

ALFA-Flex & BETA-Flex Foot Abduction Orthosis Usage Instructions



TL 3001-002

Contents

1. Information about our products	3
1.1 Warning and safety instructions	3
1.2 ALFA-Flex & BETA-Flex foot abduction orthosis	5
1.2.1 Specific function	5
1.2.2 How it works	5
1.2.3 Foot support	5
1.2.4 The AFLA-Flex Brace foot abduction splint / ALFA-Flex XL Brace foot abduction splint	5
1.2.5 Die BETA-Flex Brace foot abduction splint	6
1.3 Accessories	7
1.3.1 ALFA-Flex XL central oval, extension kit	7
1.3.2 BETA-Flex Mini	7
1.3.3 ALFA-Soft heel pad	7
1.3.4 Protective pad for the foot abduction splints	8
1.3.5 ALFA-Flex sole plates	8
2. Application	9
2.1 Putting on the orthoses	9
2.2 Redness and pressure points	9
2.3 Foot sweat and moisture	10
2.4 Clothing	10
2.5 Adjusting the splints	10
2.5.1 The AFLA-Flex Brace foot abduction splint / ALFA-Flex XL Brace foot abduction splint	10
2.5.2 The BETA-Flex Brace foot abduction splint	10
2.6 Cleaning the ALFA-Flex or BETA-Flex foot abduction orthosis	10
2.7 Known contraindications and side effects when using the ALFA-Flex or BETA-Flex foot abduction orthosis	10
2.8 Fitting the ALFA-Flex or BETA-Flex foot abduction orthosis	11
2.9 Training or specific qualifications of the product user	11
2.10 Decommissioning	11
2.11 Reporting serious incidents	11
3. Addresses	11
3.1 Manufacturer (name, address, contact details)	11
4. Performance data	12
4.1 Technical specifications of the ALFA-Flex foot abduction orthosis	12
4.1.1 Specific properties of the ALFA-Flex Brace foot abduction splint / ALFA-Flex XL Brace foot abduction splint	12
4.1.2 Specific properties of the foot supports	13
4.2 Technical specifications of the BETA-Flex foot abduction orthosis	13
4.2.1 Specific properties of the BETA-Flex Brace foot abduction splint	13
4.2.2 Specific characteristics of the foot supports	14
4.3 Technical specifications of the foot supports	14
4.3.1 Specific characteristics of ALFA-Flex foot supports	14
4.3.2 Specific characteristics of COMFOOT bandage shoes / foot supports	15
4.4 Definition of symbols and identifying colours	16
5. Assembly instructions (for orthopaedic technicians only)	17
5.1 Assembly instructions for the ALFA-Flex Brace foot abduction orthosis	17
5.2 Assembly instructions for the ALFA-Flex Brace XL foot abduction orthosis	18
5.3 Assembly instructions for BETA-Flex foot abduction orthosis	19
5.4 Assembly instructions for BETA-Flex Mini, short splint bar	21
6. More Solutions from the World of Semeda	23

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).



semada
ORTHOPAEDIC PRODUCTS

...step by step forward



If a defect occurs in the ALFA-Flex or BETA-Flex 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.



The 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 ALFA-Flex Brace and BETA-Flex Brace 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 ALFA-Flex Brace and BETA-Flex Brace foot abduction splint yourself, as this could lead to a relapse! 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 ALFA-Flex and BETA-Flex foot abduction orthosis

1.2.1 Specific function

The ALFA-Flex and BETA-Flex 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.

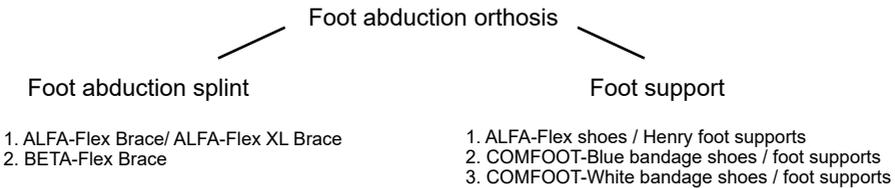
The orthopaedist prescribes an orthosis to continue their treatment. The orthopaedic technician (or orthopaedic shoemaker) fits the orthosis to the children on the basis of the orthopaedist's prescription. The parents of affected children put the orthosis on daily. The orthosis is a reusable product.

1.2.2 How it works

The foot abduction orthosis consists of a foot abduction splint (ALFA-Flex Brace/ ALFA-Flex Brace XL or BETA-Flex Brace) and a foot support (ALFA-Flex shoes / foot supports or COMFOOT bandage shoes / foot supports).

There are three different models of foot supports, each of which fits the ALFA-Flex Brace foot abduction splint / ALFA-Flex XL Brace foot abduction splint and BETA-Flex Brace 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.

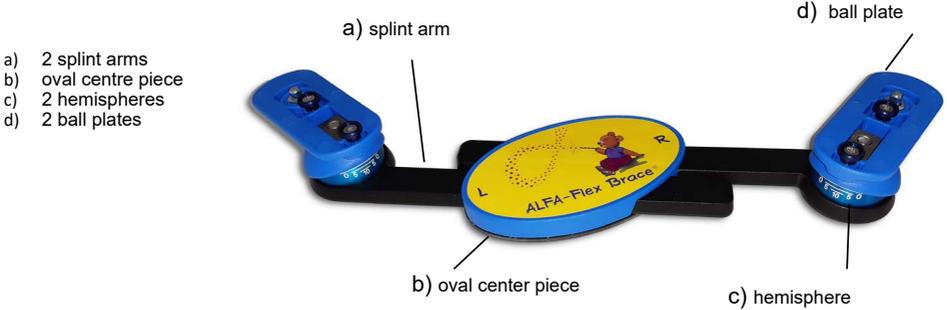
1.2.4 The AFLA-Flex Brace foot abduction splint / ALFA-Flex XL Brace foot abduction splint

The AFLA-Flex Brace foot abduction splint and the ALFA-Flex XL Brace foot abduction splint are considered together here. The ALFA-Flex XL Brace foot abduction splint is listed as a variant of the ALFA-Flex Brace foot abduction splint. It is created in a configuration with the accessory part of the ALFA-Flex XL central oval, extension kit. The ALFA-Flex XL Brace foot abduction splint can also be purchased separately.

The ALFA-Flex Brace foot abduction splint / ALFA-Flex XL Brace 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°). Furthermore, the ALFA-Flex Brace foot abduction splint / ALFA-Flex XL Brace foot abduction splint offers the possibility to adjust the dorsal extension (0° – 20°).

The **ALFA-Flex Brace foot abduction splint** has a continuously adjustable splint length up to 29 cm in width and grows with the patient over the entire treatment period. The ALFA-Flex XL Brace foot abduction splint has a maximum width of 37 cm.

The main functional elements of the ALFA-Flex Brace foot abduction splint / the ALFA-Flex XL Brace foot abduction splint are:



The ALFA-Flex XL Brace foot abduction splint has a larger central section than the ALFA-Flex Brace foot abduction splint shown here. This can be seen in the illustrations under the item Accessories.

1.2.5 The BETA-Flex Brace foot abduction splint

The BETA-Flex Brace foot abduction splint immobilises the feet in an abduction angle that can be adjusted between 0° and 70°; the dorsal extension is fixed in the therapeutic range of 5°. During splint treatment, two spring-back joints enable the child to make light kicking movements and crawl in opposite directions. The built-in spring automatically returns the foot to the therapeutic position when the child relaxes.

The BETA-Flex Brace foot abduction splint (continuously adjustable splint length up to 29 cm width) grows with the child throughout the entire therapy period.

The main functional elements of the BETA-Flex Brace foot abduction splint are:



1.3 Accessories

1.3.1 ALFA-Flex XL central oval, extension kit

The ALFA-Flex XL central oval, extension kit makes it possible to extend the ALFA-Flex Brace foot abduction splint for particularly tall children so that treatment can be continued for longer. The ALFA-Flex XL central oval, extension kit increases the maximum splint width to 37 cm.



After inserting the ALFA-Flex XL central oval, extension kit, the ALFA-Flex Brace foot abduction splint becomes the ALFA Flex XL Brace foot abduction splint in configuration.

The ALFA Flex XL Brace foot abduction splint is a foot abduction splint especially for taller children (from shoe size 150 mm upon initial fitting). It can be extended to a splint width of 37 cm.



1.3.2 BETA-Flex Mini

On request, an especially small and light middle section, the BETA/Flex Mini, is available for the BETA-Flex Brace foot abduction splint (e.g. for especially small or premature babies).

As the child grows, the middle piece is exchanged for the length-adjustable standard module.



1.3.3 ALFA-Soft heel pad

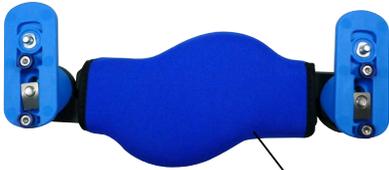
The ALFA-Soft heel pad is particularly suitable for use with the ALFA-Flex shoes / foot supports.

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.

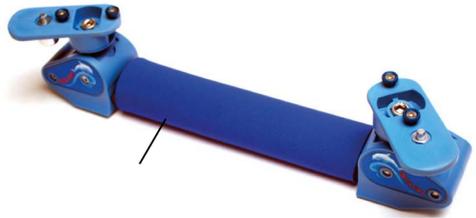


1.3.4 Protective pad for the foot abduction splints

An ALFA-Flex protective pad or a BETA-Flex protective pad is available as an accessory for the particular foot abduction splint. These can be attached around the respective splint bar or around the central oval. The protective pad serves, for instance, to prevent injuries to children, but also to protect furniture and floors from scratches.



ALFA-Flex protective pad



BETA-Flex protective pad

1.3.5 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 systems 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.



6. When both shoes are fastened, your child must see the bear dolphin the right way round.



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

2.5.1 The AFLA-Flex Brace foot abduction splint / ALFA-Flex XL Brace foot abduction splint

The ALFA-Flex Brace Foot Abduction Splint / ALFA-Flex XL Brace foot abduction splint is usually initially adjusted to 70° external rotation (abduction) for a clubfoot and 40° for an unaffected foot. Dorsal extension – i.e. flexion of the foot towards the shin – is set at 5 – 10°. These settings may seem extreme to people who are not familiar with the Ponseti method, but they are normal and necessary for the treatment. If you look at your child's last cast, you will notice a similar position. The length of the splint should be slightly above your child's shoulder width.

2.5.2 The BETA-Flex Brace foot abduction splint

The BETA-Flex Brace foot abduction splint allows young patients more freedom of movement with full therapeutic functionality. The abduction angle can be set between 0° and 70°; the dorsal extension is fixed at 5° in the therapeutic area.

Two spring-back joints enable a child to more naturally kick and crawl during splint treatment. The reset forces mean that the feet are always realigned into the desired therapeutic position.

2.6 Cleaning your ALFA-Flex or BETA-Flex foot abduction orthosis

Your 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 ALFA-Flex or BETA-Flex 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 ALFA-Flex or BETA-Flex 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 ALFA-Flex or BETA Flex foot abduction orthosis is fitted, the orthopaedic technician/shoemaker and the attending physician instruct the parents and, if applicable, the children being treated in its use.

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

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

Email: info@sameda.de

Web: www.sameda.de

4. Performance data

4.1 Technical specifications of the ALFA-Flex foot abduction orthosis

4.1.1 Specific properties of the ALFA-Flex Brace foot abduction splint / ALFA-Flex XL Brace foot abduction splint

Product name	ALFA-Flex Brace foot abduction splint
Item number	0700-000
Medical device item	23.03.02.1001
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 ALFA-Flex 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 30cm
Colour	Black/blue
Material	Plastic
Features	Round oval in the splint bar with bear sticker
Adjustment of abduction angle	Range between 0 and 80°
Adjustment of dorsal extension	Range between 0 and 20°
Click fasteners for adapting the foot supports	X
Splint versions	
ALFA-Flex XL Brace foot abduction splint	X
Item number	AL 0700-0XL
Size/width	Up to 37 cm
Accessories for the product	
ALFA-Flex protective pad	X
Item number	AL 0700-001
ALFA-Flex XL central oval, extension kit	X
Item number	AL 0700-1XL
ALFA-Flex sole plates	X
Item number	ET 0700-003

4.1.2 Specific properties of the foot supports

Both the ALFA-Flex shoes / foot supports and the COMFOOT bandage shoes / foot supports can be used as components of the ALFA-Flex foot abduction orthosis. These foot supports can also be used in the BETA-Flex Brace foot abduction splint system. In order to avoid listing them twice, the specific characteristics of the foot supports are dealt with under point 4.3.

4.2 Technical specifications of the BETA-Flex foot abduction orthosis

4.2.1 Specific properties of the BETA-Flex Brace foot abduction splint

Product name	Beta-Flex Brace foot abduction splint
Item number	BE 0600-000
Medical device item	23.03.02.1004
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 BETA-Flex Brace 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 rotors enable the child to have a limited kicking movement.
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	Variable from 200 to 290 mm
Colour	Black/blue
Material	Plastic
Features	Blue rotor housing with dolphin sticker
Adjustment of abduction angle	Between 0 und 70°
Adjustment of dorsal extension	Fixed at 5°
Click fasteners for adapting the foot supports	X
Accessories for the product	
BETA-Flex protective pad	X
Item number	BE 0600-001
BETA-Flex Mini, short splint bar	X
Item numbers	BE 0600-002
ALFA-Flex sole plates	X
Item number	ET 0700-003

4.2.2 Specific characteristics of foot supports

Both the ALFA-Flex shoes/foot supports and the COMFOOT bandage shoes/foot supports can be used as components of the BETA-Flex foot abduction orthosis. These foot supports can also be used in the ALFA-Flex Brace foot abduction splint system. In order to avoid listing them twice, the specific characteristics of the foot supports are dealt with under point 4.3.

4.3 Technical specifications of the foot supports

4.3.1 Specific characteristics of ALFA-Flex foot supports

Product name	ALFA-Flex shoes / Henry foot supports
Item number	AL 1411-size-side
Medical device item	The assistive device position of the ALFA-Flex Brace or BETA-Flex Brace foot abduction splint is used.
Used with:	The AFLA-Flex Brace foot abduction splint / ALFA-Flex XL Brace foot abduction splint Beta-Flex Brace foot abduction splint
Specific function	As a system orthosis with the foot abduction splint: The ALFA-Flex 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	070–210 (foot length in mm)
Colour	blue
Material	Leather + textile
Features	
Click fastener to the splint	X
Thorn strap	1
Velcro fasteners	2
Accessories 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

4.3.2 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
Medical device item	The assistive device position of the ALFA-Flex Brace or BETA-Flex Brace foot abduction splint is used.	
Used with:	The AFLA-Flex Brace foot abduction splint / ALFA-Flex XL Brace foot abduction splint Beta-Flex Brace foot abduction splint	
Specific function	As a system orthosis with the foot abduction splint: The ALFA-Flex 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	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	-	



4.4 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 ALFA-Flex Brace foot abduction orthosis

ALFA-Flex Brace® - ASSEMBLY INSTRUCTIONS - for Orthopaedic Technicians

Foot Abduction Brace for after-care of idiopathic clubfoot as part of the Ponseti Therapy.
Recommended period of treatment: from removal of last plaster cast to child's 4th/5th year of age.

 <p>Contents</p> <ul style="list-style-type: none"> ALFA-Flex or COMFOOT-Blue Shoes Allen-key 4 mm Tork-key TX20 ALFA-Flex Foot Abduction Brace <p>Important information:</p> <p>Brace: Intended for a max. therapy period of 5 years. Total lifespan: 8 years.</p> <p>Shoes: Lifespan 8 years</p> <p>The year of manufacture can be determined by the first two figures of the batch number.</p> <p>Storage: Protected from frost and direct sunlight, medium humidity</p>	 <p>Adjustment of length:</p> <p>Variable length adjustment: 180-300mm</p> <p>Unscrew 6 screws by using the Torx-key. Adjust bars to child's shoulder-width as a minimum. Tighten screws with 3 or more turns and secure with "LOCTITE 222"</p>	 <p>Adjustment of angles:</p> <ol style="list-style-type: none"> Unscrew screws by using the allen-key Choose dorsal extension at scale on ball (unless given other instructions by doctor: 5-10°) Choose abduction in the window of the bar (unless given other instructions by doctor: 70° for a clubfoot, 40° for a healthy foot) Strongly tighten screw, to avoid accidental loosening secure with "LOCTITE 222". (important: otherwise the child might swallow or choke on the parts) 	 <p>Putting on Shoes and Brace:</p> <ol style="list-style-type: none"> Place the foot into the shoe - the heel must be placed at the backmost bottom part of the shoe (check in the heel window) First close the middle strap tightly (keeps the heel in the right position). Close the other straps booser Place the shoe on the click system from above and pull the brace back in direction of the heel until the bolt snaps in <p>Open the brace by pulling the bolt, push brace to block in direction of the toes and lift</p> <p>Shoes not suitable for walking! Danger of slipping!</p>
--	--	---	--

5.2 Assembly instructions for the ALFA-Flex Brace XL foot abduction orthosis

Foot abduction orthosis for follow-up treatment of idiopathic clubfoot as part of Ponseti therapy.
Recommended duration of treatment: from the time of the last cast removal until the child is 4/5 years



Mounting ALFA-Flex XL centre oval, extension kit (AL 0700 - 1XL):

1. Loosen and remove 6 screws of the original centre oval on the rail (Torx key) and remove the rail arms.
2. Loosen and remove 6 screws of the XL centre oval, extension kit (Torx key) and remove the cover plate.
3. Insert the rail arms into the base body (blue) as shown in picture 1.
4. Put on the cover plate and tighten the screws.
5. Adjust the rail length to at least(!) the shoulder width of the child.
6. Tighten the screws in 3 or more passes, secure with "LOCTITE 222"!

5.3 Assembly instructions for BETA-Flex foot abduction orthosis

ASSEMBLY INSTRUCTIONS for the BETA Flex Brace - for Orthopaedic Technicians



Foot Abduction Brace for after-care of idiopathic clubfoot as part of the Ponseti Therapy.
Recommended period of treatment: from removal of the last plaster cast to the child's 4th / 5th year of age.



Contents

1. ALFA-Flex or COMFOOT Shoes
2. BETA-Flex Foot Abduction Brace
3. Allen-key 5 mm
4. Torx-key T 20 and T 10
5. 2 additional springs with higher resistance
6. 4 Locking pins (of which 2 are replacements)

Important information:

Brace: Intended for a max. therapy period of 5 years. Lifespan: 6 years
Shoes: Lifespan 8 years
The year of manufacture can be determined by the first two figures on the batch number
Storage: Protected from frost and direct sunlight, medium humidity



Adjusting the length:

Variable length adjustment from 200 to 290 mm.
Unscrew 2 screws (Torx-key T 20).
Adjust the brace length to at least (!) the child's shoulder-width.
Re-tighten the screws firmly.



Adjustment of angles:

Unscrew the screws one quarter turn on the upper side of the brace using the Allen-key.
Turn the plate gradually outwards and let it lock into place at the desired angle-degree (see window under the shoe support plate). Ponseti recommends 70 ° for clubfoot, 40 ° for a healthy foot.
Re-tighten the screw firmly.



Putting on Shoes and Brace:

1. Insert the foot into the shoe so that the heel is firmly at the back, and on the sole - check in the heel window.
2. First close the middle strap tightly (keeps the heel in the correct position). Close the other straps more loosely.
3. Place the shoe on the click system from above and slide the brace backwards in the direction of the heel until the bolt snaps into place. Open the brace by pulling the bolt, push the brace as far as it will go in the direction of the toes and lift off.

Shoes not suitable for walking! Danger of slipping!



For infants with a shoulder-width of less than 20 cm, we offer the extra-light BETA-Flex mini. The 8.5 cm long base can be connected to the rotors of the BETA-Flex Brace.

Locking the BETA Flex Brace



1



2



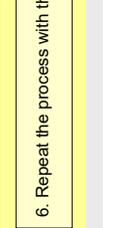
3a



3b



4



5

6. Repeat the process with the other rotor casing.

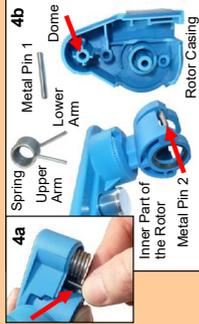
Inserting the stronger springs

1. Lubricate the new springs with spindle grease on the inside and outside.
2. Open the rotor casing according to points 1 and 2 in the instructions on the left.



3

3. Remove the rotor casing from the brace base.



4a

4. Remove the metal pin from its position between the arms of the spring. Then remove the spring. This loosens the inner part of the rotor.

4b

5. Insert the inner part of the rotor into the rotor case again and keep it fixed in its position.

6. Insert the new spring so the lower spring arm is over metal pin 2, and the upper spring arm is under metal pin 2.

7. Turn the spring into the correct position while keeping the tension and push it onto the plastic dome of the rotor casing.

8. Insert metal pin 1 into the hole provided in the rotor casing between the spring arms.

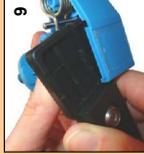


5

6

7

8



9. Replace the brace base in the rotor casing.

10. Close the rotor casing according to points 4 and 5 in the instructions on the left.

11. Repeat the process with the other rotor casing.

5.4 Assembly instructions for BETA-Flex Mini, short splint bar



Inserting the BETA-Flex Mini



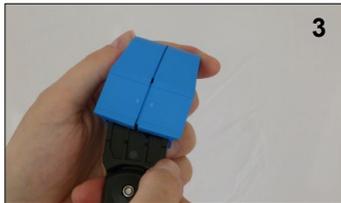
1

1. Loosen both screws that hold the two halves of the rotor casing together by two full rotations (Torx-key T 10).



2

2. Then open the rotor casing from the bottom a gap wide.



3

3. Pull the bar out of the rotor casing.



4

4. In its place, insert the BETA-Flex Mini.



5

5. Press the two halves of the rotor casing together again firmly and tighten the screws again.

6. Repeat the process with the other rotor casing.



semeda[®]
ORTHOPAEDIC PRODUCTS

...step by step forward

The conformity of the ALFA-Flex and BETA-Flex foot abduction orthoses 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.semesta.de under the section english/download/technicians.



6. More solutions from the world of Sameda

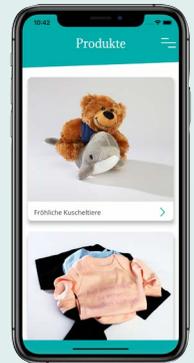
Sameda information material for parents – practical information about splint treatment

In our information material for parents, we have summarised the most important information for parents about our orthoses and correct splint treatment. Interested parties can download the brochures in various languages from our website at www.semesta.de under the section english/download/parents..



NEW! The Sameda Wearing Diary app – everything under control digitally

A consistent daily implementation of splint treatment is an important building block for a lasting therapeutic success. With the Sameda Wearing Diary app, I can easily and conveniently record my wearing times digitally and thus optimally implement my therapy scheme. Many other practical functions make the app a smart companion during splint treatment. Available now free of charge in the Playstore and the App Store



Play time: video section at www.semesta.de

You will find a video section on our website with an overview, background information and case studies of the Ponseti Method and splint treatment.



Film ab - Ponseti in Spanien



 Hospital General Universitario Gregorio Marañón



Das Madrider Universitätsklinikum stellt sein ganzheitliches Ponseti-Programm vor



semeda[®]

ORTHOPAEDIC PRODUCTS

... step by step forward

SEMEDA GmbH

Am Petersberg 36
D-29389 Bad Bodenteich
Deutschland/Germany

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

Mail: info@semeda.de
Web: www.semeda.de