



MD

Blatchford:

Footwear additions 829022

Custom-made Medical Device

EN Instructions For Use



Blatchford is a multi-award-winning manufacturer of some of the world's most advanced prosthetic technology, bespoke seating solutions and orthotic devices. The range of Orthotic devices provided by Blatchford complements the wide variety of specialisations practiced by our mainly dual qualified Orthotic Clinicians. These specialisations include orthotics for diabetes, neurological disorders, orthopaedics, spinal pathologies, orthopaedic footwear and treatment ranges from paediatric provision through to disorders related to old age.

Our Orthotists work with both NHS Hospitals and GP referrals to supply devices that support the body, encourage active lifestyles and reduce pain or pathological developments. Blatchford uses a combination of made to measure and off the shelf devices to ensure optimum treatment effect and comfort. Digital scanning and computer aided manufacture of insoles and braces ensures that our Orthoses¹ are manufactured to a high degree of accuracy.

Our team of Orthotists maintains a training regime that ensures they are up to date with the latest technologies and rehabilitation thinking. This means that each patient can be provided with appropriate treatments, optimised designs and lightweight materials. We have access to gait analysis systems in many of our clinics which measures the effectiveness of chosen devices and treatments regimes

Blatchford maintains a QMS system which is ISO 9001 and ISO 13485 accredited. Blatchford products and systems meet the essential requirements of EU Medical Devices Regulation 2017 (MDR).

Product Description

Footwear additions are classed as custom made medical devices. They are defined by the MDR as devices manufactured specifically in accordance with a written prescription of a registered medical practitioner, or other person authorised to write such a prescription by virtue of his professional qualification. This provides under their responsibility, specific characteristics as to its design and is intended for the sole use of a named patient. This does not include a mass-produced product which comprises a medical device and medicinal product forming a single integral product which needs to be adapted to meet the specific requirements of the medical practitioner or professional user.

Blatchford footwear additions to the sole unit are custom-made medical devices and involves alteration to the outside of the shoe. Work to the sole unit of your footwear involves the addition of foam (thermoplastic) materials. Your healthcare professional will be able to advise on the optimum addition for your needs.

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

Safety Information



If after use of the addition you see any red marks 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 addition immediately.



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



• The custom device must be regularly maintained to the maintenance schedule in this IFU.



If any of the additions 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.



• Always use a handrail when descending stairs and at any other time if available.



• Avoid strong magnetic fields, sources of electrical interference, atmospheres containing liquids and/or powders.



• 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 a showering orthosis unless specified for this purpose by your healthcare professional.



• The device is not suitable for extreme sports, running or cycle racing, ice and snow sports, extreme slopes and steps. 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 additions may include flammable materials. Be aware of fire hazards where possible.



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



A regular check on your footwear addition is essential and looking out for any signs of wear and tear. Ensure that the sole unit is glued in place with the base unit. If this becomes loose it can cause a hazard for tripping. If the pattern of the sole unit has worn down, the shoes need repaired.



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 heel 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.

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 addition. Footwear additions can be prescribed for a variety of reasons such as:

A raise for a short leg

A wedge or flare to alter your foot position and providing support when walking

A socket for a Blatchford custom-made below-knee (BK) Iron

Please be aware that you may have to provide your own footwear for the sole unit addition.

The most common conditions for shoe additions include:

- **To reduce flexibility in the sole due to painful forefoot or forefoot amputation**
- **To reduce a crouch gait.**
- **To prevent drop foot.**
- **To stabilise the heel firmly inside the 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 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 and designed for low to medium activity levels. Your healthcare professional will advise on the optimum footwear addition for your needs.

Footwear additions are intended for the sole use of the patient named on the conformity documentation. If the addition is no longer required it must be safely disposed. Please follow the guidelines below.



- * **Removal of the label**
- * **Remove any parts which can be dismantled to reduce the risk of re-use. Follow recycling guidelines where possible.**
- * **Ensure the healthcare professional is aware that the device is no longer required.**
- * **Be careful of sharp edges. Always wear gloves when dismantling and ensure the shoe or shoes are secured on a table to perform the task.**
- * **Do not re-use any components unless a healthcare professional has provided a local risk assessment.**



Everyday Use

Choosing the right footwear for additions is important. Your healthcare professional will advise you which style of footwear are the most appropriate for alteration. The footwear needs to be comfortable and fit securely, especially at the heel. It also needs to be in a 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

* 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 are 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 at the heel.

At first, the addition to your 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.

Recommended 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 this table. Your healthcare professional will provide you with a personalised wearing regime.

Intended Performance of Device

Lifting Loads: 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 addition 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 shoe 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. Additions are recommended for use between -10 C and 50 C (14 F to 122 F).

Activity: Additions are intended to be used for standing, walking and low risk 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 footwear additions are evaluated by a healthcare professional after 12 months of use to determine suitability of use.

Maintenance:

Cleaning

Footwear made from leather should be polished regularly. Nubuck and suede footwear should be cleaned using brushes and specialist cleaners – 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.

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

Maintenance Schedule

Monthly

* Check for wear and tear of the rubber sole unit. If the pattern on the sole unit has worn down and is not visible anymore, the sole unit needs to be repaired.

* Check that the sole unit and the addition remains glued to the base unit. If there are areas where it is unstuck, it will need repairing.

Six months

* Reviews every six to twelve months are essential as your condition or presentation may change over time or the footwear which has been adapted is beyond repair and needs replaced.

Long-term Use : The footwear addition was 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 your 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.

Warranty

For all warranty enquiries please refer the website under the warranty section.

Label Identifier

A label is located on each custom-made medical device. Due to the custom nature of the product it will be positioned where practicable.

Blatchford! Custom-made device. MD	
Serial No.	X
Identifier	
Location	
Product	
Description	Orthosis D of M
Device incorporates tissues of animal origin as referred to in Regulation (EU) No 722/2012	
YES	<input type="checkbox"/>
NO	<input type="checkbox"/>
936252 s1 04/20	
Blatchford Limited: Atlas Way: S4 7QQ orthoticsales@blatchford.co.uk	
Blatchford Products Limited : Lister Road : Basingstoke : RG22 4AH	

Serial No. Quote this number with any enquiry

Identifier. Customer name or Initials (if applicable)

Location. Hospital/Clinic

Product. Product description

D of M . Date of Manufacture



Single user Use Only



Manufacturer of Medical Device



Must consult information for user



Medical Device



MD

Please report any serious incident that has occurred in relation to the device to the manufacturer and the MHRA

Manufacturer's Registered Address
Blatchford Products Limited, Lister Road, Basingstoke RG22 4AH, UK.

Manufactured by
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