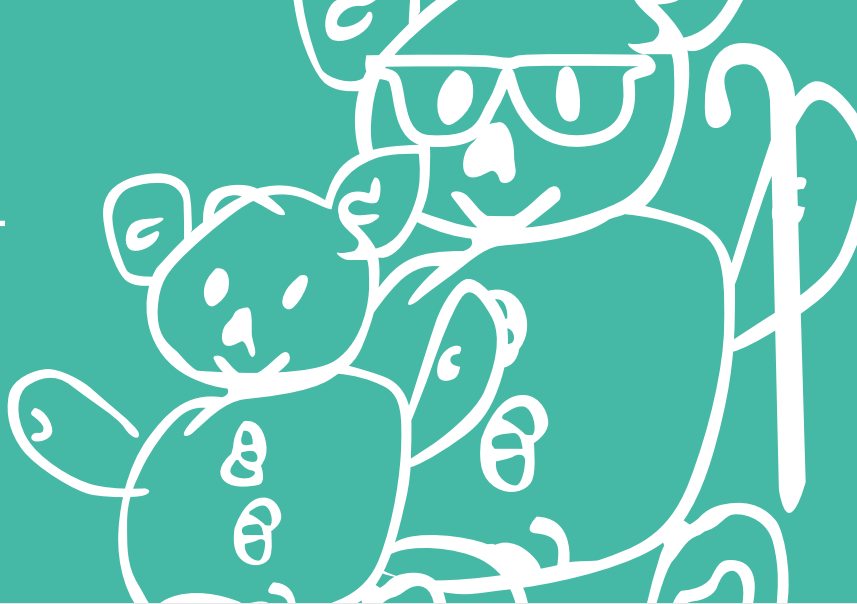


Fibre wedge

INSTRUCTIONS FOR USE



MANUFACTURED BY SIMPLE STUFF WORKS ASSOCIATES



PLEASE NOTE

It is unsafe to assemble and use the equipment without **fully reading** the instructions

1. User Assistance

If you are experiencing problems with any part of your sleep system, refer to troubleshooting section and the online video.

If you cannot find the answer contact us:

UK Telephone number : **01827 307870**

USA Telephone number : **1-888-213-8416**

Support Email : **admin@simplestuffworks.co.uk**

Simple Stuff Works

UK

Simple Stuff Works Associates Ltd
Units 4 and 5, Cavendish
Tamworth
Staffs
B79 7XH

USA

Simple Stuff Works Inc.
One Commerce Centre,
1201 Orange St #600,
Wilmington,
New Castle,
Zip Code 19899
USA

Product Info

The product in this specific manual is the **Fibre Wedge** as part of **Mattress Flotation Therapy**

Product code : **IKY**

Device listing number : **D258510**

Proprietary Name : **Non-powered Sleep System**

Regulation Description : **Non-powered flotation therapy mattress**

Other Useful Contacts

Please fill in accordingly:

Home medical equipment supplier :

Home healthcare agency :

Doctor :

2. Table of Contents

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3. Warnings and Cautions

A warning is a statement that alerts users to the possibility of injury, death or other serious adverse reactions.

! WARNING

The fibre wedge is not to be eaten or placed in any orifice

1. This could result in harm to the individual.
2. If this is considered a risk then an alternative is to be sought from the registered health professional.

! WARNING

The wedge and sheets should not be exposed to heat, for example, a naked flame.

1. This could result in burns to the individual and damage to the product.
2. Establish and remove the source of the heat.
3. If this is considered a risk then an alternative is to be sought from the registered health professional.

A caution is a statement that alerts users about the possibility of a problem associated with use.

! CAUTION

Only use Simple Stuff Works components and accessories

1. Any unauthorized use of the system may put the patient and the care giver at risk.
2. Failure to follow these instructions will invalidate the warranty.

Warnings and Cautions

A caution is a statement that alerts users about the possibility of a problem associated with use.

! CAUTION

The fibre wedge and sheets should be free of objects and creases.

1. Any objects trapped in the fibre wedge, between, underneath or on top of the sheets will be a potential risk for pressure ulcer development.
2. Any creases in the sheets will be a potential risk for pressure ulcer development.
3. The user to smooth the sheets to check for unwanted objects and creases.

! CAUTION

The equipment poses an infection control risk if used between patients.

1. Ensure the correct local infection control measures are taken if redistributing to other patients.

! CAUTION

Cleaning care and maintenance instructions should be followed at all times.

1. Not following the instructions will result in damage to the fibre wedges, placing the patient at risk.
2. Fully read the accompanying cleaning and care document.
3. Do not use the fibre wedges if damage does occur and consult your registered health professional.

! CAUTION

In hot environmental temperatures pooling of body moisture can occur under the sheets as moisture is wicked away from the body.

1. An absorbent material such as an incontinence sheet should be placed under the sheets to absorb the excess moisture.
2. The care giver should continue to monitor the skin.

Warnings and Cautions

A caution is a statement that alerts users about the possibility of a problem associated with use.

! CAUTION

The equipment should only be used for the patient it was ordered for and for its intended use.

1. This could result in pain and deformity to the unintended patient.
2. Do not give any unused systems or part of to another patient, a risk assessment by a registered health professional will be required to determine the suitability of any equipment.

! CAUTION

The fibre wedges should **ONLY** be used on a foam mattress with the stabilizing mesh base system.

1. The sheets cannot be used in conjunction with a low air loss or airflow mattress.
2. Any layer between the patient and this type of mattress has been known to increase the risk of pressure ulcers.
3. Always adhere to the manufacturers guidelines.

4. Purpose of the Device

- The soft fibre wedge increases the patient's base of support - this can spread the load and reduce the tone. It is preferable to use a soft fibre wedge to support the patient, in a therapeutic manner. The fibre wedge counters the forces acting on the patient's body.
- Other supports will be chosen, where forces acting on the body are stronger.
- The wedges will be used at different points of the body such as the pelvis, ribcage, head. This will have the effect of maintaining the body's position or improving it.
- The intended purpose of the sleep system is therapeutic positioning in the lying posture, it is a gentle therapy used by people with movement difficulties. When used correctly it may help protect and restore an individual's body shape.

- The Simple Stuff Works positioning system has no Velcro or screw action fixings so silent changes of position can be made with little disruption to the person whilst in bed.
- The positioning and use of the fibre wedges and any accessories should be determined by an appropriately qualified and registered professional.

5. Description of the device

This is the fibre wedge it is tapered at one end to allow it to be positioned close to the person. It is made of specialised fibre material that wicks sweat away from the body. It can be used between the base layers of mesh.

See figure 1.

The wedge is positioned between two layers of mesh alongside the patient's body. The wedge can be used to support the patient in a variety of assessed positions including, supine and side lying. The positioning of the wedge should be assessed by a registered health professional.



Figure 1

6. Environmental conditions that affect use

- The properties of the system naturally wicks moisture away from the body. This may result in moisture pooling on the mattress underneath the base layers.
- In hot environmental conditions use an incontinence sheet underneath the base layers, this will absorb any moisture that is wicked away from the body.
- After moving the patient, check for objects or creases.
- If the wedge moves by the patient's body movements, reposition and consider if another type of support is required.
- Remove any objects and smooth creases.
- To transport the equipment place all parts into a bag to ensure all the parts stay together.
- After unpacking check all parts are present and intact.



Conditions under which the device should and should not be used

- The soft fibre wedge should only be used in conjunction with a foam base mattress.
- The stabilizing mesh base system should only be used in conjunction with a foam base mattress.
- The soft fibre wedges should not be used in conjunction with low air loss or airflow mattresses. If in any doubt consult the mattress manufacturer's guidelines.
- The stabilizing mesh based system should not be used in conjunction with low air loss or airflow mattresses. If in any doubt consult the mattress manufacturer's guidelines.

7. Set up instructions of the device

List of parts

1. Soft fibre wedge
2. Appropriate mesh base system
3. Cotton sheet

No tools required for set up

Device placement

1. The mesh bottom sheet is placed over the foam mattress of the bed.
2. The flat top sheet is placed on top of the mesh sheet base sheet.
3. Place the fibre wedges in between these two layers at the appropriately determined therapeutic positions. This will have been decided by a registered healthcare professional.

! CAUTION

The soft fibre wedge may not hold the patient's body in position.

1. Contact your registered health professional if the patient's condition has changed.
2. Contact your supplier for a reassessment, a firmer support may be required.

! CAUTION

The mattress and sheets should be free of objects and creases.

1. Any objects trapped between, underneath or on top of the sheets will be a potential risk for pressure ulcer development.
2. Any creases in the sheets will be a potential risk for pressure ulcer development.
3. The user to smooth the sheets to check for unwanted objects and creases.

! CAUTION

The soft fibre wedges should **ONLY** be used on a foam mattress.

1. The fibre wedges cannot be used in conjunction with a low air loss or airflow mattress.
2. Any layer between the patient and this type of mattress has been known to increase the risk of pressure ulcers.
3. Always adhere to the manufacturers guidelines.

4. The care giver to ensure that there are no creases or objects, on top of, below or in-between in the sheets.
5. The system is designed to be removed for cleaning and then replaced

For assistance with set up issues refer to the corresponding video and to page 1 for our contact details.

8. Check out procedures

Check with every use or daily

- Ensure the fibre wedge and sheets are intact and contact your supplier for a replacement and advice if required.
- Prior to each use visually check and ensure the sheets are free from objects and creases.
- Smooth out any creases and remove objects from the sheets.

For assistance with set up issues refer to the corresponding video and to page 1 for our contact details.

9. Operating instructions of the device

! CAUTION

The fibre wedge mattress and sheets should be free of objects and creases.

1. Any objects trapped in the fibre wedge, between, underneath or on top of the sheets will be a potential risk for pressure ulcer development.
2. Any creases in the sheets will be a potential risk for pressure ulcer development.
3. The user to smooth the sheets to check for unwanted objects and creases.

! CAUTION

The fibre wedges and sheets should **ONLY** be used on a foam mattress.

1. The fibre wedges cannot be used in conjunction with a low air loss or airflow mattress.
2. Any layer between the patient and this type of mattress has been known to increase the risk of pressure ulcers.
3. Always adhere to the manufacturers guidelines.

! CAUTION

The fibre wedge may not hold the patient's body in position.

1. Contact your registered health professional if the patient's condition has changed.
2. Contact your supplier for a reassessment, a firmer support may be required.

1. This is the fibre wedge. Its shape is tapered at one side to allow it to be positioned close to the patient. It is made out of specialised fibre that wicks moisture away from the body.



2. The wedge is to be used between the base layers of mesh.



3. Here is the typical position of the wedge, it is shown on top of the sheet prior to positioning it between the mesh layers. The position is at the side of the chest.



Fibre wedge

INSTRUCTIONS FOR USE

4. In this instance the longest side of the wedge is against the person's body and their arm will be around the tapered section



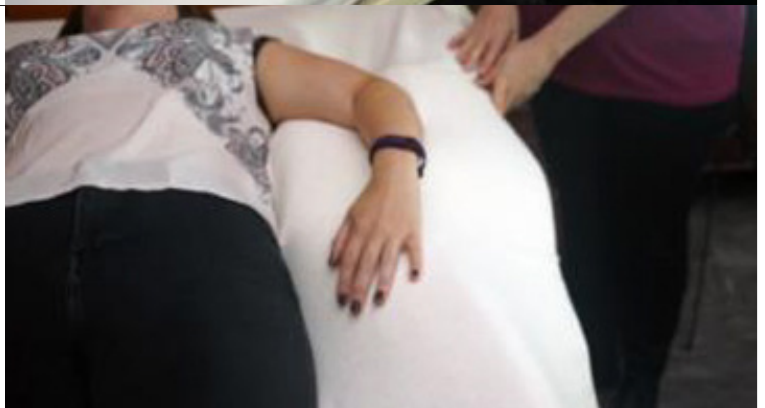
5. . Lifting the cotton sheet, the topper and the top mesh sheet allows the care giver access to position the wedge. The exact positioning of the wedge should always be determined by the appropriately qualified and registered health professional.



6. To secure the wedge into position tuck the cotton sheet under the mattress.



7. Position the patient's limb as advised by the qualified and registered health professional.



Fibre wedge

INSTRUCTIONS FOR USE

8. Another example of how the wedge may be used if advised by the appropriately qualified and registered health professional. In this example the neck pillow and the fibre wedge is supporting the head and neck whilst the patient is in supine.



9. To secure the wedge into position tuck the cotton sheet under the mattress.








It is advised the care giver seeks training and guidance in the field of manual handling. This is not covered within this guide.

10. Cleaning instructions

The fibre wedge is a fully washable product.

- How often should the fibre wedge be washed- On soiling and enough to keep clean and fresh.
- Only NON bleaching household washing powder can be used to wash the fibre wedge.
- The fibre wedge should not be washed above forty degrees Celsius, **<40C**.
- The fibre wedge should fit into a standard house hold washing machine drum, **not** a top loader and should be spun on a **slow spin cycle**, 800 revs or less.
- The fibre wedge can be air dried and tumble dried on low heat.

| | | |
|--|--|---|
| 1. Washing the system whole. Adhere to the manufacturer's instructions at all times. | PRODUCT | SYMBOLS |
| | Fibre wedges |     |
| | WHAT DO THEY MEAN? | TEMPERATURE |
| | <ul style="list-style-type: none"> • Wash at maximum 40 degrees • <u>The line underneath 40° indicates a slower spin cycle is required</u> • Do not bleach • Do not iron • Tumble dry on low heat | <p style="text-align: center;">40°C Maximum</p> |
| 2. Insert the fibre wedge directly into the washing machine. Add non bleaching washing powder and set the washing machine as per instructions. |  | |
| 3. Remove from the washing machine, allow the whole product to air dry or tumble dry on a low heat. | | |

11. Maintenance instructions

- Check that the seams are intact before use visually inspect.
- Check that the integrity of the fibre wedge has not been comprised.
- Check before every use that there are no objects that are within the fibre wedge, between, on top of or underneath the base system.
- If pooling of moisture occurs ensure that an incontinence pad is placed on the base of the mattress to absorb excess moisture.

12. Storage of the device

1. The system will deteriorate if stored in wet or damp conditions.
2. It should be stored in a room above freezing but below 90 degrees Fahrenheit. For extended storage then you need to store in plastic, sealed containers.

13. Troubleshooting section

The healthcare professional emergency assistance service should be contacted immediately if the troubleshooting reveals a patient health problem rather than a device problem.

Any adverse events should be reported using the contact information on page 1

| Anticipated problems | Solution to the problem |
|---|--|
| 1. During very hot environmental conditions there may be pools of sweat found on the mattress. This is due to the fabric wicking moisture away from the body. | 1. Place an incontinence sheet underneath the fitted base sheet. This will collect excessive moisture. Monitor the patient's skin condition when using this. |
| 2. The development of a pressure point, due to a crease in the material. | 2. Ensure that the fitted base sheet and the flat top sheet are free from creases. |
| 3. The development of a pressure point, due to an object under or between the sheets. | 3. Ensure that the fibre wedges and base layers are free from any objects. |
| 4. If the material gets damaged due to washing at temperature exceeding 40 degrees. | 4. Comply with the washing, drying and care of instructions of the fibre wedge. Contact your supplier for a replacement see page 1. |
| 5. If the material gets damaged or torn. | 5. Comply with the washing, drying and care of instructions of the fibre wedge. Contact your supplier for a replacement see page 1. |
| 6. The patient's body may not be adequately supported by a soft fibre wedge as the patient's condition may have changed. | 6. Ensure the wedge is positioned between the mesh sheets and secured in place. Contact the qualified registered health professional for a reassessment of the patient's needs. A different type of support may be required. If the patient's condition has changed also consult with their doctor. |

14. Summary page

This is not to replace the complete user's instructions and the entire manual should be read prior to using the device.

- The soft fibre wedge increases the patient's base of support. This can spread the load and reduce tone. It is preferable to use a soft fibre wedge to support the patient, in a therapeutic manner. The fibre wedge counters the forces acting on the patient's body..
- Other supports will be chosen, where forces acting on the body are stronger.
- The wedges will be used at different points of the body such as the pelvis, ribcage, head. This will have the effect of maintaining the body's position or improving it.
- The intended purpose of the sleep system is therapeutic positioning in the lying posture, it is a gentle therapy used by people with movement difficulties. When used correctly it may help protect and restore an individual's body shape.
- The additional base layers used to secure support consist of stabilizing mesh, breathable topper and a stretch cotton sheet. The positioning and use of any accessories should be determined by an appropriately qualified and registered professional.

! CAUTION

The fibre wedge, mattress and sheets should be free of objects and creases.

1. Any objects trapped between, underneath, or on top of the sheets will be a potential risk for pressure ulcer development.
2. Any creases in the sheets will be a potential risk for pressure ulcer development.
3. The user to smooth the sheets to check for unwanted objects and creases.

! CAUTION

Only use Simple Stuff Works components and accessories

1. Any unauthorized use of the system may put the patient and the care giver at risk.
2. Failure to follow these instructions will invalidate the warranty.

! CAUTION

The soft fibre wedges and sheets should **ONLY** be used on a foam mattress.

1. The fibre wedges cannot be used in conjunction with a low air loss or airflow mattress.
2. Any layer between the patient and this type of mattress has been known to increase the risk of pressure ulcers.
3. Always adhere to the manufacturers guidelines.

Contact phone number for assistance – please fill accordingly _____

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16. Date of writing the manual

October 2016

17. Accessories

All accessories that can be used have their individualized manuals and instructions, they are listed below. Individual manual to be fully read and understood. Not all of the accessories below will be considered suitable or appropriate, this will be determined by the registered health professional.

| | |
|--|-----------------------------------|
| 1. Mattress topper | 8. Foot supports |
| 2. Fitted cotton sheet | 9. Horseshoe pillow |
| 3. Flat cotton sheet | 10. Neck pillow |
| 4. Stabilizing flat mesh base system | 11. Sausage pillow |
| 5. Stabilizing fitted mesh base system | 12. Temperature regulating pillow |
| 6. Lateral supports and padded wedges | 13. Supine stabilizer |
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