



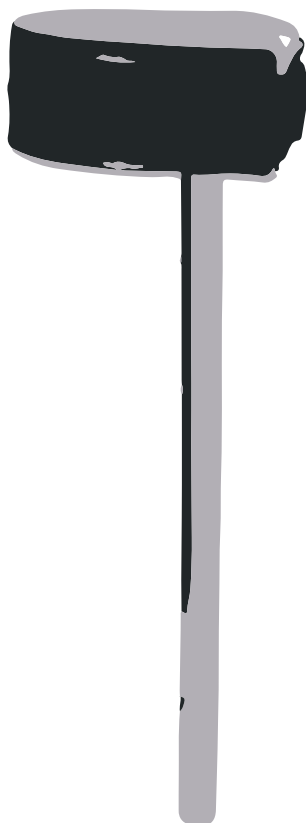
MD

Blatchford:

BKI Below Knee Irons

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 Orthotists work 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 of Orthotists 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 BKI products and systems meet the essential requirements of EU Medical Devices Regulation 2017.

Product Description

BK Irons are custom made medical devices. 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.

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 foot wear to anchor the BK Iron and form a system. Made to Measure shoes can be ordered from Blatchford separately or appropriate foot wear can be supplied by the patient where we can adapt and fit the BK Irons. 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 BKIs 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 BKI's, 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 BKI 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 a BKI immediately.



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



Should you gain more than 4kg in weight after being supplied a BKI you should contact your healthcare professional as it may affect the BKI performance



• 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 performance



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



• Should the BKI 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 BKI must be carried out by qualified, trained, healthcare professionals. Please consult a qualified medical professional should you have any problems with this custom product.



• Ankle joints(if applicable) can entrap fingers or clothing. Be aware when operating the BKI



• 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 BKI



• BKI may include flammable materials. Be aware of fire hazards where possible

Intended Use

A custom BKI is provided to compensate for muscle weakness, or skeletal problems which cause lower 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**

The most common conditions include:

- **Drop foot syndrome**
- **Plantar-flexion resistance**
- **Neurological deficits**
- **Dorsi-flexion assistance**
- **Medial-lateral foot or leg control**
- **Post stroke**

BKIs are prescribed and designed to meet the functional loss needs of each individual user rather than to treat an individual condition or pathology. BKIs 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. Any shoe to be used with the Blatchford custom BKI should be approved by the users treating medical professional to ensure it is suitable, as the heel height and pitch of the footwear can cause trips and falls whilst using a custom BKI.



BKI's are intended for users with a mass of 100kg or less and designed for low to medium activity levels. Your healthcare professional will advise on the optimum BKI build for your needs.



BKI's are intended for the sole use of the patient named on the conformity documentation. If the BKI is no longer required it must be safely 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 BKI 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 BKI applies forces 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 BKI which are:

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

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

1. Check the BKI joints and straps are free from debris and move/function freely.
 2. It is best to put the BKI on whilst sitting or lying down. Place your leg into the BKI ensuring your heel is right to the bottom and at the back of the BKI or shoe.
 3. Ensure the ankle joints are roughly level with the middle of your ankle
 4. 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 red marks where pressure has been applied. These should disappear within 30mins. 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.
- The correct footwear for any treatment will be prescribed by a treating medical 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 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's are recommended for use between -10 C and 50 C (14 F to 122 F).

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 BKIs are evaluated by a healthcare professional after 12 months of use to determine suitability of use.

Maintenance:

Cleaning

Cleaning an BKI is very important for both user safety and ensuring the longevity of the medical device. The Below Knee Iron 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. 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 BKI 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 BKI please contact your prescribing medical professional.

Maintenance Schedule

Weekly

- * User visual inspection
- * Inspect all over generally for any obvious signs of wear & 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.

Monthly

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.

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

Blatchford! Custom-made device. MD	
Serial No.	X
Identifier	
Location	
Product	
Description	Orthosis D of M
Device incorporates tissues of animal origin as referred to in Regulation (EU) No 722/2012 YES <input type="checkbox"/> NO <input type="checkbox"/>	
Blatchford Limited: Atlas Way: S4 7QQ orthoticsales@blatchford.co.uk	
Blatchford Products Limited : Lister Road : Basingstoke : RG22 4AH	

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



Must consult information for user



Manufacturer of Medical Device



Medical Device



MD

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
Blatchford Limited:Atlas Way:S4 7QQ : orthoticsales@blatchford.co.uk : +44 (0) 114 263 7900