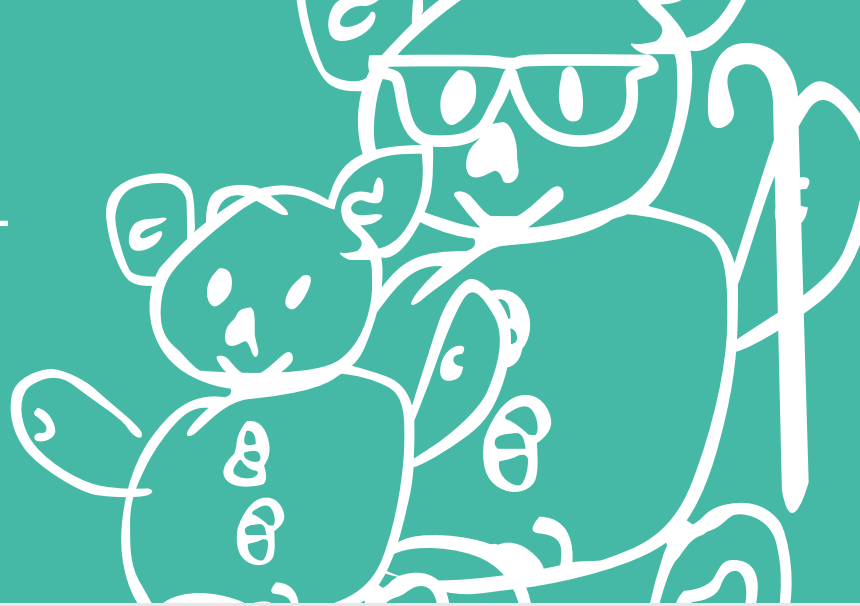


Plastazote Wedge

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

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USA

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Product Info

The product in this specific manual is the **Plastazote 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 :

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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 Plastazote 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 Plastazote 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.

! CAUTION

The Plastazote wedges, should be free of objects and creases.

1. Any objects trapped in the Plastazote 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.

Warnings and Cautions

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

! CAUTION

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

1. Not following the instructions will result in damage to the Plastazote wedge, placing the patient at risk.
2. Fully read the accompanying cleaning and care document.
3. Do not use the Plastazote wedge 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.

! 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 Plastazote Wedges should **ONLY** be used on a foam mattress with the stabilizing mesh based 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 Plastazote Wedge increases the patient's base of support-this can spread the load and reduce tone. The Plastazote Wedge counters the forces acting on the patient's body and is generally chosen should firmer support be required.
- Other supports will be chosen, where forces acting on the body are weaker.
- The Plastazote Wedge will be used at different points of the body. 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 Plastazote Wedges and any accessories should be determined by an appropriately qualified and registered professional.

5. Description of the device

This is the Plastazote Wedge it is tapered at one end to allow it to be positioned close to the person. It is made of specialised plastazote material that is waterproof. It should be used between the base layers of mesh.

See figure 1.

The Plastazote Wedge is positioned between 2 layers of mesh alongside the patient's body. The Plastazote 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.

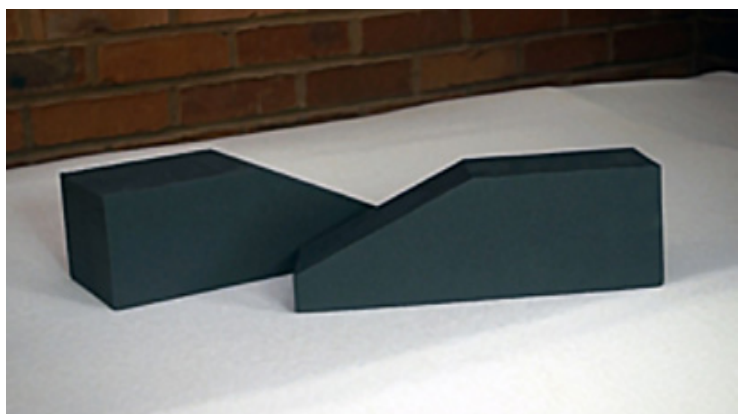


Figure 1

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 Plastazote 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 Plastazote Wedges should not be used in conjunction with low air loss or Airflo mattresses as they will not stay in place. If in any doubt consult the mattress manufacturer's guidelines.

7. Set up instructions of the device

List of parts

1. Plastazote wedge
2. Appropriate mesh base system
3. Cotton sheet
4. Appropriate other support if required

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.

! CAUTION

The Plastazote Wedge and mesh sheets should **ONLY** be used on a foam mattress.

1. The use of 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.

! CAUTION

The Plastazote 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, an additional support may be required.

3. The care giver is to ensure that there are no creases or objects, on top of, below or in-between in the sheets or Plastazote Wedges

4. Place the Plastazote Wedge in between these two layers at the appropriately determined therapeutic positions. This will have been decided by a registered healthcare professional.

5. The Plastazote Wedge 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 Plastazote Wedge and sheets are intact and contact your supplier for a replacement and advice if required.
- Prior to each use visually check and feel the Plastazote Wedges and sheets are free from objects and creases.

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 Plastazote Wedge, mattress and sheets should be free of objects and creases.

1. Any objects on the Plastazote Wedge, 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 Plastazote Wedges and sheets should **ONLY** be used on a foam mattress.

1. The Plastazote Wedges and 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.

! CAUTION

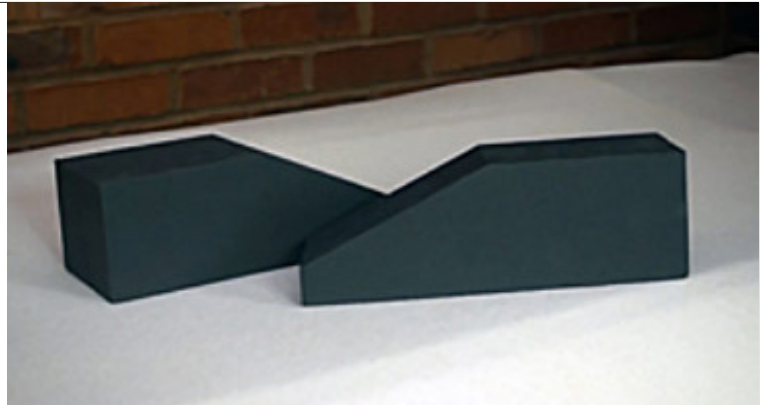
The Plastazote Wedge may not hold the patient's body in position.

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

Plastazote Wedge

INSTRUCTIONS FOR USE

1. This is the Plastazote Wedge. Its shape is tapered at one side to allow it to be positioned close to the patient. It is made out of specialised plastazote that is waterproof.



2. 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.



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



4. 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 qualified registered health professional.



5. To secure the Plastazote Wedge into position tuck the cotton sheet under the mattress.



6. Position the patient's limbs as advised by the qualified and registered health professional.



7. Another example of how the Plastazote Wedge may be used if advised by the appropriately qualified and registered health professional.



8. Placing the Plastazote Wedge into position between the mesh sheets



Plastazote Wedge

INSTRUCTIONS FOR USE

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 Plastazote Wedge is a washable product.

- How often should the Plastazote 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 or mild household detergent and warm water.
- The Plastazote Wedge should not be washed above forty degrees Celsius, **<40C**.
- The Plastazote Wedge may 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 Plastazote Wedge should be air dried. Do **NOT** tumble dry.

A / Washing the Plastazote Wedge in the washing machine

1. Adhere to the manufacturer's instructions at all times.	PRODUCT	SYMBOLS
	Plastazote Wedge	
	WHAT DO THEY MEAN?	TEMPERATURE
	<ul style="list-style-type: none"> • Wash at maximum 60 degrees • <u>The line underneath 60° indicates a slower spin cycle is required</u> • Do not bleach • Do not iron • Do not tumble dry 	<p>60°C Maximum</p>
2. Insert the Plastazote 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		

B / Washing the Plastazote Wedge in warm soapy water

1. Adhere to the manufacturer's instructions at all times.	PRODUCT	SYMBOLS
	Plastazote Wedge	   
	WHAT DO THEY MEAN?	TEMPERATURE
	<ul style="list-style-type: none"> • Wash at maximum 60 degrees • <u>The line underneath 60° indicates a slower spin cycle is required</u> • Do not bleach • Do not iron • Do not tumble dry 	<p>60°C Maximum</p>
2. Wash the Plastazote Wedge in warm soapy water and rinse the soap off the wedge..		
3. The Plastazote Wedge is to be air dried		

11. Maintenance instructions

- Check that the wedge is intact before use visually inspect.
- Check that the integrity of the Plastazote Wedge has not been comprised.
- Check before every use that there are no objects that are within the Plastazote 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 base layers are free from creases.
3. The development of a pressure point, due to an object on the Plastazote Wedge, on top, under or between the sheets.	3. Ensure that the Plastazote Wedge, fitted base sheet and the flat top sheet are free from any objects.
4. If the plastazote gets damaged due to washing at temperature exceeding 40 degrees.	4. Comply with the washing, drying and care of instructions of the Plastazote 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 Plastazote Wedge. Contact your supplier for a replacement see page 1.
6. The patient's body may not be adequately supported by a Plastazote Wedge as the patient's condition may have change.	6. Ensure the Plastazote 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.
7. The person may lie on the Plastazote Wedge, this could create a pressure point and develop into a pressure ulcer if undetected.	7. Check the positioning of the Plastazote Wedge when positioning the individual in the bed. Always position the Plastazote Wedge after the person is positioned in bed. Periodically check for movement of the patient in relation to the wedge.

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 Plastazote Wedge increases the patient's base of support. This can spread the load and reduce tone. It is preferable to use a Plastazote Wedge to provide firm support to the patient, in a therapeutic manner.
- The Plastazote Wedge counters the forces acting on the patient's body.
- Other supports may be used in addition to the Plastazote Wedge, where forces acting on the body are stronger.
- The wedges will be used at different points of the body. 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 Plastazote Wedge, mattress and sheets should be free of objects and creases.

1. Any objects on the Plastazote wedge, 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 Plastazote Wedge and sheets should **ONLY** be used on a foam mattress.

1. The use of 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.

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. Fibre Wedges	11. Sausage Pillow
5. Stabilizing Flat Mesh Base System	12. Temperature Regulating Pillow
6. Stabilizing Fitted Mesh Base System	13. Supine Stabilizer
7. Lateral Supports and Padded Covers	14. Side Lying Leg Support