the child grows; to increase the ease and adherence of use, the bar may have detachable clips for shoes into and out; the bar can have the possibility to angle the shoe to externally rotate the affected foot up to 90 degrees. The clubfoot brace should be easy for parents to fit on the child, able to fasten firmly enough to keep the child's heels down within the shoes, it should be light weight, strong, durable and easy to clean. The bar should be strong enough to maintain the shoes/feet in a position of abduction and dorsiflexion.

- Product Classification
  - APL (WHO Assistive Product Priority List): 8 (Club foot braces)
  - ISO 9999:2022: 061206 (Ankle-foot orthoses)
- Possible configuration variants

  None specified.
- Possible accessories or optional components

  None specified.
- Product goals

  Activities or functions the product is mainly intended to support, according to WHO ICF Classification:
  - Maintaining body position [d415].
- Indicated impairments

  Difficulties the product is mainly intended to address, according to the WHO ICF Classification:
  - Mobility of joint functions [b710].
- Contraindicated impairments

  Difficulties for which the product may be inappropriate:
  - Lack of sensation or skin integrity.
- Indicated environments

  Specific environments in which the product should be used:
  None specified.
- Contraindicated environments

Environments in which the product may be inappropriate:
None specified.

- Other indicated factors

Other factors or situations the product is intended to address:

  - Maintaining a standing position with proper foot alignment.
  - Walking with proper foot alignment.
  - Distortion of the foot at an early age so that the sole cannot be placed flat on the ground.
  - Foot twisted inward and downward, increasing the arc and turning the heel inward.
  - Having one foot and one leg smaller than the other.
  - Underdeveloped calf muscle in the affected leg.

- Other contraindicated factors

Other factors or situations in which the product may be inappropriate:

  - Use by children over 5 years (as there is no evidence that the shape of the foot will modify over that age).

- Points to be considered in product selection
  - Start to use it as soon as possible because the joints and tendons are very flexible: it is ideal to correct the child´s foot shape and function before he or she learns to walk.
  - Children up to 5 years are the typical users, as at that age they have completed the corrective phase of clubfoot treatment.
  - The product is widely effective under the age of two.
  - It can affect one or both feet.
  - Ensure that it should be easy for parents to fit on the child, able to fasten firmly enough to keep the child-s hell down within the shoes.
  - The device should be light weight, strong, durable, and easy to clean.
  - The bar should be strong enough to maintain the shoes/feet in a position of abduction and dorsiflexion.
  - The device can be combined with Ponseti Method, which involves a combination of casting, Achilles tendon release and bracing; widely effective under the age of two.
  - It can be combined with the French method, which involves realignment, taping, and long-term home exercises and night splinting; this is much dependent on the reliability and involvement of the caregivers.
  - Provide the proper measures.

- Points to be considered in product fitting
  - Ensure that the brace is well fitted to the size of the feet and in relation to abduction and rotation.
  - Shoes are solid and attached to a bar, the feet need to be at shoulder with apart in a position of abduction and dorsiflexion.
  - The length of the bar should be followed up and set so that the child´s heels are shoulder width apart.
  - The angle of dorsiflexion of the shoe on the bar is set to 10-15 degrees dorsiflexion.
  - The angle of abduction of the shoe on the bar is usually set to 60-70 degrees.
  - For unilateral cases, the angle of abduction is 60-70 degrees in the affected foot and in the unaffected foot is normally set to 30-40 degrees.
  - Check if the orthoses is providing the appropriate stability or correction.
  - Pad the bar: this will protect your child, yourself, and your furniture from being hit by the bar when the child is wearing the brace.

- Points to be considered in product use
  - Bracing as soon as possible and for 4-5 years every night is the most effective method to correct the distortion.
  - Wear the brace full time for the first three months and the overnight until they are 4 or 5 years old.
  - Training parents and caregivers in how to fit and when to use the brace is critical.
  - Consideration of the use if needed to combine with other approaches if the child has other/additional impairments.
  - Make the treatment a routine.
  - Dosage use program: depending on the age and the condition of the soft tissue; there are special indications on the hours of wearing time expected to make changes in the foot; it varies from 6 hours to 24 hours.

- Expect your child to fuss in the brace for the first 2-3 days.
- Explain what to do if there is discomfort or injury. If you notice any bright red spots or blistering contact your health care provider.
- Play with your child in the brace; this is a key to getting quickly over the child's irritability.
- Show your child pictures of other children with clubfoot wearing their brace.Use rewards and incentives to help your child understand the importance of the brace.

- Points to be considered in product maintenance / follow-up
  - Regularly check the size of the shoe.
  - Replace the stick with a new one if the shaft is broken or damaged.
  - Regularly check the distance of separation of the feet in the bar.
  - Look for clinical or technical help if: the brace is broken in any part of it; there are health problems affecting the child; it has not been fit correctly; the user´s family has not learned correct use; you find any difficult to use the device.
  - Carry out follow-up checks about every six months if there is no other sign of concern about the correct use of the brace.
- Examples of products available on the market
  - Live product search in the EASTIN website https://www.eastin.eu/en/searches/products/list?iso=061206

Source

This Fact Sheet was compiled in 2021 by an international team of experts, to provide the initial knowledge base for a project ("An online system to assist the selection of assistive product") supported by the World Health Organization in 2020-2021 within the GATE Initiative (Global collaboration on Assistive Product). Fact Sheets were compiled for each of the 50 types of products included in the WHO APL (Assistive Product Priority List).

The team was composed of Renzo Andrich (Italy, group leader), Natasha Layton (Australia), Stefan von Prondzinski (Italy), Jerry Weisman (USA), Silvana Contepomi (Argentina) and Hasan Minto (Pakistan).

The project led to a prototype online tool called ASPREX (ASsistive PRoduct EXplorer). At the end of the project, it was transferred to a WHO collaborating center (the Global Disability Hub in the UK), in view of possible future developments.