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Patient Information for Use document:
DMO® Custom Single & Double Shoulder



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

● Wear instructions	P3
● Washing instructions	P4
● Contraindications and precautions	P5

Custom Single & Double Shoulder	P6
● Single Intended purpose	P6
● Effective for patients	P6
● Clinical benefits	P6
● Double Intended purpose	P7
● Effective for patients	P7
● Clinical benefits	P7
● How to put on and take off	P9
● Disposal of Device Statement	P14
● Serious Incident Statement	P14
● Explanation of symbols used	P15

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 all day and 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 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.

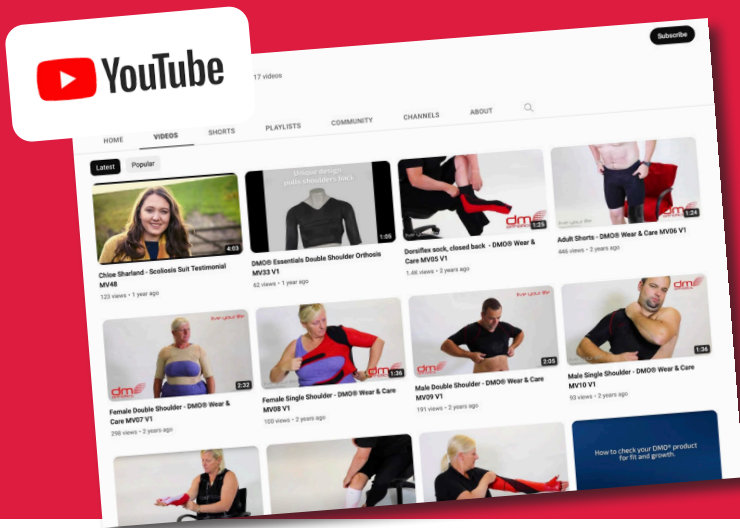


Wearing our products

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 Shoulder

Intended Purpose

The intended purpose of the DM40/41 unilateral/bilateral shoulder orthoses is to provide upper trunk, shoulder, upper limb stabilisation and realignment. They can assist and prevent shoulder subluxations and dislocations, improve sensory and proprioceptive feedback, reduce pain and fatigue.

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/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 shoulder orthosis, depending on the functional capabilities of the wearer.

Intended Users

The DM40/41 unilateral/bilateral shoulder 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 shoulder orthosis and to provide further specification advice to improve the fit of the product where required.

The wearer of the shoulder 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 shoulder orthosis is a custom-made medical device 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 measurements by DM Orthotics. A range of different reinforcement panels must also be prescribed as appropriate by the trained healthcare professional.

DMO® Custom Single Shoulder

Developed from extensive research, their unique design pulls the shoulders back, supports the shoulder blades and stabilises the shoulder joints, providing greater comfort, improved posture, and range of movement.

The DMO® Custom Shoulder Stability Orthosis is made-to-measure and will require an assessment prior to purchase.

Effective for:

- Shoulder subluxation
- Shoulder dislocation
- Shoulder instability
- Neurological shoulder pain
- Brachial Plexus injury (Erbs Palsy)
- Cerebral Palsy
- Ehlers Danlos Syndromes
- Multiple Sclerosis
- Stroke
- Spinal Injury

Provides:

- Shoulder complex realignment
- Improved distal function
- Improved range of movement
- Improved posture
- Pain relief



DMO® Custom Single Shoulder (Female)



DMO® Custom Single Shoulder (Child)

DMO® Custom Double Shoulder

Developed from extensive research, their unique design pulls the shoulders back, supports the shoulder blades and stabilises the shoulder joints, providing greater comfort, improved posture, and range of movement.

The DMO® Custom Double Shoulder Stability Orthosis is designed to manage shoulder impairments. It has a unique design that pulls the shoulders back, supports the shoulder blades and stabilises the shoulder joints, providing greater comfort, improved posture and range of movement.

Effective for:

- Shoulder subluxation
- Shoulder dislocation
- Shoulder instability
- Neurological shoulder pain
- Brachial Plexus injury (Erbs Palsy)
- Cerebral Palsy
- Ehlers Danlos Syndromes
- Multiple Sclerosis
- Stroke
- Spinal Injury
- & more

Provides:

- Shoulder complex realignment
- Improved distal function
- Improved range of movement
- Improved posture
- Pain relief

Additional features:

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

DMO® Custom Double Shoulder (Female)



DMO® Custom Double Shoulder (Male)



DMO® Single Shoulder Orthosis application instructions

How to apply the DMO® Single Shoulder Orthosis.

Precautions:

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



Place the arm of the affected side into the sleeve ensuring that the orthosis is pulled well up onto the shoulder.



Place the affected arm on top of the orthosis as shown if you are able. This holds the orthosis in place, whilst you reach round behind your back to grab the wide band.



Pull the back portion of the orthosis sideways until the elastic is fully extended (This sideways movement is critical to ensuring the orthosis functions as designed). Keeping the extended arm out move the hand forward and bring the extended flap around over the torso until the hook and loop fastening of the velcro connects. Continue to attach the hook & loop fastening fully on the front position.



How the single shoulder orthosis looks for children and men when worn correctly.



For the female single shoulder orthosis, there will be two straps instead of one. Please follow the instructions as No. 3, pulling the top strap over to meet the velcro and then pulling the lower strap next. Ensure the velcro is comfortable when fastened.

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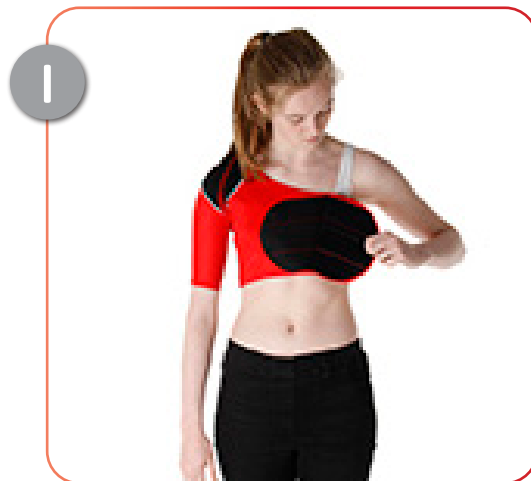
How to remove the DMO® Single Shoulder Orthosis.

How the single shoulder should look when on:

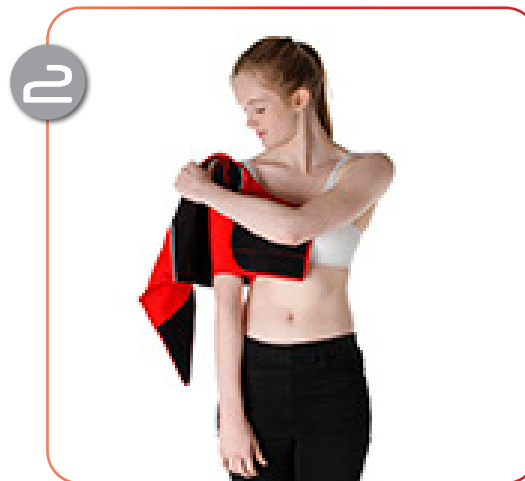
Child/Male:



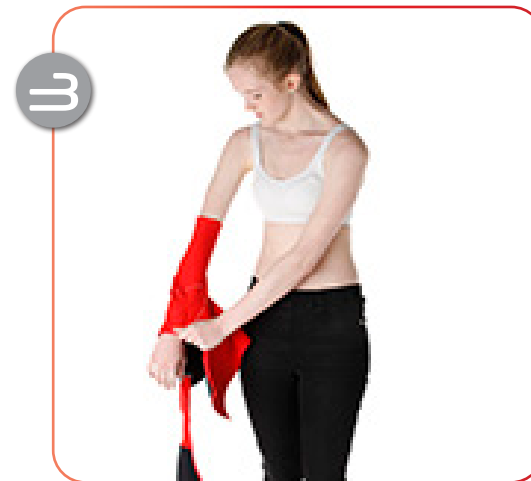
Female:



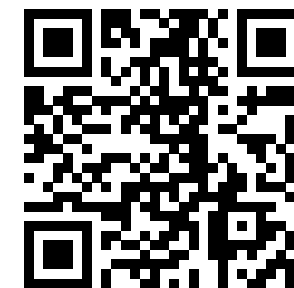
For the child and male version, pull the hook and loop fastening velcro apart at the front and let the straps fall away. For the female version, pull the two straps apart from the velcro fastenings and let the straps fall away.



Remove the orthosis from the affected side.



Remove arm from sleeve of orthosis.



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

DMO® Double Shoulder Orthosis application instructions

How to apply the DMO® Double Shoulder Orthosis.

Precautions:

- The instructions below are for both the female and male shoulder stability orthosis.
- We recommend that you sit down to put on the shoulder orthosis.
- The double shoulder orthosis is put on forwards to avoid stress on the shoulder joints.

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 remove and talk to your referring therapist if you have one.

Children's Double Shoulder Orthosis

The instructions for putting on the children's version of this product are the same as the adult male instructions.



1 Undo all the Velcro straps of the shoulder orthosis.



2 Place your arms into the sleeves of the shoulder orthosis and gently pull it up over the shoulders one at a time, using your other hand to help you do this, so that it is fully over the shoulders as shown. **NB. When putting on the female orthosis, ensure the opening at the front is above and below the breasts as shown. For the male and children's orthosis, the front layer has no opening for the bust. Ensure the material at the front is pulled gently down so it is comfortable on the ribs.**



3 Take hold of the two straps at the right side of the orthosis as shown. Take them around your back and slide them through the opening on the left side of the orthosis under the arm section.



4 Next, hold the strap(s) you have threaded through the opening and pull the bottom strap firmly but gently out and down away from your body. Fasten to the bottom velcro at the front of the orthosis.



5 Hold the top strap and gently pull out and down away from your body and fasten to the upper velcro at the front of the orthosis.

You may prefer to fasten the top strap first as this can help reposition the shoulder better for some patients. Fasten the bottom strap second.

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6



Repeat with the remaining straps on the right side of the body. Gently pull the bottom strap down and away from the body and fasten onto the bottom velcro at the front of the body.

7

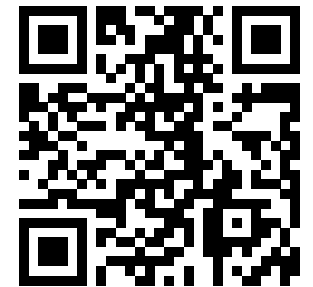


Repeat with the orthosis strap (as for fig. 6) Ensure you pull the body section of the shoulder wrap down at the back and the front so that you can benefit from the improved position it can give you. Ensure the pull is comfortable for your needs over your shoulders and ribs.

8



Ensure the sleeve section is in place.



Use the QR code above to
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How the double shoulder
should look when on:

Male:



Female:



Child:



How to remove the DMO® Double Shoulder Orthosis.

1



Loosen the Velcro strap on both sides.

2



Gently place your opposite hand
onto the shoulder section and begin
to pull it down over your arm.

3



Repeat this with the other side of
the shoulder orthosis.

4



Remove the strap(s) when loose
and gently slip out of the wrap.

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



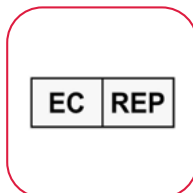
Manufactured in Britain



Distributor



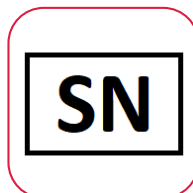
MedEnvoy Global BV
Pr. Margrietplantsoen 33
Suite 123
2595 AM Den Haag
Netherlands



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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Designed and constructed in the UK

UDI-DI:
5054522000234 Unilateral Shoulder Orthosis
5054522000241 Bilateral Shoulder Orthosis



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EC

REP

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