

SleepShape



SleepShape
Lying and Positioning System
User Manual

User Name

Lot Number

IMPORTANT CONSUMER INFORMATION NOTICE:
Please keep these instructions and give them to the user. They include important safety information.

MD: This product is a Medical Device included in the Australian Register of Therapeutic Goods (ARTG).

Instructions are available on our website spexseating.com/user-manuals

You can get a paper copy by emailing solutions@spexseating.com

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Introduction

SleepShape is a range of positioning cushions designed to support posture in lying. With a choice of microbead or adjustable microfibre fill, and either comfort or wipeable covers, the range can be tailored to different clinical needs, environments and sensory preferences. From smaller supports to larger, full-body shapes, SleepShape helps promote alignment, comfort and pressure management for people who are unable to change position independently.

Spex recommends that a clinician with knowledge of lying support system assess and prescribe this product. This may be an Occupational Therapist or other health professional with specific training in lying support for people with disabilities.

If any serious incident occurs with this cushion, you must report the incident to the manufacturer, Spex Ltd (solutions@spexseating.com). Please also inform your local distributor.

Disclaimer: Spex takes no responsibility as to the therapeutic effectiveness of our products. Our claims relate to the ability of the products to provide safe and reliable positioning. Always check clinical guidelines and follow the prescribing clinician's instruction.

Intended Use

SleepShape is a positioning system to enhance comfort, alignment, and pressure relief. That are suitable for use in home, clinical, and care environments by individuals requiring additional support due to medical or physical conditions.

Safe Use Information



Ask for help if you are unsure about any of the following points:

	Do not use a cushion that is broken or damaged. If you see any damage, stop using it and tell your healthcare professional.
	To stay safe, always use the cushion the way your healthcare professional showed you.
	Be careful with things that don't let air through near your mouth or nose. These areas must never be blocked.
	If you notice any signs of an allergic reaction, stop using the cushion and tell your healthcare professional.

Precautions

- Only trained people should set up the cushion.
- Make sure the cushion is in the right place before using it.
- Do not take off labels.
- Watch the person when changing their position.
- Use only the parts and covers that came with the cushion. Do not change or add anything.
- If you need a new cover, get the same kind from the supplier.
- Do not change the cushion or make your own fixes.
- When starting or changing a position plan, check the skin for red spots or signs of pressure.

Indications for Use

Type of Cushion	Indications for Use
Universal Cushion	Generally used to support, offload, correct or align a body segment or area, particularly where the user does not have the muscular control of the body area or segment or where that control can be transient. Suitable for use in a variety of applications specific to the individual, their care needs and goals.
Cylinder Cushion	Generally used to support, offload, correct or align a body segment or area, particularly where the user does not have the muscular control of the body area or segment or where that control can be transient. Suitable for use in a variety of applications specific to the individual, their care needs and goals.
Triangular Cushion	Generally used to support, offload, correct or align a body segment or area, particularly where the user does not have the muscular control of the body area or segment or where that control can be transient. Suitable for use in a variety of applications specific to the individual, their care needs and goals.
Semifowler Cushion	Generally used to support, offload, correct or align a body segment or area, particularly where the user does not have the muscular control of the body area or segment or where that control can be transient. Suitable for use in a variety of applications specific to the individual, their care needs and goals.
S Cushion	Generally used to support, offload, correct or align a body segment or area, particularly where the user does not have the muscular control of the body area or segment or where that control can be transient. Suitable for use in a variety of applications specific to the individual, their care needs and goals.
Ring Cushion	Generally used to support, offload, correct or align a body segment or area, particularly where the user does not have the muscular control of the body area or segment or where that control can be transient. Suitable for use in a variety of applications specific to the individual, their care needs and goals.

Indications for Use

Type of Cushion	Indications for Use
Half Moon Cushion	Generally used to support, offload, correct or align a body segment or area, particularly where the user does not have the muscular control of the body area or segment or where that control can be transient. Suitable for use in a variety of applications specific to the individual, their care needs and goals.
Abduction Cushion	Generally used to support, offload, correct or align a body segment or area, particularly where the user does not have the muscular control of the body area or segment or where that control can be transient. Suitable for use in a variety of applications specific to the individual, their care needs and goals. Intended for use between the lower limbs to prevent unwanted adduction at the hip joint and/or to promote a neutral or abducted position of the hip joint.
Wedge Cushion	Generally used to support, offload, correct or align a body segment or area, particularly where the user does not have the muscular control of the body area or segment or where that control can be transient. Suitable for use in a variety of applications specific to the individual, their care needs and goals.
Calf Support Cushion	Generally used to support, offload, correct or align a body segment or area, particularly where the user does not have the muscular control of the body area or segment or where that control can be transient. Suitable for use in a variety of applications specific to the individual, their care needs and goals. Intended for use under the lower limbs, usually behind the calves, when the user is in a supine lying position (user on their back), with the goal of elevating the feet and ankle off the support surface (usually mattress) with the intention of offloading the heels to reduce areas of peak pressure.
Half Ring Cushion	Generally used to support, offload, correct or align a body segment or area, particularly where the user does not have the muscular control of the body area or segment or where that control can be transient. Suitable for use in a variety of applications specific to the individual, their care needs and goals.

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Type of Cushion	Indications for Use
Hemi Comfort Cushion	Generally used to support, offload, correct or align a body segment or area, particularly where the user does not have the muscular control of the body area or segment or where that control can be transient. Suitable for use in a variety of applications specific to the individual, their care needs and goals. Intended for use under the forearm and elbow when the user is in a reclined or seated position with the intention of supporting the upper limb to increase comfort, reduce pain and assist with positioning of the upper limb generally.
Ear Cushion	Intended for use under the side of the head, providing a cut out for the user's ear to sit within for the purposes of offloading pressure and aiding in comfort.
Foot Wrap Cushion	Intended for use around the foot and the ankle, to aid with positioning of the fore and hind foot and assist with distributing pressure and decreasing risk of pressure injury.
Heel Raiser Cushion	Intended for use under the lower limbs, when the user is in a supine lying position (user on their back).
Occiput	Generally used to support, offload, correct or align a body segment or area, particularly where the user does not have the muscular control of the body area or segment or where that control can be transient. Suitable for use in a variety of applications specific to the individual, their care needs and goals. Intended for use under the head when the user is in a supine position to support the head, offload pressure on the occiput, increase comfort and reduce pain.

Contraindications

Patients with unstable fractures or conditions contraindicating passive positioning.

Inspection

 **CAUTION: Check cushion regularly for signs of wear and tear or damage**

Before using the product:

- Clean the product (see instructions on next page).
- Visually inspect the products seams, cover/fabric and filter (hygiene range) for damage or holes. A product with holes or damaged fabric should be disposed of.

Everyday use:

- Visually inspect the products seams, cover/fabric and filter (hygiene range) for damage or holes.
- Replace any parts with holes or damaged fabric.
- Clean the cover at least once a week or when soiled.
- Cushions need to be fluffed to maintain the fluffiness of the fibres.
- Make sure all cleaning products follow the rules from the company that made them.

Maintenance and Cleaning

- **CAUTION:** Avoid sharp objects. This could damage the cushion
- **CAUTION:** Different cover and filling materials have different washing instructions.
Check the care label on each part of your cushion.

Regular cleaning will help extend the life of the cushion. Refer to care label for further information.

Material	Instruction
Removable Wipeable Covers (Light Blue) 55% Polyurethane 45% Polyamide	Wash at up to 40°C (with zipper open) Tumble dry on a low heat (air drying preferred) (tumble dry inside out with zipper open)
Removable Comfort Cover (White) Film: 100% Polyurethane Textile: 52% Viscose, 48% Lyocell	Wash at up to 40°C (with zipper open) Tumble dry on a low heat (air drying preferred) (tumble dry inside out with zipper open)
Fibre Filled Inner Cushion Cover material: 100% Polyester Filling: 100% PET fibre	Wipe clean with mild detergent and water solution, refer table below for approved cleaning products Do not Machine wash Do not Tumble dry
Microbead Filled Inner Cushion Cover material: 100% Polyester Filling: 100% Polystyrene microbeads	Wash at up to 40°C Tumble dry on a low heat (air drying preferred)
Hygiene Cushion Range Cover material: 55% Polyurethane, 45% Polyamide Filling: 100% Polystyrene microbeads	Clean with mild detergent and water solution, refer table below for approved cleaning products Do not Machine wash Do not Tumble dry
Foot Wrap Cover material: 55% Polyurethane, 45% Polyamide Filling: PET fibre	Clean with mild detergent and water solution, refer table below for approved cleaning products Do not Machine wash Do not Tumble dry
Heel Raiser	Remove cover and wash as per above instructions

Spex is not responsible for any damage from cleaning.

If you have any additional questions regarding cleaning procedures, please contact your Spex distributor.

Cleaning and disinfectant products that can be used on Hygiene range (code: 7107-xxxx-300)

- 1% Hydrogene Peroxide Solution
- Amonium Compounds
- Aniospray Quick
- Antifect extra
- AntiGone
- Bacillol AF
- Bacillol Foam
- Bactacid Wipes
- Chemisept wipes
- Chlorine Dioxide Solution, 10.000 ppm
- Chlorine Dioxide Solution, 1000 ppm
- Chlorine Releasing Solution, 1000 ppm
- Clinell Alcohol Wipes
- Clinell Sporicidal Wipe
- Clinell Universal Spray
- Cavi Cide Surface Decontaminant Cleaner
- Cavi wipes
- Descosept PUR Wipes RTU
- Dismozon® plus
- Ecopine, (5% Solution in Water)
- Incidin Foam & Incidin Plus
- Incidin OxyFoam S
- Incidin OxyWipes
- Incidin Pro
- Isopropyl Alcohol, %70
- Kohrsolin FF
- Life Clean
- Meliseptol Rapid
- Microbac Forte
- Mikrozid AF Liquid
- Mikrozid Sensitive Liquid
- Mikrozid Sensitive wipes
- Oxivir Plus
- Perform 1% and 3%
- Phenol Solution, %1
- PDI Sani Cloth AF3 Wipes
- Pursept AF
- Rely+ON Perasafe
- Rely+ON Virkon
- Sani-Cloth Active
- Spray Off
- Sterisept wipes
- Super Sani Cloth Germicidal Disposable Wipe
- Terralin® protect (max. 4%)
- TPH Protect • ULTRASOL® active
- Virusolve (5% & 10% Solution in Water)
- Wet Wipe

Note: After using cleaning agents containing chlorine, it is recommended to clean the surfaces with a damp cloth, because chlorine can damage the surface of the cover fabric of the product during long-term use and make it more sensitive to mechanical damage.

**CAUTION: Cleaning and disinfection products that are not recommended for use:**

- Disclean ENDO PAA (Peracetic Acid Solution).
- PDI Sani-Cloth Bleach Germicidal Disposable Wipe.
- Peracetic Acid.

This list is not exhaustive. Strictly follow and do not exceed the concentrations provided in the instructions.

Re-issuing to Another User

When one person stops using a product and it will be reissued to someone else, it must be cleaned and checked carefully first.

Follow these steps:

- Wash and disinfect the product (see instructions above) before anyone else uses it.
- Spex suggests using AHP disinfectant wipes (Accelerated Hydrogen Peroxide). Always follow the instructions on the disinfectant label.
- Inspect the products seams, fabric, and filter (hygiene range) for damage or holes. Replace any parts with holes or damaged fabric.

Storage



CAUTION: Hygiene products: do not bend the cushion; this might damage the PneumaPure® filter

- Do not place weights on the cushion
- Store in a dry room at a temperature of +10...+30 °C.

Disposal and Recycling

Follow all local laws and regulations when disposing of your cushion.

Warranty

We guarantee that your SleepShape Cushions will be free from defects in materials and workmanship for a period of 24 months from the date of purchase, assuming normal use.

Should a defect in materials or workmanship occur within 24 months from the original date of purchase, Spex will, at its discretion, provide a free repair or replacement. This warranty applies to all components.

Please note that this warranty does not cover general wear and tear, such as punctures, tears, burns, or customer misuse of any cushion.

Claims and repairs should be processed through the nearest authorized Spex supplier. Except for express warranties made herein, all other warranties, including implied warranties of merchantability and warranties of fitness for a particular purpose are excluded. There are no warranties which extend beyond the description on the face hereof. Remedies for breach of express warranties herein are limited to repair or replacement of the goods. In no event shall damages for breach of any warranty include any consequential damages or exceed the cost of non-conforming goods sold.

The serial number of your SleepShape cushion can be located on the care label attached to the cushion.



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