Instructions for Use (IFU) – Custom-Made Orthotic Device

Intended Purpose

This custom-made orthotic device is specifically designed and manufactured for the individual patient, based on a prescription from a qualified podiatrist or healthcare professional. It is intended to provide support, stability, and pain relief for specific musculoskeletal conditions of the lower limb.

Fitting and Use

- Fitting: This device must be fitted by a qualified healthcare professional. Do not attempt to modify or adjust the device yourself.
- Break-in Period: Wear the orthotic for short periods initially, gradually increasing wear time as advised by your healthcare provider.
- Footwear: Use the orthotic in the footwear recommended by your healthcare professional to ensure optimal fit and function.

User Instructions

- Monitoring: If you experience persistent pain, discomfort, redness, or blisters, discontinue use and contact your healthcare provider.
- Care: Wipe clean with a damp cloth and mild soap. Do not expose to excessive heat or moisture. Store in a cool, dry place.
- Replacement: Replace the device if it shows signs of excessive wear, cracking, or loss of structural integrity, or as advised by your healthcare professional.
- Single Patient Use: This device is intended for use by the prescribed individual only.

Warnings & Precautions

- Do not use if the device is visibly damaged.
- Do not use on broken or ulcerated skin unless specifically directed by your healthcare provider.
- Not suitable for individuals with diabetes unless prescribed and monitored by a healthcare professional.
- It is recommended to wear socks or hosiery when using this device to reduce friction, minimize the risk of skin irritation or blisters, and help preserve the hygiene and quality of the orthotic.

Quality Concerns

If you are dissatisfied with the quality, safety, or performance of this device, you should promptly contact your prescribing podiatrist or healthcare provider in the first instance. They will assess your concerns and, if necessary, report the issue to the manufacturer and the appropriate regulatory authority in accordance with the UK Medical Devices Regulations 2002.

Incident Reporting

If you experience a serious incident related to this device, you should report it to your healthcare provider, the manufacturer, and the relevant authority (e.g., MHRA in the UK via https://yellowcard.mhra.gov.uk/).

Manufacturer Details
A. Algeo Ltd
Sheridan House, Bridge Industrial Estate, Speke Hall Road, Liverpool, L24 9HB
Website: www.algeos.com
Contact: info@algeos.com