

Custom-made Medical Device

Instructions for Use

829021 Modular footwear

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1 Description and Intended Purpose

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

The term footwear is used throughout these instructions for use to refer to Custom-made Blatchford Modular footwear products.

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

Components for Blatchford Modular footwear products are manufactured by Mendivil (Camino) and final manufacture and distribution is performed by Blatchford.

2 Safety Information



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



Should you develop any sores or blisters you should stop use of the footwear immediately.



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



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



If Modular footwear parts come loose please immediately stop use and contact your healthcare professional.



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



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



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. Any such activities undertaken are done so completely at the users own risk.



If you have a lack of sensation or compromised tissue viability it is vital to check your skin regularly after wearing your footwear.



Ensure that you follow the guidance on putting on your footwear which has been adapted correctly as instructed by your Orthotist, i.e. ensure that your foot is placed at the back of the shoe and the fastening is holding your foot snug and secure within.



Some repairs to your footwear should be carried out by the orthotic service; your healthcare professional will advise you where this is required. Where footwear has standard soles and heels, some repairs may be carried out by a high street cobbler. It is important that you maintain the condition of your footwear, including regular cleaning, checking for wear and arranging repairs promptly, to help ensure it lasts as long as possible.



If there is a change in your condition or to your lifestyle and you experience a negative impact in your walking or comfort, please arrange a review appointment with your Orthotist.



Ensure you are wearing socks with your footwear which reduces the friction between your skin and shoe.



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

3 Everyday Use

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

Most of our footwear come with three inlays to allow flexibility of fit. You may have an insole made if this is needed for your condition. The footwear is made deeper to accommodate these insoles. Soles and heels may be adapted on the outside to improve the way you walk.

We recommend wearing your footwear with a pair of socks. Certain medical conditions can make feet more at risk to injury. You may require a check before and after wearing the footwear. This could avoid injury to your feet. To avoid injury to your feet, check inside your shoes each time before you put them on for: grit, stones, pins or loose objects.

Check your feet after wearing your footwear to ensure that there is no discoloration lasting longer than 30 minutes, blisters, swelling or cuts. If you find any of the above changes whilst wearing your footwear, you should stop wearing the footwear immediately and contact the healthcare professional for an appointment.

Putting on your footwear

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

- Open the fastening (Velcro or laces) all the way down for ease of donning. If you have been provided with insoles, ensure that there are no creases present and in the correct side of the shoe.
- After checking the inside of your shoe for foreign bodies and ensuring no wrinkles in your socks, place your foot inside the shoe ensuring your heel is fitting right at the back of the shoe.
- Finally fasten the shoe laces/Velcro securely.

It is important that your foot is held securely in your footwear. This prevents your foot from moving forward and crushing your toes or slipping out of the heel.

At first Blatchford footwear may feel slightly heavy and unfamiliar, so we recommend to gradually build up the amount of time you wear it each day. Your healthcare professional will tell you how long you should build up to, or what activities to wear it for.

Recommend initial use. Day 1: 30-60 minutes, Day 2: 1-2 hours, Day 3: 3-4 hours, Day 4: 4-5 hours

Certain medical conditions may require deviation away from the above timings Your healthcare professional will provide you with a personalised wearing regime.

4 Intended Use

Blatchford Modular footwear is designed specifically for an individual. Your healthcare professional will explain the intended aim and functional objective of your footwear.

Please be aware that some footwear may appear bulky and could feel heavier than off the shelf products. Always remember why the footwear has been prescribed. Slim, fashion footwear are more likely to cause long term damage to your feet. Your healthcare professional will always strive to have footwear manufactured that has the style of standard footwear, where possible, whilst still meeting your needs. The footwear is individually made, so it is not always possible to achieve style and patterns which are available with mass produced shoes. We can offer a choice of colours, styles and materials. The Orthotist will advise what is best for you.

Modular footwear is intended for users with any mass or size. Your healthcare professional will advise on the optimum footwear product for your needs. Modular footwear is intended for the sole use of the patient named on the conformity documentation. If the footwear is no longer required, it must be safely disposed. Please follow the guidelines below:

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

5 Intended Performance

Lifting Loads

If carrying heavy loads is an activity of daily living, the user must inform their medical professional of this requirement.

Environment

Avoid exposing the footwear 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. Footwear is recommended for use between -10°C and $+50^{\circ}\text{C}$ (14 F to 122 F).



Suitable for outdoor use

Activity

Footwear is intended to be used for standing, walking and weight bearing activities. They are not generally designed for extreme sports. Any such activities undertaken are done so completely at the user's own risk.

Lifetime

It is recommended that Modular footwear is evaluated by an orthotist after every 12 months of use as a minimum to determine continued suitability of use.

6 Maintenance

Cleaning

Footwear made from leather should be polished regularly. Nubuck and Suede footwear should be cleaned using brushers and specialized cleaners which are available at most shoe shops. Wet footwear should be allowed to dry thoroughly before wearing. Dry in a well-ventilated area at room temperature. Do not put your footwear on a radiator, near a fire, in a tumble dryer or in an airing cupboard. Mud and heavy soiling should be removed with a damp cloth before they are left to dry.

6.1 Maintenance Schedule

Daily

- Check for wear and tear of the rubber sole. If the pattern on the sole has worn down and is not visible anymore, the sole unit needs to be repaired.
- Check that the sole unit remains glued to the base unit. If there are areas where it is unstuck, it will need repairing.

12 months

- Reviews every twelve months are recommended as your condition or presentation may change over time or the footwear which has been worn is beyond repair and needs replaced.

Long Term Use: The Modular footwear is designed to match your condition and the characteristics of your walking pattern at the time of your assessment. If you find that there is a change to your condition which impends you're walking and comfort of your footwear, a review is necessary. In general, if you find that there are any negative changes to your walking pattern or comfort, contact your healthcare professional for a review. A new referral from your healthcare professional may be needed before a review can be made. Your healthcare professional will advise you on this regulation at your appointment.

6.2 Transport & Storage

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

Ensure the footwear 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.

Manufacturer's Registered Address

Blatchford Products Limited, Unit D Antura, Bond Close, Basingstoke, RG24 8PZ, UK

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