

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 Jobskin® Classic 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 Jobskin® Classic 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 your Jobskin® Classic garments are washed daily.



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 Jobskin® Classic garment in a dry place away from direct sunlight.

Made-to-measure Jobskin® Classic 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 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 Jobskin® Classic 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

Jobskin® Classic

MTM Pressure Garment for Scar Management

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 Jobskin® Classic garment
3. Donning your Jobskin® Classic garment
4. Types of Jobskin® Classic garment available
5. Indications
6. Contraindications
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1. Intended use

A Jobskin® Classic pressure garment is a made-to-measure, tight fitting but stretchy item of clothing made from a fabric containing Lycra®. The garment is designed and made to your individual measurements to provide a smooth constant and firm pressure over the scarred areas of your body.

The purpose of the Jobskin® Classic pressure garment is to manage problem scars. The garment provides a compression on areas of raised hypertrophic scarring to flatten, soften and reduce scarring and erythema of the scar and aid the natural scar maturation process.

Your new Medigarments Ltd garment has been designed & manufactured in Long Eaton, Nottingham in the UK and will have been professionally measured and prescribed by a certified clinician.

2. When to wear your Jobskin® Classic garment

Please note this Jobskin® Classic 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.

It is important that you are measured and reviewed by a suitably qualified clinician experienced in measuring and fitting compression garments.

It is the responsibility of the treating clinician to review your garment and advise when a new garment is required. It is recommended that your garment should be checked by your clinician at least every 3 months for children and 4-6 months for adults to ensure fit and to review progress.

Worn, loose or damaged garments should be replaced, therefore, it is important to attend your regular review appointments.

You begin compression therapy as soon as a wound has closed and full pressure can be tolerated. This way, maximum use can be made of the time in which the scar is active.

Wearing Schedule:


- It is important that Jobskin® Classic pressure garments are worn consistently for between 12-24 months or until scar maturity for 23 hours a day. This ensures the full benefit is achieved for optimum results in scar management, both aesthetically and functionally
- The garments are typically removed 3 times a day for bathing and creaming the scar and masks can be removed during meal times
- Once you have the compression garment in place, ensure it lays smoothly against your skin and feels snug but not painful
- It is advised that the fit of the garment is reviewed on a regular basis by the clinician to make sure that the desired effect is being achieved

Other factors that influence the duration of treatment:

- The severity of the scarring
- Genetics and hormones - healing responses may vary

from person to person

- Infection or delayed healing
- The site of the scar and the surface affected
- Compliance to treatment regime

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

3. Donning your Jobskin® Classic garment

IMPORTANT: Please refer to the additional instruction leaflet if your garment contains Silon-TEX® II inserts.

Please follow the advice of your treating clinician before you wear this Jobskin® Classic garment.

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

Donning and Doffing compression garments can be a little challenging at the start but they do stretch after a little wear. There are some general rules to live by that can assist with the garments as follows:

- Read through this instruction booklet, paying particular attention to section **8. Warnings and Precautions**, and **14. Additional Information** regarding creams and oils, prior to donning your Jobskin® Classic garment
- Use a silicone or water-based moisturiser and ensure it is dried well into the skin before donning your garment
- It is advisable your garment is put on first thing in the morning and worn for 23 hours, only removing it for bathing purposes
- Your clinician may also advise on aids to help with the donning and doffing of your garment
- Ensure your hands are clean and you have no sharp fingernails or toenails that may damage the fabric, avoid sticking your fingernails into the fabric when pulling the garment on
- Do not overstretch the material
- Open all zips/fastenings
- Temporarily remove jewellery from hands, wrists and ankles if applicable, whilst donning and doffing your garment. Jewellery such as stone encrusted rings may snag your garment

Lower Extremity Garments

Check the label on your Jobskin® Classic garment for left or right, starting with the garment inside out, tuck the foot portion inside up to the heel and hold with both hands, seam facing down. Pull it up over your foot past the ankle, it should now be right side out. Adjust the garment so that the heel is in place.

Waist High Garments

Adjust your garment so that it is snug at your midsection. This will keep it from slipping down. Slip your hands palm out, into the back and lift it away from your skin. Let it fall back to fit snugly over the buttocks

Arm Sleeves

Slip your hand through the entire sleeve keeping the seam in line with your little finger, ease the sleeve up your arm. It may be helpful to brace your hand against a wall. If a gauntlet is attached, the seam should run from palm to your hand, then curve over your elbow to your upper arm.

Gloves

Adjust the fingers by carefully pulling on the seams until the glove fits snugly into the web spaces between the fingers. Be sure the fabric is smoothed out evenly over the fingers and hand.

Face Masks

Please note: when pressure garments are used to manage children's facial scarring, it is recommended that an orthodontic review is undertaken beforehand.

Open closure, hold chin in place by pressing chin against upper sternum or with one hand if you have assistance. Gather fabric and stretch over head. Adjust the facial features, the face mask must have the fabric distributed to fit properly. Adjustment may be made by slipping fingers through openings and placing were desired.

Torso Garments

Open closure, insert one arm at a time, adjust to fit snugly on each arm. Pull the two sides towards the centre and close zip. Make sure fabric is smooth and fitting snugly, when fitted, ensure there is no discomfort especially at the bend of the arms and axilla areas.

4. Types of Jobskin® Classic garment available

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

1. Head & Face
 - Full or open face mask
 - Wide chin strap
2. Upper Extremity/Torso
 - Vest sleeveless or with short or long sleeves
 - Leotard sleeveless or with short or long sleeves
 - Armsleeve with shoulder flap
 - Sternal garment
 - Vest with one arm with short or long sleeves
 - Shrug with short or long sleeves
3. Arm
 - Sleeve
4. Hands, Gauntlets and Gloves
 - Glove
 - Gauntlet
5. Lower Extremity
 - Leggings short or long leg
 - Leg sleeve
 - Single leg hip style
5. Foot
 - Sock
 - Below knee sock

5. Indications

The management and prophylactic treatment of problem scarring, including hypertrophic and keloid scars caused by damage to the skin following burns, trauma or post-operative surgical scar complications.

The evidence gathered through international research shows that the early application of pressure therapy garments with the correct wearing regime is successful in helping to control the growth of abnormal scar tissue in problem scarring.

They are successful in producing a flatter, softer more pliable scar which results in an improved cosmetic appearance and reduction of potential contractures.

The continuous pressure provided by pressure garments can yield a high degree of non-surgical control of hypertrophic scar formation and scar contractures to achieve a softer, flatter and paler scar.

6. Contraindications

With a made-to-measure garment that is regularly checked by a health professional, contraindications are very rare.

- Uncompensated organ failure (i.e. heart, liver, or renal)
- Untreated deep vein thrombosis or phlebitis
- Severe arterial disease (ABI 0.49 or less)

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 Jobskin® Classic garment. If you have not alerted your clinician to any of the conditions above, please DO NOT wear this garment until your clinician confirms it is safe to do so.

8. Warnings and Precautions

There are no known side effects when wearing this garment in the correct manner as directed by your clinician. 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.

Jobskin® Classic 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 compression garment can be applied.