

# Custom Soft Goods Products

## Description and performance characteristics

This medical device has been designed and manufactured to a specification prepared for you by a suitably qualified Healthcare Professional who has prescribed this custom product to meet your personal therapeutic needs. The device is intended to be worn over intact skin to provide joint immobilisation and/or provide joint support and/or control abnormal muscle tone

## Fitting Instructions

Your Healthcare Professional will provide an explanation of the product features, its function and in-depth instructions to you and/or your Carer to ensure optimal benefit from the use of your orthoses. These instructions will include the correct fitment, the length of time each day and/or night you can wear the device, including its safe removal. You and/or your Carer must completely understand label contents and warnings, information and instructions provided, since incorrect fitting or use may result in loss of device function, resulting in lack of intended therapy.

You may be requested to wear an interface garment between the device and your skin for comfort and protection of your skin.

## Contraindications

- Must not be used by individuals for whom compression is contraindicated
- Do not use on open wounds
- Any known allergy and/or hypersensitivity to any material listed in the product composition

## Warnings and Precautions

- Initial fitting of the device must be conducted by a suitably qualified Healthcare Professional who will advise the correct fitment, including the period(s) of use
- Carefully read all instructions and warnings before use
- Abide by your Healthcare Professional's instructions to ensure proper use and performance of the device
- If you are unsure of the instructions or label provided, do not use the device until you fully understand
- Follow all instructions to ensure proper performance of the brace
- Do not use if liniments, ointments, gels, creams or any other substances have been applied to the affected area
- Do not permit other person(s) to use your device, doing so risks cross infection and will compromise device integrity
- To ensure the straps are not over tightened, perform regular skin and circulation checks, especially for patients with diabetes, vascular deficiencies and neurological conditions
- Should any adverse reactions occur, please remove, do not use and contact your healthcare professional or provider
- Perform regular skin and circulation checks, especially if you have diabetes, vascular deficiencies and / or suffer from neurological conditions
- Check the brace and all components for wear and tear
- Any hook and loop fasteners must always be fastened, when the device is not being worn or washed
- The durability of the device may be compromised by certain factors, e.g. objects with sharp edges or damage to the hook and loop fasteners
- Do not attempt to alter the device since any alteration may result in compromising your treatment, device safety and performance
- Do not place the device adjacent to any heat source such as fire or radiator since it may become malformed

## Washing and care instructions

- Cover all the hook and loop straps and remove any removable metal bar
- Hand wash the brace in cool water using a mild detergent
- Rinse and air dry flat
- Do not spin or tumble dry
- Do not use fabric conditioner at any time
- Check for any degradation that may affect use
- Periodically check the hook and loop straps are operating securely
- Before using the brace again, replace any removed metal bars

## Care & Maintenance

- Before you or your Carer put on the device it is necessary to check:
  - ✓ There are no loose or missing parts
  - ✓ Fastening straps have no tears or slits and are securely fixed to the orthosis
- In the absence of washing instructions on the device label, the device should be wiped clean daily using a mild detergent
- Products can be cleaned by hand washing (see Washing Precautions), and must be completely dried prior to re-use
- Should your device contain hinges/articulation they must be kept clean and free from any debris to ensure correct function and engagement of any locking mechanism present. The hinges/articulations should be lubricated with a light lubricant, such as silicon spray, a clean lubricant that should not stain clothing
- Any hook and loop closures and/or fastenings should be kept closed when not wearing the device
- Your Healthcare Professional will advise if you are required to attend the clinic for any product reviews

### Product composition

The Device may contain:

- Thermoplastics such as Polypropylene, Polyethylene
- Metals such as Stainless Steel, Mild Steel, Aluminium
- Fabric such as Neoprene, Elastic, Velfoam, Cotton, Polyester, Spandex, Nylon
- Leatherette
- Hook and loop
- Latex

### Storage and transport conditions

Store in a cool, dry place out of direct sunlight and in the original packaging.

### Recycling and disposal

Packaging and constituent parts should be recycled or safely disposed of in accordance with local or national laws. When your Healthcare Professional has indicated your device is no longer required, is beyond reasonable repair or broken, the device should be returned to the original provider, (Clinician, NHS Trust, or Private Clinic), for safe disposition in accordance with their policies.

### Serious incident

Report any serious incident to the manufacturer and the competent authority of the EU Member State, or Country in which you reside.

### Wash symbols



Hand wash



Dry flat



Do not tumble dry



Do not bleach



Do not dry clean



Do not iron



May contain natural rubber latex



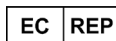
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This Medical Device conforms to the requirements of Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017



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