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Patient Information for Use document:
DMO® Custom Hand Shoulder Stability Orthosis



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, 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 to a prescription specific to an individual patient that is sent with your product. 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, wear every day 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 your DMO at night time, unless recommended by your doctor or clinician. e.g. in the case of EDS patients, wear at night can be beneficial.

Washing instructions

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

DO

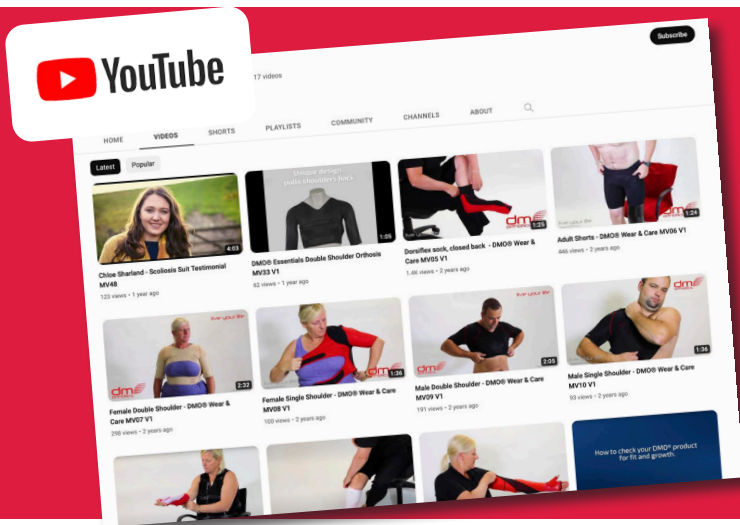
- The orthosis should be washed at least every 2-3 days.
- The orthosis can be hand washed cool or machine washed at 30°C degrees.
- Wash separately
- Short spin only or roll up in a dry towel to remove excess moisture.
- Allow to completely dry overnight by hanging up indoors.

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® 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 Hand Shoulder Stability Orthosis

Intended Purpose

The intended purpose of the DM50 Custom Hand Shoulder Stability Orthosis is to provide upper trunk, shoulder, upper limb, wrist and hand stabilisation and realignment. They can assist and prevent shoulder subluxations and dislocations, improve sensory and proprioceptive feedback, reduce pain, fatigue and improve function.

Indications

Children or adults who present with low or high muscle tone which require stabilisation of the effected joints and also realignment of the joints/upper trunk. This realignment can help with function and prevent contractures. The orthoses can help reduce pain and help manage fatigue.

Intended Patient Population

Male and female adults or children who present with low or high muscle tone who require assistance with posture and alignment of their trunk, shoulder and upper limbs.

A carer may be required to assist with donning and doffing the orthosis, depending on the functional capabilities of the wearer.

Intended Users

The DM50 Hand shoulder stability orthosis 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® (DMO®). A competent healthcare professional will also be required to assess the fit of the orthosis and to provide further specification advice to improve the fit of the product where required.

The wearer of the orthosis will typically be a lay person.

The wearer's carer who may be involved in the donning and doffing of the product, the washing of the product and the reporting of any issues with the product 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. A range of different reinforcement panels must also be prescribed as appropriate by the trained healthcare professional.



DMO® Custom Hand Shoulder Stability Orthosis

Effective for:

- Cerebral Palsy
- Stroke
- Multiple Sclerosis
- Ataxia
- Acquired and Traumatic Brain Injury
- Ehlers-Danlos Syndromes
- Dystonia
- Shoulder subluxation/dislocation/instability
- Neurological shoulder pain
- Brachial Plexus injury (Erbs Palsy)

Provides:

- Improved alignment of shoulder complex, elbow, fingers, thumb and wrist
- Supination of the forearm
- Influences muscle tone
- Improved sensory awareness
- Improved range of movement and distal function
- Pain relief

Additional features:

- Compression fabric for comfort and movement
- Hook and loop fastening
- Available with long or short arm
- Reinforcement panelling for strength and stability
- Worn under clothing



DMO® Custom Hand Shoulder Stability Orthosis application instructions

How to apply the DMO® Hand Shoulder Stability Orthosis.

Precautions:

- Remove watches and jewellery before applying the orthosis.
- The orthosis 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 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.



Turn the whole orthosis inside out except for the fingers as shown.



Place fingers into the finger holes - use the finger sleeve if you have one and slip your hand into the glove as shown.



Place your hand into the sleeve of the inside out orthosis and slowly bring your hand through the sleeve until your hand is coming out at the other end.



Bring the sleeve of the orthosis up towards your shoulder as shown and gently pull the shoulder section up over your shoulder so that it is fitting well.

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DMO® Custom Hand Shoulder Stability Orthosis application instructions

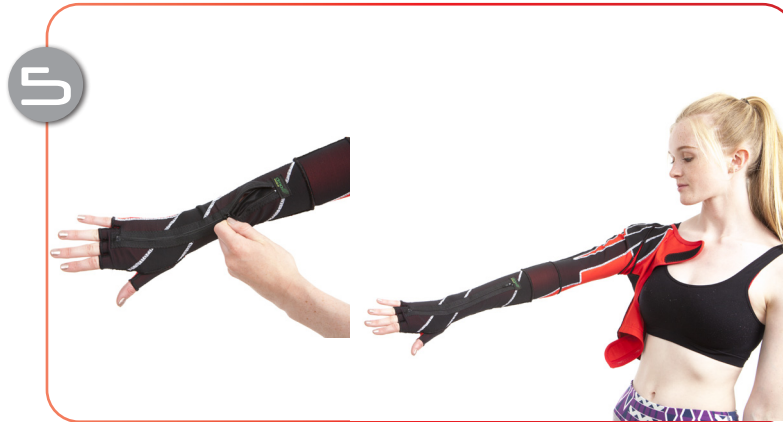
How to apply the DMO® Hand Shoulder Stability Orthosis.

How the Hand shoulder stability orthosis should look when on:



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

www.dmorthotics.com/productcare



Fasten the zip as shown being careful to keep the safety material in place so as not to nip the skin.



Bring the back section around your back and pull the bottom strap gently but firmly out sideways until fully stretched. (this movement is critical to ensure the orthosis functions correctly).



Keeping the arm stretched, bring the bottom strap over the front of your body and fasten together over the velcro tabs.



Now hold the top smaller strap and again stretch out sideways until extended and bring this strap over your body and fasten to the upper velcro strap as shown.

The child and adult male version of this orthosis has only one large strap. Please put on by bringing the strap over the front of your body and fasten the velcro section in the same way.

How to remove the DMO® Hand Shoulder Stability Orthosis.

Precautions:

- Remove watches and jewellery before applying the orthosis.
- The orthosis 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 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.



Undo the top velcro strap as shown.



Undo the bottom velcro strap as shown.



Remove the shoulder section of the orthosis



Undo the zip fully. Then remove the sleeve section of the orthosis, pulling it gently inside out as shown.



Continue to pull the orthosis off the fingers as shown.

The child and adult male version of this orthosis has only one large strap. Please remove by undoing the one velcro strap and following the instructions for removing the arm section.

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



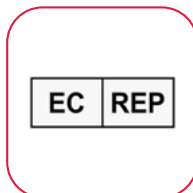
Manufactured in Britain



Distributor



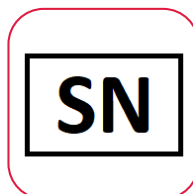
MedEnvoy Global BV
Pr. Margrietplantsoen 33
Suite 123
2595 AM Den Haag
Netherlands



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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Redruth
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TR15 1SS

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Designed and constructed in the UK

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EC

REP

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