

Custom-Made Medical Device

Instructions for Use

Knee Brace Range
829017KN Plastic Knee

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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.

Knee orthoses are custom made medical devices. They are prescribed by clinicians and individually shaped to meet the customer's needs.

2 Safety Information



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



Should you develop any sores or blisters you should stop use of the device at once.



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



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



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



Knee Brace may include flammable materials. Be aware of fire hazards where possible.



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



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



The device is not suitable for extreme sports, rugby or cycle racing, ice and snow sports. Any such activities undertaken are done so completely at the users own risk.



Do not remove any serial or warning labels from the Knee Brace



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 as a showering orthosis unless specified for this purpose by your healthcare professional.



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 you experience any weight or activity changes contact your healthcare professional as it may affect the Knee Brace's performance



Avoid strong magnetic fields, sources of electrical interference.



Should the Knee Brace display any changes of performance or any fittings on the device come loose please immediately stop use and contact your healthcare professional.



Knee joints can entrap fingers or clothing, be cautious of this when operating the Knee Brace.



All straps MUST be secured firmly when putting the Knee Brace on. Appropriate fixation of the strap is important, as the straps hold the custom Knee Brace onto the limb and if not fastened correctly could result in the failure of the device.

3 Everyday Use

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

Blatchford Knee Brace applies forces to the body segment 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 long cotton socks or tights under the Knee Brace which are:

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

When putting the Knee Brace on daily the following steps should be taken:

- Check the Knee Joints and straps on daily are free from debris and move/function freely.
- It is best to put the Knee Brace on whilst sitting or lying down.
- Ensure the knee joints are roughly level with the middle of your knee cap.
- Finally fasten the straps firmly.

At first, the Knee Brace may feel uncomfortable so you should gradually build up the amount of time you wear it each day. Your Orthotist will tell you how long you should build up to, or what activities to wear it for.

It is normal to see red marks where pressure has been applied. These should disappear within 30 minutes. IF NOT CONTACT YOUR HEALTHCARE PROFESSIONAL

4 Intended Use

A custom Blatchford Knee Brace is provided to compensate for muscle weakness, paralysis or skeletal problems which may cause lower limb instability. The Knee Brace is designed to:

- Provide support to weakened or weakening joints and muscles
- Realign some or all of the joints in the leg
- Prevent movement which is unhelpful or painful
- Provide protection
- Improve stability for safe standing
- Improve mobility

Knee Braces have been designed to meet the functional loss of each individual user rather than to treat an individual condition or pathology. Knee Braces are suitable for use on one or both limbs and can be used by infants through to adulthood.

Knee Braces should be approved by the user's treating medical professional to ensure suitability. Secure, well-fitting footwear should be used to reduce the risk of tripping or falling.

Indications

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

Contraindications

Users with a weight over 100 kg.

Knee Braces are intended for the sole use if the patient named on the conformity documentation. For the purposes of any recycling, if the Knee Brace is no longer required, it must be safely disposed of by the orthotic department and your clinical records updated. Please follow the guidelines below:

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

5 Intended Performance

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



Suitable for outdoor use

Activity

Knee Brace's are intended to be used for standing, walking and non-weight bearing activities. They are not 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 Knee Brace's are evaluated by a healthcare professional after every 6 months of use as a minimum to determine continued suitability of use.

6 Maintenance

Cleaning

Cleaning any Knee Brace is important for both user safety and ensuring the longevity of the medical device. The Knee Brace should be wiped clean daily. Please note that stains caused by bodily fluids should be removed immediately. When cleaning the Knee Brace 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 Knee Brace. Use a clean cotton cloth to wipe the area and dry the surface of the Knee Brace 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 Knee Brace, please contact your prescribing medical professional.

6.1 Maintenance Schedule

Daily

- User visual inspection
- Inspect Knee Brace 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 in the Knee Brace's calf and thigh section. Signs include cracks, chips, and stress lines in the material.
- User check for any noise (creaks) in the joints within the Knee Brace when moving the knee joint (if present) through its full range of motion.

6 Monthly

- We recommend each Knee Brace is fully serviced 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 Knee Brace
- Failure to comply may invalidate the warranty.

6.2 Transport & Storage

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

Ensure the Knee Brace 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. 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 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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