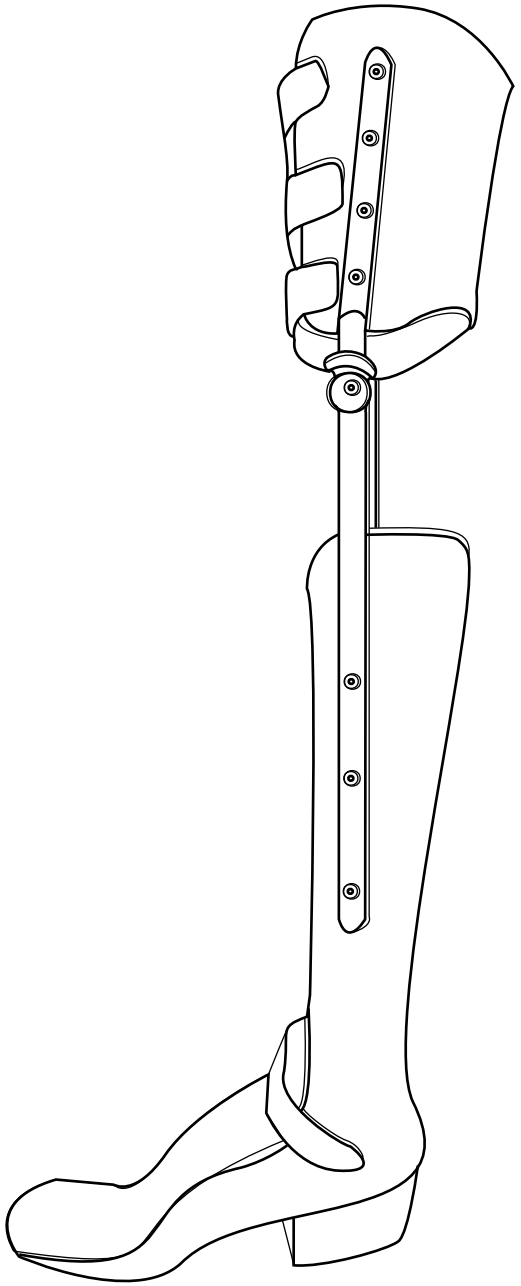
MD

Blatchford
KAFO Range

Custom-made Medical Device

829017 Composite KAFO
829018 Plastic KAFO
829019 Conventional KAFO

EN Instructions For Use



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About Us

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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 Orthoses[1] 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 KAFO products and systems meet the essential requirements of EU Medical Devices Regulation 2017.

Product Description

KAFO's or 'Knee Ankle Foot Orthoses' are full leg splints classed and are deemed custom medical devices. They are prescribed by clinicians and individually shaped to meet the customers' needs.

Our KAFO products support the knee, ankle and foot joints and to control movement throughout the full length of the lower limb. This can help relieve painful motion and improve mobilisation due to lower limb weakness. There are many knee and ankle joint components that can be used for focused movement or immobilisation. These include stance phase control knee joints which provide full stability upon weight bearing, and release on swinging the leg through. This provides the KAFO user with a more natural and energy efficient gait pattern.

A Blatchford KAFO is a custom made medical device. 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.

The prescription may take the form of a letter from a qualified person or a moulded impression of the shape of the required device together with the order specifying customer details, and a request to 'make as pattern'. It is the qualified person who is responsible for specifying the specific design characteristics of the product. Blatchford, the manufacturer of KAFO meets the particular requirements of the Medical Devices Regulations which relate to custom-made devices The activities carried out by Blatchford in supplying or fitting a KAFO (e.g. preparation, impression taking, prescribing, final fitting and any adaptation), are not considered to fall within the scope of the Medical Devices Regulations.

Safety Information

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If after use of the KAFO 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 KAFO 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 KAFO immediately.

The KAFO 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 KAFO you should contact your healthcare professional as it may affect the custom KAFO's performance.

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

• The custom KAFO must be regularly maintained to the maintnance schedule in this IFU.

• Should the KAFO 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 adjustment to the custom KAFO 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 and ankle joints can entrap fingers or clothing, be cautious of this when operating the KAFO.

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

• 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.

• Any excessive changes in heel height after programming will adversely affect limb function and should be immediately reported to your service provider.

• 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 and falls whilst using a custom KAFO.

• Do not remove any serial or warning labels from the KAFO.

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

Intended Use

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A custom Blatchford KAFO is provided to compensate for muscle weakness, paralysis or skeletal problems which cause lower limb instability. A KAFO is intended 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**

The most common conditions include:

- **Poliomyelitis**
- **Muscular Dystrophy**
- **Multiple Sclerosis**
- **Spinal Cord Injury**

KAFO's are prescribed and designed to meet the functional loss needs of each individual user rather than to treat an individual condition or pathology. KAFO's are suitable for use on one or both limbs and can be used by infants through to adulthood. KAFO's are always intended to be used inside a shoe or in the case of a conventional KAFO attached to the outside of a shoe. Any shoe to be used with the Blatchford custom KAFO should be approved by the users treating medical professional to ensure it is suitable, as the heel height and pitch of the footwear can affect the KAFO's function and stability in weight bearing. Secure, well-fitting footwear also reduces the risk of trips and falls whilst using a custom KAFO.

KAFO is 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 KAFO for your needs and may be able to provide specific options for higher user masses or activity levels by consulting with 3rd party manufacturers

KAFO is intended for the sole use of the patient named on the conformity documentation. If the KAFO is no longer required it must be safety 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 and finger traps. Always wear gloves when dismantling and ensure the KAFO 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.**



risk assessment.

Everyday Use

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Blatchford KAFO 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 KAFO which are:
• Well fitting.
• Un-patterned.
• Pulled up firmly to eliminate creases

When putting the KAFO on daily the following steps should be taken,
1. Check the KAFO joints and straps are free from debris and move/function freely.
2. It is best to put the KAFO on whilst sitting or lying down. Place your leg into the KAFO ensuring your heel is right to the bottom and at the back of the (Ankle Foot Orthosis) AFO or shoe.
3. Ensure the knee joints are roughly level with the middle of your knee cap.
4. Finally fasten the straps firmly.
5. If you have a metal and leather KAFO it is usually easiest to leave it connected to your shoe and put them both on at the same time

At first, the KAFO 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.

• The wearer should check the skin where the KAFO has been in contact every time you take the KAFO off.
• 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 KAFO should always be worn with ordinary enclosed footwear with a fastening, i.e. laces or hook and loop.(picture example)
• Look for shoes which have a low opening as this will help to put them on.
• Shoes with removable insoles can offer extra depth to accommodate the KAFO.
• Avoid high heels. The height of the heel affects the alignment of the KAFO, so before changing your footwear please discuss this with your 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 KAFO'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 KAFO 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. KAFO's are recommended for use between -10 C and 50 C (14 F to 122 F).

Activity: KAFO'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 recommended that KAFOs are evaluated by a healthcare professional after 12 months of use to determine suitability of use.

Maintenance:

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Cleaning

Cleaning a KAFO is very important for both user safety and ensuring the longevity of the medical device. The KAFO should be wiped clean daily. Please note that stains caused by bodily fluids should be removed immediately. When cleaning the KAFO 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 KAFO. 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 KAFO 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 KAFO please contact your prescribing medical professional.

Maintenance Schedule

Weekly

* User visual inspection
* Inspect KAFO 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 KAFO's calf and thigh section. Signs include cracks, chips and stress lines in the material.

Monthly

User check for any noise (creaks) in the joints within the KAFO when moving the knee and ankle joint (if present) through its full range of motion.

Six months

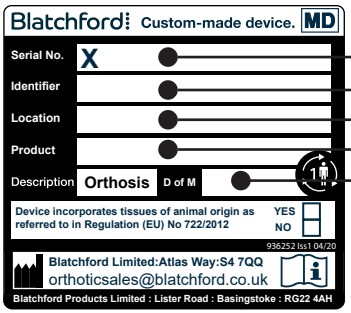
We recommend each KAFO is fully serviced by the manufacturer and any worn parts should be repaired and replaced as appropriate Ensure all labels on the product are intact and never remove any warning or serial numbers from the KAFO Failure to comply may invalidate the warranty

Warranty

For all warranty enquiries please refer the website under the warranty section.

Label Indentifier

A label is located on each custom-made medical device. Due the custom nature of the product it may be positioned where practicable.



Serial No. Quote this number with any enquiry

Identifier. Customer name or Initials (if applicable)

Location. Hospital/Clinic

Product. Product descrption

D of M . Date of Manufacture

Single user Use Only

Must consult information for user

Manufacturer of Medical Device

MD **Medical Device**

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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
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