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Patient Information for Use document:
DMO® Custom Structural 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 conform to the regulations according to Annex XIII of the EU MDR.

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.

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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.

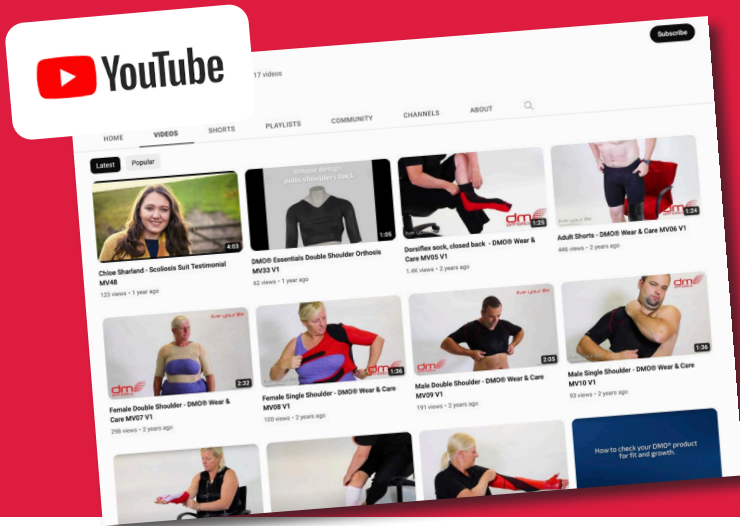


Wearing our products

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 Structural Scoliosis Suit

Intended Purpose

The intended purpose of the DM Orthotics Structural 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. The structural scoliosis suit is intended to be used specifically where there is rotation of the spine due to scoliosis to reduce or prevent further degeneration of this rotation whilst also reducing or maintaining frontal and/or sagittal curvature due to scoliosis.”

Before Spinal Maturity:

- Neuropathic Scoliosis with rotation
- Idiopathic Scoliosis with rotation

Following Spinal Maturity:

Neuropathic Scoliosis with rotation where there is progression of the condition and/or pain due to muscular instability. The DMO® Custom Structural Scoliosis Suit is for patients who have more advanced Scoliosis. It is specifically designed to help the management and reduction of Neuropathic and Idiopathic Scoliosis curves.

The DMO® Custom Structural Scoliosis Suit has been designed to correct spinal curvature and rotation. Unlike traditional rigid splinting, this design can assist with the reduction of rotation which occurs in Neuropathic and Structural Idiopathic Scoliosis.

Intended Patient Population

Those diagnosed with scoliosis where there is rotation of spine present. Ages 2 and over 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 and muscle tone is required for those who will be putting on and taking off the suit themselves. A carer will be required to assist with putting on and taking off the suit where this is not the case.



Intended Users

The suit will require prescription and specification by a competent healthcare professional, typically a qualified orthotist or physiotherapist, who has received appropriate training in the prescription and use of dynamic movement orthoses 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 who may be involved in the putting on and taking off 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 dynamic movement orthoses for scoliosis management. This will require a set of measurements which the healthcare professional will have been trained in taking. They will have met the criteria for scoliosis training set by DM Orthotics and they will have attended specialist scoliosis training provided by a DM Orthotics clinical specialist.

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

Effective for patients with:-

- Idiopathic Scoliosis
- Neuropathic Scoliosis (where rotation is present)

Provides/clinical benefits

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

Use with other Orthotics

- can be used with other DMO products
- can have additional requirements for gastrostomy, stoma and other medical conditions taken into account during the prescription phase and added at fitting phase. Please discuss this with your professional clinician at the time of the assessment.
- can be returned for alteration for fit issues at time of fitting
- can be returned for alteration at any time for fitting or growth at a cost.
- can be used with other medical devices as prescribed by your medical practitioner.



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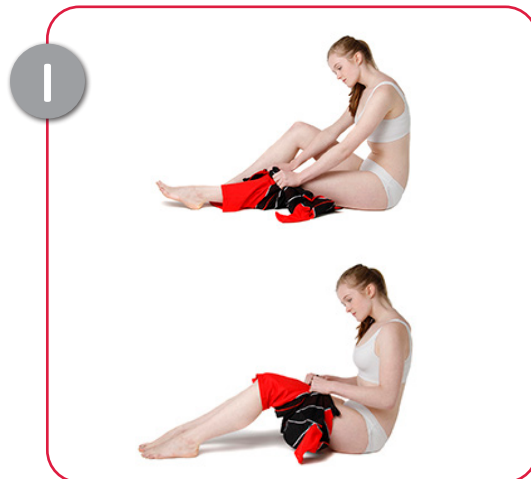
DMO® Structural Scoliosis Suit application instructions

How to apply the DMO® Structural Scoliosis Suit.

Patient will need to lie down to ensure balance and safety and that the suit is on correctly.

Precautions:

- Ensure the zip liners are in place over the skin prior to pulling up zips and not rolled back.
- When doing up the inner leg zips (if suit is fitted with zips), please ensure that you pull the orthosis away from the skin when zipping 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, then please remove and inform your clinical team immediately for further assessment.
- Remember your structural scoliosis suit should be worn a minimum of 13 hours up to a maximum of 22 hours per day (except when being washed).



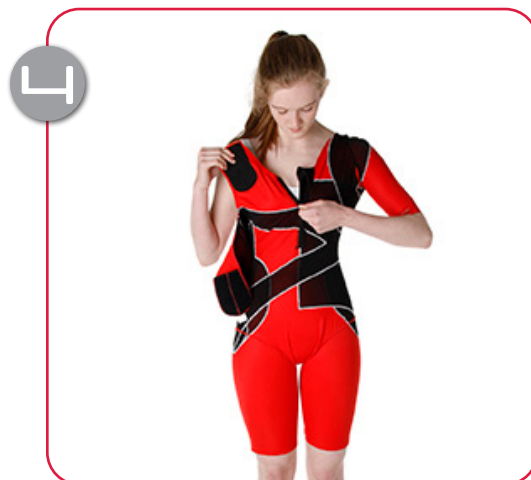
Feed the legs through and pull suit up over the knees.



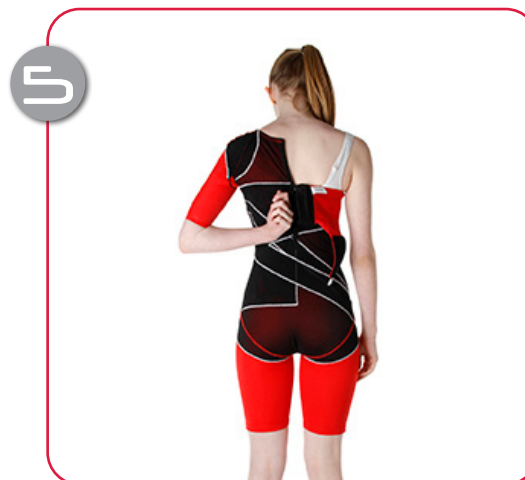
Work suit up over hips. (This will feel tight over the pelvis) until it is fully up.



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



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



Fasten back zip in the same way.



Lay strap over shoulder - do not pull hard.

How to remove the DMO® Structural Scoliosis Suit.

Patient will need to lie down to ensure balance and safety and to ensure the suit is on correctly.

How the structural scoliosis suit should look when on:

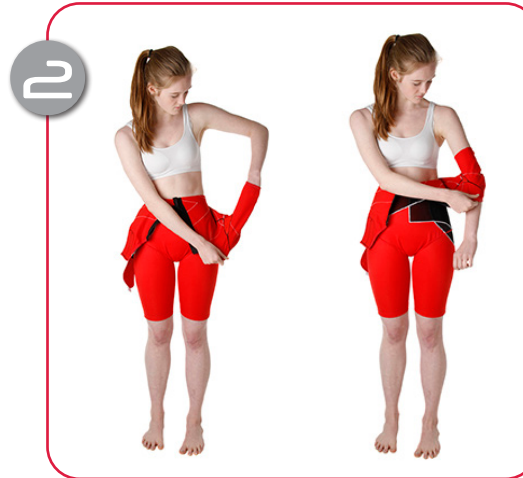


Use the QR code above to access our wear and care videos or go to:

www.dmorthotics.com/productcare



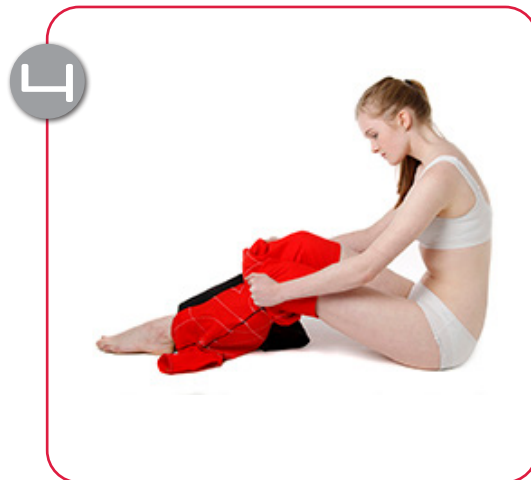
Undo the back zip first then the front zip, taking care to protect skin from entrapment. Undo shoulder strap.



Remove arm from sleeve.



Roll suit down towards knees.



Roll suit down to feet and legs and slide out.



To check the fit:

- The suit should be a tight fit, but you should be able to fit your index finger under the bottom of the sleeves and legs of the suit, as well as around the neck line.
- The stitching/ends of the orthosis may leave slight indentations in the skin, when removed, but if any marks are overly red after 20-30 minutes of its removal, then it may be too tight.
- If in any doubt, as to its appropriate fit, then please notify your therapist immediately, as the orthosis will only be altered free of charge within the first 6 weeks.

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



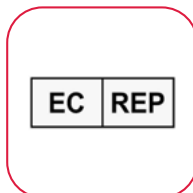
Manufactured in Britain



Distributor



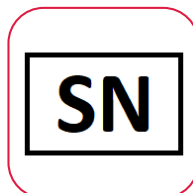
MedEnvoy Global BV
Pr. Margrietplantsoen 33
Suite 123
2595 AM Den Haag
Netherlands



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 5054522000227



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