

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 SDO® Lite garment.

Wash your garment separately for the first time to avoid any colour run. We recommend turning your garment inside out and securing any fastenings 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® Lite 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® Lite garments are washed 2-3 days a week to help rejuvenate the fabric.



Hand Wash



Machine Wash at 40°C



Do Not Bleach



Iron Low Heat



Dry Clean



Tumble Dry Low Setting



Do Not Wring



Dry Flat



Drip Dry

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.

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® Lite garment in a dry place away from direct sunlight.

Ready-to-wear SDO® Lite garments are recommended for immediate use as body measurements may change over time.

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

Please do not wear a garment that is too tight or too loose as this can cause delays in your therapeutic success.

Your new ready-to-wear SDO® Lite garment is for single patient usage only, please do not share this garment with 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
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SDO® Lite
Instructions For Use



Medigarments Ltd
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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® Lite garment
3. Donning your SDO® Lite garment
4. Types of SDO® Lite garments available
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6. Contraindications
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1. Intended use

Medigarments Ltd SDO[®] Lite garments have many uses from assessment tools used to identify whether a made-to-measure SDO[®] garment will be of benefit to long term garments for sensory processing difficulties. Our SDO[®] range including SDO[®] Lite can be used for patients with neuromuscular or musculoskeletal conditions. Your clinician will explain to you the reason you have been prescribed our SDO[®] Lite garments.

The garment gives clinicians a tool to assess the potential value of dynamic compression in patients with but not limited to: poor postural control, decreased proximal stability, hyper mobility, increased or decreased tone and decreased sensory feedback. Patients may find our SDO[®] Lite garments provide sufficient correction however your clinician will decide this and refer you to our made-to-measure garments if more correction is required.

Your new SDO[®] Lite garment has been designed and manufactured in Long Eaton, Nottingham in the UK and will have been recommended by an SDO[®] certified clinician.

2. When to wear your SDO[®] Lite garment

Please note this garment has been designed for use by a single patient and must be worn by the user only. It must not be applied to anyone else once already worn.

The garment should offer a snug fit and can be expected to cause red marks initially. 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.

Wearing Schedule:

- On the first day of wear the garment 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 in the garment, unless the garment has been prescribed for night time use.
- To obtain maximum benefit from the garment it is important that it is worn daily as prescribed by a certified clinician (unless any adverse effects/contraindications/precautions identified).



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

3. Donning your SDO[®] Lite garment

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

For all SDO[®] Lite 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 section **14. Additional Information** regarding creams and oils before wearing your new SDO[®] Lite garment
- Ensure your hands are clean and you have no sharp fingernails or toenails. Temporarily remove jewellery from hands, wrists and ankles if applicable.
- Open all fastenings
- Avoid using your garment 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 garment and contact your treating clinician immediately
- If you have a medical condition that may be affected by wearing an SDO[®] Lite garment, please seek medical clearance

LUMBAR BELT:

The SDO[®] Lite lumbar belt is used to identify whether there is diminished sensory and proprioceptive feedback to the core. The belt is fitted from the lower ribs to the anterior superior iliac spine (ASIS) to identify the effect on postural control and trunk stability.

- Position the lumbar support from the lower ribs to the bony prominences (ASIS) at the front of the hips
- Pull the support around the trunk until you have a snug fit (you should be able to get a flat two fingers between the belt and the body) and attach using the hook and loop fastening edge of the base support
- Pull the rotation straps around to achieve the required correction and attach using the hook and loop fastening
- Remove by first peeling off the rotation straps and then the base belt hook and loop edge

SLEEVE:

Fitted from just above the wrist to the axillary crease (armpit) and provides feedback through the arm.

- Slip your hands through the entire sleeve keeping the seam in-line with your little finger, ease sleeve up the arm into position
- Make sure the fabric is smoothed out evenly over the arm, do not fold up or down

GAUNTLET:

Fitted from the palmer crease including the thumb to the

wrist with a reinforcement panel to resist wrist flexion.

- Slip your hand through the wrist of the gauntlet
- Adjust the thumb carefully until it fits snugly into the first web space
- Make sure the fabric is smoothed out evenly over the thumb and hand.

SOCK:

Fitted from the metatarsal heads in the foot to below knee to provide sensory and proprioceptive feedback the lower limb. The SDO[®] Lite sock has a reinforcement panel to assist with dorsiflexion at the ankle.

- Slip the foot into the sock and feed over the foot
- Adjust the sock carefully until it fits snugly over the foot and ankle
- Make sure that the fabric is smoothed out evenly over the foot and leg
- Remove by peeling off the sock away from the skin

VEST:

The SDO[®] Lite vest with short sleeves and open front zip provides sensory and proprioceptive feedback to the trunk. The vest has a built in reinforcement to encourage shoulder retraction and back extension.

- Undo front zip
- Place arms into garment
- Ensure seams are straight and garment is not rotated
- Fasten front zip

SHORTS:

Fitted from the hips to the mid thigh, SDO[®] Lite shorts come with a reinforcement panel to assist with hip alignment.

- Simple pull on design
- Please ensure seams and reinforcement panels are aligned with the body
- Remove by peeling off away from the skin

NOTE: When removing the garments, peel off gradually taking care not to place extreme pressure on seams.

NOTE: If your garments are tight, slack or damaged they will need to be replaced by your clinician/provider immediately.

4. Types of SDO[®] Lite garment available

SDO[®] Lite garments are ready-to-wear garments that have a multitude of uses. The types of SDO[®] Lite garment are broken down into the categories listed below:

1. Lumbar belt
2. Sleeve
3. Gauntlet
4. Sock
5. Vest
6. Shorts

5. Indications

- Neuromuscular/musculoskeletal conditions that need light support
- Assessment garments (help with alignment/posture for complex patient measures)
- Sensory processing difficulties including Autism and ADHD
- Stroke rehabilitation
- Tremor reduction
- Athletic training
- Funding applications

6. Contraindications

- Scleroderma
- Dislocated joints (not reduced)
- Fixed contractures/Soft tissue shortening
- Oedema
- Skeletal conditions including Osteogenesis imperfecta
- Open wounds

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[®] 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 e.g. Eczema
- Vascular/Circulation problems
- Oedema
- Weight fluctuations
- Epilepsy

8. Warnings and Precautions

There are no known side effects when wearing this garment in the correct manner as directed by your clinician, surgeon or GP. If your medical condition deteriorates whilst wearing this garment, please consult your doctor or 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 by the user. Your garment must be regularly maintained to the maintenance schedule in this IFU.

SDO[®] Lite 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
- 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.

Please note: wearing your garment for extended periods, for example over 10 hours a day may encourage excessive muscle stimulation and therefore can cause fatigue.