

Custom-Made Medical Device

Instructions for Use

829039SC Atlas Scrum Helmet
829039H Atlas Hard Helmet
829039SL Atlas Slimline Helmet
829039A Atlas Adjustable Helmet
829039F Atlas Full Helmet

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1 Description and Intended Purpose

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

A Blatchford helmet is a custom-made medical device.

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

Blatchford Protective helmets provide the wearer with protection from impact. They can be used for a wide variety of reasons and also come in a range of styles. This enables healthcare professionals to be able to select the most appropriate helmet for the patient.

Blatchford clinicians use evidence-based practice to design helmets and have considered the unique requirements of the intended user.

2 Safety Information



If after use, you see any discolouration on the skin that is in contact with the device, which does not disappear after 30 minutes, stop using the Helmet and contact your healthcare professional for advice as it may need adjusting.



Blatchford helmets 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 device please contact your healthcare professional as it could affect the performance of the device.



Avoid strong magnetic fields and sources of electrical interference.



Repairs and adjustments to the Blatchford Helmet 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.



Blatchford Helmets may include flammable materials. Always be aware of fire hazards.



Blatchford helmet straps can cause strangulation or restricted breathing if not correctly fitted. Ensure the strap is firmly fitted under the chin and away from the neck. Don't leave a helmet user unattended.



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 Blatchford Helmet.



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



Do not place near any heat source. Do not leave in direct sunshine or inside a car in hot weather.



The helmet is not intended for use when immersed in water or as a shower prosthesis (unless specified as such by your practitioner). If the limb comes into contact with water wipe dry.



Blatchford helmets provide protection only from minor falls or glancing with objects. Blatchford helmets are not classed as full protection helmets and should not be used as a replacement for protective helmets such as work or cycle helmets.

3 Everyday Use

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

Blatchford Helmets are designed to protect the user from minor impacts due to medical conditions. The interface components have been designed to avoid unacceptable pressure and stress levels on body tissues.

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

- Check the Blatchford Helmet straps are free from debris and move/function freely.
- Place the helmet on the user's head, ensuring the helmet is correctly orientated.
- Finally fasten the straps firmly.
- It is normal to see discolouration where pressure has been applied. This should however disappear within 30 minutes. If not contact your Orthotist.

The feel of the Blatchford Helmet may take some time to get used to. The Blatchford Helmet should not cause any pain however it is not unusual to feel some initial discomfort. If you experience rubbing or blisters, please book an appointment with your Healthcare professional for immediate attention. If you are experiencing discomfort after two weeks, please book a follow up appointment with your Orthotist.

We recommend booking a follow-up appointment with your healthcare professional if you experience any change in condition. Your healthcare professional can determine what changes are required and provide recommendations for alternative treatment.

4 Intended Use

Blatchford helmets provide the user with protection from minor impacts. They can be used for a variety of reasons including the risk of injury from falls or poor balance, seizure disorders and skull abnormalities.

Blatchford Helmets are prescribed and designed to meet the functional loss needs of each individual user rather than to treat an individual condition or pathology. Blatchford Helmets are suitable for a single user and can be used by all ages. Blatchford Helmets are always and only intended to be used where specified.

Blatchford Helmets are intended for users of any mass, shape or size and are designed for low impact levels. Your healthcare professional will advise on the optimum Blatchford Helmet for your needs.

Blatchford Helmets are intended for the sole use of the patient named on the conformity documentation. For the purposes of any recycling, if the helmet is no longer required, it must be safely disposed of by the orthotic department and your clinical records updated. Please follow the guidelines below:

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

5 Intended Performance

Environment

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

Suitable for outdoor use



Activity

Our Helmets are not designed for extreme sports. Any such activities undertaken are done so completely at the user's own risk.

Lifetime

It is recommended that Blatchford Helmets are evaluated by a healthcare professional after every 12 months of use as a minimum to determine continued suitability of use. Your healthcare professional will advise on how to contact them for review. If you experience any issues or feel your clinical needs have changed, please contact your healthcare professional.

6 Maintenance

Cleaning

We recommend daily cleaning of any Blatchford Helmet. The custom helmet should be wiped clean using a soapy soft cotton cloth and dried. Gently rub with circular movements to remove any stubborn dirt utilizing domestically available anti-bacterial cleaning products. Please note that stains caused by bodily fluids should be removed immediately.

Do not pressure wash your helmet.

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

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. Signs include cracks, chips, and stress lines in the material.

6.2 Transport & Storage

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

Ensure the helmet 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.



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.

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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