

Custom-Made Medical Device

Instructions for Use

8290004.005.006 FFO
Functional Foot Orthosis

EN	Instructions for Use	2
----	----------------------	---

Contents

1	Description and Intended Purpose.....	3
2	Safety Information	3
3	Everyday Use.....	4
4	Intended Performance.....	5
5	Maintenance	6
6	Manufacturer’s Declarations and Legal Information.....	7

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.

FFO's or Functional Foot Orthoses 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 FFO 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.

An FFO is not a mass-produced product, and it requires 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 FFO (e.g. preparation, impression taking, prescribing, final fitting and any adaption) are not considered to fall within the scope of the Medical Devices Regulations.

Our FFO products support the foot to enable the user to mobilize safely. FFO's can be designed to fully balance the lower limb to provide maximum support to the leg or knee.

FFO's can be made of different materials including thermoplastics, advanced composites or rubber. FFO's are only to be worn as inserts into your shoe.

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 FFO and contact your healthcare professional. Should you develop any sores or blisters you should stop use of the FFO immediately.



Use well fitting footwear to reduce the risks of trips.



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



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



The device is not intended for use when immersed in water.

- | | |
|---|---|
|  <p>Repairs and adjustments to the FFO must be carried out by qualified, trained healthcare professionals. Please consult a qualified medical professional should you have any problems with this custom product.</p> |  <p>Do not place near any heat source. Do not leave in direct sunshine or inside a car in hot weather.</p> |
|  <p>Do not remove any serial or warning labels from the FFO.</p> |  <p>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.</p> |
|  <p>FFO may include flammable materials. Be aware of fire hazards where possible.</p> |  <p>May contain animal tissues such as leather. Conformity certificate is available for further details should this be required.</p> |
|  <p>Should your functional requirements or condition change during the life cycle of the FFO please contact your healthcare professional as this could affect the custom FFO's performance.</p> |  <p>If unusual behaviour or loose fittings are identified, please contact your healthcare professional.</p> |

3 Everyday Use

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

Blatchford FFO relieves forces to the foot. The functional foot orthosis components have been designed to avoid unacceptable pressure and stress levels in body tissues.

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

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

Footwear advice

Your FFO 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 Use/ Purpose

The FFO is designed to:

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

FFOs are prescribed and designed to meet the functional loss of each individual user rather than to treat an individual condition or pathology. FFOs are suitable for use on one or both limbs and can be used by infants through to adulthood. FFO builds are always intended to be used inside a shoe.

Indications

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

Contraindications

Users with a weight over 100 kg.

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

- Ensure the orthotist is aware the FFO is no longer required.
- Return the FFO for safe disposal.

4 Intended Performance

Lifting Loads

Load carried 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 FFO's prescription.

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. FFO's are recommended for use between -10°C and $+50^{\circ}\text{C}$ (14 F to 122 F).



Activity

FFO's are intended to be used for standing, walking and weight bearing activities. Any such activities undertaken are done so completely at the user's own risk.

Lifetime

It is recommended that FFO's are evaluated by a healthcare professional after every 12 months of use as a minimum to determine continued suitability of use.

5 Maintenance

Cleaning

1. Hand wash in cool water using mild detergent.
2. Rinse and dry flat.
3. Do not spin or tumble dry.
4. Do not use fabric conditioner at any time.

5. Check for any degradation that may affect use 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 FFO, please contact your prescribing medical professional.

5.1 Maintenance Schedule

Daily

- User visual inspection
- Inspect all over generally for any obvious signs of wear and tear
- User check for any noise (creaks) in the FFO (carbon and thermoplastic only)

5.2 Storage and Transport Conditions

Store the FFO in a safe, clean and dry place, out of direct sunlight and keep away from heat, in the original packaging.

6 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

 Blatchford Limited: Atlas Way, Sheffield, S4 7QQ, UK orthoticscs@blatchford.co.uk:
+44 (0) 141 263 7900

Manufacturer's Registered Address

Blatchford Products Limited, Unit D Antura, Bond Close, Basingstoke, RG24 8PZ, UK

© Blatchford Products Limited 2021. All rights reserved.