

Please note: SDO® Original garments encourage muscle stimulation and it is the users that actively correct their postural control and musculoskeletal alignment. This can cause fatigue in some users if they wear it for prolonged periods, therefore the wearing regime should be individually evaluated.

9. In Case of Serious Incident

In the event of a serious incident that may result in the deterioration of a patient's medical condition or may risk death, **STOP** using your garment immediately and contact:

- The manufacturer Medigarments Ltd.
- The relevant authority in the Member State
- The UK Medicines and Healthcare products Regulatory Agency (MHRA)

In the event of manufacturing faults such as damage to the fabric and stitching or if you have any concerns regarding the fitting of your garment, please contact your treating clinician immediately.

10. Latex

This garment does not contain latex.

11. Fabric composition

The fabric composition is printed on the silk label inside your garment.

Medigarments Ltd
DESIGNED AROUND YOU

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13. Washing instructions

Please follow the washing instructions below to maintain the elasticity and longevity of your garment, a copy of which is printed on the silk label sewn into your garment. Wash your garment separately for the first time to avoid any colour run. We recommend turning your garment inside out and fastening any zips prior to washing as this helps to protect and prolong the life of your garment.

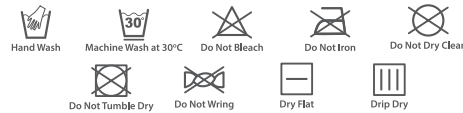
TIP: Using a laundry bag inside your washing machine helps to protect your new SDO® Original garment.

TIP: After hand washing, tightly roll your garment inside a thick towel to remove excess moisture, then dry flat on a second dry towel.

Key points to note:

- Wash dark colours separately
- DO USE a non-biological mild detergent
- Please do not use a fabric conditioner
- Please do not dry in direct sunlight
- Please do not dry on a radiator
- Please do not dry in a tumble dryer
- When hand washing, please rinse well and do not wring

We advise that SDO® Original garments are washed 2-3 days a week to help rejuvenate the fabric.



14. Additional information

Please follow instructions provided by your treating clinician and wear as prescribed to achieve optimum results. You may have to seek help with donning and doffing your garment and your treating clinician should be made aware of this.

Although Medigarments Ltd garments are resilient to most creams and oils, please note the following as some creams may damage the fabric, reduce the elasticity and the effectiveness of your pressure garment.

- Avoid using creams containing wax, paraffin or petroleum
- Use water or silicone-based moisturiser or cream

Always check garment and skin daily before use. Do not use if you have hypersensitivity or an allergic response to the garment materials. Please report to your treating clinician urgently.

When re-applying your garment after bathing, creaming and massaging, make sure the skin is dry and no residue cream remains on the skin.

If wearing your garment whilst swimming, you must rinse out the chlorine or sea-salt immediately afterwards to preserve and protect the fabric.

Repairs and adjustments to your garment must be carried out by Medigarments Ltd or a qualified healthcare professional. If you have any problems with your garment, please contact your clinician as soon as possible.

Important: Please do not remove the silk label within your garment as the warranty will be void.

15. Definition of Symbols

	Read instructions before use
	Manufacturer name and address
	Date of manufacture
	EC REP, European Authorised Representative to represent Medigarments Ltd in the EU and ensure compliance with the European Directives
	Medical Device
	CE marking
	UK Conformity Assessed marking
	Single Patient Use, do not share this garment
	Patient number
	Keep Dry
	Protect from Sunlight
	Disposal in household waste

16. Storage and shelf life information

Please store your new SDO® Original garment in a dry place away from direct sunlight.

Made-to-measure SDO® Original garments are designed for immediate use as body measurements may change over time.

With the correct handling and care, your garment may last for up to 6 months repeated wearing (usage period), after which time you will need to consult your medical professional to be measured for a new garment.

Please contact your treating clinician if the following occurs:

- You gain or lose a significant amount of weight
- Your condition changes
- Your garment has degraded and needs to be replaced

Should the above conditions apply, a new garment may be required before the 6 month period has elapsed. Please do not wear a garment that is too tight or too loose as this can cause delays in your therapeutic success.

Your new made-to-measure SDO® Original garment is intended for your usage only, please do not give this garment to a third party.

17. Disposal of your garment

There are no specific instructions for garment disposal. Please dispose of your used garments in your household waste or clothing recycling bank.



Medigarments Ltd
DESIGNED AROUND YOU

SDO® Original Sensory Dynamic Orthosis MTM Compression Garment Instructions For Use



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Contents

Please keep this leaflet in a safe place as you may need to refer to it again. If you have any questions that have not been covered in this leaflet or are not sure about anything, please ask your treating clinician for guidance.

This leaflet contains details about the following:

1. Intended Use
2. When to wear your SDO® Original garment
3. Donning your SDO® Original garment
4. Types of SDO® Original garments available
5. Indications
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7. Existing medical conditions
8. Warnings and Precautions
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1. Intended use

Our SDO® Original garments are intended to provide sensory and proprioceptive feedback to the area of the body they cover. The dynamic compression provided by our garments aims to enhance the function of our patients and help normalise activities of daily living. SDO® therapy is a long-term treatment that requires patient compliance in order to be successful, when medically directed and only on the instructions of a medical professional. Your new SDO® Original garment has been designed and manufactured in Long Eaton, Nottingham in the UK and will have been professionally measured and prescribed by an SDO® certified clinician.

2. When to wear your SDO® Original garment

Please note this garment has been expertly measured and designed for the user and must be worn by the user only. It must not be applied to anyone else.

The garment should offer a snug fit and can be expected to cause red marks initially (most commonly around the neck, armpits and under the seams). These soft tissue marks should disappear within 30-40 minutes of removing the garment. If the marks persist for longer than 30-40 minutes do not increase the wearing time and inform your treating clinician directly.

It is the responsibility of the treating clinician to monitor the SDO® Original garment and advise when a new garment is required. It is advised that your garment is reviewed every 4-6 months to ensure that the fit has not changed and to accommodate any growth. If your garment becomes too tight or too loose then please contact your treating clinician for a re-measure.

Please note: The recommended wearing schedule has been effective for people with diagnosis of cerebral palsy and sensory issues. Any other diagnosis will depend on clinical presentation and the advice of the treating clinician.

Sleep Suit Only

It is anticipated that the wearing of an SDO® Original sleep suit leads to improvement in the alignment of the body and hips when at rest. The aim is to gradually correct alignment and posture over time where passive correction is available or to limit any further deformation of alignment and posture. A sleep suit is not advised where no passive correction is available. The wearing of this garment may also enhance sleep quality for the user and contribute to an improved sleep pattern with a reduction in sleep disturbance. A sleep suit is often used in combination with, but not instead of a prescribed sleep system.

Wearing Schedule:

- On the first day of wear the SDO® should be worn for a maximum of two hours at any one time. If after two hours there are no adverse reactions then increase the next wearing time by one hour.
- Continue to increase wearing time by one hour until the minimum recommended wearing time of 6-8 hours is reached, or as recommended by the treating clinician.
- It is advised that you should not sleep all night in the SDO® unless the SDO® has been prescribed for night time use.

- To obtain maximum benefit from the SDO® Original garment it is important to wear daily as prescribed by a treating clinician (unless any adverse effects/contraindications/precautions identified).



This device should be fitted and periodically checked by a suitably qualified person only

3. Donning your SDO® Original garment

Please follow the advice of your treating clinician before you wear this SDO® Original garment.

Fitting - Two finger test: when checking fit, one should be able to easily slide two fingers under the end of the garment at the wrist, neck, groin, knee or ankle.

For all SDO® Original garments, please follow the standard instructions below before reading the specific donning instructions for your type of garment:

- Read through this instruction booklet, paying particular attention to section **8. Warnings and Precautions**, and **14. Additional Information** prior to donning your SDO® Original garment
- Ensure your hands are clean with no sharp fingernails or toenails. Temporarily remove jewellery from hands, wrists and ankles if applicable
- Open all zips/fastenings
- Avoid using your SDO® if you have any acute skin rashes or if a vascular/circulation problem arises until cleared by your treating clinician
- Watch for signs of discomfort and any change in hand/feet colour or temperature that may indicate problems with circulation. If this occurs remove the SDO® Original garment and contact your treating clinician immediately
- If you have a medical condition that may be affected by wearing an SDO® Original garment, please seek medical clearance

Suits:

- Pull each leg over the knee, ensure that the knee panels are central
- Pull up over the buttocks and hips
- Insert arms one at a time and then pull up over the shoulders, ensure that the elbow panels are central
- Ensure that the seams and reinforcements are straight/aligned correctly down the side of the trunk, arms and legs
- Fasten back zip and then the front zip. (Sometimes it may be easier to fasten the front zip first)
- A donning aid may make the arm or leg slide more easily

Sleep Suits:

- Lay the back of the garment flat on the bed/change table, roll individual onto one side and then roll back onto the garment
- Bring the front of the garment through the legs and onto the front of the body
- Fasten the over shoulder straps and fasten hip straps
- Fasten side with least resistance first, followed by the other side, allow the garment to bring the hips and

body into alignment

- Ensure that the seams and reinforcements on the garment are in an optimum alignment and adjust the shoulder and side straps until a good fit and correction is achieved

Vests & Leotards:

- Place one arm in at a time, ensuring any seams and reinforcements are in the correct position
- Fasten zips/fastenings one at a time starting with the easiest first
- Ensure pulled down to correct height and all seams are central

Short & Long Leggings:

- Pull on over knee on both legs to ensure seams and reinforcements are centred
- Pull up to hips and again check seams and reinforcements are in the correct position
- Once happy with positioning, fasten all zips/fastenings starting with the easiest first

Sleeves, Gauntlets and Gloves:

- Starting at the fingers/wrist work the garment up the arm, ensure all seams and reinforcements are central (no rotation)
- Fasten all zips/fastenings

Socks:

- Starting at the toes work the sock up and over the heel
- Ensure all seams and reinforcements are central (no rotation)
- Fasten all zips/fastenings

4. Types of SDO® Original garment available

SDO® Original garments are bespoke and made-to-measure for each individual. The types of SDO® Original garment are broken down into the categories listed below:

1. Suits
 - Sleeveless
 - Short sleeve
 - Long sleeve
 - Short leg
 - Long leg
 - Open crotch
 - Closed crotch
2. Sleep suit/shorts
3. Double Zip suit for individuals with fluctuating weight
4. Vests & Leotards
 - Sleeveless
 - Short sleeve
 - Long sleeve
5. Leggings
 - Short leg
 - Long leg
 - Open crotch
 - Closed crotch
6. Sleeves, Gauntlets and Gloves
7. Socks

5. Indications

Neuromuscular and musculoskeletal conditions including but not limited to:

- Acquired Brain Injury such as Stroke
- Cerebral Palsy
- Muscular Dystrophy
- Spinal Muscular Atrophy
- Ehlers-Danlos Syndrome
- Multiple Sclerosis
- Neuromuscular Scoliosis
- Rett Syndrome

Developmental disabilities including but not limited to:

- Autism Spectrum Disorder
- Attention Deficit Hyperactivity Disorder
- Developmental Coordination Disorder

SDO® Original garments can help to improve postural control, aid pain management and increase the general well-being of the patient. This improvement in control helps facilitate breathing, feeding and swallowing and greatly improves ease of handling for the parent or carer.

6. Contraindications

Do not use SDO® Original garments without consulting a doctor if you have:

- Cardiovascular diseases or other types of related conditions
- Bone fractures or recent surgeries
- Skin disease, rashes or other skin problems such as scleroderma or cellulitis
- Fever

7. Existing Medical Conditions

Your clinician should be made aware of any existing medical conditions you may have so this can be considered when prescribing your SDO® Original garment. If you have not alerted your clinician to any of the conditions below, please DO NOT wear this garment until your clinician confirms it is safe to do so.

Existing medical conditions include but are not limited to:

- Certain skin conditions such as eczema
- Vascular/circulation problems
- Oedema
- Weight fluctuations
- Chronic Fatigue
- Reflux

8. Warnings and Precautions

There are no known side effects when wearing this garment in the correct manner as directed by your treating clinician, surgeon or GP. If your medical condition deteriorates whilst wearing this garment, please consult your doctor or treating clinician immediately.

The manufacturer is not liable for any damages, conditions or injuries that occur from handling or using this garment incorrectly. This includes any alterations or tampering not carried out by Medigarments Ltd. Your garment must be regularly maintained to the maintenance schedule in this IFU.

SDO® Original garments are not flame retardant, please avoid naked flames when wearing.

Please stop wear and contact your treating clinician if any of the below occur:

- Allergic reaction
- Discolouration or a change in body temperature showing circulation or vascular problems
- Lasting redness or skin abrasions
- Continuously raised temperature

If you have any open wounds in the area to be treated, these need to be covered with an appropriate wound dressing or bandage, before the garment can be applied.