

Custom-Made Medical Device

Instructions for Use

1386 Momentum Strut

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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.

Momentum is a custom carbon fibre Ankle Foot Orthosis (AFO). Designed to partially offload the foot and ankle to relieve pressure and pain following complex lower limb injury. The unique design and carbon fibre construction is lightweight yet strong, making the brace ideal for both daily use and high impact activities. The brace is not suitable for those with excessive lower limb swelling or open wounds.

Momentum is a custom made medical device.

2 Safety Information

 **If after use, you see any discolouration or blisters on skin that is in contact with the device, which does not disappear after 30 minutes, stop using the Momentum and contact your healthcare professional for advice as it may need adjusting.**

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

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

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

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

 **Use in extreme sports is undertaken completely at the users own risk. Do not remove any serial or warning labels from the Momentum**

 **Momentum 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.



Should you gain more than 4KG in weight after being supplied a Momentum you should contact your healthcare professional as it may affect the Momentum's performance.



Should the Momentum performance change or any fittings on the device come loose please immediately stop use and contact your healthcare professional.



If unusual behaviour or loose fittings are identified, please contact your healthcare professional.



Use well fitting footwear to reduce the risk of trips. The heel height of your shoe will impact the function of the Momentum, discuss any changes with your Orthotist.



Avoid strong magnetic fields, sources of electrical interference.

3 Everyday Use

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

Blatchford Momentum 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 that patients should wear long cotton socks or tights under the Momentum which are:

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

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

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

It is normal to see discolouration where pressure has been applied. These should disappear within 30 minutes. **IF NOT CONTACT YOUR HEALTHCARE PROFESSIONAL**

Footwear advice

- Your Momentum should always be worn with ordinary enclosed footwear with a fastening device.

- Look for shoes which have a low opening as this will help to put them on. Avoid high heeled shoes.

4 Intended Use

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

The Momentum is prescribed and designed to meet the functional loss of each individual user rather than to treat an individual condition or pathology. Momentum is suitable for use on one or both limbs.

Indications

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

Contraindications

Users with a weight over 100 kg.

The Momentum is designed for medium to high activity levels. Your healthcare professional will advise on the optimum Momentum build for your needs. Momentum is intended for the sole use of the patient named on the conformity documentation. If the Momentum is no longer required, it must be safely disposed. Please follow the guidelines below:

- Removal of the label.
- 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 Momentum 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.

5 Intended Performance

Lifting Loads

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



Suitable for outdoor use

Activity

Momentum's are intended to be used for standing, walking, running, cycling and non-weight bearing activities. They are not designed for extreme sports. Any such activities undertaken are done so completely at the user's own risk.

Lifetime

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

6.1 Maintenance Schedule

Daily

- User visual inspection.
- Inspect Momentum 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 Momentum. Signs include cracks, chips, and stress lines in the material.
- User check for any noise (creaks) within the Momentum when undertaking activities.

6 Monthly

- We recommend each Momentum 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 Momentum.
- Failure to comply may invalidate the warranty.

6.2 Transport & Storage

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

Ensure the Momentum 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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