

ECO-Brace Light Foot Abduction Orthosis Usage Instructions





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IMPORTANT

PLEASE READ CAREFULLY BEFORE USE STORE FOR LATER REFERENCE

Read these usage instructions carefully. Observe all instructions. Keep these usage instructions in a safe place for future reference. If other people use this product, please make these usage instructions available to them.

1. Information about our products

1.1 Warning and safety instructions



Check the correct connection of the foot abduction splint with the foot supports each time you put on your orthosis.



Make sure that your foot is correctly and firmly seated in the foot support, otherwise pressure marks, blisters and redness may occur.



Your foot supports should be aired twice a day for 30 minutes.



If your feet perspire heavily, change your socks several times a day.



Check at regular intervals that the screws on the splint do not loosen.



The foot abduction orthosis (one pair of foot supports and one foot abduction splint each) may only be fitted by professionally trained personnel (orthopaedic shoemaker or orthopaedic technician).



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ORTHOPAEDIC PRODUCTS

... step by step forward



If a defect occurs in the ECO-Brace Light foot abduction orthosis, please contact your orthopaedic technician or orthopaedic shoemaker.



Foot abduction splints should not be hit on hard objects (e.g. by the child bouncing on the floor). The splint could break!



When the orthosis is not being worn, it must be kept out of the reach of children.



A foot abduction orthosis may only be worn with socks!



The foot supports are not running shoes and should only be worn in combination with the splint!



Please do not use any harsh cleaning agents, as these can attack the plastic and the leather.



Safe fitting of the ECO-Brace Light foot abduction splint can and must only be carried out by the fitting orthopaedic shoemaker or orthopaedic technician. Please do not change/adjust the settings of the ECO-Brace Light foot abduction splint yourself, as this could lead to a recurrence! If you have any questions or problems regarding the settings, please contact your orthopaedic shoemaker, orthopaedic technician or prescribing paediatric orthopaedist to fit them for you. Sameda accepts no liability for unauthorised and improper fitting!

1.2 The ECO-Brace Light foot abduction orthosis

1.2.1 Specific function

The ECO-Brace Light foot abduction orthosis is used for babies/toddlers and children diagnosed with idiopathic clubfoot according to the conservative therapy approach of Dr Ponseti.

It serves to maintain the correction of the foot that has been achieved by a plaster corrective. It serves to prevent a relapse (renewed deterioration) and has no corrective effect.

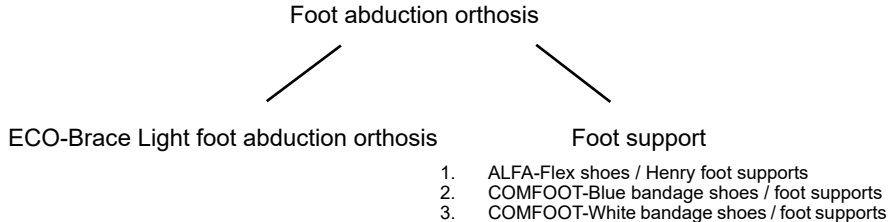
The orthopaedist prescribes an orthosis to continue their treatment. The orthopaedic technician (or orthopaedic shoemaker) fits the orthosis to the children on the basis of the orthopaedist's prescription. The parents of affected children put the orthosis on daily. The orthosis is a reusable product.

1.2.2 How it works

The foot abduction orthosis consists of an ECO-Brace Light foot abduction splint and a foot support.

There are three different models of foot supports that fit the ECO-Brace Light foot abduction splint:

1. ALFA-Flex shoes / Henry foot supports
2. COMFOOT-Blue bandage shoes / foot supports
3. COMFOOT-White bandage shoes / foot supports



1.2.3 Foot support

The respective foot support is used to immobilise the child's feet that are to be treated. It is connected to the brace by means of a click fastener.

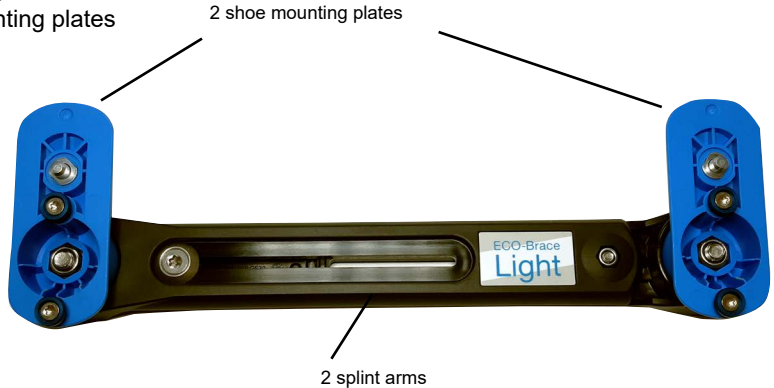
1.2.4 The ECO-Brace Light foot abduction orthosis

The ECO-Brace Light foot abduction splint has two ball joints that can be moved in both directions to set the therapeutic angles defined by the orthopaedist (abduction angle 0°-80°). A dorsal extension of 5° is firmly incorporated into the shoe mounting plate.

The ECO-Brace Light foot abduction splint has a continuously adjustable splint length up to 30 cm width and grows with the child throughout the entire therapy period.

The main functional elements of the ECO-Brace Light foot abduction splint are:

- a) 2 splint arms
- b) 2 shoe mounting plates



The two splint arms lie on top of each other and are connected with two screws. To change the splint length, loosen the screws with the enclosed keys, move the splint arms to the desired length and tighten the screws again.

Each splint arm ends in a semi-circular end at the outer end. A shoe mounting plate is attached to each of them by means of an Allen screw. A measuring scale with angle information from 0 – 80° can be seen through the viewing window at the end and thus the shoe mounting plate can be turned to the desired angle measurement for abduction.



A dorsal extension of 5° is firmly incorporated into the shoe mounting plate. There are two sliding blocks on the top of the shoe mounting plate and a spring-loaded locking pin on the bottom. These are used to connect to the foot holder (see 2.1).

1.3 Accessories

1.3.1 ALFA-Soft heel pad

The ALFA-Soft heel pad is particularly suitable for use with the ALFA-Flex shoes / foot supports. This heel pad gives the foot additional support and prevents or relieves pressure points. It is available in two sizes, can be glued into the shoe and can be individually cut to size.



1.3.2 ALFA-Flex sole plates



The ALFA-Flex sole plates are a potential accessory for the foot abduction splints. Their use results in a system modification of the orthosis. The ALFA-Flex sole plates are used in rare cases to attach external custom-made foot supports to a foot abduction splint manufactured by Sameda.

The use of the foot abduction splint with the custom-made device does not correspond to the orthotic system described here. Therefore, we only accept liability for the accessories provided by us i.e. the sole plate.

2. How to use

2.1 Putting on the orthoses

When you receive the splint from your doctor or orthopaedic technician, they will adjust the angles and the length of the splint. Please do not change these settings – they are therapeutically necessary!

1. **Be sure** to put socks or tights on your child.
Open all of the shoe's fasteners.



2. Place the foot in the shoe so that the heel is all the way back and down. Check that the shoe is fitted correctly using the viewing window.



3. Now close the middle strap first. It must be done up firmly as it keeps the heel in the correct position.



4. Pull the socks on from above and at the toe to straighten the folds. Then loosely close the remaining straps and repeat these steps with the second shoe.



5. To attach the splint to the shoes, attach the click fastener to the recesses in the sole and slide the splint towards the heel until the fastener clicks into place.



2.2 Redness and pressure points

Babies' skin is not really made for wearing shoes yet i.e. it is very sensitive. Although these shoes are made of soft material, they can sometimes cause pressure marks or blisters. Red marks or blisters, especially on the back of the heel, usually indicate that the shoe has not been worn firmly enough. Therefore, it is very important to make sure that the foot is really tight in the shoe, as slipping slightly back and forth in the shoe can cause pressure marks very quickly. Make sure that the heel rests against the sole at the bottom of the shoe by tightening the strap another hole. Never use lotion on red patches of skin. Lotion can make the problem worse.

Reddening of the skin that disappears a short time after the shoe has been removed is not a cause for concern. **However, if the redness becomes more severe and darker, or if a blister forms, please see your doctor as soon as possible.** They will decide how to proceed. If necessary, a plaster cast will be applied again, leaving the affected area of skin exposed so that it can heal. This is because if there are persistent problems when wearing them, it can be an early sign of a relapse.

2.3 Foot sweat and moisture

For children who are prone to heavy foot perspiration, the unusually long wearing time of 23 hours a day can cause shoes to be continuously damp. If you use shoes with a leather lining, it can also lead to mould on the inner leather in rare cases, as this is only tanned with vegetable substances to prevent allergies. We therefore always recommend, regardless of the lining material:

- air your shoes twice a day for half an hour
- if your feet perspire heavily, change socks several times a day

2.4 Clothing

The foot supports must always be worn with socks or tights. It is important to avoid pressure points. It is advisable to use socks with few threads and seams on the inside and to make sure that there are no creases in the fabric.

2.5 Adjusting the splints

The ECO-Brace Light foot abduction orthosis is usually initially adjusted to 70° external rotation (abduction) for a clubfoot and 40° for an unaffected foot. The dorsal extension – i.e. the flexion of the foot towards the tibia is fixed at 5° by the procurement of the splint. The length of the splint should be slightly above your child's shoulder width.

2.6 Cleaning the ECO-Brace Light foot abduction orthosis

The foot abduction splints can be cleaned with soap and water without any problems. There is no need to disinfect them. However, if you use a spray for disinfection or other harsh cleaning agents, the material could be attacked.

2.7 Known contraindications and side effects when using the ECO-Brace Light foot abduction orthosis

An absolute contraindication is an incomplete plaster corrective, especially if the heel is still raised. In this case, the foot does not sit properly in the shoe and the dorsiflexion set on the splint cannot fulfil its purpose (prevention of drop foot recurrence).

Relative contraindications are multiple impairments in the children to be treated. These are determined in advance by the respective treating physician of the respective centre of competence for clubfoot treatment according to Ponseti.

Blisters or redness could occur as side effects. In this case, parents should contact the responsible orthopaedic technician.

No other side effects are known.

2.8 Fitting the ECO-Brace Light foot abduction orthosis

The fitting of the respective foot abduction orthosis is to be carried out exclusively by a person specially trained for this purpose. These are orthopaedic technicians or orthopaedic shoemakers.

2.9 Training or specific qualifications of the product user

When the ECO-BRACE Light foot abduction orthosis is fitted, the orthopaedic technician/shoemaker and the attending physician instruct the parents of the children to be treated on how to use it.

The qualification of the orthopaedic technician/shoemaker should be a completed vocational training in their field of work. The orthopaedic technician/shoemaker should have carefully read the Sameda usage instructions.

2.10 Decommissioning



Safe disposal of the product is carried out by the parents or also by the fitting orthopaedic technician. The product can be disposed of in household waste according to local regulations.

2.11 Reporting serious incidents



All serious incidents occurring in connection with the use of the product must be reported to the manufacturer (see section 3) and to the authority responsible for the monitoring of medical devices at the user's place of business.

3. Addresses

3.1 Manufacturer (name, address, contact details)

Sameda GmbH
Am Petersberg 36
29389 Bad Bodenteich

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Fax.: +49-(0)5824 98 555-20

Email: info@semeda.de

Web: www.semeda.de

4. Performance data

4.1 Technical specifications of the ECO-Brace Light foot abduction orthosis

4.1.1 Specific properties of the ECO-Brace Light foot abduction splint

Product name	ECO-Brace Light foot abduction orthosis
Item number	EC 0500 -002
Used with:	Foot supports: ALFA-Flex shoes / Henry foot supports COMFOOT-Blue bandage shoes / foot supports COMFOOT-White bandage shoes / foot supports
Specific function	As a system orthosis with the foot supports: The ECO-Brace Light foot abduction orthosis is used for babies/toddlers and children diagnosed with idiopathic clubfoot according to the conservative therapy approach of Dr Ponseti. It serves to maintain the correction of the foot that has been achieved by a plaster corrective. It serves to prevent a relapse (renewed deterioration) and has no corrective effect.
Indication	For the treatment of idiopathic clubfoot
Therapeutic principle	Immobilisation of the foot to prevent a recurrence of clubfoot
Patient group	Babies/toddlers/children aged 0–5 years
Size/width	Splint length up to 30 cm
Colour	Black/blue
Material	Plastic
Features	
Adjustment of abduction angle	Range between 0 and 80°
Adjustment of dorsal extension	Applied at 5°
Click fasteners for adapting the foot supports	X
Splint versions	
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Extras/accessories for the product	
ALFA-Flex sole plates	X
Item number	ET 0700-003

4.2 Technical specifications of the foot supports

4.2.1 Specific characteristics of ALFA-Flex foot supports

Product name	ALFA-Flex shoes / Henry foot supports
Item number	AL 1411-size-side
Used with:	ECO-Brace foot abduction splint
Specific function	<p>As a system orthosis with the foot abduction splint: The foot abduction orthosis is used for babies/toddlers and children diagnosed with idiopathic clubfoot according to the conservative therapy approach of Dr Ponseti.</p> <p>It serves to maintain the correction of the foot that has been achieved by a plaster corrective. It serves to prevent a relapse (renewed deterioration) and has no corrective effect.</p>
Indication	For the treatment of idiopathic clubfoot
Therapeutic principle	Immobilisation of the foot to prevent a recurrence of clubfoot
Patient group	Babies/toddlers/children aged 0–5 years
Size	070–210 (foot length in mm)
Colour	Blue
Material	leather + textile
Features	
Click fastener to the splint	X
Thorn strap	--
Velcro fasteners	3
Extras for the product	
Heel pad ALFA-Soft 1: Small, for shoe sizes 70 – 100, item no.: AL 1700-001	X
Heel pad ALFA-Soft 2: for shoe sizes from 110, item no.: AL 1700-002	X

4.2.2 Specific characteristics of COMFOOT bandage shoes / foot supports

Product name	COMFOOT-White bandage shoes / foot supports	COMFOOT-Blue bandage shoes / foot supports
Item number	CW 1833-size-side	CB 1811-size-side
Used with:	ECO-Brace Light foot abduction splint	
Specific function	<p>As a system orthosis with the foot abduction splint: The foot abduction orthosis is used for babies/toddlers and children diagnosed with idiopathic clubfoot according to the conservative therapy approach of Dr Ponseti.</p> <p>It serves to maintain the correction of the foot that has been achieved by a plaster corrective. It serves to prevent a relapse (renewed deterioration) and has no corrective effect.</p>	
Indication	For the treatment of idiopathic clubfoot	
Therapeutic principle	Immobilisation of the foot to prevent a recurrence of clubfoot	
Patient group	Babies/toddlers/children aged 0–5 years	
Size	070–180 (foot length in mm)	070–180 (foot length in mm)
Colour	White	Blue
Material	Leather, neoprene and lycra	Leather, neoprene and lycra
Features		
Click fastener to the splint	X	X
Thorn strap	3	1
Velcro fasteners	--	2
Extras for the product	-	

4.3 Definition of symbols and identifying colours

The following symbols are used in the usage instructions and on the product:



CAUTION: This symbol identifies warnings and precautions in the usage instructions.



FOLLOW USAGE INSTRUCTIONS: This symbol indicates the need for the user to consult the usage instructions.



ITEM NUMBER: Indicates the manufacturer's item number so that the medical device can be identified.



LOT NUMBER: Displays the manufacturer's lot number so that an individual medical device can be identified.



DATE OF MANUFACTURE: Displays the date the medical device was manufactured.



MEDICAL DEVICE: Symbol indicating that the product is a medical device.



MANUFACTURER: Indicates the manufacturer of the medical device according to the EU Medical Devices Regulation 2017/745 (MDR).

5. Assembly instructions (for orthopaedic technicians only)

5.1 Assembly instructions for the ECO-Brace Light foot abduction orthosis

INSTRUCTIONS OF USE for ECO-Brace Light for Orthopaedic Technicians

Foot abduction braces are used for the after-treatment of an idiopathic clubfoot, according to the Ponseti method. Recommended period of treatment: From date of plaster cast removal up to 4 - 5 years of age.



Scope of delivery

1. ALFA-Flex or COMFOOT-Blue Shoes
2. Hexagon socket key 4/5 mm,
3. Torx key TX 10/20
4. ECO Brace Light Foot Abduction Brace

Important information:

Brace: Intended for a max. therapy period of 5 years. Total lifespan: 8 years.

Shoes: Lifespan 8 years

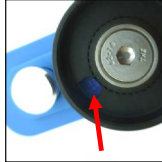
The year of manufacture can be determined by the first two figures in front of the serial number.

Storage: Protected from frost and direct sunlight, medium humidity



Adjusting the length of the brace:

- Variable length from 200 – 290 mm
- Loosen the 2 screws which connect the brace parts (Torx-key TX20)
- Adjust the rail length to at least (!) the shoulder width of the child
- Fasten the self-locking screw tightly



Abduction angle setting:

- Use the hexagon socket key to loosen the screw underneath the brace by a **quarter turn**.
- Then gradually rotate the plate outwards and allow it to engage at the desired angle (degree increments can be read via the view window). (The Ponseti method recommends 70° for a clubfoot, 40° for a healthy foot.)
- Fasten the self-locking screw tightly

Wearing the shoes and brace:

1. Place the foot in the shoe with the heel right back and seated down in the shoe – check the correct position via the heel window
2. Close and **tighten** the **middle strap** first (helps to hold the heel in the correct position), loosely tighten the other strap
3. Push the shoe downwards onto the click-system fastener, and push the brace towards the heel until the pin locks into position. To **release** the brace, extract the pin, push the brace as far as possible towards the toes and then lift it off.

The shoes are not suitable for walking! Risk of slipping!

The conformity of the ECO-Brace Light foot abduction orthosis from Sameda is confirmed by the CE mark. The current version of the EU declaration of conformity can be requested from Sameda at any time. For orthopaedic technicians, the declaration of conformity is available for download at www.semēda.de under the section [english/download/technicians](#).





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