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Patient Information for Use document:
DMO® Custom Sock



Our products

Our Custom Made Dynamic Movement Orthoses® use a soft, flexible elastomeric fabric that ensures a close fit and creates compression forces to enhance proprioceptive feedback. This base fabric is light-weight, breathable and strong.

This is combined with reinforcement panels made using a powernet material to provide strength and stability where required improving posture and biomechanical alignment.

Our made to measure orthoses work by using strategically placed reinforcements, which position the body into improved postural alignment. This new biomechanical state combined with enhanced proprioception, stimulates and adjusts the neuro-sensory system, training muscles to work with improved tone, strength and performance.

DMO®'s help both adults and children manage the physical effects of their neurological, musculoskeletal and genetic conditions.

DMO® Custom products are individually made-to-measure, and all fastenings, openings and reinforcements are individually prescribed according to the functional needs and preferences of each individual patient.

Get in Touch

To find out more about our DMO® Product ranges, contact your local DMO® provider or distributor or DM Orthotics directly to find out who that is. Email: admin@dmorthotics.com visit: www.dmorthotics.com call: +44 (0) 1209 219205

How we intend our products to be used by patients

DM Orthotics custom-made orthotic devices are intended for the **exclusive use of a single specific patient** to support and correct posture and joint alignment. It should not be worn by any other person who it was not individually measured and prescribed for.

All DM Orthotics custom made orthoses are medical devices as defined by the EU MDR (2017/745) and are declared to conform to the regulations according to Annex II and III EU MDR, and are covered under the definition of an orthotic device: a brace, splint, or other artificial external device serving to support the limbs or spine or to prevent or assist relative movement.

The devices are custom made (according to Annex XIII MDR) and comply with the applicable requirements of the MDR (Medical Devices Regulation) (2017/745) : Custom Made Product

Date of Issue

Our custom made devices are manufactured to a specific prescription to an individual patient and will be issued with a date of manufacture on the accompanying statement form that is sent with your product. This is for the end user to keep for their records.

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Wear instructions

Follow the care instructions carefully. By taking care of your orthosis you will **prolong its wear and prevent damage.**

DO

- Put the orthosis on and off as advised by your therapist/ supplier. See website: www.dmorthotics.com/productcare
- Take care when putting it on and taking it off, follow the instructions in this booklet carefully– pulling it on and off roughly and long finger nails can cause damage.
- It is important to build up wear time as per your individual instructions.
- Follow the washing instructions carefully or it can become damaged.

DO NOT

- Do not put on or take off your made to measure product roughly - this can cause damage to the product with ladders or tears or holes in the fabric.
- Do not put on or take off with long finger nails, this can also damage the fabric.

FIT OR SAFETY CONCERNS

Contact your therapist / supplier **IMMEDIATELY** if it is getting really tight, causing red marks or has developed ladders and /or holes.

DMO® products are designed to complement therapy and physical exercise, so should not be removed for exercising unless advised by your therapist, or you have any other concerns that they can help you with.

Wearing time

DO

- Build up wearing time slowly over the first week, as stated below, doubling the amount of time daily until the orthosis is worn throughout the working day.

e.g. 1st day - 1 hour

2nd day - 2 hours

3rd day - 4 hours

4th day - 8 hours

5th day - all day during the day. Thereafter, wear every day during the day.

DO NOT

- Wear all day immediately. Wear needs to be built up to ensure sensory input, biomechanical changes and fit are monitored.
- Do not wear your DMO sock at night time unless recommended by your doctor or clinician e.g. in the case of EDS patients where this can be beneficial.

Washing instructions

Follow the care instructions carefully. By taking care of your orthosis you will **prolong its wear and prevent damage**.

DO

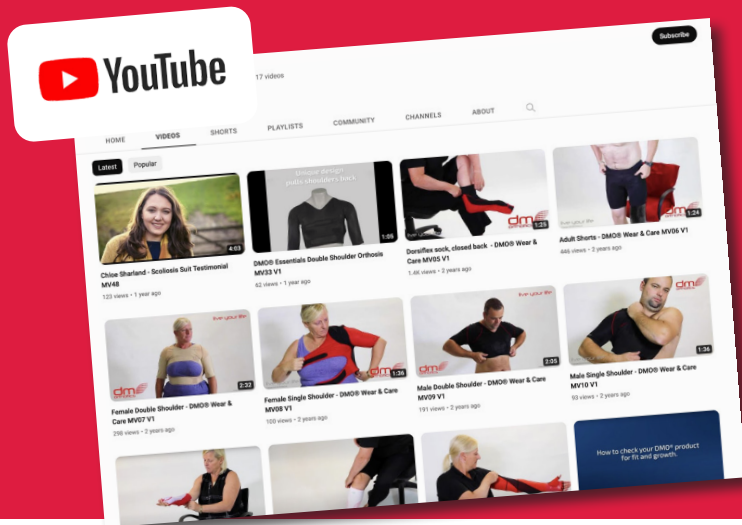
- The orthosis should be washed at least every 2-3 days.
- The orthosis can be hand washed cool or machine washed at 30 degrees.
- Short spin only or roll up in a dry towel to remove excess moisture.
- Allow to completely dry overnight by hanging up indoors.

DO NOT

- DO NOT dry in strong direct sunlight or on a radiator.
- DO NOT WRING OUT– it will stretch out of shape and will cause damage to the materials.
- DO NOT IRON.
- DO NOT USE BLEACH, OR WHITENING AGENTS
- DO NOT USE FABRIC CONDITIONER
- DO NOT DRY CLEAN.
- DO NOT TUMBLE DRY– it will shrink.

For further help and support, we have added how to put on and take off your orthosis to our website please visit: www.dmorthotics.com/productcare.

Regular and correct care of the orthosis will prevent it from developing odour and keep the material supple. If your orthosis is silver treated, this will need to be re-applied after 100 washes as the silver ions start to disperse after 50 washes.



Wearing our products

We have created a range of video guides to help our customers to get the best out of their product. These guides include helpful tips and tricks to wearing our products and how you can best care for them when putting on or taking off.

To view them visit: www.dmorthotics.com/productcare

DMO® products should be worn next to the skin. It is important to build up wear time slowly over the first week, doubling the amount of time daily until worn throughout the day. e.g.

CONTRAINDICATIONS AND PRECAUTIONS/CONSIDERATIONS

Contraindications

There are no known contraindications for using a DMO®. The assessment for a DMO® Custom made product should be undertaken by an authorised medical professional with the correct professional qualifications.

Precautions/Considerations

The following is a list of possible precautions to consider before going ahead with the prescription of a DMO® Custom made product. This should be discussed with your professionally qualified medical professional who may suggest an alternative DMO® product or altering the preferred DMO® product.

Poor temperature regulatory control

A DMO will have no affect on the temperature regulatory centre of the body. However, DMO should be treated as a layer of clothing and clothing layers will need to be adjusted for hot or cold climates accordingly. Adjustments to the prescription can be made such as short legs and arms to help improve heat control.

Primary circulation disorders

Certain primary respiratory problems where muscles are growing weaker due to deterioration of the nerves/muscles, will need careful consideration and may require discussion with the patients medical practitioner - although the suit specification may be changed to accommodate this. Secondary circulation problems associated with Cerebral Palsy can be improved due to improved posture of the trunk/body and improved position of the ribs.

Skin conditions

Skin conditions that might be exacerbated by close contact with synthetic materials for prolonged periods may require further consultation with a healthcare professional who is overseeing the patient's dermatological treatment but this is rarely a contraindication.

Skeletal fragility/brittle bones

Some conditions can be well supported by a DMO® product but this should be discussed with your medical practitioner. Alterations can be made to the preferred product such as the addition of zips or poppers or the use of short arms or legs instead of long arms or legs.

DMO® Custom Sock

Intended Purpose

The intended purpose of the DM33/37 sock is to stabilise and provide a dorsiflexion assist to the foot and ankle. Panels to correct or prevent inversion or eversion of the ankle can also be added. Proprioception and sensory feedback occurs also through the compression provided.

Indications

Instability, poor muscle control or where alignment requires correction or to be maintained, in the foot and ankle complex.

Intended Patient Population

Male and female patients. There are no age limits on the wearer of the DM33/37 socks and many conditions which present with instability or malalignment of the foot and ankle complex could benefit from the product.

A reasonably high degree of dexterity and muscle tone is required for those who will be donning and doffing the socks themselves. A carer will be required to assist with donning and doffing the socks where this is not the case.

Intended users

The DM33/37 socks will require prescription and specification by a competent healthcare professional, typically a qualified orthotist, physiotherapist or occupational therapist, who has received appropriate training in the prescription and use of Dynamic Movement Orthoses® (DMO®). Such a competent healthcare professional will also be required to assess the fit of the socks and to provide further specification advice to improve the fit where required.

The wearer will typically be a lay person.

The wearer's carer may be involved in the donning and doffing of the sock, the washing of the sock and the reporting of any issues with the sock will typically be a lay person.

The device in question is made to measure and requires specification by a healthcare professional trained in the use of DMO®. This will require a set of measurements which the healthcare professional will have been trained in taking by DM Orthotics. A range of different reinforcement panels are available which must also be prescribed as appropriate by the trained healthcare professional.



The DMO Custom Dorsiflex Sock is designed to assist weak dorsiflexors of the patient and improve foot contact with the floor when both walking and running (active dorsiflexion).

The DMO® Custom Dorsiflex Sock will improve walking patterns, improve ankle stability and provide additional uplift for patients with reduced strength.

Effective for:

- Cerebral Palsy
- Ehlers-Danlos Syndromes
- Stroke
- Dystonia
- Duchenne Muscular Dystrophy (DMD)
- Acquired Brain Injury
- Multiple Sclerosis
- Parkinson's disease
- & more

Provides:

- Assistance into dorsiflexion
- Support for over pronation or supination (if additional reinforcements added)
- Compression
- Pain relief
- Improved ankle stability

Additional features:

- Compression fabric for comfort and movement
- Optional open or closed back
- Reinforcement panelling for strength and stability
- Optional open or closed toe



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DMO® Sock application instructions

How to apply the DMO® Custom Dorsiflex Closed Back and Open Back Sock.

Precautions:

- Take care when adjusting the silicon band at the top of the orthosis to protect hairs and skin from being pulled.
- If there are any concerns with fit i.e. extremities turning blue or feeling overly cold to the touch, then please remove and inform your clinical team immediately for further assessment.

To check the fit:

- The DMO® logo at the top of the sock should be aligned with the mid line of the knee cap.
- The heel should be closely fitted into the back of the sock and the front sides of sock should be forward of the front wide joints (metatarsals) so that the sock finishes at the crease under your toes.



Remove the sock and silk applicator from its packaging.



Turn the sock inside out except for the foot.



Slide the foot into the silk applicator.



Slide foot and applicator inside the sock and push/pull towards the heel.



Roll the sock up and around the heel. The silk applicator should still be in place.



Roll the sock up the leg, **taking care not to dig nails into the sock and not to pull too hard.**



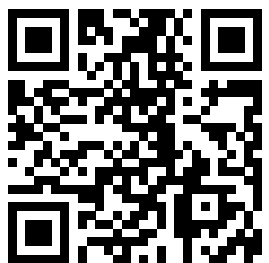
Roll sock into position as shown.



Remove the silk applicator. This is how the sock should look in the correct position.

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How the dorsiflex closed back sock should look when on:



Use the QR code above to access our wear and care videos or go to:

www.dmorthotics.com/productcare

How to remove the DMO® Custom Dorsiflex Closed Back and Open BackSock.



Pull the top of the sock down gently, towards the ankle.



Continue to roll the sock down towards the ankle.



Remove the sock over the heel of the foot.



Pull the sock completely off the foot. The sock will be inside out.

Disposal of Device Statement

The devices manufactured by DM Orthotics are class 1 / custom made orthotic devices. There are no precautions required to be taken to dispose of DMO® devices. The materials used for manufacture can be disposed of in line with your local arrangements for clothing / materials disposal. We do ask that you please wash the device before disposal.

Serious Incident Statement

If any serious incident occurs in relation to your DMO® device, you should report it immediately to the manufacturer (DM Orthotics) and the competent authority responsible for medical devices in your Member State for example in the UK this would be the Medicines and Healthcare products Regulatory Agency MHRA.

Manufacturer



Patient identification



Product/model ID



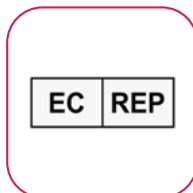
Manufactured in Britain



Distributor



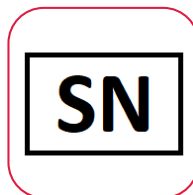
MedEnvoy Global BV
Pr. Margrietplantsoen 33
Suite 123
2595 AM Den Haag
Netherlands



Clinician name



Order number



Medical Device



Please note user modification is not recommended and by altering the orthosis yourself your warranty can be affected or deemed void. Please contact your clinical specialist or DM Orthotics for information on alterations and product modifications.



Manufacturer:
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Redruth
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TR15 1SS

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Designed and constructed in the UK

UDI-DI:
DM33 Dorsiflex sock 5054522000197
DM37 Dorsiflex assist open back sock 5054522000210



Manufacturer: DM Orthotics Ltd
Unit 2 Cardrew Way
Cardrew Industrial Estate
Redruth, Cornwall, UK
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EC

REP

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