



MD

Blatchford:

Custom made Prosthetic Socket

129101 Thermoplastic Socket

129201 Carbon Socket

129301 Glass-Fibre Socket

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 team works with both NHS Hospitals and GP referrals to supply devices that support the body, encourage active lifestyles and reduce pain or pathological developments. Blatchford uses a combination of made to measure and off the shelf devices to ensure optimum treatment effect and comfort. Digital scanning and computer aided manufacture of insoles and braces ensures that our Orthoses¹ are manufactured to a high degree of accuracy.

Our team 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 custom products and systems meet the essential requirements of EU Medical Devices Regulation 2017.

Product Description

A Blatchford socket is a custom made medical device. They are defined by the Medical Devices Regulation as a device 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.

A socket can be manufactured from various materials including Thermoplastic, Carbon or Glass Fibre. The socket will include an adapter to mount the prosthesis. The prosthetist will determine which material choice, material thickness and CE marked socket is best for you based on user mass and activity level. You may discuss alternative options with your healthcare professional.

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

Safety Information



If after use of the socket 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 socket 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 socket immediately.



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



If you exceed the products specification limits after being supplied a socket you should contact your healthcare professional as it may affect the sockets performance.



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



The custom socket must be regularly maintained to the maintenance schedule in this IFU.



Should the socket display any unusual behaviour, changes of performance or any fittings on the device come loose please immediately stop use and contact your healthcare professional.



Repairs and adjustments to the custom socket 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, running or cycle racing, ice and snow sports, extreme slopes and steps. Any such activities undertaken are done so completely at the users' own risk.



Ensure only suitably retrofitted vehicles are used when driving. All persons are required to observe their respective driving laws when operating motor vehicles. It is the responsibility of the user to discuss this matter with the DVLA.



Use well fitting footwear to reduce the risk of trips.



Do not remove any serial or warning labels from the custom made socket.



The socket may contain flammable materials. Be careful of fire hazards where possible.



Only used the adapter which was prescribed for the socket.



Always check the socket and adapter for tight fit and function. Ensure the products are interfaced securely and always check for cracks, deformation or de-lamination.

Intended Use

A custom made socket is the part of the prosthesis that wraps around your residual limb. The socket should always fit properly, allowing you to comfortably use your prosthesis. A well-fitting socket has benefits including

- * Providing comfort to the user.
- * Increased stability
- * Correct distribution of weight bearing forces.
- * Mobility to the user.

Custom sockets are typically used in combination with liners or socks to provide additional comfort and security to the user.

There are different socket designs for each amputation level, each customised to the individual user. Our healthcare professionals will take into account how and where load bearing forces are distributed through your limb.

There are multiple options for socket suspension and how the socket is attached to your limb. Your prosthetist will work with you to determine the best design for you based on your individual needs and the location, shape, and condition of your limb.

Locking Liner Suspension : A pin attached to the end of your liner locks your prosthesis in place.

Suction Suspension: A silicone sleeve worn over the outside of the prosthesis creates an airtight seal between the prosthesis and your limb.

Vacuum Sockets : A vacuum pump within the socket that removes air from the system creating a better seal between limb and socket.

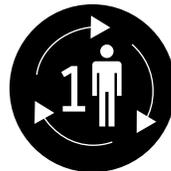


Sockets are intended for users with a mass of 125kg or less and designed for low to medium activity levels. Your healthcare professional will advise on the optimum custom made socket build for your needs.

Sockets are intended for the sole use of the patient named on the conformity documentation. If the socket is no longer required it must be safety disposed. 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 socket 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 socket supports 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.

We advise patients should wear liners or long cotton socks, tights under the sockets which are:

- Well fitting.
- Un-patterned.
- Pulled up firmly to eliminate creases

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

1. Check the socket is free from debris.
 2. It is best to put the socket on whilst sitting or lying down. Place your leg into the socket ensuring your limb is right to the bottom.
- At first the socket may feel uncomfortable so you should gradually build up the amount of time you wear it each day. Your prosthetist will tell you how long you should build up to, or what activities to wear it for.
 - Always check skin contact areas for rubbing.
 - It is normal to see red marks where pressure has been applied. These should disappear within 30mins. IF NOT CONTACT YOUR HEALTHCARE PROFESSIONAL.

Intended Performance of Device

Lifting Loads: User weight and activity is governed by the stated limits provided by third party component manufactures. 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 socket'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 socket 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. Sockets are recommended for use between -10 C and 50 C (14 F to 122 F).

Activity: Sockets are intended to be used for standing, walking and low impact activities. They are not generally 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 that sockets are evaluated by a healthcare professional after 12 months of use to determine suitability of use.

Maintenance:

Cleaning

Cleaning a socket is very important for both user safety and ensuring the longevity of the medical device. The custom socket should be wiped clean daily. Please note that stains caused by bodily fluids should be removed immediately. When cleaning the socket 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 Socket. 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 socket 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 socket please contact your prescribing medical professional.

Maintenance Schedule

Weekly

- * User visual inspection
- * Inspect all over generally for any obvious signs of wear & tear
- * No visible signs of material fatigue. Signs include cracks, chips and stress lines in the material.

Monthly

User check for any noise (creaks) in the socket or between the socket and adpater.

Six months

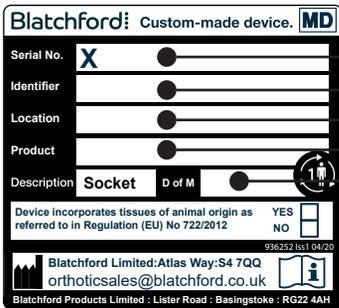
We recommend each device is fully serviced by the manufacturer and any worn parts should be repaired and replaced as appropriate. Ensure all labels on the product are intact and never remove any warning or serial numbers from the device. Failure to comply may invalidate the warranty

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 to the custom nature of the product it may be positioned where practicable.



- 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

Manufacturer of Medical Device

Must consult information for user

MD Medical Device



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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
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