

Custom-Made Medical Device

Instructions for Use

819049 Custom Made Headrest

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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.

Blatchford headrests are custom made devices.

Blatchford Custom headrests provide a bespoke head support solution to the occupant. Available in various shapes and sizes to provide optimum support and correction combined with excellent accommodation for the user. Blatchford custom made headrests are designed to offer high levels of support and pressure relief and can be interfaced onto most wheelchairs in the marketplace whilst being easily removable for cleaning and maintenance.

2 Safety Information



If after use, you see any discolouration on skin that is in contact with the device, which doesn't disappear after 30 minutes, stop using the Custom headrest 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.



Custom headrests have been designed and prescribed for an individual's needs and should only be used by that sole user.



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



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



Should your functional requirements or condition change during the life cycle of the device please contact your healthcare professional as this could affect the devices performance.



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

-  **Do not remove any serial or warning labels from the Custom headrests.**
-  **Custom headrests may include flammable materials. Be aware of fire hazards where possible.**
-  **May contain animal tissues such as leather. Conformity certificate is available for further details should this be required.**
-  **No alterations should be made to the Custom headrests nor should third party manufacturers products be fitted without the prior agreement of your healthcare professional.**
-  **The Custom headrests must only be used with the wheelchair it was manufactured for. If a different wheelchair is going to be used contact the Approved Healthcare Professional for help or advice.**
-  **The device is not intended for use when immersed in water or in a shower unless specified for this purpose by your healthcare professional**

-  **If there is any indication that the user's head could become trapped, either behind or under the head support, stop using the seating and contact the wheelchair service provider. Always be aware of finger traps. Pay attention when inserting/removing the headrest into the mount.**
-  **If unusual behaviour or loose fittings are identified, please contact your healthcare professional.**
-  **Children whose mass is less than 22kg must be transferred from their seating system into an appropriate child restraint system intended for use in motor vehicles.**
-  **Never leave an occupant unattended. Ensure the Custom headrests is fitted correctly and ensure they are fitted during transportation. If the user shows any continued signs of distress or discomfort, stop using the product and immediately contact the wheelchair service provider.**
-  **Ensure the headrest is correctly fitted before use, ensuring the users head cannot be trapped in area around the headset.**

3 Everyday Use

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

The headrest materials have been designed to avoid unacceptable pressure on and stress levels in body tissues.

When seating an occupant the following steps should be taken:

- Check the headrest is secure, free from debris and functions correctly.
- Seat the occupant, ensuring the head is correctly orientated. Ensure creases are removed and belts and harnesses engaged (if applicable).
- It is normal to see discoloration of skin where pressure has been applied. This should disappear within 30 minutes.

IF NOT CONTACT YOUR HEALTHCARE PROFESSIONAL

The fit and feel of the custom headrest may take some time to get used to. The custom headrest should not be painful; however, it is not unusual to feel some initial discomfort. If you experience rubbing or blistering, please book an appointment with your Healthcare professional for immediate attention. If you are experiencing pain after two weeks please book a follow up appointment with your healthcare professional.

Pre-Use Checks

Important Safety Information

Before using your custom-made headrest, please check the following:

- The headrest is secured to the wheelbase and/or seating securely.
- The headrest is not restricting any hoist equipment or belts and harnesses.
- The headrest is correctly orientated and free from excessive movement.
- The occupants head cannot be trapped underneath or to the side of the headrest.
- The headrest is free from dirt/debris and the materials are free from defects.

4 Safe Transportation

The custom headrest has been tested in combination with seating products to allow the seat and its user to be transported in a forward facing position in a wheelchair in a vehicle designed for the purpose (for example, in a suitably equipped minibus).

This information should be available for services making transport arrangements (e.g. schools and other organizations).

Securing the user, the Carved headrest and the host wheelchair in a vehicle:

- 1) During travel the Custom headrest must be securely fastened into its wheelchair as described earlier in this manual.
- 2) Posture belts and postural harnesses supplied as part of the seating system are designed to give postural support only. Where these items are fitted, they should be used during travel, but they must not be used as the only safety restraints.
- 3) The wheelchair itself must be fastened in the vehicle – this must be in accordance with the wheelchair manufacturer's instructions. (The wheelchair manufacturer will issue these instructions separately. In case of query contact your healthcare professional).
- 4) A suitable, separate, passenger seat belt (fastened into the vehicle) must be used by the occupant during travel. In order to achieve occupant restraint and optimum protection in a crash situation the seatbelt should have both pelvic and upper body sections (for example a 3-point type with the upper sectioned fastened into the vehicle at the upper level) as a minimum standard.
- 5) The headrest should always be used during travel.
- 6) Always follow the guidance from the wheelbase manufacture, third party devices and accessory IFU's in combination with this manual.

Never leave an occupant unattended. Ensure the headrest is fitted correctly and used during transportation. Check that all secondary support devices are secure and function correctly. Always remove trays and knee blocks prior to transportation. Always secure your wheelchair with WTORS four-point, strap type tiedowns. Ensure your seating system is fully attached to the wheelbase prior to transportation. Check before and after fitting the tiedowns.

5 Intended Use

Indications

Intended for users with a weight of 100 kg or less.

Contraindications

Users with a weight over 100 kg.

Custom made headrests are intended for the sole use of the patient named on the conformity documentation. The headrest is made to the prescription of the healthcare professional and they will provide advice on custom products and add on third party products such as straps, controls and postural belts.

Blatchford Products are prescribed and designed to meet the functional loss needs of each individual user rather than to treat an individual condition or pathology. Blatchford Products are suitable for use on one or more wheelbases and can be used by most ages. Custom made headrests are always and only intended to be used where specified.

For the purposes of any recycling, if the Custom Headrest is no longer required, it must be safely disposed of by the providing service and your clinical records updated. Please follow the guidelines below:

- Ensure the healthcare professional is aware the Custom Headrest is no longer required.
- Return the Custom Headrest to the wheelchair service for disposal.

6 Intended Performance

Environment

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



Suitable for outdoor use

Activity

Our headrests are not intended to be used for high activity sport such as wheelchair basketball, or skate ramps. Any such activities undertaken are done so completely at the user's own risk.

Lifetime

It is recommended that Custom made headrest 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.

7 Maintenance

Maintenance

Cleaning

Cleaning any Custom made headrest is very important for both user safety and ensuring the longevity of the medical device. The device should be wiped clean daily. Please note that stains caused by bodily fluids should be removed immediately. When cleaning the device use a soapy soft cotton cloth and gently rub with circular movements to remove stubborn dirt utilizing domestically available anti-bacterial cleaning products. Do not pressure wash your device. Use a clean cotton cloth to wipe the area and dry the surface of the device after cleaning.

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 device, please contact your prescribing medical professional.

7.1 Maintenance Schedule

Daily

- User visual inspection
- Inspect all over generally for any obvious signs of wear and tear
- Check that the user's shape is still accommodated by the shape of the Custom-made headrest.
- Check that the Custom-made headrest is not too restrictive for the user.
- Check there is no structural; damage to the shells or any of the brackets and that all securing bolts are still in place.
- Check the quality of the foam, particularly load areas.
- Check that all locking knobs on the brackets are in place and functioning correctly.

12 months

- Please refer to 3rd party product manufacturers maintenance schedules detailed in their IFUs.
- The Custom Foam Seating should be reviewed for wear and tear as part of these maintenance checks.

- Ensure all labels on the products are intact and never remove any warning labels or serial numbers from the device.
- Failure to comply may invalidate the warranty.

7.2 Transport & Storage

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

Ensure the Custom-made headrest is thoroughly protected from damage in transit.

8 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 Seating products are warranted for a period of 12 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.

Manufactured by

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