

Custom-Made Medical Device

Instructions for Use

829036 Fabric Gaiter Range
829035U Fabric Gaiter Upper Limb
829036L Fabric Gaiter Lower Limb

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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.

Gaiters feature structural inserts which immobilize 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 straight and stabilized.

A Fabric Gaiter is a custom-made medical device.

2 Safety Information



If after use, you see any discolouration on your skin that is in contact with the device, which does not disappear after 30 minutes, stop using the FFO and contact your healthcare professional.



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



The Fabric Gaiters must be regularly maintained to the maintenance schedule in this IFU by a trained professional.



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



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



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



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 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 Fabric Gaiters.



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



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



If unusual behaviour or loose fittings are identified, please contact your healthcare professional.



All persons are required to observe their respective driving laws when operating motor vehicles. It's the responsibility of the user to discuss this matter with the DVLA.

3 Everyday Use

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

Blatchford gaiters 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.

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

- Check the gaiter straps are free from debris and move/function freely.
- It is best to put the gaiter on whilst sitting or lying down. Place your leg into the gaiter ensuring your limb is correctly orientated.
- Finally fasten the straps firmly.
- It is normal to see discolouration where pressure has been applied. These should disappear within 30 minutes.

IF NOT CONTACT YOUR HEALTHCARE PROFESSIONAL

4 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.

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 both 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 Gaiters are no longer required, they must be safely disposed of. Please follow the guidelines below:

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

5 Intended Performance

Lifting Loads

User weight and activity is governed by the stated limits provided by third party component manufacturers. 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 $+50^{\circ}\text{C}$ (14 F to 122 F).



Suitable for outdoor use

Activity

Gaiters 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 you contact your healthcare professional for review and to determine continued suitability of use.

6 Maintenance

Cleaning

Washing and Care Instructions

1. Hand wash in cool water using mild detergent.
2. Rinse and dry flat.
3. Do not spin or tumble dry.
4. Do not use fabric conditioner at any time.
5. Check for any degradation that may affect use

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 including fraying.

6.2 Transport & Storage

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

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.

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