



Sleepform

User Manual



Supporting
Children



Sleepform supports a child in a symmetric posture while they are asleep and can be used reduce the build-up of pressure points, thus increasing comfort and the likelihood of an undisturbed night's sleep for both them and their family. It can be easily transported so is ideal for use at home, holiday or respite facilities and plays an important part in 24 hour postural management.

- 1** 0-1 YEARS - COT
- 2** 1-5 YEARS - COT
- 3** 1-5 YEARS - SINGLE BED
- 4** 5-18 YEARS - SINGLE BED

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SECTION 01: INTENDED USE

Intended Use

The Leckey Sleepform system is intended to help prevent the long-term implications of poor sleep postures.

Indications for use

The Leckey Sleepform system is designed to support the needs of children with a variety of disabilities which affect their ability to sleep in a desirable posture/position. It is indicated for use primarily within an indoor home environment. There are four sizes, with a maximum user weight of 19kg/42lbs (sizes 1 & 2) and 76kg/167.2lbs (sizes 3 & 4).

The postural support offered by the Sleepform system is indicated for use for children with moderate to complex needs [GMFCS III-V].

SECTION 02: DECLARATION OF CONFORMITY

The Sleepform is classified as a Class I Medical Device under EU and UK regulations. James Leckey Design Ltd as manufacturer with sole responsibility declares that the Leckey Sleepform conforms to the requirements of the 93/42/EEC Guidelines, Medical Device Regulations 2017, UK Medical Devices Regulation 2002 and EN 12182 Technical aids for disabled persons and test methods.



Notice to the user and/or

patient: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

SECTION 03: WARNING AND CAUTIONS

WARNING SUFFOCATION HAZARD

Always place the breathable mattress on top of the mouldable base as the PVC material in the base is not breathable and could present a suffocation hazard to the user.

WARNING OCCUPANT SECURITY

The Leckey Sleepform system is intended to encourage postural positioning only. Children at risk of falling out of bed should always be reliant on 3rd party bedframe designs.

WARNING SUDDEN INFANT DEATH SYNDROME (SIDS)

The use of sleep positioning devices with children under the age of 1 is not recommended unless deemed safe and a necessity by a qualified and experienced health professional and a risk assessment has been carried out. For more advice related to SIDS, refer to external resources such as the lullabytrust.org.uk or other reputable online resources, your health visitor, paediatrician] or GP.

CAUTION INFLATION

As with all valves, over time the valve will allow inflation of the mouldable base and result in reduced levels of support. The mouldable base should be checked daily and air extracted at least once per week.

CAUTION DAILY CHECKS

The Sleepform system should be checked daily before use to ensure it is adequately deflated and all additional supports and accessories are securely fitted.

CAUTION CLEANING

Clean the product regularly in accordance with the cleaning instructions outlined in this document. Do not use abrasive cleaners. Carry out maintenance checks on a regular basis to ensure your product is in good working condition.

SECTION 04: TERMS OF WARRANTY

The warranty applies only when the product is used according to the specified conditions and for the intended purposes, following all manufacturers' recommendations [also see general terms of sales, delivery and payment on our website (<https://www.leckey.com/terms-and-conditions-of-sale>). A three-year warranty is provided on all Leckey manufactured products and components.

SECTION 5: PRODUCT HISTORY RECORD

Your Leckey product is a medical device and should only be prescribed, set up or reissued for use by a technically competent person who has been trained in the use of this product. Leckey recommend that a written record is maintained to provide details of all setups, reissue inspections and annual inspections of this product.

SECTION 6: PRODUCT TRAINING RECORD

(PARENTS, TEACHERS & CARERS)

Your Leckey product is a prescribed Class 1 medical device and Leckey recommend that parents, teachers and carers using the equipment should be made aware of the following sections of this user manual by a technically competent person:

- **SECTION 7** Safety Information
- **SECTION 9** Configuring the Sleepform System
- **SECTION 10** Cleaning and Care
- **SECTION 11** Daily Product Inspection

Leckey recommend that a written record is maintained of all those who have been trained in the correct use of this product.

SECTION 7: SAFETY INFORMATION

- 7.1** Always read instructions fully before use.
- 7.2** Ensure that you have carried out an in-depth risk assessment before issuing the Sleepform system to your client.
- 7.3** Always place the breathable mattress on top of the mouldable base as the PVC material in the base is not breathable and could present a suffocation hazard to the user.
- 7.4** Ensure parents and carers are clear about any potential hazards identified during the risk assessment.
- 7.5** Only use Leckey approved components with your product. Never modify the product in any way. Failure to follow instructions may put the user or carer at risk and will invalidate the warranty on the product.
- 7.6** If in any doubt to the safe use of your Leckey product or if any parts should fail, please cease using the product and contact our customer services department or your local dealer as soon as possible.
- 7.7** Leckey products comply product conforms to the Medical Device Regulation (2017/745), UK Medical Device Regulations 2002, Medical Device Directive [93/42EEC] and EN 12182:2012 Assistive products for persons with disability, general requirements and test methods.
- 7.8** Clean the product regularly in accordance with our cleaning instructions outlined in this document. Do not use abrasive cleaners. Carry out maintenance checks on a regular basis to ensure your product is in good working condition.
- 7.9** The product is designed for domestic indoor use and when not in use should be stored in a dry place that is not subject to extremes of temperature. The safe operating temperature range is +5°C to +40°C.

SECTION 8: PRECAUTIONS AND CONTRAINDICATIONS

Precautions

- Children under the age of 1 year
- Fixed spinal deformities such as scoliosis or kyphosis
- Severe muscle contractures
- Severe muscular or skeletal asymmetry including hip dislocation
- Progressive and muscle wasting conditions
- High risk or recent history of bone fractures
- High risk of pressure related injury or open sores
- Strong, uncontrolled movement patterns
- Poorly controlled seizure activity
- Children dependent on the use of percutaneous endoscopic gastrostomy
- Medical instability including compromised respiratory or cardiovascular function
- Dependant on 3rd party life-sustaining apparatus such as oxygen tanks
- Significant learning disabilities and/or behavioural issues

Contraindications

There are no contraindications associated with the Leckey Sleepform product.

All precautions and contraindications are taken at the discretion of the prescribing clinician. Leckey recommends a trained and experienced clinician to be present during the initial assessment, set up, configuration and re-issue to minimise risk.

SECTION 9: CONFIGURING THE SLEEPFORM SYSTEM

Parents and carers should be shown how to make frequent adjustments and be made aware of the safety checks in Section 7 by a technically and clinically competent person who has been trained in the use of the product. Leckey recommend that a written record is maintained of all parents and carers who have been trained in the use of this product.

The Sleepform system consists of a core: a mouldable base and breathable mattress, and optional supports to help create the desired supported sleep position for the child.

Additionally, there are accessories to help with incontinence and temperature regulation.

SLEEPFORM COMPONENTS

Core

Mouldable base



Pump



Breathable mattress



Optional Supports

Cushioned hip/chest guides and under bed mattress straps



Breathable knee pillow
(mainly used in side-lying)



Knee roll



Cushioned leg/knee guides and under bed
mattress straps



Accessories

- Temperature control sheet
- Waterproof mattress protector



Note: The particular components chosen will determine how the Sleepform system is set-up

Scenario 1 (Core without optional supports)

1. Mould with child lying on mouldable base
2. Take child out
3. Place the breathable mattress on top of the mouldable base
4. Place accessories on top of the breathable mattress (Temperature control sheet, then waterproof mattress protector)
5. Place standard bedsheet on top
6. Reassess to ensure child is comfortable and well positioned

Scenario 2 (Core with optional supports)

1. Position under bed mattress straps
2. Buckle chest/hip and leg/knee guides on top of mouldable base
3. Mould with child lying on base and using chest/hip and knee/leg guides
4. Take child out
5. Unbuckle and remove guides but leave under bed mattress straps in place
6. Place breathable mattress on top of base
7. Place accessories on top (Temperature control sheet, then waterproof mattress protector)
8. Place standard bedsheet on top
9. Position and re-buckle hip/chest and leg/knee guides
10. Position knee pillow or roll if using
11. Reassess to ensure child is comfortable and well positioned

Core

Mouldable base & Pump

The mouldable base contains beads which will form and retain a unique shape when air is extracted using the pump provided. The mouldable base is the core element to provide support to the child.

Orientation

The mouldable base is designed in a 'U' shape with one end having more beads - this is the end which the valve is attached to.

The mouldable base should always be placed in the middle of the bed with the channel in the middle, either at the top or bottom.



U-shape facing downwards to support head & trunk positioning

To provide increased support at the lower limbs, the U-Shape should be positioned upwards. Alternatively, to focus on head or trunk positioning, position the U-shape downwards.



U-shape facing upwards to support lower limb positioning

Deflation

Attach nozzle



Open the valve



Extract air



Close valve



To extract air from the mouldable base use the hand pump. The slower you pull on the handle, the quieter it will be. As you extract air you will feel the base become less flexible. It can be easier to mould if you have extracted a small amount of air first.

When you have finished moulding the base and extracting the air, close the valve before removing the nozzle.

We recommend you check the mouldable base daily and remove air at least once per week if you find it is getting soft.

Inflation

To allow air into the base for remoulding, simply open the valve with the pump nozzle detached.

OPTIONAL: If Attaching hip/chest or leg/knee guides

To prevent the hip/chest or leg/knee straps compressing the mouldable base it is advised that these parts are attached over the base during initial moulding. This creates a channel in the moulding for the belts. They can then be removed and placed over the top of the sheet for subsequent attachment to the child.

Correct usage



Incorrect usage



First, place the long strap(s) underneath the bed's mattress positioned roughly underneath the desired area of use. Knowing your child's dimensions beforehand is beneficial.



Then when the underside straps are positioned as desired, attach the Hip/chest and Knee/Leg supports to the receiving ends.

Next mould the mouldable base to the desired shape whilst creating small channels in the mouldable base for each of the straps to fall into.

Following this, unbuckle the Chest/Hip and Knee/Leg supports from the receiving end. These straps will be reattached when the remainder of the Sleepform system has been configured.

Breathable Mattress



WARNING: The breathable mattress must always be used when using the mouldable base. This is because the mouldable base is an air-tight support and could present as a risk of suffocation to the child.

The breathable mattress is an open celled structure that provides a comfortable pressure relieving support where air can flow freely and prevent heat and moisture build up. The breathable mattress is always used over the mouldable base.

OPTIONAL: If using the temperature control sheet AND/OR waterproof mattress protector

The temperature control is a technical fabric which has been designed to help regulate body temperature. The unique wax cells absorb heat and keep the child cool. They also store heat and keep you warm if you get too cold. Simply place the cool sheet on top of the breathable mattress. If an incontinency sheet is being used it is best to place the cool sheet under this to help prevent soiling.

Finally, fit a standard sheet over the breathable mattress. For a single bed you may have to use a double bed size sheet and for a cot you may need to use a single bed size sheet – this will depend on the components being used.

Placing a child into the configured Sleepform

Place your child back onto the bed. Make sure the mouldable base is not moulded too tightly around your child. If it is too tight you may have to open the valve and allow some air into the base again. Always remember to extract the air again once the desired shape has been achieved. Finally close the valve and remove the pump.

If using any of the chest/hip or knee/leg supports, these can now be reattached to the receiving buckles beneath the mattress.

Similarly, if the knee roll or knee pillow are to be used, these can now be placed at your child's legs.



Note: The knee roll and knee pillow ARE NOT attached to any strap OR buckle.

SECTION 10: CLEANING AND CARE INFORMATION

Leg/Knee Guides and Chest/Hip Guides

The whole component can be placed in the washing machine and washed at 40 degrees Celsius.

Breathable Knee Pillow, Breathable Mattress, Knee Rolls

The outer covers can be zipped off and machined washed at 40 degrees Celsius. The special fibre of the breathable mattress, knee pillow and knee roll can be rinsed clean under a tap/showerhead and air dried. These will dry extremely quickly. Additional or replacement covers are available.

Mouldable base

Wipe clean with soap and warm water. Allow the pillow to dry completely before storing it. If necessary to disinfect, wipe the complete pillow with a solution containing 70% alcohol. If your child occasionally soils the bed, we recommend you use a waterproof and breathable under sheet.

Temperature Control Sheet

The temperature control sheet can be machine washed at 60 degrees Celsius.

SECTION 11: DAILY PRODUCT INSPECTION

We recommend that daily visual checks of the equipment are carried out by therapists, carers or parents to ensure the product is safe for use. The recommended daily checks are detailed below.

1. Check that the product is clean and there are no signs of soiling.
2. Check that all fabrics, webbing, Velcro and plastic buckles are in good condition and do not show signs of wear and tear or fraying.
3. Check the mouldable base is firm enough to maintain your child in the desired position; air can be extracted if the mouldable mattress has become soft. Should the child have lost the desired position, the mouldable mattress should be remoulded again to the desired shape.
4. Check the mouldable base for scratches, scores or punctures. Seal any holes with the repair patches supplied with the product.

Holes can be found by visual inspection or by fully inflating the mouldable base, covering the surface of the pillow with soapy water and watching for air bubbles. If a hole has been found clean the area and let it dry. Select a patch and put glue on it and on the area around the hole. Wait for 2 minutes and firmly press the patch over the hole ensuring that no air remains under the patch. The bond will be complete after 24 hours. **DO NOT FULLY IMMERSE THE MOULDABLE BASE**

SECTION 12: ANNUAL PRODUCT INSPECTION

Leckey recommend that each product should be subject to a detailed inspection at least one a year and every time the product is reissued for use. This inspection should be carried out by a technically competent person who has been trained in the use of the product and should include the following checks as a minimum requirement.

1. Check that the product is clean and there are no signs of soiling.
2. Check that all fabrics, webbing, Velcro and plastic buckles are in good condition and do not show signs of wear and tear or fraying.
3. Check that all buckles lock securely when clipped together.
4. Check the mouldable base is air-tight - extract air and check that the product does not lose its shape after the valve has been closed.
5. Check the valve on the mouldable base is working properly.
6. Check the mouldable base for scratches, scores or punctures. Seal any holes with the repair patches supplied with the product. Holes can be found by visual inspection or by fully inflating the mouldable base, covering the surface of the pillow with soapy water and watching for air bubbles. If a hole has been found clean the area and let it dry. Select a patch and put glue on it and on the area around the hole. Wait for 2 minutes and firmly press the patch over the hole ensuring that no air remains under the patch. The bond will be complete after 24 hours. **DO NOT FULLY IMMERSE THE MOULDABLE BASE.**
7. Check the breathable mattress is intact and that the cushion is even and flat and that it has not gathered in within the cover.

SECTION 13: RE-ISSUING LECKEY PRODUCTS

Most Leckey products are assessed and ordered to meet the needs of an individual user. Before reissuing a product we recommend that the therapist prescribing the product has carried out an equipment compatibility check for the new user and has ensured that the product being re-issued contains no modifications or special attachments. A detailed technical inspection should be carried on the product prior to re-issuing. This should be carried out by a technically competent person who has been trained in the use and inspection of the product. Ensure the product has been cleaned thoroughly in accordance with the cleaning and care section of this manual. Ensure a copy of the user manual is supplied with the product. A copy can be downloaded from our website **www.leckey.com**

Leckey recommend that a written record is maintained of all product inspections carried out during the reissue of the product. If in any doubt to the continued safe use of your Leckey product or if any parts should fail, please cease using the product and contact our customer service department or your local dealer as soon as possible.

SECTION 14: PRODUCT SERVICING

Servicing of all Leckey products should only be carried out by technically competent persons who have been trained in the use of the product. All international service enquiries should be directed to the appropriate Leckey distributor who will be delighted to assist you. For further information on Leckey distributors please visit our website **www.leckey.com**

SECTION 15: PRODUCT SERVICING

Product	Accessory codes
Sleepform Kit Size 1	110-1634
Sleepform Kit Size 2	110-2634
Sleepform Kit Size 3	110-3634
Sleepform Kit Size 4	110-4634
[includes Sleepform mattress, chest/hip guide, leg/knee guide and air flow mattress.]	
Therapist Assessment Kit (Sizes 1 & 2) [includes Chest/hip guides, leg/knee guides, air flow knee pillow, small & large knee rolls, air flow mattress, Sleepform mattress.]	110-2635
Therapist Assessment Kit (Sizes 3 & 4) [includes Chest/hip guides, leg/knee guides, air flow knee pillow, small & large knee rolls, air flow mattress, Sleepform mattress.]	110-3635
Therapist Assessment Kit (Sizes 1-4) [includes all sizes of chest/hip guides, leg/knee guides, air flow knee pillow, small & large knee rolls air flow mattress, Sleepform mattress. All of the above comes with an extra Sleepform bag.]	110-1636
Chest/Hip Guide	110-1601
Leg/Knee Guide	110-1602
Chest/Hip Guide	110-2601
Leg/Knee Guide	110-2602
Air Flow Knee Pillow	110-2603
Knee Roll Large	110-2604
Knee Roll Small	110-2605
Air Flow Mattress	110-2606
Cot Attachment Strap	110-2609
Chest/Hip Guide	110-3601
Leg/Knee Guide	110-3602
Air Flow Knee Pillow	110-3603
Knee Roll Large	110-3604
Knee Roll Small	110-3605
Air Flow Mattress	110-3606
Single Bed Attachment Strap	110-3609
Chest/Hip Guide	110-4601
Leg/Knee Guide	110-4602
Sleepform Mattress [includes mattress, pump and Sleepform bag]	110-3607
Sleepform Pump	NTL20
Sleepform Bag	10-3633
Temperature Control Sheet Sizes 1 & 2	110-2636
Temperature Control Sheet Sizes 3 & 4	110-3636
Waterproof Mattress Protector	NTL27

DIMENSIONAL & TECHNICAL DATA

Product Dimensions			
Component	Size	Dimension mm (Inches)	
Sleepform Mattress	One size	950 X 950mm [37.25" X 37.25"]	
Airflow Mattress	1 & 2	960 X 1180 X 15mm [3775" X 46.5" X 0.6"]	
	3 & 4	1000 X 2000 X 30mm [39.4" X 78.75" X 1.2"]	
Airflow Knee Pillow	1 & 2	230 X 330 X 60mm [9" X 13" X 2.4"]	
	3 & 4	450 X 650 X 60mm [17.7" X 25.6" X 2.4"]	
Knee Roll	1 & 2 Small	140 X 50 X 500mm [5.5" X 2" X 19.7"]	
	1 & 2	140 X 100 X 500mm [5.5" X 2" X 19.7"]	
	3 & 4	195 X 75 X 900mm [7.7" X 3" X 35.4"]	
	3 & 4	195 X 125 X 900mm [7.7" X 5" X 35.4"]	
Cushioned Chest & Hip Guides		min – max (mm)	min – max (inches)
1	Width	115 - 160	4.6 – 6.6
	Circumference	345 - 485	13.8 – 19.4
2	Width	160 - 196	6.4 – 7.8
	Circumference	478 - 601	19.1 - 24
3	Width	160 - 196	6.4 – 7.8
	Circumference	478 - 601	19.1 - 24
4	Width	175 - 328	7 – 13.1
	Circumference	550 - 1007	22 – 40.2
Cushioned Leg & Knee Guides		min – max (mm)	min – max (inches)
1	Circumference	137 - 271	5.5 – 10.8
2	Circumference	181 - 322	7.2 – 12.8
3	Circumference	181 - 322	7.2 – 12.8
4	Circumference	230 - 553	9.2 – 22.1
Under mattress Straps	1 & 2	630mm [24.8"] Strap length	
	3 & 4	1020mm [40.2"] Strap length	
Temperature Control Sheet	1 & 2	810 X 1220mm [32.4" X 48.8"]	
	3 & 4	1000 X 2000mm [40" X 80"]	
Waterproof Mattress Protecto	One size	860 X 760mm [34" X 30"]	

TECHNICAL CONSIDERATIONS

Medical Devices Regulations 2002	
Component	Complies
Sleepform Mattress	BS-EN 1021-1 and 2; 1994 BS EN 597-1:1995 BS EN 597-2:1995 BS 7177:1996 Complies with NHS Firecode Document HTM 87
Knee Rolls	BS EN ISO 12952-2 :1999 clause 3.3.4 [Pillows/Bolsters]
Air Flow Mattress Air Flow Knee Pillow	BS EN 597-1 :1995
Inner Cover	BS7175:1989:Sect.3, Ignition sources 0,1,5 100% Vapour Permeable Does not contain Latex
Outer Cover [100% Brushed Cotton]	100% Vapour Permeable Does not contain Latex
Foam	All foam used is CMHR [combustion modified high resilience] and complies
Knee Roll	CAA Spec 8 Issue 2 Part 2.2b Foam is class V [BS3379].
Fibre	Inherently low flame response – Schedule 2 Part 1 The Furniture and Furnishings [Fire] [Safety] Regulations 1988 [based on BS 5852:1982 Part 2]
Air Flow Mattress, Air Flow Knee Pillow, Leg & Knee Guides Chest & Hip Guides	Performance Requirements for Air Flow - BS 6595 : 1985 : Clause 3.3 BS 4578 : 1970 [91]
Maximum User Weight	
Size 1&2 Air Flow Mattress	19kg [42 lbs]
Size 3&4 Air Flow Mattress	76kg [167.2 lbs]
Cleaning Cycles	There are no restrictions on the number of cleaning cycles for this product
Product Warranty	2 years
Life Expectancy	Should exceed 5 years
Labelling	> CE marked for Class 1 Medical Devices [MDD 93/42 EEC] > Year of manufacture > Name of manufacturer > Material composition > Care Instructions

SECTION 16: CLINICAL SETUP FOR POSTURAL MANAGEMENT

Using the leg/chest straps

The leg/knee and chest/hip straps are elasticated. This enables the child to move slightly while bringing them back to the desired position. This can be useful to increase your child's acceptance of the product and of the new position.

In cases where tone causes adduction and/or internal hip rotation[scissored gait], the leg straps can be beneficial in encouraging neutral alignment. Position the guides just above or below the knee.

Where hips rest in external rotation, the leg guides can help encourage neutral alignment. In this instance, position the leg guides at midhigh level as this provides increased proximal control at the hip.

Product maintenance

Like all valves, over time air will slowly enter the mouldable base resulting in loss of shape. We recommend that daily product inspections are made to ensure the Sleepform system is firm enough to support the desired position of the user. To ensure a firm support, we recommend you extract air on a weekly basis and remould entirely if you feel that the original position has changed.

Make sure the mouldable base is not moulded too tightly around your child. If it is too tight you may have to open the valve and allow some air into the base again. Always remember to extract the air again once the desired shape has been achieved. Finally close the valve and remove the pump.

Choosing a suitable level of support

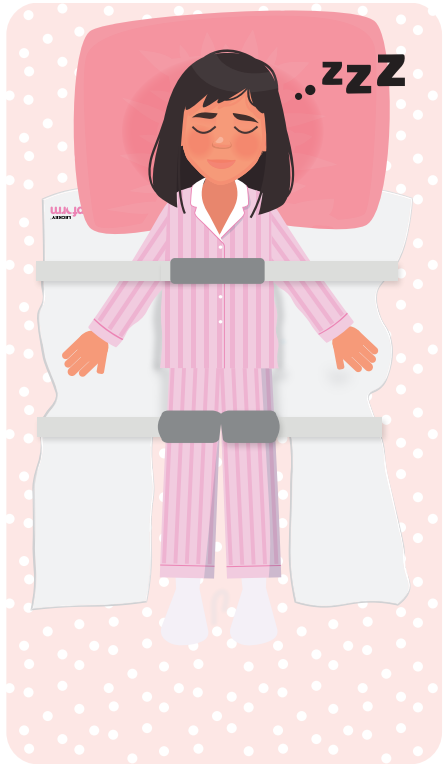
Clinical experience has shown that the majority of children do not require, 'whole-body' support. Instead, children benefit from proximal supports to target the main area(s) of concern – once these areas are supported the children are able to sleep in a more symmetrical and comfortable position. This can keep kept the amount of accessories [hip/chest/leg/knee guides] to a minimum.

Top tip: Bear in mind that your initial set up may not be the final set up as the child may not be able to tolerate a rapid change in sleep positioning. Overtime, you may wish to slowly introduce or remove supports, or look to mould the Sleepform system differently.

Tips to increase tolerance

Introducing a new sleep position can be difficult for some children, particularly for older ones who may already have a preferred position to sleep in or whose body shape has changed with time.

Where the child struggles to tolerate supports or a new posture introduce the Sleepform slowly over time. For example let the child spend short periods in the device during the day or only attaching additional supports once the child had fallen asleep.



Using at the head

Clinical and parental experience has shown that older children prefer their own pillow.

For younger children, the proprioceptive feedback of having the head cradled in a 'cocoon-like' position helped calm them whilst also maintaining a midline position.

Side-lying

The Sleepform system can be moulded to accommodate a side-lying position.

Where this is the desired position, utilising the chest and/or hip straps can be useful to discourage rolling.

For increased pressure distribution and comfort place the air-flow knee pillow between the legs.


















Use for children under one year old

Based on current sleep guidance for children under 1 year, it is recommended that a cot is left free of ALL external supports, positioning devices, comforters and toys (which includes soft-toys). Children under 1 year should always be placed in on their backs to sleep unless advised otherwise by a trained and experienced healthcare professional.

It is strongly recommended therefore that use of the Sleepform system with children under 1 year, is carefully considered and done so under the guidance of trained and experienced healthcare or medical professional.



Table of Symbols

Symbol	Meaning
	Manufacturer
	Max occupancy weight
	Serial number
	Product code
	Read the Instructions for Use
	CE mark
	UKCA mark
	Medical Device
	Warning
	Date of Manufacture
	Latex free
	Unique Device Identification
	Machine wash- water temperature 40°C
	Do not bleach
	Do not tumble-dry
	Do not iron
	Do not dry-clean

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