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Patient Information for Use document:
DMO® Pre-sized Sensory Vest



Our products

DMO® Sensory Range

DM Orthotics developed the DMO® Sensory Product Range in response to requests from clinicians for a compression product, without reinforcement panelling, that improves proprioceptive feedback and core stability. As the name suggests it has been developed to support individuals with sensory difficulties.

The compression forces of the fabric orthoses design can enhance the proprioceptive feedback received by the brain through the neuro-sensory system. This in turn influences muscle tone and body awareness, which can lead to an improvement in the body's ability to sense its location, movement, and actions.

The deep pressure effect can help reduce both overactive and low endurance sensory presentations, lead to a positive effect on core stability, body alignment and improved spatial awareness. When combined, this can improve fine and gross motor skills.

The Pre-Sized Sensory Vest is available in a number of set sizes for both children and adults and cannot be altered to accommodate individual patient needs.

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 pre-sized 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 pre-sized 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 pre-sized and are designed and manufactured to comply with the applicable requirements of the EU MDR (Medical Devices Regulation) (2017/745) and are declared to conform to the regulations according to Annex II and III EU MDR.

Date of Issue

Our pre-sized devices are manufactured to a specific prescription and will be 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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Pre-sized Sensory Vest

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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 all day, 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.

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.

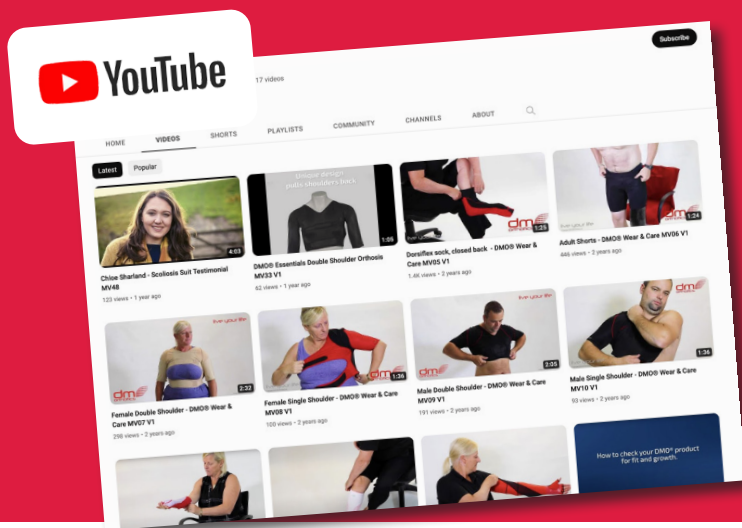


Wearing our products

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 a DMO® product. This should be discussed with your professionally qualified medical professional.

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® Pre-sized Sensory Vest

Intended Purpose

The intended purpose of the Sensory vest, is to improve sensory proprioceptive feedback and core stability which is facilitated by the application of deep pressure. This is exerted through the skin by the compression force applied by the fabric.

Improving body awareness can have a positive effect. When the core becomes more stable, the body aligned and spatial awareness improved, fine and gross motor skills can also be improved.

Indications

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

Intended Patient Population

Male and female patients usually aged two or above, although children under two may benefit. The lower age threshold was set due to increased growth at this stage, not due to the inability to achieve the intended purpose. There is no upper age limit to the vest.

Various medical conditions present with symptoms which the vest can help with.

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

Intended users

The Pre-sized Sensory vests can be prescribed by a competent healthcare professional, typically a qualified orthotist or physiotherapist or occupational therapist, who has received appropriate training in the prescription and use of dynamic movement orthoses.

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



DMO® Pre-sized Sensory Vest

Suitable for:

Adults and children requiring compression to improve body awareness and reduce overactivity. This can provide a calming effect and improve core stability and midline orientation.

Effective for:

- Sensory difficulties
- Some people with Autism, ADHD and Sensory Processing Disorder

Provides:

- Increased sensory awareness
- Support for overactive or low endurance sensory presentations
- Increased spatial awareness and concentration
- Reduced tactile sensitivity

Benefits include:

- Can be worn all day
- Polycotton fibre mix
- Breathable and washable material
- Worn under clothing but can be worn as the main clothing if desired particularly in hot climates
- Outside seams to improve the inside feel of the product and avoid itchy areas
- Oeko-Tex Certification – standard 100



DMO® Pre-sized Sensory Vest application instructions

Precautions:

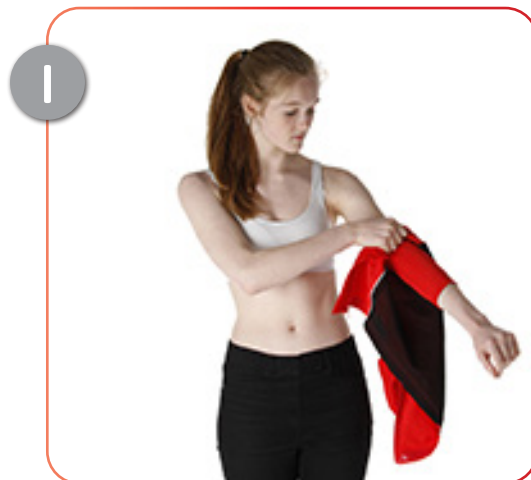
- Ensure the zip liners are in place over the skin prior to pulling up zips and not rolled back.
- The vest should be removed if the patient is sick or has a temperature.
- If there are any concerns with fit i.e. extremities turning blue or feeling overly cold to the touch, then please remove and inform your clinical team immediately for further assessment.

To check the fit:

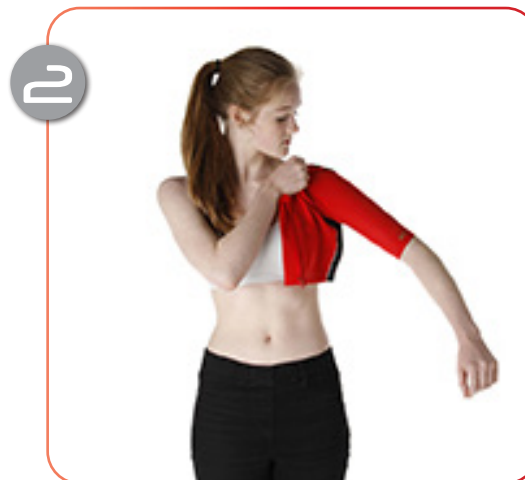
- The vest should be a tight fit, but you should be able to fit your index finger under the bottom of the sleeves & around the neck line.
- When removed, the stitching/ ends of the orthosis may leave red marks in the skin. If overly red after 20-30 mins of removal, then it may be too tight.
- If in any doubt as to appropriate fit, then please return to our Head Office for a different size or a refund. Please return the product unused and in the original packaging as per our returns policy. If you do have a therapist involved in your care, please do contact them for advice.

How to apply the DMO® Sensory Vest.

The DMO® pre-sized sensory vest is put on and taken off the same way as the DMO Custom vest which has been used for illustrative purposes.



Remove from packaging and undo the zip. Place your arm into the correct sleeve section.



Pull well up to the shoulder.



Take orthosis behind back and feed other arm into the other sleeve behind your back.



Pull front panel round.



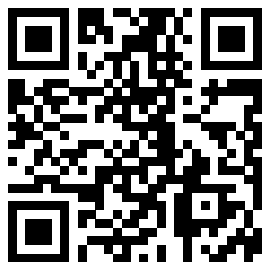
Fasten front zip taking care to protect the skin from entrapment.

Please note. Your orthosis may be longer than the one shown here. Ensure when you have fastened the zip that you gently pull your orthosis down to ensure it is covering your body well.

Also ensure that the zip liner is in place over the skin to ensure the zip does not trap the skin.

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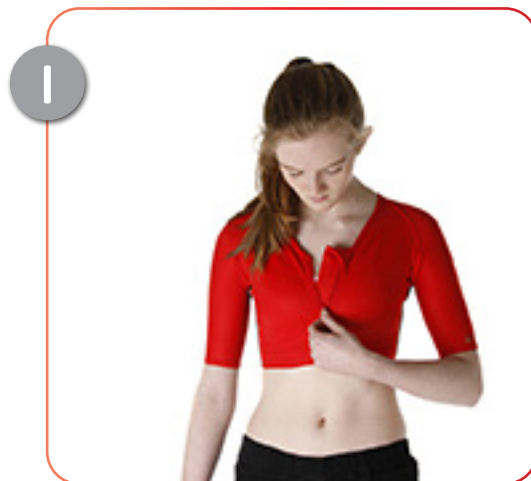
How the Sensory pre-sized vest should look when on:



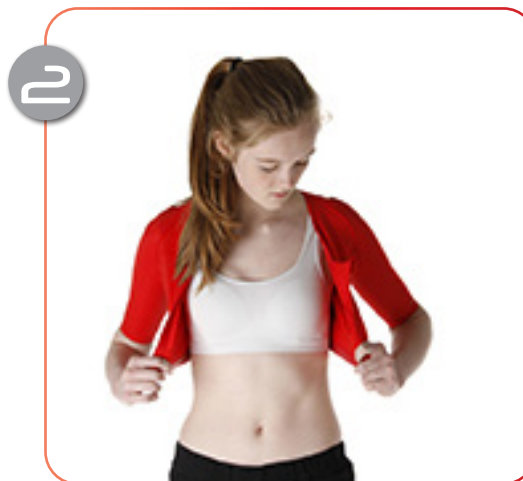
Use the QR code above to access our wear and care videos or go to:

www.dmorthotics.com/productcare

How to remove the DMO® Sensory Vest. (For illustrative purposes Custom Vest has been used)



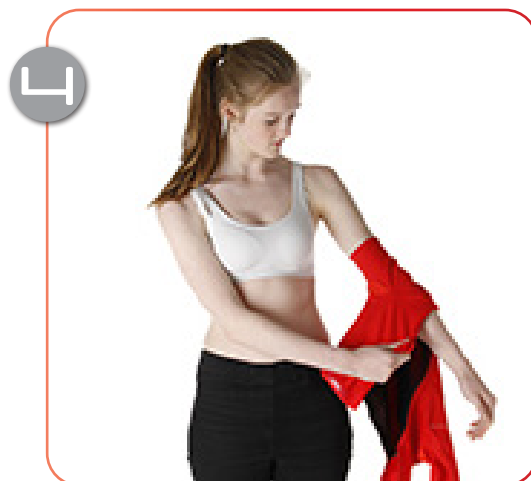
Undo the front zip taking care to protect the skin from entrapment.



Open vest at front.



Remove one arm from orthosis.



Remove the other arm and slide orthosis off over the hand.

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



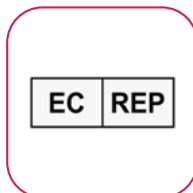
Manufactured in Britain



Distributor



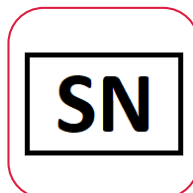
MedEnvoy Global BV
Pr. Margrietplantsoen 33
Suite 123
2595 AM Den Haag
Netherlands



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: 5054522SENSORYZ6

UDI-DI:

5054522001880 Sensory Vest Child - 1
5054522001897 Sensory Vest Child - 2
5054522001903 Sensory Vest Child - 3
5054522001910 Sensory Vest Child - 4
5054522001927 Sensory Vest Child - 5
5054522001934 Sensory Vest Child - 6
5054522001941 Sensory Vest Child - 7
5054522001958 Sensory Vest Child - 8
5054522001828 Sensory Vest Adult - XS
5054522001835 Sensory Vest Adult - S
5054522001842 Sensory Vest Adult - M
5054522001859 Sensory Vest Adult - L
5054522001866 Sensory Vest Adult - XL
5054522001873 Sensory Vest Adult - XXL



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EC

REP

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