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Patient Information for Use document:

DMO® Custom Sleeve, glove/gauntlet and open palm glove



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 conform to the regulations according to Annex XIII of the EU MDR.

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.

Contents

● Wear instructions	P3
● Washing instructions	P4
● Contraindications and precautions	P5
● Intended purpose	P6
● Intended patient population	P6
● Intended users	P7
● Effective for patients	P7
● Clinical benefits	P7
● Use with other orthotics	P7

Custom Glove/Gauntlet	P6
● How to put on and take off	P8

Custom Sleeve	P6
● How to put on and take off	P11

Custom Open palm glove (SOPOG)	P6
● How to put on and take off	P13

● Disposal of Device Statement	P10
● Serious Incident Statement	P10
● Explanation of symbols used	P11

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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 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, where this 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.

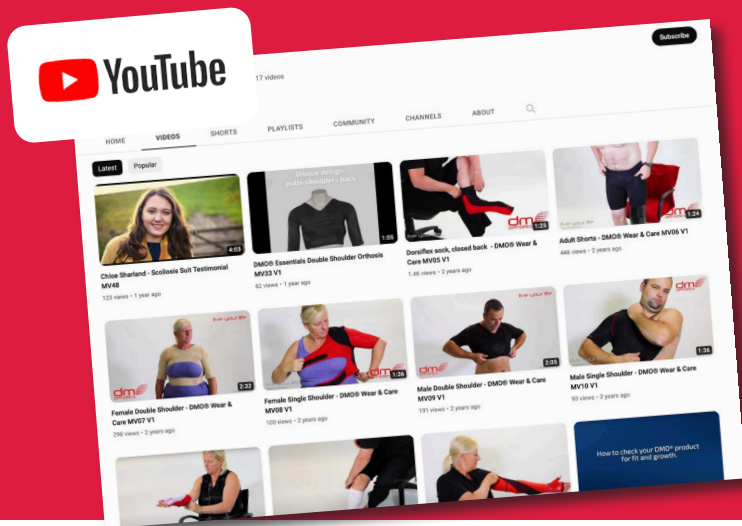


Wearing our products

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.

DMO® Custom glove/gauntlet, Sleeve and open palm glove

Intended Purpose

The intended purpose of the DM11 sleeve, DM16/17/18 glove/gauntlet and DM49 open palm glove is to align the upper limb which includes the elbow, wrist and hand (where the glove section is included). The sleeve/glove gives a non-restrictive and highly effective level of support to maximise stability. The sleeve/glove also aids distal control and positively influences muscle tone to enhance function. The glove/sleeve can also have a positive impact on shoulder positioning even if the shoulder is not included in the orthosis.

Children or adults presenting with low or high muscle tone, sensory or proprioception issues. Children or adults who have pain associated with poor alignment or fatigue caused by their inability to maintain a corrected upper limb posture.

Intended Patient Population

Male and female patients are usually aged two or above, although children under two may benefit from the gloves/sleeves. The lower age threshold was set due to increased growth at this stage that would require glove/sleeve adjustment or remake, not due to the inability to achieve the intended purpose. There is no upper age limit to the glove/sleeve.

A reasonably high degree of dexterity and muscle tone is required for those who will be donning and doffing the glove/sleeve themselves. A carer will be required to assist with donning and doffing the glove/sleeve where this is not the case.

Intended users

The DM11 sleeve, DM16/17/18 glove/gauntlet and DM49 open palm glove 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. Such a competent healthcare professional will also be required to assess the fit of the DM11 sleeve, DM16/17/18 glove/gauntlet and Dm49 open palm glove and to provide further specification advice to improve the fit where required.

The wearer of the DM11 sleeve, DM16/17/18 glove/gauntlet and DM49 open palm glove 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 DM11 sleeve, DM16/17/18 glove/gauntlet and DM49 open palm glove will typically be a layperson.

The device in question is made to measure and requires specification by a healthcare professional trained in the use of dynamic movement orthoses. 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.



Sleeve

Effective for:

- Cerebral Palsy
- Upper limb impairments
- Multiple Sclerosis
- Ehlers-Danlos Syndromes
- High and low muscle tone
- Sensory impairments

Provides:

- Increased sensory awareness
- Improved posture
- Improved positioning (where reinforcements added)
- Pain relief

Additional features:

- Compression fabric for comfort and movement
- Reinforcement panelling for strength and stability
- Worn under clothing

Open Palm Glove (SOPOG)

Effective for:

- Cerebral Palsy
- Stroke
- Dystonia
- Sensory impairments
- Ataxia

Provides:

- Improved alignment of fingers, thumb and wrist
- Influences muscle tone
- Improved sensory awareness

Additional features:

- Compressive fabric for comfort and movement

Glove/gauntlet with sleeve

Effective for:

- Cerebral Palsy
- Stroke
- Multiple Sclerosis
- Ataxia
- Acquired and Traumatic Brain Injury
- Ehlers-Danlos Syndromes
- Dystonia
- & more

Provides:

- Improved alignment of fingers, thumb and wrist
- Improved alignment of elbow extension (with full length glove)
- Supination of the forearm (or pronation if required)
- Influences muscle tone
- Improved sensory awareness

Additional features:

- Compression fabric for comfort and movement
- Silicone pads to aid grip
- Reinforcement panelling for strength and stability
- Available with long or short arm



DMO® Custom glove/gauntlet application instructions

There are different ways to apply the glove/gauntlet depending on personal preference. Remove the glove/gauntlet and finger applicator (if a glove) from its packaging and undo any zips. For DMO® Gauntlet follow Option 1 of application instructions. You can also watch our videos at www.dmorthotics.com/productcare on how to put on and take off your DMO® product.

Precautions:

- Remove watches and rings until after the orthosis has been fitted.
- When fastening/unfastening zips take care to protect the skin from entrapment.
- Take care when adjusting the silicon band at the top of the orthosis to protect hairs and skin from being pulled.
- If there are any concerns with fit (ie. fingers turning blue or overly cold to the touch) then please remove and inform your clinical team immediately for further assessment.

To check the fit:

- Red fingers - the glove should be a snug fit. The fingers may be slightly red at first due to the applying process. This is common and the redness will soon fade.
- Blue fingers - If glove/gauntlet is correctly aligned and fingers are blue, remove the orthosis and return to issuing clinician immediately for review.

Option 1. Suitable for gloves/gauntlet without finger applicator.

The DMO® Custom Gauntlet has no individual fingers, but is still applied in the same manner as a glove.



Put the hand into the glove through the open zip making sure fingers and thumb are in the correct hole. Continue to push fingers through the glove finger holes until fully on. For the gauntlet, make sure the thumb and index finger (if index finger is included in the design) are in the correct hole.



Feed hand through open end of glove until hand appears through zip.



Push hand with glove through the hole.



Continue to push hand through hole.



Pull the glove up the arm (roll back silicon band). Fasten zip taking care not to entrap skin.



Correctly aligned glove. The zip should look as if it is crooked when hand is resting. If the zip is straight the glove is on incorrectly.

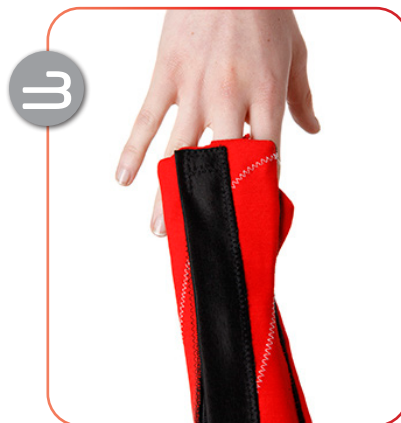
Option 2. Suitable for gloves with finger applicator.



1 Undo the zip, turn the glove inside out making sure the end of the glove holes are fully open with a pencil (this is to make sure that the fingers slide into the glove).



2 Place finger applicator on middle finger.



3 With finger applicator on middle finger (longest finger), push it into the middle finger hole.



4 Pull the finger applicator off leaving the glove in place on the middle finger.



5 Repeat step 3 and 4 for each finger in this order:- middle finger
fourth finger (ring finger)
little finger, first finger (index finger)
until all fingers are in place in the glove.



6 Place finger applicator on the thumb and repeat step 3 once more. Remove applicator with glove in place on the thumb.



7 Pull the glove into position on wrist. Push the hand down through the sleeve of the glove.



8 Pull the glove up the arm ensuring that the seam behind the thumb runs up to the bony prominence at the outside of the elbow - the lateral epicondyle. For a long glove, slowly pull it up to the top of the arm. The two horizontal lines should be either side of the elbow joint. Once the glove is fully on roll the silicon back to hold glove in position.



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

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How to remove the DMO® Custom Gauntlet/Glove

The DMO® Custom Gauntlet has no individual fingers holes unlike the glove. Removal is the same for all DMO® Gloves and Gauntlets.

How the glove should look when on:



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



DO NOT remove by pulling at the fingers. Undo the zip taking care to protect skin from entrapment.



Pull the top of the glove down towards the hand. Take care to roll the silicon band over so as not to pull the hairs on skin.



Gently pull the glove inside out over the wrist and then the fingers.



If removing a glove, ensure you gently ease the fingers out of each fingerhole.

DMO® Custom Arm Sleeve application instructions

How to put on the Custom Arm Sleeve.

Precautions:

- Remove watches and rings until after the orthosis has been fitted.
- When fastening/unfastening zips take care to protect the skin from entrapment.
- Take care when adjusting the silicon band at the top of the orthosis to protect hairs and skin from being pulled.
- If there are any concerns with fit then please remove and inform your clinical team immediately for further assessment.

To check the fit:

- You should be able to run your finger around the rim of the edge of the orthosis at the wrist and the axilla. If this is too loose or too tight, please contact your clinician.



1 Remove from packaging and lay out silk applicator and arm sleeve



2 Place the hand into the silk applicator and begin to place the sleeve over the hand.



3 Once the sleeve is on the child's arm, gently remove the silk applicator from the hand.



4 Gently pull the sleeve up over the elbow to the top of the arm.



5 Ensure the arm sleeve is positioned up to the top of the arm and the silicone band is in position over the skin.

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DMO® Custom Arm Sleeve

How to remove the DMO® Arm Sleeve

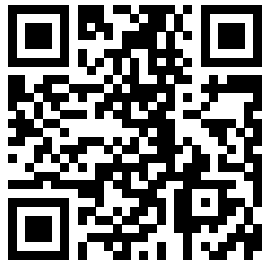
How the sleeve should look when on:



Turn the top of the sleeve inside out at the silicone band.



Continue to gently pull the sleeve inside out, down over the elbow and off over the hand.



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

www.dmorthotics.com/productcare

DMO® Custom Open palm glove (SOPOG) application instructions

Precautions:

- Remove watches and rings until after the orthosis has been fitted.
- When fastening/unfastening take care to protect the skin from entrapment.
- If there are any concerns with fit (ie. fingers turning blue or overly cold to the touch) then please remove and inform your clinical team immediately for further assessment.

To check the fit:

- Red fingers - the glove should be a snug fit. The fingers may be slightly red at first due to the applying process. This is common and the redness will soon fade.
- Blue fingers - If glove is correctly aligned and fingers are blue, remove the orthosis and return to issuing clinician immediately for review.



Remove glove from packaging.



Slide fingers through individual finger holes except thumb hole.



Peel back glove to the thumb hole and insert thumb.



Pull thumb hole and rest of glove towards the wrist as shown in the pictures.



Place the palm face down on a flat surface as shown. Take tab and pull it round the back of your hand. Ensure your arm is positioned vertically upward as in the illustration otherwise the orthosis will not work.



DMO® Custom Open palm glove (SOPOG) application instructions

Precautions:

- Remove watches and rings until after the orthosis has been fitted.
- When fastening/unfastening take care to protect the skin from entrapment.
- If there are any concerns with fit (ie. fingers turning blue or overly cold to the touch) then please remove and inform your clinical team immediately for further assessment.

To check the fit:

- Red fingers - the glove should be a snug fit. The fingers may be slightly red at first due to the applying process. This is common and the redness will soon fade.
- Blue fingers - If glove is correctly aligned and fingers are blue, remove the orthosis and return to issuing clinician immediately for review.



Secure the tab at the front of the glove as shown above.



What the glove should look like when fitted.

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How to remove the DMO® Custom Open palm glove (SOPOG)

How the glove should look when on:



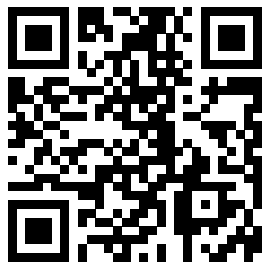
Undo the tab and pull round the back of the wrist.



Pull glove towards the tips of the fingers.



Remove glove by pulling inside out, over the tips of the fingers.



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

www.dmorthotics.com/productcare

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



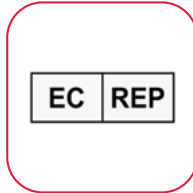
Manufactured in Britain



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

DM11 – 5054522000104 (UDI-DI)
DM16 – 5054522000111 (UDI-DI)
DM17 – 5054522000128 (UDI-DI)
DM18 – 5054522000135 (UDI-DI)
DM49 – 5054522000265 (UDI-DI)



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