



Blatchford:

Atlas scrum helmet 829039SC

Atlas hard helmet 829039H

Atlas slimline helmet 829039SL

Atlas adjustable helmet 829039A

Atlas full helmet 829039F

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

Product Description

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.

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

Blatchford helmets are custom made devices. They are defined by the Medical Devices Regulation 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.

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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 Blatchford Helmet 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.



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.



• Blatchford helmets must be regularly maintained to the maintenance schedule in this IFU.



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.



• 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, 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



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.



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.

Intended Use

Blatchford Helmets provide the user with protection from minor impacts. They can be used for a wide variety of reasons including reducing the risk of injury from falls or poor balance, seizure disorders and skull abnormalities. Blatchford helmets are available in a range of styles, this enables healthcare professionals to be able to select the most appropriate helmet for the patient.

The most common conditions include:

- * Epilepsy
- * Autistic Spectrum conditions
- * Disorders causing balance or coordination difficulties.
- * Craniostomy
- * Hypermobility
- * Drop fits
- * Seizure

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.

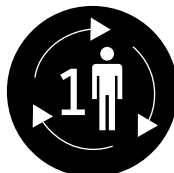
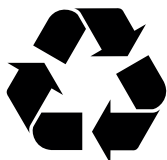


Blatchford Helmets are intended for users of any mass, shape or size and are designed for low impact levels. Your healthcare professional will advise on the optimum Blatchford Helmet for your needs.



Blatchford Helmets are intended for the sole use of the patient named on the conformity documentation. If the Blatchford Helmet is no longer required it must be safely disposed of. 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 Blatchford Helmet 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 Helmets are designed to protect the user from minor impacts due to medical conditions. The interface components have been designed to avoid unacceptable pressure on and stress levels in body tissues.

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

1. Check the Blatchford helmet straps are free from debris and move/function freely.
 2. Place the helmet on the user's head, ensuring the helmet 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.

The feel of the Blatchford Helmet may take some time to get used to. The Blatchford Helmet should 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 Certified Orthotist.

We recommend to book 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.

Intended Performance of Device

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 C (14 F to 122 F).

Activity: Our Helmets are not designed for high activity sport such as kayaking, climbing, cycling or snow 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 12 months of use to determine suitability of use.

Maintenance:

Cleaning

Cleaning any Blatchford helmet is very important for both user safety and ensuring the longevity of the medical device. The helmet should be wiped clean daily. Please note that stains caused by bodily fluids should be removed immediately. When cleaning the helmet 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 orthosis. 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 helmet 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 helmet 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. Signs include cracks, chips and stress lines in the material.

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 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



Must consult information for user



Manufacturer of Medical Device



Medical Device



MD



Blatchford
Blatchford Helmet (Cranial Orthosis)

Helmet Straps have the potential to cause strangulation. Ensure the straps are fitted under the chin and away from the neck. Never leave a helmet user unattended.

Do not use your helmet for sports or as a full protection helmet. Blatchford custom helmets are intended to provide protection from trips, falls or minor impacts.

Helmet Warning label

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