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



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.

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.

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 declaration. 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 DMO® 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.

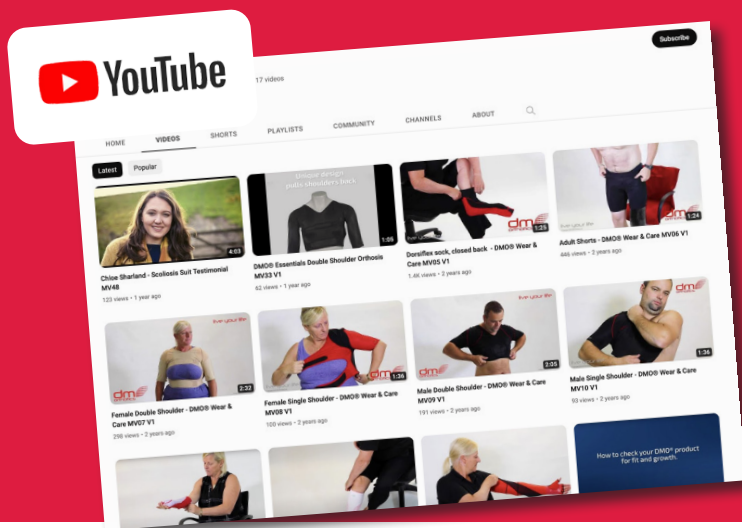


Wearing our products

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 the prescription of a DMO® made 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 Leggings

Intended Purpose

The intended purpose of the SENLA/SENLC sensory leggings 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 leggings.

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 SENLA/SENLC sensory leggings 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.

The device in question is made to measure and requires specification by a healthcare professional trained in the use of DMO®. This will require a set of measurements which the healthcare professional will have been trained in taking by DM Orthotics.

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:

- Open crotch can be added to the leggings for ease of toileting
- 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 Leggings

UDI-DI & Basic UDI-DI

PRODUCT IDENTIFICATION			
Product Name	Catalogue Number	UDI-DI	Basic UDI-DI
Sensory Leggings (stock)			
Sensory Legging Adult – XXS	SENLA0	5054522001965	5054522SENSORYZ6
Sensory Legging Adult – XS	SENLA1	5054522001972	5054522SENSORYZ6
Sensory Legging Adult – S	SENLA2	5054522001989	5054522SENSORYZ6
Sensory Legging Adult – M	SENLA3	5054522001996	5054522SENSORYZ6
Sensory Legging Adult – L	SENLA4	5054522002009	5054522SENSORYZ6
Sensory Legging Adult – XL	SENLA5	5054522002023	5054522SENSORYZ6
Sensory Legging Adult – XXL	SENLA6	5054522002030	5054522SENSORYZ6
Sensory Legging Child – 1	SENLC1	5054522002047	5054522SENSORYZ6
Sensory Legging Child – 2	SENLC2	5054522002054	5054522SENSORYZ6
Sensory Legging Child – 3	SENLC3	5054522002061	5054522SENSORYZ6
Sensory Legging Child – 4	SENLC4	5054522002078	5054522SENSORYZ6
Sensory Legging Child – 5	SENLC5	5054522002085	5054522SENSORYZ6
Sensory Legging Child – 6	SENLC6	5054522002092	5054522SENSORYZ6
Sensory Legging Child – 7	SENLC7	5054522002108	5054522SENSORYZ6
Sensory Legging Child – 8	SENLC8	5054522002115	5054522SENSORYZ6

DMO® Pre-sized Sensory Leggings application instructions

How to apply the DMO® Presized Sensory Leggings.

The DMO pre-sized sensory leggings are put on and taken off the same way as the DMO custom leggings, which have been used for illustrative purposes.

Precautions:

- Remove watches and jewellery before applying the orthosis.
- Ensure the zip liners are in place over the skin prior to pulling up and zips are not rolled back.
- The leggings should never be worn at night unless discussed with a doctor or physiotherapist. Some EDS patients may benefit from night wear but this must be confirmed before doing so). or when the user is sick or has a temperature.
- If there are any concerns with fit ie 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 leggings should be a tight fit, but you should be able to fit your index finger under the lower edge of the leggings and waist.



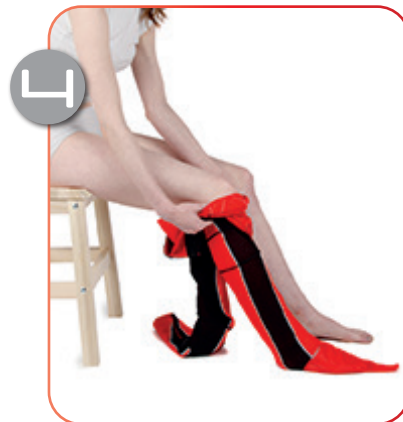
Remove the orthosis from its packaging undo any zips (if applicable).



Apply the silk foot applicator. If requested and provided.



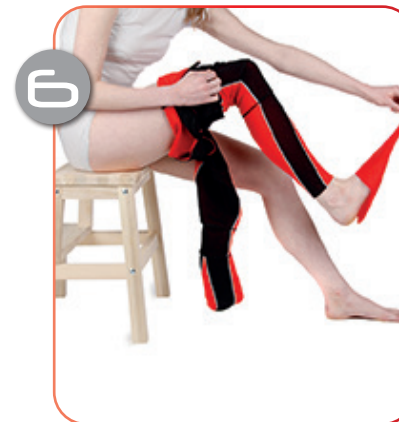
Push right leg through right leg of the orthosis.



Gently pull the right leg of the orthosis towards the knee.



Keep pulling gently towards the knee until the bottom of the right leg orthosis is above the ankle.

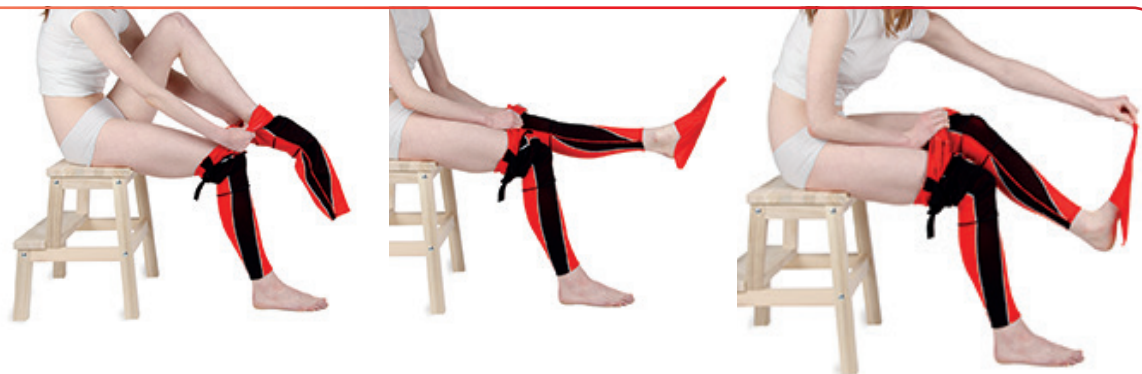


Remove silk applicator from right foot.



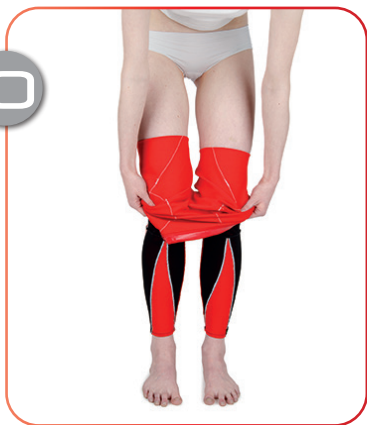
Apply the silk applicator to the left foot.

9



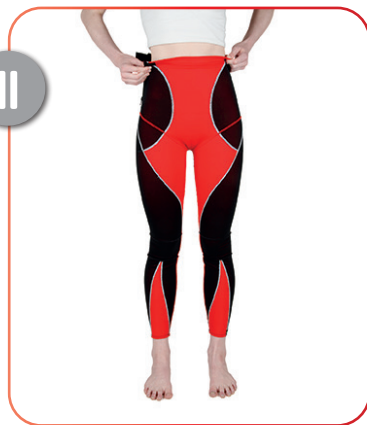
Repeat steps 4 to 7. Then remove the silk applicator from the foot. Make sure you have gently pulled the leggings up to the thigh before attempting to pull over the hips and the body.

10



Pull leggings gently upwards towards the hips.

11



Make sure the silicone is in contact with the skin at the top of the orthosis and fasten any zips.

12



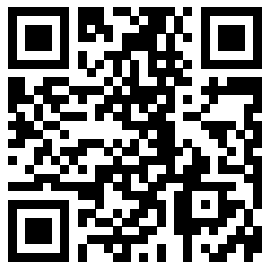
How the leggings should look when worn correctly.

To check the fit Cont.:

- The stitching/ends of the leggings may leave slight indentations in the skin, when removed, but if any marks are overly red after 25-30 minutes after its removal, then it may be too tight.
- If in any doubt about fit please discuss with your clinical practitioner. If purchased from our online shop,, please remeasure your hip (J) measure. pre-sized leggings can be replaced with a larger or smaller size or returned for a refund, providing they are unworn and returned in their original packaging. See our terms and conditions.

live your life.

How the pre-sized sensory leggings 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 DM0® Pre-sized Sensory Leggings.



Undo any zips. Roll the top of the leggings down towards the knees.



Sitting down continue to roll the leggings down towards the knees.



Sitting down continue to roll the leggings down towards the knees.



Roll leggings down to the ankles on both legs.



Remove each foot from the leggings.

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



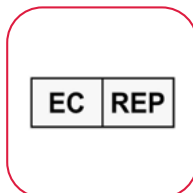
Manufactured in Britain



Distributor



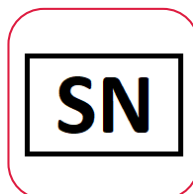
MedEnvoy Global BV
Pr. Margrietplantsoen 33
Suite 123
2595 AM Den Haag
Netherlands



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

Sensory Legging Child - 1 SENLC1
BASIC UDI: 5054522SENSORYZ6
UDI: 5054522002047

Sensory Legging Child - 2 SENLC2
BASIC UDI: 5054522SENSORYZ6
UDI: 5054522002054

Sensory Legging Child - 3 SENLC3
BASIC UDI: 5054522SENSORYZ6
UDI: 5054522002061

Sensory Legging Child - 4 SENLC4
BASIC UDI: 5054522SENSORYZ6
UDI: 5054522002078

Sensory Legging Child - 5 SENLC5
BASIC UDI: 5054522SENSORYZ6
UDI: 5054522002085

Sensory Legging Child - 6 SENLC6
BASIC UDI: 5054522SENSORYZ6
UDI: 5054522002092

Sensory Legging Child - 7 SENLC7
BASIC UDI: 5054522SENSORYZ6
UDI: 5054522002108

Sensory Legging Child - 8 SENLC8
BASIC UDI: 5054522SENSORYZ6
UDI: 5054522002115

Sensory Legging Adult - XXS SENLA0
BASIC UDI: 5054522SENSORYZ6
UDI: 5054522001965

Sensory Legging Adult - XS SENLA1
BASIC UDI: 5054522SENSORYZ6
UDI: 5054522001972

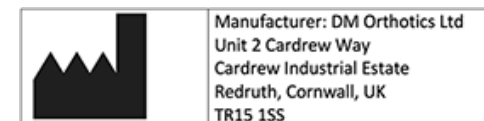
Sensory Legging Adult - S SENLA2
BASIC UDI: 5054522SENSORYZ6
UDI: 5054522001989

Sensory Legging Adult - M SENLA3
BASIC UDI: 5054522SENSORYZ6
UDI: 5054522001996

Sensory Legging Adult - L SENLA4
BASIC UDI: 5054522SENSORYZ6
UDI: 5054522002009

Sensory Legging Adult - XL SENLA5
BASIC UDI: 5054522SENSORYZ6
UDI: 5054522002023

Sensory Legging Adult - XXL SENLA6
BASIC UDI: 5054522SENSORYZ6
UDI: 5054522002030



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