

Custom-Made Medical Device

Instructions for Use

829010BK BKL Below Knee
Irons

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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 irons are a custom-made medical device.

Custom BK Irons can be designed with single, double or Rizolli irons for different purposes. All BK irons require a socket system in the base of the footwear to anchor the BK iron and form a system. Your healthcare professional will advise on the appropriate combinations,

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

2 Safety Information



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



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



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



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



Avoid strong magnetic fields, sources of electrical interference.



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



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.



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 BKI and contact your healthcare professional for advice as it may need adjusting.

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|  Do not remove any serial or warning labels from the BKL. |  Ankle joints (if applicable) can entrap fingers or clothing, be aware when operating the BKL. |
|  BKL may include flammable materials. Be aware of fire hazards where possible. |  Using well fitted footwear to reduce the risk of trips. |
|  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. |
|  Should the BKL display any changes of performance or any fittings on the device come loose please immediately stop use and contact your healthcare professional. | |

3 Everyday Use

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

Blatchford BKL applies force to 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 long cotton socks or tights under the AFO which are:

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

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

- Check the BKL joints and straps are free from debris and move/function freely.
- It is best to put the BKL on whilst sitting. Place your leg into the BKL ensuring your heel is right to the bottom and at the back of the BKL or shoe.
- Ensure the ankle joints are roughly level with the middle of your ankle.
- Finally fasten the straps firmly.
- Your Orthotist 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 discoloration where pressure has been applied. This should disappear within 30 minutes.

IF NOT CONTACT YOUR HEALTHCARE PROFESSIONAL

Footwear advice

- Your BKI should always be worn with socket mounted, modified footwear, which have been prescribed to the same user as the BK Irons.
- Advice on the correct footwear will be provided by a treating medical professional.

4 Intended Use

A Custom BKI is provided to compensate for muscle weakness, or skeletal problems which cause lower limb instability. BKI 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
- Lift the foot where required

BKI's are prescribed and designed to meet the functional loss needs of each individual user rather than to treat an individual condition or pathology. BKI's are suitable for use on one or both limbs and can be used by infants through to adulthood. BKI builds are always intended to be used with a socket mounted to a shoe.

Indications

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

Contraindications

Users with a weight over 100 kg.

BKI's are intended for the sole use if the patient named on the conformity documentation. If the BKI is no longer required it must be safely disposed of. Please follow the guidelines below:

- Ensure the orthotist is aware the BKI is no longer required.
- Return the BKI 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 BKI'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 BKI 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. BKI are recommended for use between -10°C and $+50^{\circ}\text{C}$ (14 F to 122 F).



Suitable for outdoor use

Activity

BKI'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 BKI's are evaluated by a healthcare professional after every 12 months of use as a minimum to determine continued suitability of use.

6 Maintenance

Cleaning

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

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 in the calf section. Signs include cracks, chips, and stress lines in the material.
- User check for any noise (creaks) in the joints within the device when moving the ankle joint (if present) through its full range of motion.

6 Monthly

- We mandate each BKI is fully serviced by the manufacturer and any worn parts should be repaired or replaced as appropriate.

6.2 Transport & Storage

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

Ensure the BKI 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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