

Custom-made Prosthetic Socket

Instructions for Use

129101 Thermoplastic Socket

129201 Carbon Socket

129301 Glass-Fiber Socket

EN

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.

A Blatchford socket is a custom-made medical device.

A socket can be manufactured from various materials including thermoplastic, carbon, or glass fibre. The socket will include an adapter to mount to the prosthesis. The prosthetist will determine which material choice, material thickness and CE marked socket componentry is best for you based on your weight and activity level. You may discuss alternative options with your prosthetist.

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

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

- A comfortable and secure connection between prosthesis and residual limb
- Increased stability
- Correct distribution of weight bearing forces
- Mobility to the user

2 Safety Information



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



Always check the socket and adapter for tight fit and function. Ensure the products are interfaced securely.



May contain animal tissues such as leather. Conformity certificate is available for further details should this be required.



Avoid strong magnetic fields and sources of electrical interference.



Assembly, adjustment, maintenance and repair of the device must only be conducted by a suitably qualified practitioner (prosthetic or prosthetic technician)



Do not tamper with the setup of the device.



Use well-fitting footwear to avoid the risk of slips or trips.



If you start to develop any sores or blisters by using the socket, stop using the socket immediately and report this to your prosthetist.

 Do not remove any serial or warning labels from the Blatchford Socket. Only use the adaptor prescribed for the socket.

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

 If the socket or its fittings show any signs of a change in performance and function, cracks, or delamination, then stop using the socket immediately and report this to your prosthetist.

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

 The socket 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.

 Unless agreed with your prosthetist, this device is not suitable for extreme sports. Any such activities undertaken are done so completely at the users' own risk.

 Report any weight or activity changes to your prosthetist. If you exceed the maximum weight limit after being supplied, you should discontinue use and contact your prosthetist immediately.

 Do not carry any load that would make your combined weight (your weight plus weight of that load) exceed the maximum weight limit. It is recommended to use a handrail when descending stairs and at any other time if available.

 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.

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

 Only use the components which were prescribed for the socket.

3 Everyday Use

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

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

- Check the socket is free from debris.
- It is best to put the socket on whilst sitting. Place your residual limb into the socket ensuring it is correctly located before mobilising.
- 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 advise you on a wear schedule, how long you

should build up to and what activities to wear it for.

- Always check skin contact areas for signs of rubbing or excess pressure.
- It is normal to see discoloration where pressure has been applied. This should however disappear within 30 minutes. If not, contact your prosthetist.

4 Intended Use

Indications

Intended for users with a weight of 125 kg or less.

Contraindications

Users with a weight over 125 kg.

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

- Ensure the prosthetist is aware the socket is no longer required.
- Return the socket to your prosthetic clinic for disposal.

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.

5 Intended Performance

Lifting Loads

User weight and activity is governed by the stated limits provided by component manufacturers. Load carrying by the user should be kept to a minimum and based on a local risk assessment conducted by the treating prosthetist responsible for the socket's prescription. If carrying heavy loads is an activity of daily living, the user must inform their prosthetist of this requirement immediately.

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 $+50^{\circ}\text{C}$ (14F to 122F).



Suitable for outdoor use

Activity

Sockets are intended to be used for standing, walking and low impact activities. They 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 sockets are evaluated by a prosthetist every 12 months of use to determine continued suitability of use.

6 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. Use a clean cotton cloth to wipe the area and dry the surface of the socket after cleaning. Do not pressure wash your socket.

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 socket, please contact your prosthetist.

6.1 Maintenance Schedule

Daily

- User visual inspection.
- Inspect all over generally for any obvious signs of wear and tear.
- No visible signs of material fatigue. Signs include cracks, chips, delamination, and stress lines in the material.
- Check for any noise (creaks) in the socket or between the socket and adapter.

12 Months

- We recommend your limb is reviewed in line with the requirements stated by any 3rd party manufacturer products used in construction of the limb. Your prosthetist will

advise on your review schedule.

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

6.2 Transport & Storage

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

Ensure the socket 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 Sockets 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.

Manufactured by



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