

Custom-Made Medical Device

Instructions for Use

829017H Composite HKAFO
829018H Thermoplastic HKAFO

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Instructions for Use

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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.

HKAFO's or 'Hip, Knee Ankle, Foot Orthoses' are full leg devices and are deemed custom medical devices. They are prescribed by clinicians and individually designed to meet the customer's needs.

Our HKAFO products support the hip, knee, ankle and foot joints 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 hip, knee and ankle joint components that can be used for focused movement or immobilisation

It is the qualified healthcare professional who is responsible for specifying the specific design characteristics of the product.

2 Safety Information



If after use, you see any discolouration on skin that is in contact with the device, which does not disappear after 30 minutes, stop using the HKAFO and contact your healthcare professional



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



The HKAFO must be regularly maintained to the maintenance schedule in this IFU.



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



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



Always use a handrail when descending stairs and at any other time if available.



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 HKAFO



HKAFO 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.

-  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's the responsibility of the user to discuss this matter with the DVLA.
-  If your weight changes significantly and effects the fit of the device please contact your Orthotist professional as it may affect the HKAFO's performance.
-  Excessive changes in heel heights of shoes worn with device can effect the function, discuss this with your Orthotist
-  Hip, Knee and Ankle joints can entrap fingers or clothing, be cautious of this when operating the HKAFO.
-  All straps **MUST** be secured firmly when putting the HKAFO on. Appropriate fixation of the strap is important, as the straps hold the custom KAFO onto the limb and if not fastened correctly could result in the failure of the device.
-  Avoid strong magnetic fields, sources of electrical interference.
-  Use well fitting footwear to reduce the risks of trips whilst using a custom HKAFO.
-  If unusual behaviour or loose fittings are identified, please contact your healthcare professional.

3 Everyday Use

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

Blatchford HKAFO applies forces to the body segment to which they are attached. The interface components have been designed to avoid unacceptable pressure and stress levels in body tissues.

We advise patients should wear long cotton socks or tights under the HKAFO which are:

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

When putting the HKAFO on daily the following steps should be taken:

- Check the HKAFO joints are free from debris and move/function freely.
- It is best to put the HKAFO on whilst sitting or lying down. Place your leg into the HKAFO ensuring your heel is right to the bottom and at the back of the heel section.
- Ensure the knee joints are roughly level with the middle of your knee cap.
- Finally fasten the straps firmly.

- If you have a metal and leather HKAFO it is usually easiest to leave it connected to your shoe and put them both on at the same time.

At first, the HKAFO 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 HKAFO has been in contact, every time you remove the HKAFO.
- It is normal to see discoloration where pressure has been applied. These should disappear within 30 minutes. IF NOT CONTACT YOUR HEALTHCARE PROFESSIONAL

Footwear advice

- Your HKAFO should always be worn with ordinary enclosed footwear with a fastening i.e. laces or hook and loop
- 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 HKAFO.

4 Intended Use

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

HKAFO's are prescribed and designed to meet the functional loss needs of each individual user rather than to treat an individual condition or pathology. HKAFO's are suitable for use on one or both limbs and can be used by infants through to adulthood. HKAFO's are always intended to be used inside a shoe or in the case of a conventional HKAFO attached to the outside of the shoe. Secure, well-fitting footwear reduces the risk of trips and falls whilst using a custom HKAFO.



HKAFO 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 HKAFO build for your needs and may be able to provide specific options for higher use masses or activity levels by consulting with third party manufacturers.

Indications

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

Contraindications

Users with a weight over 100 kg.

HKAFO's are intended for the sole use of the patient named on the conformity documentation. For the purposes of any recycling, if the KAFO 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 HKAFO'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 HKAFO 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. HKAFO's are recommended for use between -10°C and $+50^{\circ}\text{C}$ (14 F to 122 F).



Suitable for outdoor use

Activity

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

6.1 Maintenance Schedule

Daily

- User visual inspection
- Inspect HKAFO 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 HKAFO'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 HKAFO when moving the hip, knee and ankle joint (if present) through its full range of motion.

6 Monthly

- We mandate each HKAFO 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 HKAFO
- Failure to comply may invalidate the warranty.

6.2 Transport & Storage

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

Ensure the HKAFO 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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