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dm orthotics

Patient Information for Use document:

DMO® Custom Early Intervention 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.

Contents

live your life.

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 all day and everyday 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 at night unless recommended by your doctor or clinician.

Washing instructions

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

DO

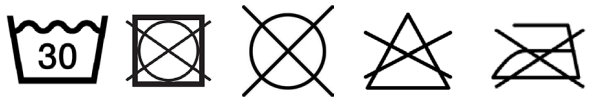
- The orthosis should be washed at least every 2-3 days.
- The orthosis can be hand washed cool or machine washed at 30 degrees.
- Short spin only or roll up in a dry towel to remove excess moisture.
- Allow to completely dry overnight by hanging up indoors.

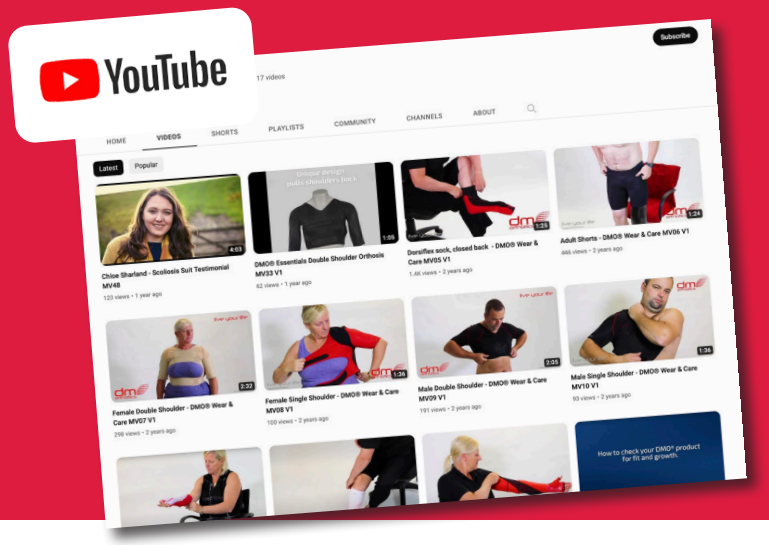
DO NOT

- 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. They will ensure any possible contraindications to use are discussed with you before the decision is made to proceed with a DMO® product. Certain cardiovascular circulatory disorders may be contraindicated and further consultation with the patient's cardiologist may be required.

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 Early Intervention suit

Intended Purpose
The intended purpose of the DM03 early intervention suit is to help with some of the problems faced when caring for a young child, who may present with either low or high muscle tone which results in poor trunk and head control.

Indications
- Children born pre-term, or children usually under the age of two who present with.
- Low Muscle Tone
- High Muscle Tone
- Sensory Seeking/ Sensory Issues
- Poor Trunk or Head control

Intended Patient Population
The Early Intervention suit would be intended for children usually under the age of two years (or can be used in older children where prescriber's deem appropriate), who have either low of high muscle tone and who require support for postural and head control.

A carer will be required to assist with donning and doffing the suit due to the age of the wearer.

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. 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 will typically be a lay person.

The wearer's carer 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 dynamic movement orthoses. This will require a set of measurements which the healthcare professional will have been trained in taking measurements by DM Orthotics.

Optional reinforcement panels must also be prescribed as appropriate by the trained healthcare professional.

Effective for:
- Children with high or low tone issues
- Sensory seeking babies
- Improved posture
- Sensory feedback
- Improved head and trunk control

Additional features:
- Popper fastening for easy nappy changing
- Leaves arms and legs free

Provides:
- Adjustable hook and loop straps
- Compression fabric for comfort and movement
- Available in standard sizes and made to measure

DMO® Custom Early Intervention suit application instructions

How to apply the DMO® Custom Early Intervention suit.
Patient will need to lie down to ensure balance and safety and that the suit is on correctly.

To check the fit:

- The early intervention suit should be a snug/tight fit but you should be able to fit your finger into the bottom of the legs and at the shoulder/ under arm section as well as the neck area.

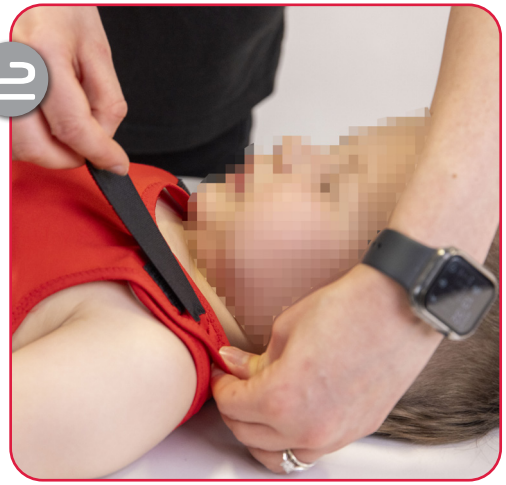
- The stitching/ends of the orthosis may leave slight indentations in the skin, when removed, but if any marks are overly red after 20-30 minutes of its removal, then it may be too tight.

- 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.

1

Open the top and side panel velcro and lay the suit on the floor. Leave the poppers between the legs fastened. Bring the front of the suit down. Lie your baby on top of the suit.

2



Bring the front of the suit up over your child, putting their legs either side of the poppers. Fasten the velcro tabs at the shoulders.

3

Now bring the velcro straps around your babys body and begin by fastening the velcro at the top of the leg/hip area.

4

Begin to fasten the velcro from the hips up the sides of the body to the under arm area, ensuring they are comfortably tight, to ensure they are getting sensory stimulation.

5

Once the suit is fastened with the velcro, re-check the shoulders and ensure it is not fastened too tight.

How to remove the DMO® Custom Early Intervention suit.

Patient will need to lie down to ensure balance and safety.

How the Early Intervention suit suit should look when on:

Use the QR code above to access our wear and care videos or go to:
www.dmorthotics.com/productcare

1

Undo the velcro from the legs and then from the sides of the body.

2

Undo the straps across the shoulders.

3

Bring the suit down from the front of the child.

4

Lift your child away from the open suit.

Precautions:

- Ensure the body liners/extra material at the sides of the body, are in place over the child/skin before doing up the velcro straps.
- 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.

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.

dm orthotics

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DM Orthotics Ltd
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TR15 1SS

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Designed and constructed in the UK

UDI-DI: 5054522000029

MD

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EC REP

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