MD

Blatchford

SFI Simple Flat Insole

Custom-made Medical Device

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 SFI products and systems meet the essential requirements of EU Medical Devices Regulation 2017.

Product Description

Blatchford simple flat insoles (SFIs) are custom made medical devices. They are defined by the MDR 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.

A Simple Flat Insole is not mass produced and is required to be adapted to meet the specific requirements of the user and their treating medical practitioner. The activities carried out by Blatchford in supplying or fitting a SFI (e.g. preparation, impression taking, prescribing, final fitting and any adaptation), are not considered to fall within the scope of the Medical Devices Regulations.

Simple Flat Insoles can be made from different materials including thermoplastic (foam) or hard-shell (plastic or carbon-fibre shell). The orthotist will determine which material choice is best for you and for use in your own environment. You may discuss alternative options with your orthotist. If you have any allergies, please let the orthotist know.

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Safety Information

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If after use of the SFI 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 SFI 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 SFI immediately.

The SFI 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 SFI you should contact your healthcare professional as it may afect the SFIs performance

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

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

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

• 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.

• 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 SFI

• SFI may contain flammable materials. Be Aware of fire hazards where possible

Intended Use

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A custom SFI is provided to compensate for muscle weakness which may cause lower limb instability.
The SFI is designed to:

- **Provide support to weakened or weakening joints and muscles.**
- **Provide protection.**
- **Improve stability for safe standing**
- **Improve mobility**

The most common conditions include:

* Injury caused imbalances
* Foot instability
* Relieve painful areas of the foot

SFI's are prescribed and designed to meet the functional loss needs of each individual user rather than to treat an individual condition or pathology. SFI's are suitable for use on one or both limbs and can be used by infants through to adulthood. SFI builds are always intended to be used inside a shoe . Any shoe to be used with the Blatchford custom SFI should be approved by the users treating medical professional to ensure it is suitable, as the heel height and pitch of the footwear can trips and falls whilst using a custom SFI.

SFI'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 SFI build for your needs and may be party manufacturers.

SFI's are intended for the sole use of the patient named on the conformity documentation. If the SFI 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. Always wear gloves when dismantling and ensure the SFI 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.**

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Everyday Use

Blatchford SFI's relieves forces to the foot. The simple flat insole 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 SFI which are:

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

Footwear Advice

- Your SFI 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 insert the foot..

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 SFI'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 FFO 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. SFI's are recommended for use between -10 C and 50 C (14 F to 122 F).

Activity: SFI'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 SFIs are evaluated by a healthcare professional after 12 months of use to determine suitability of use.

Maintenance:

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Cleaning

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

Maintenance Schedule

Weekly

* User visual inspection
* Inspect all over generally for any obvious signs of wear & tear
* Signs include cracks, chips and stress lines in the material.

Monthly

User check for any noise (creaks) in the SFI (carbon and thermoplastic versions only)

Six months

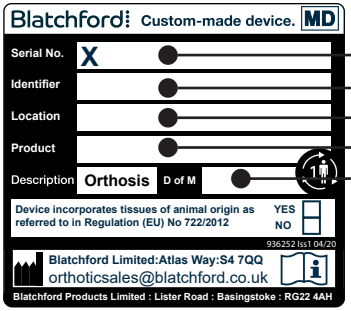
We recommend each device is fully serviced by the manufacturer and any worn parts should be repaired and replaced as appropriate. Ensure all labels on the product are intact and never remove any warning or serial numbers from the device. Failure to comply may invalidate the warranty

Warranty

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

Label 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**

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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