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Patient Information for Use document:

DMO® Custom leggings, leg sleeves and shorts



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 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.

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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 leggings/shorts 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

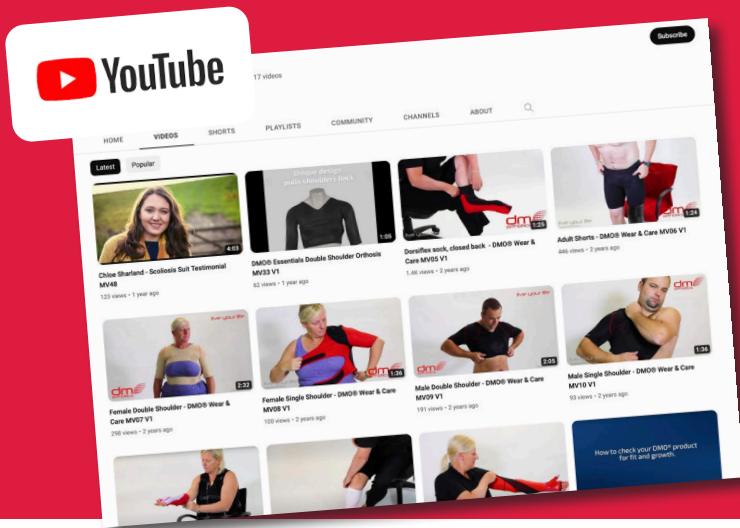
- The orthosis should be washed at least every 2-3 days.
- The orthosis can be hand washed cool or machine washed at 30 degrees.
- Short spin only or roll up in a dry towel to remove excess moisture.
- Allow to completely dry overnight by hanging up indoors.

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. They will ensure any possible contraindications to use are discussed with you before the decision is made to proceed with a DMO® product. Certain cardiovascular circulatory disorders may be contraindicated and further consultation with the patient's cardiologist may be required.

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 leggings, leg sleeves and shorts

Intended Purpose

The intended purpose of the DM28 leggings, DM30/31 leg sleeves and DM32 shorts is to align the lower trunk, pelvis, hips and lower limb. The exact location of the effect is determined by the choice of product. It improves symmetry and assists stabilisation. The DM28 leggings, DM30/31 leg sleeves and DM32 shorts give a non-restrictive and highly effective level of support to maximise pelvic and lower limb stability. The product also aids distal control and positively influences muscle tone to enhance function.

Indications

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

Considerations

Depending on the height of the trunk support of the chosen product, the following would have to be considered.

Certain primary respiratory problems where muscles are growing weaker due to deterioration of the nerves/ muscles although the orthosis specification may be changed to accommodate this.

Secondary respiratory problems associated with cerebral palsy can be improved due to improved posture of the trunk/body and improved position of the ribs. See previous page for other contraindications/ considerations.



Intended Patient Population

Male and female patients are usually aged two or above, although children under two may benefit from the DM28 leggings, DM30/31 leg sleeves and DM32 shorts. The lower age threshold was set due to increased growth at this stage that would require adjustment or remake, not due to the inability to achieve the intended purpose. There is no upper age limit to the DM28 leggings, DM30/31 leg sleeves and DM32 shorts.

Various medical conditions present with symptoms which the DM28 leggings, DM30/31 leg sleeves and DM32 shorts can help with these include see page 8 (not exhaustive).

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 DM28 leggings, DM30/31 leg sleeves and DM32 shorts will require prescription and specification by a competent healthcare professional, typically a qualified orthotist or physiotherapist, 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 product 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, 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 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.



DMO® Custom Leggings

Effective for:

- Cerebral Palsy
- Lower limb impairments
- Multiple Sclerosis
- Ehlers-Danlos Syndromes
- High and low muscle tone
- & more

Provides:

- Pelvic stability
- Improvement in hip and knee alignment
- Improved internal/external hip rotation
- Increased sensory awareness
- Improved posture
- Improved muscle function
- Pain relief
- Reinforcement panelling for strength and stability

Additional features:

- Optional crotch opening
- Compression fabric for comfort and movement
- Improved leg positioning
- Worn under clothing

DMO® Custom Shorts

Effective for:

- Cerebral Palsy
- Multiple Sclerosis
- Ataxia
- Low muscle tone
- Acquired and Traumatic Brain Injury
- Ehlers-Danlos Syndromes
- Impaired walking patterns
- Stroke
- Parkinson's disease
- Huntington's Chorea
- & more

Provides:

- Pelvic stability
- Hip and knee extension
- Reduced external/internal hip rotation
- Increased sensory awareness
- Improved posture
- Improved muscle function
- Pain reduction

Additional features:

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

DMO® Leg Sleeve

Effective for:

- Cerebral Palsy
- Lower limb impairments
- Multiple Sclerosis
- Ehlers-Danlos Syndromes
- High and low muscle tone
- & more

Provides:

- Pelvic stability
- Improvement in hip and knee alignment
- Improved internal/external hip rotation
- Increased sensory awareness
- Improved posture
- Improved muscle function
- Pain relief
- Reinforcement panelling for strength and stability

Additional features:

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

DMO® Leg sleeve with attachment

Effective for:

- Cerebral Palsy
- Lower limb impairments
- Multiple Sclerosis
- Ehlers-Danlos Syndromes
- High and low muscle tone
- & more

Provides:

- Pelvic stability
- Improvement in hip and knee alignment
- Improved internal/external hip rotation
- Increased sensory awareness
- Improved posture
- Improved muscle function
- Pain relief
- Reinforcement panelling for strength and stability

Additional features:

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

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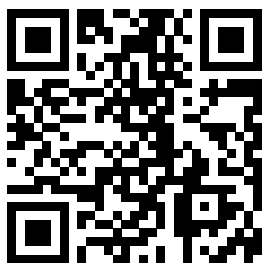
DMO® Custom shorts application instructions

How to apply the DMO® Custom shorts.

Patient will need to sit down to ensure balance and safety and make sure the shorts are on correctly.

Precautions:

- Remove watches and jewellery before applying the orthosis.
- If the shorts have been fitted with a zip, ensure the zip liners are in place over the skin prior to pulling up zips and not rolled back.
- The shorts should be removed if the patient 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.



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1



If the shorts are supplied with a zip on waist then undo before pulling them on. Take the shorts (with the label at the back) and pull them up the legs (as you would a pair of tights). Make sure you pull them over the knees and up the thighs before beginning to pull them up across the hips.

2



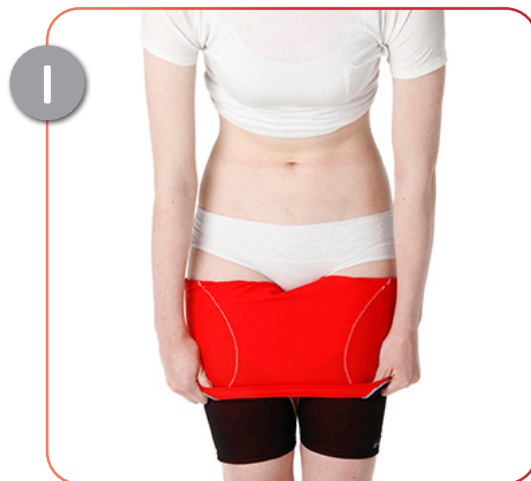
Pull the shorts up to the waist and fasten the zip if fitted with one.

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How to remove the DMO® Custom shorts.

Patient will need to sit down to ensure balance and safety and make sure the shorts are removed correctly.

How the shorts should look when on:



Roll the shorts down the legs towards the feet, gently pulling inside out.



Slide each leg out of the orthosis.

To check the fit:

- The shorts should be a tight fit, but you should be able to fit your index finger under the lower edge of the shorts and waist.
- The stitching/ends of the orthosis may leave slight indentations in the skin, when removed, but if any marks are overly red after 25-30 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 six weeks.

DMO® Custom Leggings application instructions

How to apply the DMO® Leggings.

Patient will need to sit or lie down to ensure balance and safety.

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.



If body or ankle zips are fitted, please undo these first before putting on the leggings.



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.

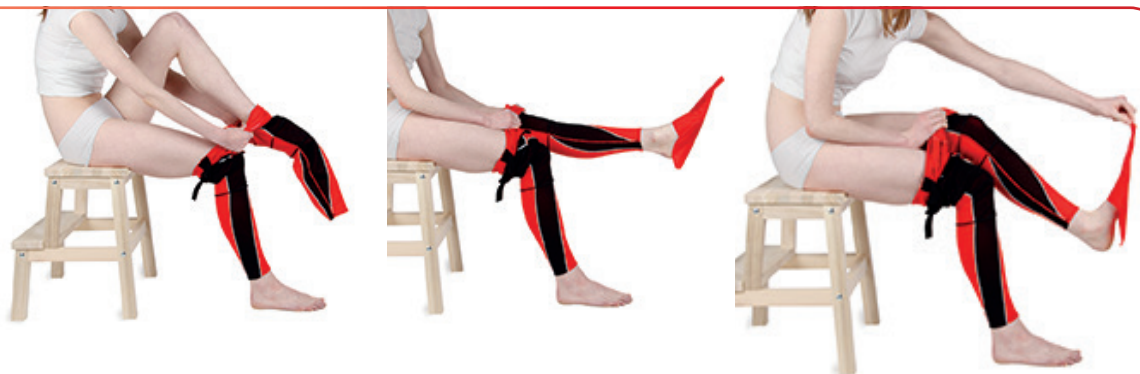


Remove silk applicator from right foot.



Apply the silk applicator to the left foot. For the leg sleeve, please go to picture 10

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



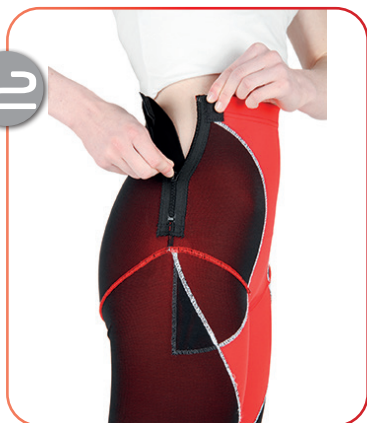
Pull leggings gently upwards towards the hips.

11



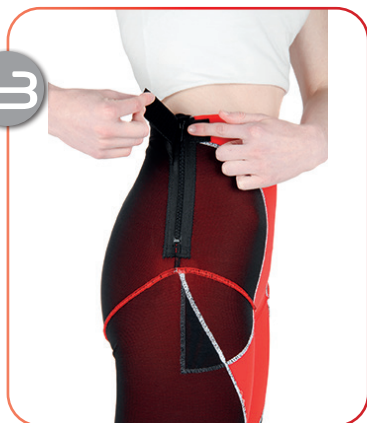
Make sure the silicone is in contact with the skin at the top of the orthosis and fasten any leg zips.

12



Fasten the side zip if included.

13



Fasten the tab towards the front. Only provided where zip is requested.

14



Image shows the tab secured at the front of the orthosis.

15



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 as to its appropriate fit, then please notify your therapist immediately as the orthosis will only be altered free of charge within the first six weeks.

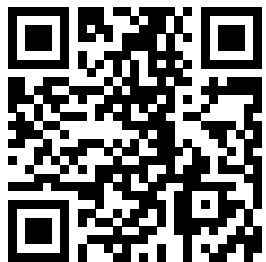
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DMO® Custom Leggings application instructions

How to remove the DMO® Leggings.

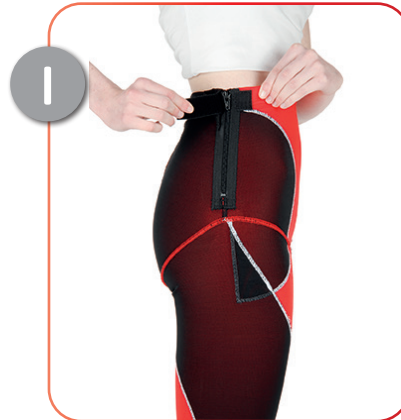
Patient will need to sit or lie down to ensure balance and safety.

How the leggings should look when on:



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Undo the tab if fitted.



Unfasten the body zip if added. Undo the ankle zips if added.



Roll the top of the leggings down towards the knees, gently pulling inside out.



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.

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DMO® Custom Leg sleeve application instructions

How to apply the DMO® Leg sleeve - with or without attachment.

Patient will need to sit or lie down to ensure balance and safety.

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.



Apply the silk foot applicator. If requested and provided.



Gently pull the leg sleeve up towards the knee.



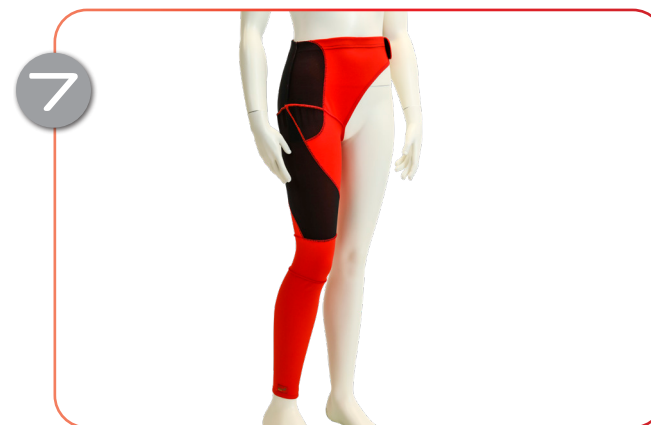
Then remove the silk applicator from the foot.



For leg sleeve without attachment, gently bring the leg sleeve up to the thigh and ensure the top silicone band is in the correct place at the top of the leg.



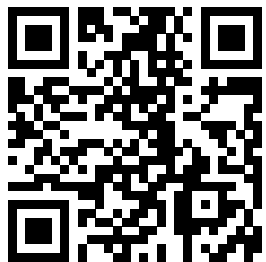
Make sure the silicone is in contact with the skin at the top of the orthosis.



For leg sleeve with attachment, gently pull the sleeve up towards the hip. Make sure you have gently pulled the leggings up to the thigh before attempting to pull over the hip and the body. Now fasten the velcro attachment at the opposite hip.

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How the leg sleeves with and without attachment will look when on.



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DMO® Custom Leg sleeve application instructions

How to remove the DMO® Leg sleeve - with or without attachment.

Patient will need to sit or lie down to ensure balance and safety.



Undo the velcro tap at the
opposite hip.



For the leg sleeve, gently bring the leg sleeve down the leg towards the knee pulling gently inside out.



Continue to gently roll the leg sleeve off the leg, over the knee
and off the foot.

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



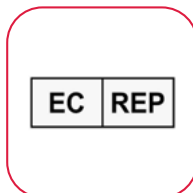
Manufactured in Britain



Distributor



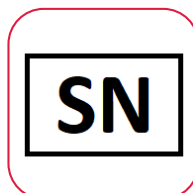
MedEnvoy Global BV
Pr. Margrietplantsoen 33
Suite 123
2595 AM Den Haag
Netherlands



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

DM28 – 5054522000142 (UDI-DI)
DM30 – 5054522000166 (UDI-DI)
DM31 – 5054522000173 (UDI-DI)
DM32 – 5054522000180 (UDI-DI)



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EC

REP

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