



MiracleFeet Brace

Healthcare Provider Guide



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The Role of Bracing in Clubfoot Treatment

Bracing is the final stage of the Ponseti treatment method.

Brace use prevents relapse. It does not correct the position of the foot (this is achieved through serial casting and, in most cases, a tenotomy).

Children need to wear a brace for 23 hours a day for the first three months and then while sleeping until the child is 4 or 5 years old.

Most children quickly become accustomed to wearing the brace at night and it does not affect their development. During the day when not wearing the brace, children can crawl, walk, run, attend school, and play.





The MiracleFeet Brace Story

MiracleFeet is a US-based non-profit on a mission to create universal access to clubfoot treatment. Our award-winning, patented brace is a critical component in ensuring that comprehensive, affordable clubfoot care is available in low and middle-income countries.

We designed the brace in partnership with Stanford University's Design for Extreme Affordability Program. Using a human-centered design approach, we collaborated with parents, children, and providers to design an affordable, high-quality brace prioritizing ease of use, durability, and comfort. Thanks to cutting-edge design and the generosity of our manufacturing partners, Suncast, Clarks Shoes and ByFoot, the brace can be mass-produced for a fraction of the cost of most US and European models.

The MiracleFeet brace has been used successfully by thousands of children around the world. Since the brace was introduced in 2015, we have distributed over 50,000 pairs of shoes and bars to over 30 countries.

Key Features of the MiracleFeet Brace

- ❑ **Modular design:** 3 bars sizes (150, 180, 220 mm) & 7 shoe sizes to fit children 3 months–5 years old.
- ❑ **Easy to use:** Shoes clip on and off the bar to make putting the brace on the child much easier.
- ❑ **Comfortable:** Soft canvas shoes are lined to prevent blisters. Pronounced internal heel cup and inspection hole helps ensure the foot is positioned correctly in the shoe.
- ❑ **Washable:** Shoes and bar can be hand washed.
- ❑ **Durable:** Bar and shoes can be reused if in good condition.
- ❑ **Child friendly design:** Many parents report that this colorful, plastic brace feels less stigmatizing than other models.
- ❑ **Medically Compliant:** Meets Ponseti Method and WHO Assistive Technology product specifications. Registered with the US FDA.
- ❑ **Adjustable:** Shoes can be set to 65° or 45° of abduction to accommodate bi- and unilateral cases.
- ❑ **Manufacturing:** Plastic parts are injection molded in the US. The shoes are made in China.

PATENT STATUS: The MiracleFeet brace technology is covered by a patent (Foot Abduction Brace US patent 10,314,730 B2) assigned to the Board of Trustees of Stanford University. Stanford's Office of Technology Licensing has granted MiracleFeet the exclusive right to use the brace technology for the life of the patent at no cost as long as all revenue generated is used to treat low-income children born with clubfoot.

Sizing and Components

Shoe Size	Length (Insole)
0	88 mm
1	105 mm
2	119 mm
3	136 mm
4	148 mm
5	169 mm
6	182 mm

Bar Size	Length (Insole)
Small	150 mm
Medium	180 mm
Large	220 mm

Bar Length

Although the choice of bar length is at the discretion of the supervising healthcare provider, suggested bar lengths for different shoe sizes are as follows:

- Shoe sizes 0-1: 150mm bar
- Shoe sizes 2-3: 180mm bar
- Shoe sizes 4-6: 220mm bar



A brace kit includes:

- ❑ **Bar** 3 sizes: 50 mm, 180mm, 220mm
- ❑ **Uppers:** 7 shoe sizes to fit children from 3 months to 5 years of age
- ❑ **Spare parts kit**

Instructions on use of the MiracleFeet brace

It is critical that all members of the clinic team are familiar with how to instruct parents in the use of the brace.

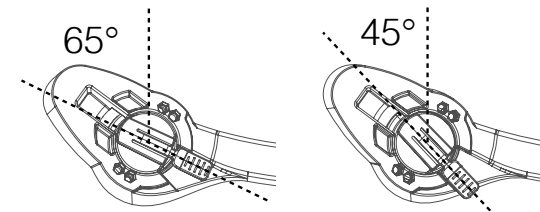
Hours of Use:

- ❑ Pre-walking aged children (typically under the age of one) should wear the brace **23 hours a day for the first three months** after the feet are corrected. The parents can remove the brace for an hour a day to wash their baby.
- ❑ **After three months**, the parents should be counseled to use the brace whenever their baby is sleeping (nights and naps).
- ❑ **There are no formal guidelines for children who start treatment when they are older.** Current thinking is that these children only wear the brace while sleeping and only until they reach the age of 5. Providers treating children over the age of 5 should consult with experts (MiracleFeet can provide names of experienced doctors who can advise on brace wear for these children).



Sizing the Brace

- ❑ The bar size should be based on the **shoulder width** of the child. The distance between the shoes when attached to the bar should be approximately the same width as the child's shoulders. As the child grows, they will need larger bars.
- ❑ **Shoes should be fitted to allow for some growth.** The parents should be instructed to return for larger shoes once the toes start to protrude over the end of the shoes.



How to Adjust the Brace for Unilateral Use

The MiracleFeet brace comes with both shoes set at an angle of 65° of abduction. Ponseti method recommends that in unilateral cases that the unaffected foot is set at 45°.

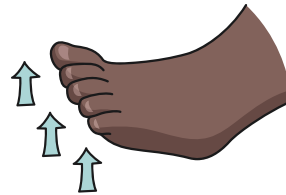
To adjust:

- ❑ Using the allen wrench, remove the two locking hub screws.
- ❑ Rotate the locking hub 20° so the screw holes align.
- ❑ Replace the screws to hold the locking hub in the new position.
- ❑ Note: there is no need to remove the locking hub.

It is important to check that the angles are correctly positioned before providing a previously used brace to a new family.

Putting on the Brace

1. Remove shoes from bar by pressing down on the tab. Loosen the laces and velcro strap on both shoes.
2. If using socks, make sure there are no wrinkles as this could cause irritation.
3. Gently stretch the foot upwards and place child's foot into the shoe. Be sure to check left and right as indicated by "L" and "R" on the insole.



4. Make sure the heel is completely flat in the shoe. Use the heel inspection window to view the position of the foot.
5. Once in the correct position, secure the velcro strap and tighten the laces snugly.
6. Attach the shoes by sliding them onto the bar. You should hear a loud "click."



Cleaning and Maintenance

All parts of the MiracleFeet Brace are easily cleaned using soap and water. If shoes get wet, allow them to dry thoroughly before a child wears them.

Troubleshooting

Examine the child's skin for redness or blisters. Redness that goes away in about twenty minutes is normal. Redness that persists for longer than twenty minutes or a blister may be caused by the following:

- ☐ The laces are too loose (the most common cause).
- ☐ The child has outgrown the shoes.
- ☐ The laces are too tight.
- ☐ The fabric of the shoes or socks is not smooth against the skin.

If redness does not go away within twenty minutes, or if a blister develops, it is important to determine the cause of the problem.

NOTE: The MiracleFeet Brace is designed to maintain alignment of a fully corrected clubfoot. If the foot has not been corrected or has relapsed, then the child should not wear a brace. It is important to counsel parents to seek advice from their provider if their child's feet look irritated.

Ordering Information

Braces can be ordered from MiracleFeet and will ship from the United States. Shoes are boxed by size with 32 pairs per box. Bars are also packed by size, with 16 bars per box. Each box of bars contains the tool to adjust the brace angle and some spare screws and a replacement locking hub.

Prices are available upon request and vary slightly with size. Non-MiracleFeet partners can expect to pay \$20-30 for one pair of shoes and a bar. Shipping is extra and varies based on location.

To order, contact: braces@miraclefeet.org

For more information

Learn more about the MiracleFeet brace:

www.miraclefeet.org/the-miraclefeet-brace

Learn more about MiracleFeet:

www.miraclefeet.org

Call: 919-240-5572

Email: braces@miraclefeet.org

