



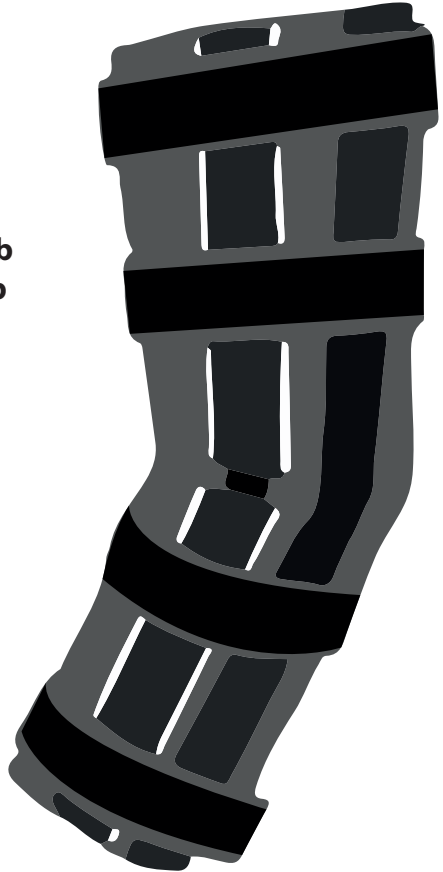
MD

Blatchford:

Fabric Gaiter 829036 Range
Fabric Gaiter 829036U Upper Limb
Fabric Gaiter 829036L Lower Limb

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.

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 gaiter products and systems meet the essential requirements of EU Medical Devices Regulation 2017.

Product Description

Gaiters feature structural inserts which immobilise the joint to hold it in extension whilst preventing excessive movement. Straps are used to tighten the gaiter around the limb. Gaiters worn on either the arms or legs to keep the elbows or knees straight and stabilised.

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

A Fabric Gaiter is a custom made medical device. They are defined by the medical devices regulation as a device 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 maintains a QMS system which is ISO 9001 and ISO 13485 accredited. Blatchford custom gaiter products and systems meet the essential requirements of the EU Medical Devices Regulation 2017.

Safety Information



If after use, 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 Fabric Gaiters 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 device at once.



Fabric gaiters are designed and prescribed for an individual's needs and should only be used by that sole user.



• Should your functional requirements or condition change during the life cycle of the fabric gaiter please contact your healthcare professional as it could affect the performance of the device.



• The Fabric Gaiter must be regularly maintained to the maintenance schedule in this IFU.



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



• 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.



• Ensure only suitably retrofitted vehicles are used when driving. All persons are required to observe their respective driving laws when operating motor vehicles. It is the responsibility of the user to discuss this matter with the DVLA.



Do not remove any serial or warning labels from the Fabric Gaiter



Fabric Gaiters may include flammable materials. Always be aware of fire hazards

Intended Use

Gaiters are fabric orthoses which are worn on either the arms or legs and are designed to keep the elbows or knees straight. The reason for needing to keep these joints in a straight position can vary and the healthcare professional will be able to explain the reasons

The most common conditions include:

- **Cerebrovascular Accident or Stroke**
Cerebral Palsy

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



Gaiters are intended for users with any mass and designed for low to medium activity levels. Your healthcare professional will advise on the optimum gaiter build for your needs.



Gaiters are intended for the sole use of the patient named on the conformity documentation. If the gaiter 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 gaiter is 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

Blatchford gaiters apply forces 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 gaiters which are:

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

When putting the gaiter on daily the following steps should be taken,

1. Check the gaiter straps are free from debris and move/function freely.
 2. It is best to put the gaiter on whilst sitting or lying down. Place your limb into the gaiter, ensuring your limb is correctly orientated..
 3. Finally fasten the straps firmly.
- It is normal to see red marks where pressure has been applied. These should disappear within 30mins. IF NOT CONTACT YOUR HEALTHCARE PROFESSIONAL.

Intended Performance of Device

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 gaiter'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 gaiters 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. Gaiters are recommended for use between -10 C and 50 C (14 F to 122 F).

Activity: Gaiter's are intended to be used for standing, walking and non-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 gaiters are evaluated by a healthcare professional after 12 months of use to determine suitability of use.

Maintenance:

Cleaning

Cleaning an Gaiter is very important for both user safety and ensuring the longevity of the medical device. The gaiter should be wiped clean daily. Please note that stains caused by bodily fluids should be removed immediately. When cleaning the gaiter 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 gaiter. For more stubborn marks a dilute bleach solution can be used: 5% bleach to 95% water. Use a clean cotton cloth to wipe the area and dry the surface of the gaiter after cleaning.

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 gaiter please contact your prescribing medical professional.

Maintenance Schedule

Weekly

- * User visual inspection
- * Inspect all over generally for any obvious signs of wear & tear
- * Ensure straps remain well adhered and velcro is retaining fixation.
- * No visible signs of material fatigue in the calf and thigh section. 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 joint (if present) through its full range of motion.

Six months

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

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 the custom nature of the product it may 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 <table style="float: right;"> <tr> <td>YES</td> <td><input type="checkbox"/></td> </tr> <tr> <td>NO</td> <td><input type="checkbox"/></td> </tr> </table>		YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
YES	<input type="checkbox"/>				
NO	<input type="checkbox"/>				
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
Blatchford Limited: Atlas Way: S4 7QQ : orthoticsales@blatchford.co.uk : +44 (0) 114 263 7900