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Patient Information for Use document:
DMO® Custom made to measure Sensory Vest



Our products

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.

DMO® made to measure sensory 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 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 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 custom made devices are manufactured to a specific prescription to an individual patient and will be issued with a date of manufacture on the accompanying statement. This is to a prescription specific to an individual patient. 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

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

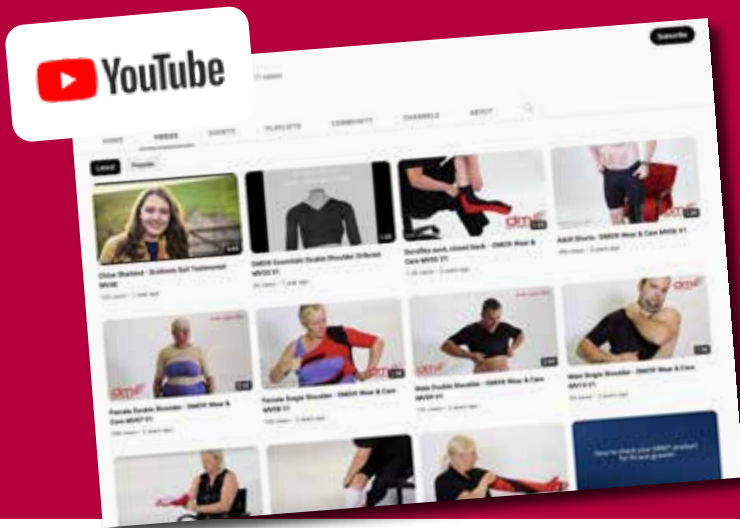
- The orthosis should be washed at least every 2-3 days.
- The orthosis can be hand washed cool or machine washed at 30 degrees.
- Short spin only or roll up in a dry towel to remove excess moisture.
- Allow to completely dry overnight by hanging up indoors.

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 made to measure Sensory Vest

Intended Purpose

The intended purpose of the SENVA/SENVV sensory vests is to improve both proprioceptive and sensory feedback. This occurs through the compression provided. Due to the compressive nature this will also provide a degree of stabilisation to the joints which are covered by the vests.

Indications

Adults and children with sensory processing disorders, ADHD, Autism etc.

Intended Patient Population

Male and female patients. There are no age limits on the wearer of the SENVA/SENVV sensory vests and many conditions presenting with symptoms affecting the sensory system may benefit from the leggings.

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® Custom made to measure 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 1



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DMO® Sensory Vest application instructions

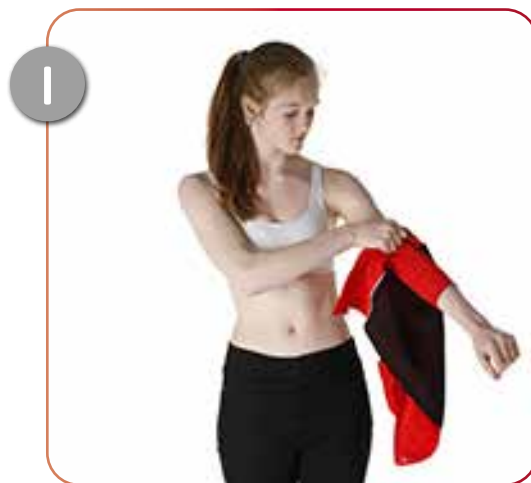
How to apply the DMO® Sensory Vest.

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 its appropriate fit, then please notify your therapist immediately, as the orthosis will only be altered free of charge within the first 6 weeks.



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.



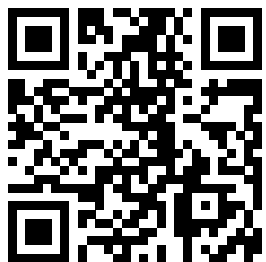
Fasten front zip taking care to protect the skin from entrapment.

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.

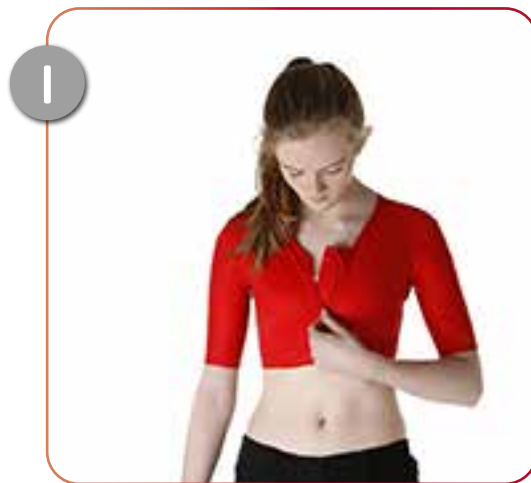
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How the vest should look when on:



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.



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.



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Unit 2 Cardrew Way
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Redruth
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TR15 1SS

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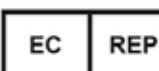


Designed and constructed in the UK

UDI-DI: 5054522002306



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Unit 2 Cardrew Way
Cardrew Industrial Estate
Redruth, Cornwall, UK
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