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Patient Information for Use document:

DMO® Custom Postural Scoliosis Suit



www.dmorthotics.com

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 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

- For **scoliosis suits** this time should be gradually increased to a minimum of 13 hours per day up to 22 hours per day.
- Do wear your scoliosis suit at night as advised by your clinician

DO NOT

- Wear all day immediately. Wear needs to be built up to ensure sensory input, biomechanical changes and fit are monitored.

Washing instructions

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

DO

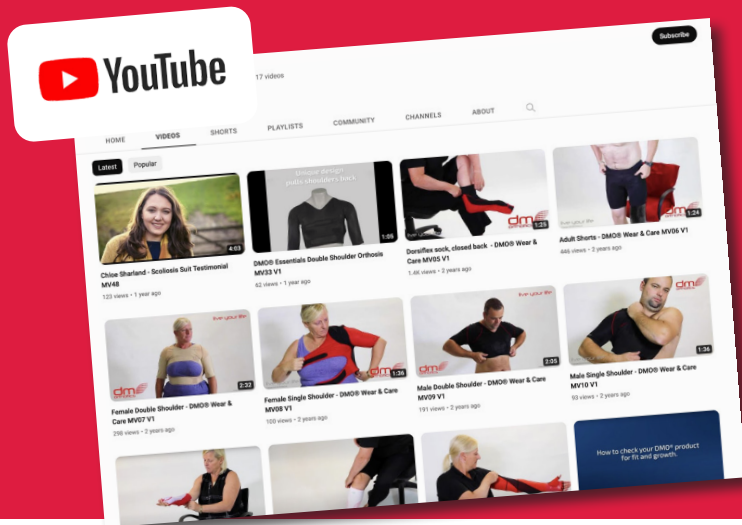
- The orthosis should be washed at least every 2-3 days.
- The orthosis can be hand washed cool or machine washed at 30 degrees.
- Short spin only or roll up in a dry towel to remove excess moisture.
- Allow to completely dry overnight by hanging up indoors.

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.

Gastrostomy, stoma and other medical requirements

We can manufacture the custom made product with a special aperture for a gastrostomy peg, stoma, suprapubic catheter etc. This will be added at the fitting stage to ensure precise placement. Please discuss this with your medical practitioner who can seek further advice from the experienced clinical team at DMO®.

DMO® Custom Postural Scoliosis Suit

Intended Purpose

The intended purpose of the DM34 Postural Scoliosis Suit is to:

“Improve, maintain or reduce the progression of neuropathic and idiopathic scoliosis during spinal development and to improve or maintain posture and reduce pain in neuropathic scoliosis following spinal maturity.”

Indications

Before Spinal Maturity:

- Neuropathic scoliosis without rotation
- Idiopathic scoliosis without rotation

Following Spinal Maturity:

Neuropathic scoliosis without rotation where there is progression of the condition and/or pain due to muscular instability.

Intended Patient Population

Males and females diagnosed with a postural scoliosis.

Ages 2 and up until maturity of spine (typically maximum of 25 years of age) for improvement, maintenance or reduction of progression of scoliosis. Any age following maturity of spine for maintenance of posture and prevention or relief of pain associated with scoliosis.

Certain individuals younger than 2 years may be indicated with guidance from a specialist in treatment of scoliosis using dynamic movement orthoses.

A reasonably high degree of dexterity is required for those who will be donning and doffing the suit themselves. Assistance will be required to assist with donning and doffing the suit if the patient is unable to achieve this independently where this is not the case.



Intended Users

The suit 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®) for scoliosis management. Such a competent healthcare professional will also be required to assess the fit of the suit and to provide further specification advice to improve the fit of the suit where required.

The wearer of the suit requiring scoliosis management will typically be a lay person.

The wearer's carer/family member/assistant etc. who may be involved in the donning and doffing of the suit, the washing of the suit and the reporting of any issues with the suit 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® for scoliosis management. This will require a set of measurements in which the healthcare professional will have been trained in taking measurements by DM Orthotics Ltd.

A range of different reinforcement panels must also be prescribed as appropriate by the trained healthcare professional.

Strategically placed panelling re-aligns the pelvis, trunk and shoulders to provide improved spinal alignment, balance and proximal core stability. Unlike traditional rigid splinting this design improves balance, posture and stability whilst also allowing range of movement.

Effective for:

- Neuropathic Onset Scoliosis
- Mobile/Postural curves

Provides:

- Improved spinal re-alignment
- Improved range of spinal movement
- Sensory feedback
- Encouragement of correct muscle function
- Pain relief

Additional features:

- Available in long and short sleeve
- Worn under clothing
- Reinforcement panelling for strength and stability
- Optional crotch opening (open crotch recommended)
- Compression fabric for comfort and movement



Precautions:

- Ensure zip liners are in place over the skin prior to pulling up zips.
- When fastening leg zips (if fitted), pull the orthosis away from the skin to ensure that no skin is trapped.
- The suit should be removed if the patient is sick or has a temperature.
- If there are any concerns with fit i.e. extremities turning blue or feeling overly cold to the touch, please remove & inform your clinical team immediately.

To check the fit:

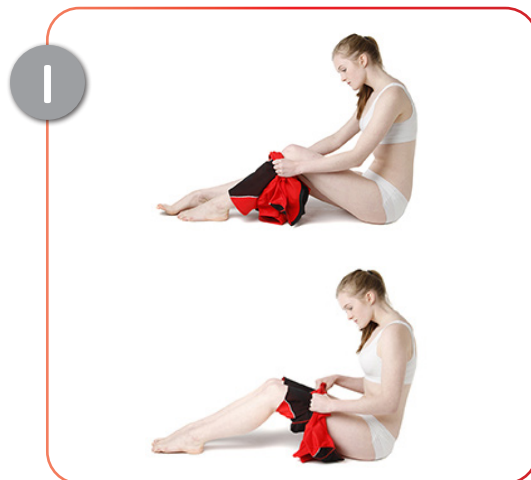
The suit should fit tightly. You should be able to fit your index finger under the bottom of the sleeves & legs, as well as around the neckline.

- The stitching/ends of the orthosis may leave slight indentations in the skin, but if any marks are overly red after 20-30 minutes after removal, then it may be too tight.
- If you have any doubt with regards to a suitable fit, please notify your therapist immediately. The orthosis will only be altered free of charge within the first 6 weeks.

DMO® Postural Scoliosis Suit application instructions

How to apply the DMO® Postural Scoliosis Suit

There are different ways to apply the suit depending on personal preference. Remove the suit from its packaging and undo any zips. You can also watch our videos at www.dmorthotics.com/productcare on how to put on and take off your DMO® product. **You may need to lie down to put the suit on properly for balance and safety.**



1 Feed the legs through and pull suit up over the knees.



2 Work suit up over hips. (This will feel tight over the pelvis) until it is fully up.



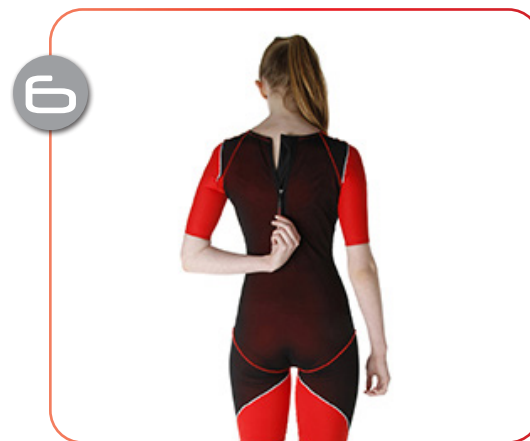
3 Feed through arm and pull the orthosis up and over the shoulder.



4 Repeat with the other arm.



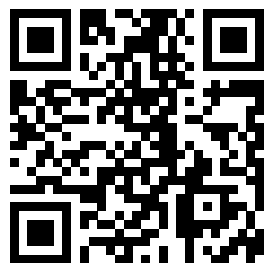
5 Fasten front zip first taking care to protect the skin from entrapment.



6 Fasten back zip last. *When wearing a postural scoliosis suit build up wear time to a minimum of 13 hours and a maximum of 22 hours (except when being washed).*

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How the Postural Scoliosis Suit 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® Postural Scoliosis Suit

You may need to lie down when taking off the suit orthosis for balance and to ensure safety of the patient



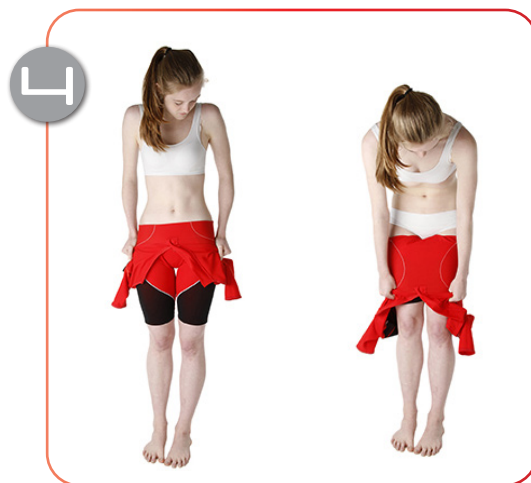
Undo the back zip first followed by the front zip, taking care to protect the skin from entrapment.



Remove arm from sleeve.



Repeat with other arm.



Roll suit down towards knees.



Roll suit down to feet and legs and slide 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



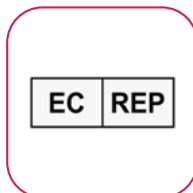
Manufactured in Britain



Distributor



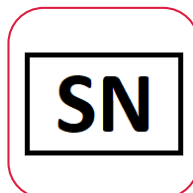
MedEnvoy Global BV
Pr. Margrietplantsoen 33
Suite 123
2595 AM Den Haag
Netherlands



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:
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

UDI-DI: 5054522000203



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