

Custom-Made Medical Device

Instructions for Use

829002.003 Insole

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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.

Insoles are in-shoe devices classed and deemed as custom medical devices. They are prescribed by clinicians and individually shaped to meet each patients' needs.

Our Insole products control movement at the foot, providing support and control which can help relieve pain.

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

2 Safety Information



If after use, you see any discolouration on your skin that is in contact with the device, which does not disappear after 30 minutes, stop using the Insole and contact your healthcare professional. Should you develop any sores or blisters you should stop use of the device at once.



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



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



Repairs and adjustments to the Insole 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 Insole please contact your healthcare professional as this could affect the Insoles's performance.



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



Do not remove any serial or warning labels from the Insole

 **Insoles 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.**

 **Use well fitting footwear to reduce the risk of trips.**

3 Everyday Use

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

Blatchford Insoles have been designed to avoid unacceptable pressure and stress levels in body tissues.

We advise patients should wear cotton socks or tights 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 e.g. lacing or Velcro.
- Look for shoes which have a low opening as this will help to put them on.

4 Intended Use

A custom Blatchford Insole is designed to:

- Provide support to weakened or weakening joints and muscles
- Provide protection
- Improve stability
- Improve mobility

Insoles are prescribed and designed to meet the functional loss of each individual user rather than to treat an individual condition or pathology. Insoles are suitable for use on one or both limbs and can be used by infants through to adulthood.

Insoles are always intended to be used inside a shoe.

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

- Ensure the orthotist is aware the Insoles are no longer required.

Return the Insoles for safe disposal.

5 Intended Performance

Lifting Loads

User weight and activity is governed by the stated limits provided by third party component manufacturers. 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 SFI 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 $+50^{\circ}\text{C}$ (14 F to 122 F).



Suitable for outdoor use

Activity

SFI's are intended to be used for standing, walking and no-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 SFI'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 Insole is very important for both user safety and ensuring the longevity of the medical device. The Insole should be wiped clean daily. Please note that stains caused by bodily fluids should be removed immediately. When cleaning the Insole 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 Insole. Use a clean cotton cloth to wipe the area and dry the surface of the Insole 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 Insoles, please contact your prescribing medical professional.

6.1 Maintenance Schedule

Daily

- User visual inspection
- Inspect Insoles all over generally for any obvious signs of wear and tear

6.2 Transport & Storage

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

Ensure the Insoles are 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.

The user should be aware that changes or modifications not expressly approved could void the warranty, operating licenses and exemptions.

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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