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Patient Information for Use document:

DMO® Essentials/pre-sized Single & Double Shoulder



www.dmorthotics.com

Our products

DM Orthotics is a world-leader in the design and manufacture of its patented Dynamic Movement Orthoses® (DMO®).

The DMO® use biomechanical panelling and strategic reinforcements to improve postural alignment and increase proprioception. These factors then stimulate and adjust the neurosensory system training muscles to work with improved tone, strength, and performance.

The DMO® Essentials double and single shoulder orthoses are a pre-sized set of fabric orthoses and a good cost effective option if you want to test whether a custom orthosis will be of benefit to a patient. They work effectively as an entry level single measurement product.

Created to provide improved comfort, posture, and range of movement to the user. Designed to be worn next to the skin, the enhanced proprioceptive feedback and biomechanical positioning of these designs help train muscles to work; leading to improved tone, strength, and performance.

All these benefits work towards a single goal – to improve function and encourage independence for the user.

DMO® Essentials are a pre-sized product that is made to set sizes for both children and adults and are a combination of our compression/sensory fabric and combined with a number of reinforcement panels that are strategically placed to benefit the patient. They are not alterable and further reinforcements are not permitted. they can be recommended by a clinician where a standard off the shelf product may be of benefit, or can be ordered direct from our website with only one measurement being required.

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

DMO Orthotic Essential products are intended to help support and correct posture and joint alignment where further individual adjustment or additional reinforcements are not required.

All DM Orthotics 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 medical 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 Device Regulation) (2017/745) and are declared to conform to the regulations according to Annex II and III EU MDR.

Date of Issue

Our medical devices are manufactured and 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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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, 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°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.

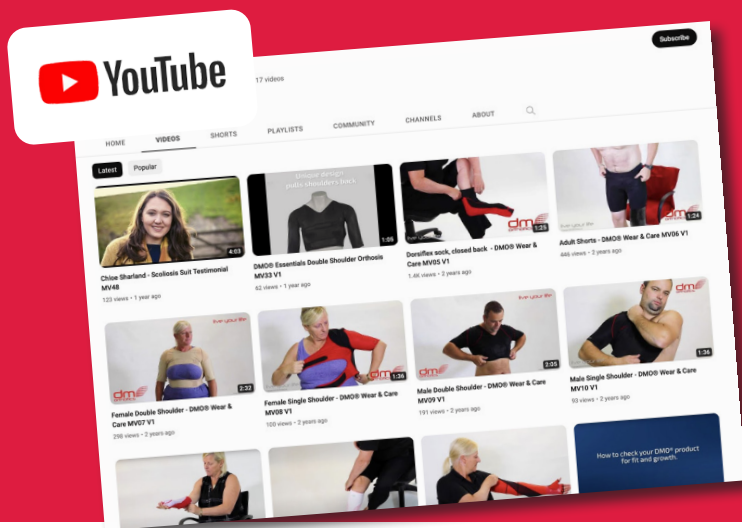


Wearing our products

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® product. This should be discussed with your professionally qualified medical professional who may suggest an alternative 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.

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® Essentials pre-sized Single Shoulder

Intended Purpose

The DMO® Shoulder Orthoses both the single and the double orthoses, are designed to manage shoulder impairments, provide trunk, shoulder and upper limb stabilisation and realignment.

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.

Intended Patient Population

Children or adults who present with low or high muscle tone which requires stabilisation of the effected joints and also realignment of the trunk, shoulder and upper limbs.

This realignment can help with function and can help reduce pain and help manage fatigue. 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

It can be prescribed by a competent healthcare professional, or chosen by the wearer, carer or parent. The wearer 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.

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® Essentials Single Shoulder (Female)



DMO® Essentials Single Shoulder (Male)



DMO® Essentials pre-sized Double Shoulder

Intended Purpose

The DMO® Shoulder Orthoses both the single and the double orthoses, are designed to manage shoulder impairments, provide trunk, shoulder and upper limb stabilisation and realignment.

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.

Intended Patient Population

Children or adults who present with low or high muscle tone which requires stabilisation of the effected joints and also realignment of the trunk, shoulder and upper limbs.

This realignment can help with function and can help reduce pain and help manage fatigue. 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

It can be prescribed by a competent healthcare professional, or chosen by the wearer, carer or parent. The wearer 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.

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® Essentials Double Shoulder (Male)

DMO® Essentials Double Shoulder (Female)



DMO® Single Shoulder Orthosis application instructions

How to apply the DMO® Single Shoulder Orthosis. (For illustrative purposes the DMO® Custom Single shoulder orthosis has been used)

Precautions:

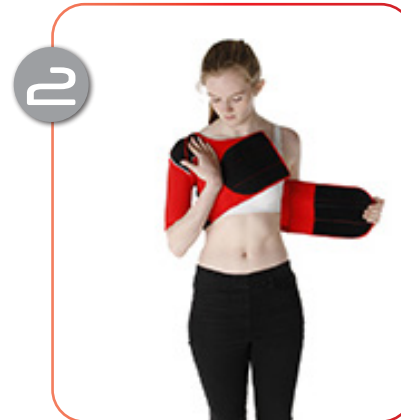
- Remove watches and jewellery before applying the orthosis.
- The single shoulder orthosis should be removed if the patient is sick or has a temperature.
- If there are any concerns with fit i.e. extremities turning blue or feeling overly cold to the touch, then please remove and inform your clinical team immediately for further assessment or if purchased on our website, contact our admin department and return them to DM Orthotics

To check the fit:

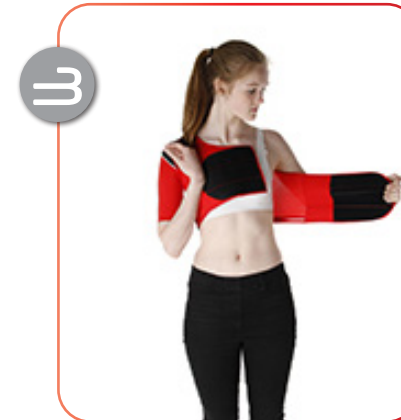
- The stitching/ends of the orthosis may leave slight indentations in the skin, when removed, but if any marks are overly red after 20-30 minutes of its removal, then it may be too tight.
- If in any doubt, as to its appropriate fit then please remove and talk to your referring therapist if you have one. or if purchased on our website, contact our admin department and return



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:

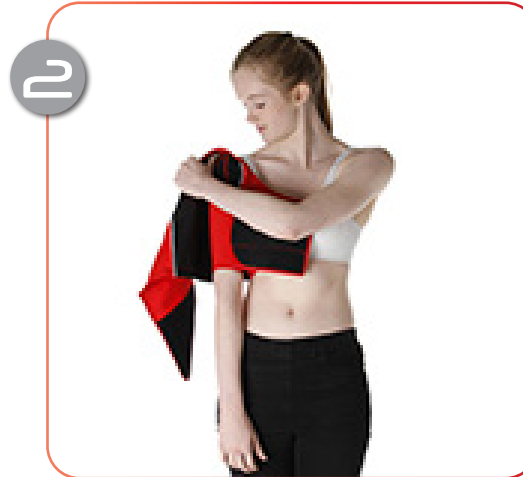
Male/Child:



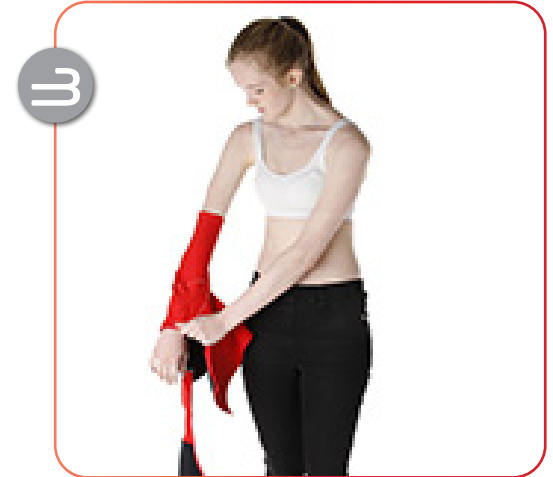
Female:



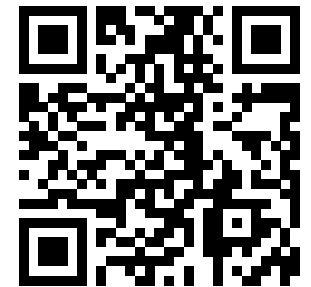
For the child and male version, pull the hook and loop fastening velcro apart at the front and let the straps fall away. For the female version, pull the two straps apart from the velcro fastenings and let the straps fall away.



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. Or if purchased on our website, contact our admin department and return them to DM Orthotics

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.



Undo all the Velcro straps of the shoulder orthosis.



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.**



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.



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.



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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**How the double shoulder
should look when on:**

Male:



Female:



Child:



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

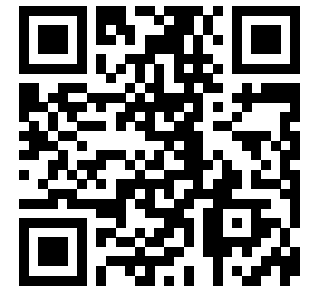


Repeat with the orthosis strap (as for fig. 6) Ensure you pull the body section of the shoulder wrap down at the back and the front so that you can benefit from the improved position it can give you. Ensure the pull is comfortable for your needs over your shoulders and ribs.

8



Ensure the sleeve section is in place.



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

live your life.

How the double shoulder should look when on:

Male:



Female:



Child:



How to remove the DMO® Double Shoulder Orthosis.



Loosen the Velcro strap on both sides.



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

Repeat this with the other side of the shoulder orthosis.

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



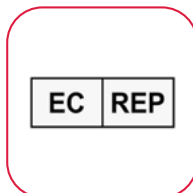
Manufactured in Britain



Distributor



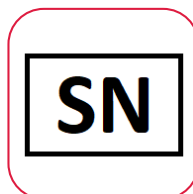
MedEnvoy Global BV
Pr. Margrietplantsoen 33
Suite 123
2595 AM Den Haag
Netherlands



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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Redruth
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Designed and constructed in the UK

Basic UDI-DI: 5054522UPPERLIMBQS

UDI-DI:

5054522001231 Child Double Shoulder - 1
5054522001248 Child Double Shoulder - 2
5054522001255 Child Double Shoulder - 3
5054522001262 Child Double Shoulder - 4
5054522001279 Child Double Shoulder - 5
5054522001286 Child Double Shoulder - 6

5054522000708 Adult Double Shoulder - XS
5054522000715 Adult Double Shoulder - S
5054522000722 Adult Double Shoulder - M
5054522000739 Adult Double Shoulder - L
5054522000746 Adult Double Shoulder - XL
5054522001224 Adult Double Shoulder - XXL

5054522001415 Child Single Shoulder Left - 1
5054522001422 Child Single Shoulder Left - 2
5054522001439 Child Single Shoulder Left - 3
5054522001446 Child Single Shoulder Left - 4
5054522001453 Child Single Shoulder Left - 5
5054522001460 Child Single Shoulder Left - 6
5054522001477 Child Single Shoulder Right - 1
5054522001484 Child Single Shoulder Right - 2
5054522001491 Child Single Shoulder Right - 3
5054522001507 Child Single Shoulder Right - 4
5054522001514 Child Single Shoulder Right - 5
5054522001521 Child Single Shoulder Right - 6

5054522001293 Adult Single Shoulder Left - XS
5054522001309 Adult Single Shoulder Left - S
5054522001316 Adult Single Shoulder Left - M
5054522001323 Adult Single Shoulder Left - L
5054522001330 Adult Single Shoulder Left - XL
5054522001347 Adult Single Shoulder Left - XXL
5054522001354 Adult Single Shoulder Right - XS
5054522001361 Adult Single Shoulder Right - S
5054522001378 Adult Single Shoulder Right - M
5054522001385 Adult Single Shoulder Right - L
5054522001392 Adult Single Shoulder Right - XL
5054522001408 Adult Single Shoulder Right - XXL



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