

Custom-Made Medical Device

Instructions for Use

819029 XS CARVED FOAM SEAT

819030 S CARVED FOAM SEAT

819031 M CARVED FOAM SEAT

819032 L CARVED FOAM SEAT

819033 XL CARVED FOAM SEAT

NSS528 (base)

NSS528 (back)

819047 (small base or back)

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Instructions for Use

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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.

Carved Foam Seats are custom made devices.

Blatchford Carved Foam Seating (CFS) is a bespoke seating solution, available as a part or full system providing optimum support and correction combined with excellent accommodation and comfort for the user. Carved Foam Seats are designed to offer high levels of pressure relief and weight distribution and can be interfaced onto most wheelchairs in the marketplace whilst being easily removable for cleaning and maintenance.

The CFS has been crash tested to ISO 16840-4 and has an extensive range of accessories available to compliment the seating solution. The system is adaptable and partially adjustable by way of alternative interfacing options, including Blatchford Adaptable interfacing system (BAIS) and V-Trak.

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 Carved Foam Seat 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.



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



The Carved Foam Seat must be regularly maintained to the maintenance schedule in this IFU by a qualified professional.

-  **Repairs and adjustments to the Carved Foam Seat 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 Carved Foam Seat please contact your healthcare professional as this could affect the Carved Foam Seat's 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 Carved Foam Seat.**
-  **Carved Foam Seat 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.**
-  **The device is not intended for use when immersed in water or in a shower unless specified for this purpose by your healthcare professional**
-  **Postural belts could cause strangulation or restricted breathing if not fitted correctly. Ensure the belts are fitted as per the belts and harness IFU and positioned away from the neck. The Carved Foam Seat must only be used with the wheelchair it was made for.**
-  **If a different wheelchair is going to be used contact the Approved Healthcare Professional for help and support.**
-  **The Carved Foam Seat is NOT designed for use as a car safety seat. Children whose mass is less than 22KG must be transferred from their seating system into an appropriated child restraint system intended for use in motor vehicles.**
-  **Due care and attention must be taken at all times when using the Carved Foam Seat. Take particular care when negotiating slopes, different services or other obstacles.**
-  **The Carved Foam Seat forms part of a system of assemblies and custom products. Each CFS is unique so it is very important that all IFU's are followed prior to use.**

-  **Never leave an occupant unattended. Ensure the headrest is fitted correctly and ensure the headrest is 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 your seating system is fully attached to the wheelbase prior to transportation. Check before and after fitting the tiedowns. The back support must be in an upright position during travelling and check that all secondary support devices are secure and function correctly. Always remove trays and knee blocks prior to transportation.**
-  **Beware of finger trap hazards when adjusting or moving any part of the Foam Carved Seat.**
-  **Always refer to the manufacturers IFU, in particular when fitting high risk items such as belts and harnesses.**
-  **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.**
-  **Use the seating system only with a wheelbase that has been tested as part of a wheelchair system that conforms to ISO 7176-19 performance requirements, and that has securement points for use with four-point, strap-type tiedown.**
-  **To achieve effective user restraint and optimum protection in a vehicle impact, both pelvic-belt and shoulderbelt restraints shall be used as part of a complete wheelchair tiedown and user restraint system (WTORS) which meets ISO 10542.**
-  **Any third party products which have not been agreed or fitted by Blatchford healthcare staff or approved repairers may compromise the warranty of the product and may have the potential to cause damage to the user or device.**
-  **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.**

3 Everyday Use

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

The interface components 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 seat surface, belts and harnesses are free from debris and move/function correctly.
- Check the seat is firmly secured to the wheelbase and tilt the seat if possible.
- Seat the occupant, ensuring the occupant is correctly orientated. Ensure creases are removed and belts and harnesses engaged (if applicable).
- It is normal to see discolouration of skin where pressure has been applied. This should disappear within 30 minutes.

IF NOT CONTACT YOUR HEALTHCARE PROFESSIONAL

The forces of the Carved Foam Seat may take some time to get used to. The Carved Foam Seat 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 Carved Foam Seat, please check the following:

- The retaining strap on the base cushion (where fitted) must be securely fastened.
- Ensure the Blatchford Adapted Interface System is correctly seated and secure. For specific guidelines follow BAIS Interface IFU.
- If third party equipment is combined with the CFS please follow the manufacturers IFU's for correct usage.
- If using V-Trak or equivalent mounting systems, the backrest must be fitted to the wheelchair correctly ensuring the mounting pins are located into the mounting blocks on the framework properly and secured with the locking levers.
- All additional postural support items such as postural straps and harnesses should be secured, free from obstructions and fitted correctly to the Carved

Foam and wheelbase. For more information, please follow the IFU supplied with each device.

4 Safe Transportation

The Carved Foam Seat must not be used as a car safety seat. The Carved Foam Seat is designed 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 Foam Seat and the host wheelchair in a vehicle:

- 1) During travel the Carved Foam Seat 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 restraint.
- 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 Carved Foam Seat headrest should 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

CFS's are intended for occupants of a mass less than 100KG with moderate to high postural needs. The Carved Foam Seat is designed to be fitted onto an approved crash tested base using an interface. CFS's are custom made to the prescription of the healthcare professional and they will provide advice on custom products and add on third party products such as headrests and postural belts. Carved Foam Seats are intended for the sole use of the patient named on the conformity documentation

Blatchford Products are prescribed and designed to meet the 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. Carved Foam Seats are always and only intended to be used where specified.

Indications

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

Contraindications

Users with a weight over 100 kg.

Carved Foam Seats are intended for the sole use of the patient named on the conformity documentation.

For the purposes of any recycling, if the Carved Foam Seat 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 Carved Foam Seat is no longer required.
- Return the Carved Foam Seat to the wheelchair service for disposal.

6 Intended Performance

Environment

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



Suitable for outdoor use

Activity

Our Systems 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 Carved Foam Seats 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

Cleaning

Cleaning any Carved Seat 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 utilising 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 there is no damage to the retaining straps (if used) and that the buckles are working properly
- Check that the user's shape is still accommodated by the shape of the Carved Foam.
- Check that the Carved Seat is not too tight for the user as a result of growth or weight gain.
- Check there is no structural damage to the plastic 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 Carved Seat in a safe, clean and dry place, out of direct sunlight and away from heat sources such as radiators and ovens.

Ensure the Carved Seat 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 authorised 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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