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Patient Information for Use document:

DMO® Essentials leggings and shorts



www.dmorthotics.com

Our products

DM Orthotics is a world-leader in the design and manufacture of its patented Dynamic Movement Orthoses® (DMO®).

The DMO® use biomechanical panelling and strategic reinforcements to improve postural alignment and increase proprioception. These factors then stimulate and adjust the neurosensory system training muscles to work with improved tone, strength, and performance.

The DMO® Essentials leggings and shorts are a pre-sized set of fabric orthoses and a good cost effective option if you want to test whether a custom orthosis will be of benefit to a patient. They work effectively as an entry level single measurement product.

Created to provide improved comfort, posture, and range of movement to the user. Designed to be worn next to the skin, the enhanced proprioceptive feedback and biomechanical positioning of these designs help train muscles to work; leading to improved tone, strength, and performance.

All these benefits work towards a single goal – to improve function and encourage independence for the user.

DMO® Essentials are a pre-sized product that is made to set sizes for both children and adults and are a combination of our compression/sensory fabric and combined with a number of reinforcement panels that are strategically placed to benefit the patient. They are not alterable and further reinforcements are not permitted. they can be recommended by a clinician where a standard off the shelf product may be of benefit, or can be ordered direct from our website with only one measurement being required.

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

DMO Orthotic Essential products are intended to help support and correct posture and joint alignment where further individual adjustment or additional reinforcements are not required.

All DM Orthotics 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 medical 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 designed and manufactured to comply with the applicable requirements of the EU MDR (Medical Device Regulation) (2017/745) and are declared to conform to the regulations according to Annex II and III EU MDR.

Date of Issue

Our medical devices are manufactured and issued with a date of manufacture on the accompanying declaration 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 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 all day and 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 leggings/shorts 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°C degrees.
- Wash separately
- 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.

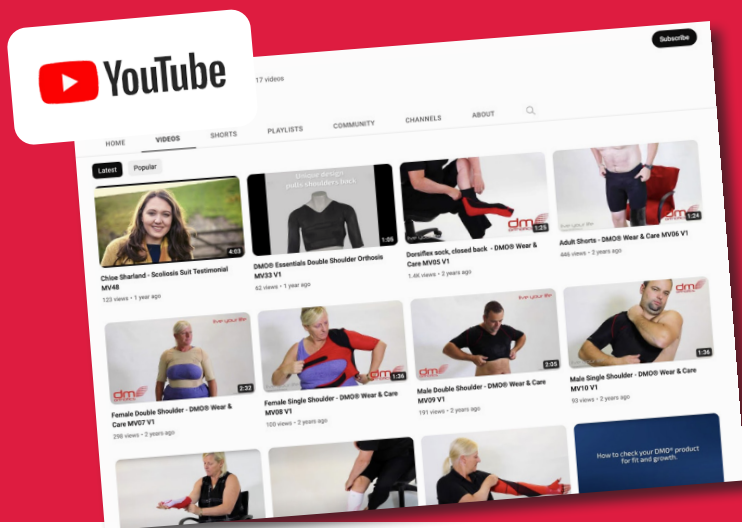


Wearing our products

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® 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® product. This should be discussed with your professionally qualified medical professional who may suggest an alternative 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.

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. 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.

DMO® Essentials leggings and shorts

Intended Purpose

The intended purpose is to align the lower trunk, pelvis, hips and lower limb. The exact location of the effect is determined by the choice of product. It improves symmetry and assists stabilisation. The leggings and shorts give a non-restrictive and highly effective level of support to maximise pelvic and lower limb stability. The product also aids distal control and positively influences muscle tone to enhance function.

Indications

Children or adults presenting with low or high muscle tone, sensory or proprioception issues, lack of core, pelvic or lower limb stability. Children or adult who have pain associated with poor alignment or fatigue caused by their inability to maintain a corrected pelvic or lower limb posture.

Intended Patient Population

Male and female patients are usually aged two or above, although children under two may benefit from the leggings and shorts.

Various medical conditions present with symptoms which the leggings and shorts can help with these include (not exhaustive) see below:

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

Intended users

The wearer of the orthosis will typically be a lay person.

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



DMO® Essentials Leggings

Effective for:

- Cerebral Palsy
- Lower limb impairments
- Multiple Sclerosis
- Ehlers-Danlos Syndromes
- High and low muscle tone
- & more

Provides:

- Pelvic stability
- Improvement in hip and knee alignment
- Improved internal/external hip rotation
- Increased sensory awareness
- Improved posture
- Improved muscle function
- Pain relief
- Reinforcement panelling for strength and stability

Additional features:

- Optional crotch opening
- Compression fabric for comfort and movement
- Improved leg positioning
- Worn under clothing

DMO® Essentials Shorts

Effective for:

- Cerebral Palsy
- Multiple Sclerosis
- Ataxia
- Low muscle tone
- Acquired and Traumatic Brain Injury
- Ehlers-Danlos Syndromes
- Impaired walking patterns
- Stroke
- Parkinson's disease
- Huntington's Chorea
- & more

Provides:

- Pelvic stability
- Hip and knee extension
- Reduced external/internal hip rotation
- Increased sensory awareness
- Improved posture
- Improved muscle function
- Pain reduction

Additional features:

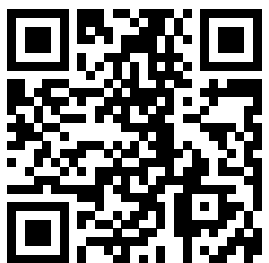
- Compression fabric for comfort and movement
- Optional crotch opening
- Reinforcement panelling for strength and stability
- Worn under clothing



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Precautions:

- Remove watches and jewellery before applying the orthosis.
- The shorts should be removed if the patient is sick or has a temperature.
- If there are any concerns with fit ie extremities turning blue or feeling overly cold to the touch, then please remove and inform your clinical team immediately for further assessment. (if you have one) or if purchased on our website, contact our admin department and return them to DM Orthotics.



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

www.dmorthotics.com/productcare

DMO® Essentials shorts application instructions

How to apply the DMO® Essentials shorts.

Patient will need to sit down to ensure balance and safety and make sure the shorts are on correctly.

The DMO® Essentials shorts are put on and taken off the same way as the DMO custom shorts, which are used for illustrative purposes.

1



Take the shorts (with the label at the back) and pull them up the legs (as you would a pair of tights). Make sure you pull them over the knees and up the thighs before beginning to pull them up across the hips.

2



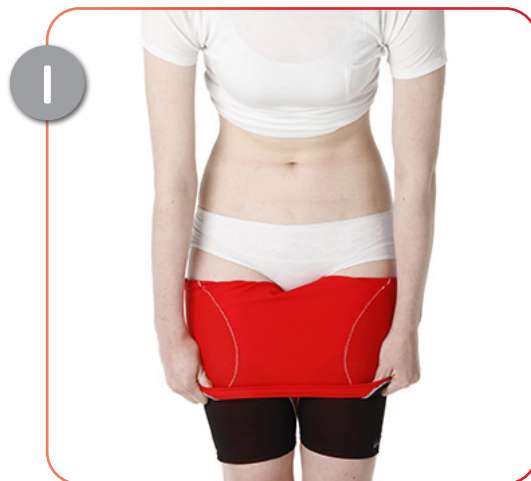
Pull the shorts up to the waist.

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How to remove the DMO® Essentials shorts.

Patient will need to sit down to ensure balance and safety and make sure the shorts are removed correctly.

How the Essentials shorts should look when on:



Roll the shorts down the legs towards the feet.



Slide each leg out of the orthosis.

To check the fit:

- The shorts should be a tight fit, but you should be able to fit your index finger under the lower edge of the shorts and waist.
- The stitching/ends of the orthosis may leave slight indentations in the skin, when removed, but if any marks are overly red after 25-30 minutes of its removal, then it may be too tight.
- If in any doubt as to its appropriate fit. If purchased on our website, contact our admin department and return them to DM Orthotics

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DMO® Essentials Leggings application instructions

How to apply the DMO® Essentials Leggings.

Patient will need to sit down to ensure balance and safety and make sure the shorts are removed correctly.

The DMO® Essentials leggings are put on and taken off the same way as the DMO custom leggings, which are used for illustrative purposes.

Precautions:

- Remove watches and jewellery before applying the orthosis.
- The leggings should never be worn at night (unless discussed with a doctor or physiotherapist. Some EDS patients may benefit from night wear but this must be confirmed before doing so). or when the user is sick or has a temperature.
- If there are any concerns with fit ie extremities turning blue or feeling overly cold to the touch, then please remove and inform your clinical team immediately for further assessment. (if you have one) or if purchased on our website, contact our admin department and return them to DM Orthotics

To check the fit:

- The leggings should be a tight fit, but you should be able to fit your index finger under the lower edge of the leggings and waist.



1 Remove the orthosis from its packaging.



2 Apply the silk foot applicator. If requested and provided.



3 Push right leg through right leg of the orthosis.



4 Gently pull the right leg of the orthosis towards the knee.



5 Keep pulling gently towards the knee until the bottom of the right leg orthosis is above the ankle.

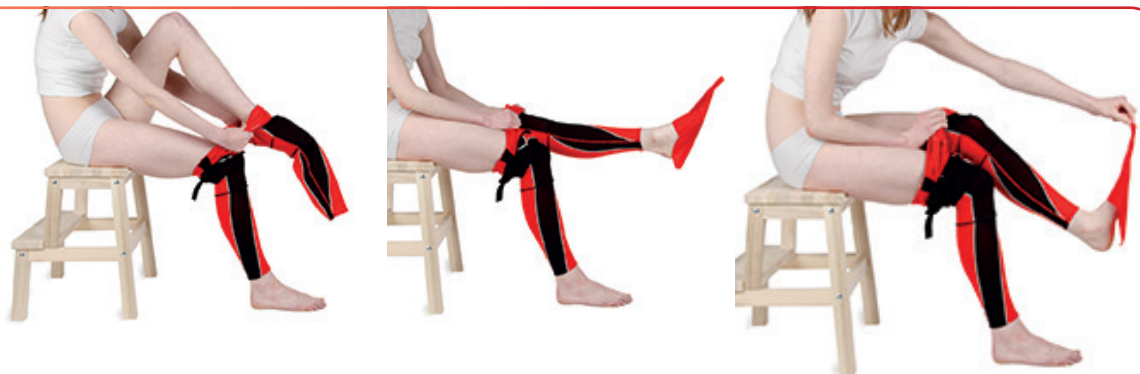


6 Remove silk applicator from right foot.



7 Apply the silk applicator to the left foot. For the leg sleeve, please go to picture 10

8



Repeat steps 4 to 7. Then remove the silk applicator from the foot. Make sure you have gently pulled the leggings up to the thigh before attempting to pull over the hips and the body.

9



Pull leggings gently upwards towards the hips.

10



Make sure the silicone is in contact with the skin at the top of the orthosis.

II



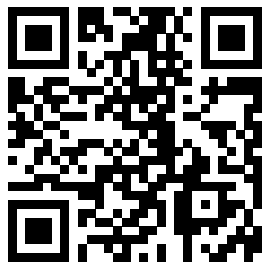
How the leggings should look when worn correctly.

To check the fit Cont.:

- The stitching/ends of the leggings may leave slight indentations in the skin, when removed, but if any marks are overly red after 25-30 minutes after its removal, then it may be too tight.
- If in any doubt as to its appropriate fit. If purchased on our website, contact our admin department and return them to DM Orthotics

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How the Essentials leggings should look when on:



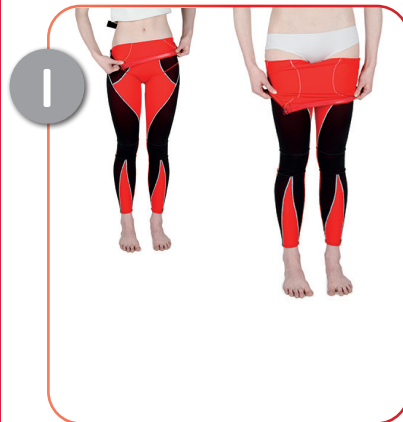
Use the QR code above to access our wear and care videos or go to:

www.dmorthotics.com/productcare

DMO® Essentials Leggings application instructions

How to remove the DMO® Essentials Leggings.

Patient will need to sit down to ensure balance and safety and make sure the shorts are removed correctly.



Roll the top of the leggings down towards the knees.



Sitting down continue to roll the leggings down towards the knees.



Sitting down continue to roll the leggings down towards the knees.



Roll leggings down to the ankles on both legs.



Remove each foot from the leggings.

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



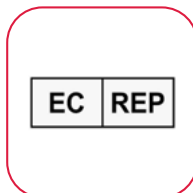
Manufactured in Britain



Distributor



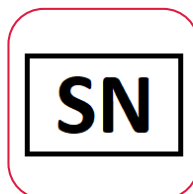
MedEnvoy Global BV
Pr. Margrietplantsoen 33
Suite 123
2595 AM Den Haag
Netherlands



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:
DM Orthotics Ltd
Unit 2 Cardrew Way
Cardrew Industrial Estate
Redruth
Cornwall, UK
TR15 1SS

+44 (0) 1209 219205
www.dmorthotics.com
admin@dmorthotics.com



Designed and constructed in the UK

Basic UDI-DI: 5054522LOWERLIMBMF

UDI-DI:

5054522001675 Adult Leggings - XXS
5054522001682 Adult Leggings - XS
5054522001699 Adult Leggings - S
5054522001705 Adult Leggings - M
5054522001712 Adult Leggings - L
5054522001729 Adult Leggings - XL
5054522001736 Adult Leggings - XXL

5054522001743 Child Leggings - 1
5054522001750 Child Leggings - 2
5054522001767 Child Leggings - 3
5054522001774 Child Leggings - 4
5054522001781 Child Leggings - 5
5054522001798 Child Leggings - 6
5054522001804 Child Leggings - 7
5054522001811 Child Leggings - 8

5054522000555 Adult Shorts - XXS
5054522000562 Adult Shorts - XS
5054522000579 Adult Shorts - S
5054522000586 Adult Shorts - M
5054522000593 Adult Shorts - L
5054522000609 Adult Shorts - XL
5054522000616 Adult Shorts - XXL

5054522000623 Child Shorts - 1
5054522000630 Child Shorts - 2
5054522000647 Child Shorts - 3
5054522000654 Child Shorts - 4
5054522000661 Child Shorts - 5
5054522000678 Child Shorts - 6
5054522000685 Child Shorts - 7
5054522000692 Child Shorts - 8



Manufacturer: DM Orthotics Ltd
Unit 2 Cardrew Way
Cardrew Industrial Estate
Redruth, Cornwall, UK
TR15 1SS



EC

REP

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