

Custom-made Medical Device

Instructions for Use

829010.011-16 AFO
Ankle Foot Orthosis

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1 Description and Intended Purpose

These instructions for use are intended for both the practitioner and user unless otherwise stated.

Please read and ensure you understand all instructions for use, in particular all safety information and maintenance instructions.

An AFO is a custom-made medical device.

An AFO can be made from different materials including thermoplastic (plastic) or thermosetting (carbon-fibre) with or without the inclusion of ankle joints or hinges. The orthotist will determine which material choice, material thickness and the inclusion/exclusion of ankle joints is best for you and for use in your own environment. You may discuss alternative options with your healthcare professional.

Blatchford AFO is designed and clinically proven to use ergonomic principles. Blatchford have taken into account the unique requirements of the intended user. Blatchford ensures all AFOs and associated components which require adjustment or operation by the user, are easily accessible and ergonomically practicable for the user.

2 Safety Information



If after use, you see any discolouration on your skin that are in contact with the device, which don't disappear after 30 minutes, stop using the AFO and contact your healthcare professional for advice as it may need adjusting.



Should your functional requirements or condition change during the life cycle of the custom AFO please contact your healthcare professional as this could affect the custom AFO's performance.



The AFO has been designed and prescribed for an individual's needs and should only be used by that sole user.



The custom AFO must be regularly maintained to the maintenance schedule in this IFU by a qualified professional.



Repairs and adjustments to the custom AFO must be carried out by qualified, trained healthcare professionals. Please consult a qualified medical professional should you have any problems with this custom product.



Avoid strong magnetic fields, sources of electrical interference.



Do not place near any heat source. Do not leave in direct sunshine or inside a car in hot weather.



The device is not suitable for extreme sports, rugby or cycle racing, ice and snow sports. Any such activities undertaken are done so completely at the users own risk.



Do not remove any serial or warning labels from the AFO.



AFO may include flammable materials. Be aware of fire hazards where possible.



The device is not intended for use when immersed in water or as a showering orthosis unless specified for this purpose by your healthcare professional.



May contain animal tissues such as leather. Conformity certificate is available for further details should this be required.



Should the AFO display changes of performance or any fittings on the device come loose please immediately stop use and contact your healthcare professional.



Ankle joints can entrap fingers or clothing, be aware when operating the AFO.



Using well fitted footwear to reduce the risk of trips.

3 Everyday Use

The instructions in this section are primarily for the user (wearer)

Blatchford AFOs applies force to the body segments to which they are attached. The interface components have been designed to avoid unacceptable pressure on and stress levels in body tissues.

We advise patients should wear long cotton socks or tights under the AFO which are:

- Well fitting
- Un-patterned
- Pulled up firmly to eliminate creases

When putting the AFO on daily, the following steps should be taken:

- Check the AFO joints and straps are free from debris and move/function freely.
- It is best to put the AFO on whilst sitting or lying down. Place your leg into the AFO ensuring your heel is right to the bottom and at the back of the AFO or shoe.
- Ensure the ankle joints are roughly level with the middle of your ankle.
- Finally fasten the straps firmly.
- If you have a metal and leather AFO it is usually easiest to leave it connected to your shoe and put them both on at the same time. At first the AFO may feel uncomfortable so you

should gradually build up the amount of time you wear it each day. Your Orthotist will tell you how long you should build up to, or what activities to wear it for.

- Always check skin contact areas for rubbing.
- It is normal to see discoloration where pressure has been applied. This should disappear within 30 minutes.

IF NOT CONTACT YOUR HEALTHCARE PROFESSIONAL

Footwear advice

- Your AFO should always be worn with ordinary enclosed footwear with a fastening, i.e. laces or hook and loop.
- Look for shoes which have a low opening as this will help to put them on.
- Shoes with removeable insoles can offer extra depth to accommodate the AFO
- Avoid high heels. The height of the heel affects the alignment of the AFO. So before changing your footwear please discuss this with your treating medical professional.

4 Intended Use

A Custom AFO is provided to compensate for muscle weakness, paralysis or skeletal problems which cause lower limb instability. AFO is designed to:

- Provide support to weakened or weakening joints and muscles
- Realign some or all of the joints in the leg
- Prevent movement which is unhelpful or painful
- Provide protection
- Improve stability for safe standing
- Improve mobility

AFO's are prescribed and designed to meet the functional loss needs of each individual user rather than to treat an individual condition or pathology. AFO's are suitable for use on one or both limbs and can be used by infants through to adulthood. AFO builds are always intended to be used inside a shoe. Any shoe to be used with the Blatchford custom AFO should be approved by the users treating medical professional to ensure it is suitable, as the heel height and pitch of the footwear can lead to trips and falls whilst using a custom AFO.

Indications

Intended for users with a weight of 100 kg or less.

Contraindications

Users with a weight over 100 kg.

AFO's are intended for the sole use if the patient named on the conformity documentation. If the AFO is no longer required, it must be safely disposed of. Please follow the guidelines below:

- Ensure the orthotist is aware the AFO is no longer required.
- Return the AFO for safe disposal.

5 Intended Performance

Lifting Loads

User weight and activity is governed by the stated limits provided by third party component manufactures. Load carrying by the user should be kept to a minimum and based on a local risk assessment carried out by the treating medical professional responsible for the AFO's prescription. If carrying heavy loads is an activity of daily living, the user must inform their medical professional of this requirement.

Environment

Avoid exposing the AFO to corrosive elements such as water, acids and other liquids. Also avoid abrasive environments such as those containing sand for example as these may promote premature wear. AFO are recommended for use between -10°C and $+50^{\circ}\text{C}$ (14 F to 122 F).



Suitable for outdoor use

Activity

AFO's are intended to be used for standing, walking and no-weight bearing activities. They are not designed for high activity sport such as running, jumping, cycle-racing, or snow sports. Any such activities undertaken are done so completely at the user's own risk.

Lifetime

It is recommended that AFO's are evaluated by a healthcare professional after every 12 months of use as a minimum to determine continued suitability of use. Your healthcare professional will advise on how to contact them for review. If you experience any issues or feel your clinical needs have changed, please contact your healthcare professional.

6 Maintenance

Cleaning

Cleaning any AFO is very important for both user safety and ensuring the longevity of the medical device. The AFO should be wiped clean daily. Please note that stains caused by bodily fluids should be removed immediately. When cleaning the AFO use a soapy soft cotton cloth and gently rub with circular movements to remove stubborn dirt utilising domestically available anti-bacterial cleaning products. Do not pressure wash your AFO. Use a clean cotton cloth to wipe the area and dry the surface of the AFO after cleaning.

Note: These are recommended or suggested methods of cleaning. Blatchford is not responsible for damage incurred whilst cleaning. If you are not sure how best to clean your AFO, please contact your prescribing medical professional.

6.1 Maintenance Schedule

Daily

- User visual inspection
- Inspect all over generally for any obvious signs of wear and tear
- Ensure straps remain well adhered and Velcro is retaining fixation
- No visible signs of material fatigue. Signs include cracks, chips, and stress lines in the material.

Monthly

- User check for any noise (creaks) in the joints within the device when moving the ankle joint (if present) through its full range of motion

6 Monthly

- We recommend each device is fully serviced by the manufacturer and any worn parts should be repaired or replaced as appropriate.
- Ensure all labels on the products are intact and never remove any warning labels or serial numbers from the device.
- Failure to comply may invalidate the warranty.

6.2 Transport & Storage

Store the AFO in a safe, clean and dry place, out of direct sunlight and away from heat sources such as radiators and ovens.

Ensure the AFO is thoroughly protected from damage in transit.

7 Manufacturer's Declarations and Legal Information

Liability

The manufacturer recommends using the device only under the specified conditions and for the intended purposes. The device must be maintained according to the instructions for use supplied with the device. The manufacturer is not liable for any adverse outcome caused by any component combinations that were not authorized by them.



Medical Device



Single Patient – multiple use

Warranty

Blatchford Orthotic products are warranted for a period of 12 months. Any straps and liners are warranted for a period of 6 months.

The user should be aware that changes or modifications not expressly approved could void the warranty, operating licenses and exemptions.

See the Blatchford website for the current full warranty statement.

Reporting of Serious Incidents

In the unlikely event of a serious incident occurring in relation to this device it should be reported to the manufacturer and your national competent authority.

Manufactured by



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