

Custom-made Medical Device

Instructions for Use

829022 Footwear Additions

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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.

Footwear additions are classed as custom made devices.

Footwear additions are externally applied modifications made to suitable footwear to support an individual's prescribed clinical and functional needs. They may include alterations such as raises, wedges, flares, stiffening or sole unit adaptations, and are intended to improve comfort, alignment, stability or walking function as directed by the prescribing healthcare professional.

2 Safety Information



If after use of the addition, 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 addition 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 addition parts come loose please immediately stop use and contact your healthcare professional.



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 intended for use when immersed in water or as showering Orthosis unless specified for this purpose by your healthcare professional.



The device is not suitable for extreme sports. Any such activities undertaken are done so completely at the users own risk.



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



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



Additions to your footwear must be carried out by a qualified, trained medical professional. Repairs due to wear and tear are considered medically necessary. Replacement of footwear due to a significant change in the users condition or irreparable wear is considered medically necessary if the device is still medically necessary.



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.



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.



Avoid strong magnetic fields, sources of electrical interference.



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

3 Everyday Use

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

Choosing the right footwear for additions is important. Your healthcare professional will advise you which style of footwear is the most appropriate for alteration. The footwear needs to be comfortable and fit securely, especially at the heel. It also needs to be in good condition, therefore do not bring in shoes which are worn down and beyond repair. Ideally, footwear should fasten with laces, a return strap or buckle.

If you are buying new footwear to be adapted, ask the store if you can return them if they are not suitable. Footwear styles not suitable are:

- Sandals
- Wellies and Doc Marten's due to their sole unit material
- Shoes with a narrow and tapered heel
- Trainers with air cells
- Footwear with hollow sole units

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 custom-made footwear additions are designed specifically for an individual. Your healthcare professional will explain the intended aim and functional objective of your footwear.

Footwear additions are prescribed and designed to meet the functional loss needs of each individual user rather than to treat an individual condition or pathology. Additions are suitable for use on one or both feet and can be used by infants through to adulthood.

All shoes which are required to have additions should be approved by the users treating medical professional to ensure they are suitable, as the materials of some footwear styles cannot be altered. We recommend footwear with rubber soles and heels glued to the upper or footwear with leather soles and leather or rubber heels.

Additions are intended for users with any mass or size. Your healthcare professional will advise on the optimum footwear product for your needs. Footwear additions are intended for the sole use of the patient named on the conformity documentation. If the adapted footwear is no longer required, it must be safely disposed, please advise your healthcare professional.

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 Additions are recommended for use between -10°C and $+50^{\circ}\text{C}$ (14 F to 122 F).



Suitable for outdoor use

Activity

Additions are intended to be used for standing, walking and low risk activities. They are not generally 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 footwear additions are evaluated by a healthcare professional 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.

Long Term Use: Your adapted 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 impedes 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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