

# Custom-Made Medical Device

## Instructions for Use

829034  
Plastic Elbow/Shoulder Orthosis  
829035  
Composite Elbow/Shoulder Orthosis

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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.

Elbow Shoulder Orthoses are custom made devices.

Blatchford Elbow Shoulder Orthoses are designed and prescribed for a variety of conditions. They can be used for positioning/stabilising the elbow and/or shoulder, for range of motion assistance, or to stop joints from flexing or extending. They can also be used for fracture management. Materials include plastic or composite.

## 2 Safety Information

-  **If after use, you see any discolouration on your skin that are in contact with the device, which don't disappear after 30 minutes, stop using the Elbow Shoulder Orthosis and contact your healthcare professional for advice as it may need adjusting.**
-  **The Elbow Shoulder Orthosis must be regularly maintained to the maintenance schedule in this IFU by qualified professional.**
-  **Do not remove any serial or warning labels from the Elbow Shoulder Orthosis.**
-  **Should you develop any sores or blisters you should stop use of the device at once.**
-  **Elbow Shoulder Orthosis has been designed and prescribed for an individual's needs and should only be used by that sole user.**
-  **Do not place near any heat source. Do not leave in direct sunshine or inside a car in hot weather.**
-  **Repairs and adjustments to the device must be carried out by qualified, trained healthcare professionals. Please consult a qualified medical profesional 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.**
-  **Elbow Shoulder Orthosis 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.**
-  **All persons are required to observe their respective driving laws when operating motor vehicles. It's the responsibility of the user to discuss this matter with the DVLA.**



**Avoid strong magnetic fields, sources of electrical interference, atmospheres containing liquids and/or powders.**



**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. Any such activities undertaken are done so completely at the users own risk.**



**Warn user to routinely check the Elbow Shoulder Orthosis for unusual behaviour and loose fittings. In the event of finding an issue they must contact their Healthcare professional.**

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## 3 Everyday Use

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

Blatchford Elbow Shoulder Orthoses only contact 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.

When putting the Elbow Shoulder Orthoses on, the following steps should be taken:

- Check the Elbow Shoulder Orthoses straps are free from debris and move/function freely.
- Place your hand into Elbow Shoulder Orthoses, ensuring your elbow is correctly orientated.
- Finally fasten the straps firmly.

It is normal to see red marks where pressure has been applied. These should disappear within 30 minutes.

### IF NOT CONTACT YOUR HEALTHCARE PROFESSIONAL

The feel of the Elbow Shoulder Orthoses may take some time to get used to. The Elbow Shoulder Orthoses should not be painful; 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 pain 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.

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## 4 Intended Use

Blatchford Elbow Shoulder Orthoses are designed and prescribed to provide joint stability, control biomechanical alignment of the elbow and shoulder, limit excessive movements in the joints and control the biomechanical alignment of the elbow and shoulder.

Blatchford Orthoses are prescribed and designed to meet the functional loss needs of each individual user rather than to treat an individual condition or pathology. Blatchford Orthoses are suitable for use on one or both arms and can be used by all ages. Blatchford Elbow Shoulder Orthoses are always and only intended to be used where specified. Elbow Shoulder Orthoses are intended for users of any mass, shape or size and are designed for low to medium activity levels. Your healthcare professional will advise on the optimum Elbow Shoulder for your needs. Orthoses are intended for the sole use of the patient named on the conformity documentation. If the Orthoses is no longer required, it must be safely disposed. Please follow the guidelines below:

- Ensure the orthotist is aware the device is no longer required.
- Return the device for safe disposal.

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## 5 Intended Performance

### Lifting Loads

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 ESO'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 Orthosis 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. ESO's are recommended for use between  $-10^{\circ}\text{C}$  and  $+50^{\circ}\text{C}$  (14 F to 122 F).



Suitable for outdoor use

### Activity

ESO's are not designed for high activity sport such as tennis, badminton, cycle racing or snow sports. Any such activities undertaken are done so completely at the user's own risk.

### Lifetime

It is recommended that Elbow Shoulder Orthoses are evaluated by a healthcare professional after every 12 months of use as a minimum to determine continued suitability of use.

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## 6 Maintenance

### Cleaning

Cleaning a Blatchford Orthosis 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 Orthosis. Use a clean cotton cloth to wipe the area and dry the surface of the device after cleaning.

### 6.1 Maintenance Schedule

#### Daily

- User visual inspection
- Inspect all over generally for any obvious signs of wear and 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

#### 12 Monthly

- We recommend a 12 monthly service by the manufacturer and any worn parts should be repaired or replaced as appropriate.
- 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.

### 6.2 Transport & Storage

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

Ensure the Orthoses is thoroughly protected from damage in transit.

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## 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. 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

### Warranty

Blatchford Orthotic products 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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