

## 10. 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.

## 11. Latex

Caution: this product contains natural rubber latex which may cause allergic reactions.



## 12. Fabric composition

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

## 14. Washing instructions

Please follow the washing instructions below to maintain the longevity of your garment, a copy of which is printed on the silk label sewn into your corset.

Wash your garment separately for the first time to avoid any colour run. We recommend closing any hook-and-loop fastenings prior to washing as this helps to protect and prolong the life of your 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 Medigarments corsets are washed 1-2 days a week to help rejuvenate the fabric.



Hand Wash



Do Not Bleach



Do Not Iron



Do Not Tumble Dry



Do Not Dry Clean



Do Not Wring



Dry Flat



Drip Dry

## 15. 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 effectiveness of your 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.

This corset is not suitable for extreme sports, running or cycle racing, ice and snow sports, extreme slopes and steps. Any such activities undertaken are done so completely at the users' own risk. The corset is not intended to be used in water or whilst showering.

Repairs and adjustments to your corset must be carried out by Medigarments Ltd or a qualified healthcare professional. If you have any problems with the device 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.**

## 16. 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

## 17. Storage and shelf life information

Please store your new corset in a dry place away from direct sunlight. Do not place near any heat source. Do not leave inside a car in hot weather.

Made-to-measure corsets 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 corset is intended for your usage only, please do not give this garment to a third party.

## 18. 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

# Corsets

## Instructions For Use



**Medigarments Ltd**  
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Sutton, BKR 4013 Matts

## 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 corset
3. Fitting instructions for clinical use only
4. Donning your corset
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# Medigarments Ltd

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## 1. Intended use

Medigarments corsets are made-to-measure external devices that support the muscular and bony structures of the spine, for the non-operative treatment of back pain. Corsets prevent unnecessary movements that may further damage the back: they provide additional muscular support that helps to align your spine and strengthen your back muscles while minimising discomfort; they act as a reminder to avoid excessive low back motion; and they help encourage proper body mechanics, such as good posture. Medigarments corsets are made from a flexible material and stiffened with bones or stays.

**Abdominal support corsets** are designed to relieve the strain on joints, ligaments and muscles caused by a pendulous abdomen and may also be used post-operatively as a binder for surgical dressings which may speed-up the recovery process.

**Lumbosacral corsets** are designed to support the muscles of the lower back and immobilise and stabilise the spine following injury or surgery, until muscle strength can perform the job independently and your back pain decreases. Lumbosacral corsets may require you to restrict some activities, however, the corset will aid your healing and may help prevent further injury.

Your new Medigarments corset has been designed and manufactured in Long Eaton, Nottingham in the UK and should be professionally measured, assessed and prescribed by a certified clinician.

## 2. When to wear your corset

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 corset should offer a snug fit and can be expected to cause red spots initially. These soft tissue marks should disappear within 15-30 minutes of removing the garment. If the marks persist for longer than 30 minutes do not increase the wearing time and inform your treating clinician directly.

When you wear your support is left to your own discretion, however most patients will find the brace to be quite helpful for the first 6 weeks after surgery, with diminishing use of the brace thereafter. During wear the muscles in your stomach and back do not work as hard as they should and there is a risk that over time they could weaken.

You should only wear a back brace while you are performing activities: when you know you are going to be active e.g. going shopping or doing the gardening; where your back may be at risk of injury such as lifting heavy objects; or if you have a spinal injury and require extra stability; or if you are experiencing back pain.

You should make sure your garment is regularly reviewed by your treating clinician. You should not rely on your corset unless you have a specific medical condition or your treating clinician tells you to.

Should your functional requirements or condition change during the life cycle of your corset please contact your treating clinician as it may affect the performance of the device.



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

## 3. Fitting instructions for clinical use only

This corset should only be fitted by a trained healthcare professional.

**Please check the patient details and the corset prescription for accuracy.**

- Mould and shape the rigid steels or metal frame, at the waistline and at the apex of the buttocks to follow the shape of the back, and insert into the casings or pocket provided

**Please note:** At this stage the steels should be marked left and right and top and bottom to assist the patient during the laundering of the garment.

- Mould and shape the concealed boning at the waistline and over the buttocks in order to fit the shape of the body. It is also necessary to instruct the patient or carer to do this because the boning may straighten during wearing and washing

**Please note:** If pads are part of the prescription ensure these are attached on a touch and close fastening in the correct position, the patient should also be instructed on the correct position.

- Centralise the garment to the patients back at the waistline and secure the fastening at the top edge (i.e. one strap or hook and eye to hold the corset in the correct place)
- Loosely fasten all hook and eye straps from the bottom edge upwards
- Check that the corset is still centred correctly, and then tighten up the straps once again starting at the bottom edge. This helps to lift the abdomen into the correct position
- Next fasten and tighten the fulcrum band and strap to give extra pressure to the lower back and abdomen
- Check to see if the patient is comfortable and the corset is giving the correct amount of support
- Ask the patient to sit on a solid surface to check that the corset is not too tight, especially at the top edge and waistline
- The support should be no higher than 2-3cms below the point at which the bottom of the breast meets the chest wall
- Examine the back to ensure that the bones are not touching the solid surface whilst the patient is sitting, this would indicate that the backbones are too long

### Fittings of special belts

- For reducible hernias it is necessary to lie the patient on a bed and ensure the hernia is massaged into the abdomen, position any pads correctly and then fasten the corset as above
- For irreducible hernias, corsets should have sufficient fullness to contain the hernia and the patient should be in prone position when the corset is fitted. Be very careful not to strangle the hernia when donning

## 4. Donning your corset

Please follow the advice of your treating clinician before you wear this corset.

**For all corsets, please follow the standard instructions below:**

- Read through this instruction booklet, paying particular attention to section **9. Warnings and Precautions** and **15. Additional Information** regarding creams and oils before wearing your new corset
- Avoid using your corset if you have any acute skin rashes or if a vascular/circulation problem arises until cleared by your treating clinician

### Fitting Instructions:

- Your corset can be put on standing up or lying down depending on the advice from your treating clinician
- Centralise the garment to your back at the waistline and secure the fastening at the top edge (i.e. one strap or hook and eye to hold the corset in the correct place). If your corset has steels at the back ensure these are on either side of your spine
- Loosely fasten all hook and eye straps from the bottom edge upwards
- Check that the corset is still centred correctly, and then tighten up the straps starting at the bottom edge. This helps to lift the abdomen into the correct position
- If your corset has a fulcrum band fasten this next to give extra pressure to the lower back and abdomen
- The fastenings on your corset should be pulled snug around your waist to ensure the corset doesn't move
- If your corset has been prescribed to support a hernia it is best to put it on when lying down and the hernia is safely reduced
- You should check the fit of your corset sitting and standing to ensure optimum comfort

## 5. Types of corset available

Medigarments corsets are made-to-measure for each individual and are categorised as follows:

- Abdominal Support
- Lumbosacral Support

## 6. Indications

Common uses are for osteoporosis, low back pain and abdominal hernias.

- Lumbar and Sacral spine strains and sprains
- Sciatica
- Intervertebral disc weakness e.g. mild disc herniation
- General back pain
- Stabilisation of lumbar spine
- Degenerative spinal changes
- Post op management
- Irritation of the Intervertebral joints and sacroiliac joint
- Minor postural disorders
- Spondylosis without vertebral slipping
- Mild Spondylosis / Spondylolisthesis
- Weak or prominent abdomen
- Hernia

## 7. Contraindications

- Non-reducible hernia
- Unstable Spinal fractures

## 8. Existing Medical Conditions

Your treating clinician should be made aware of any existing medical conditions you may have so this can be considered when prescribing your corset. 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

## 9. Warnings and Precautions

There are no known side effects when wearing this garment in the correct manner as directed by your clinician 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 corset must be regularly maintained to the maintenance schedule in this IFU.

Corsets 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, skin abrasions or blisters
- 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 over extended periods may weaken the back muscles. The corset should be worn when you are involved in activities that place your back at risk. When this at risk activity is finished, the brace should be removed.**