Sleepform Development Document

Background

Sleepform is the first night time positioning system from James Leckey Design.

Leckey have been designing and manufacturing postural support equipment for the last 25 years and are well known for seating, standing and bathing solutions ï so why did we design a sleep system?

As part of our user centred approach we looked at the daily routines of children and realised that in order to offer 24 hour postural care solutions we needed to provide comfortable and secure support for children as they rested.

The project began in June 2003 and the Sleepform system was launched in June 2006.

Design research

We began by studying the existing research literature and published reports. We also learned about the pioneering work of John and Liz Goldsmith in the area of 24 hour postural management and in particular the importance of night time positioning as a means of maintaining postural alignment.[1]

Following this we spoke to a number of children, parents and therapists in order to learn more about their experience of sleep and night-time positioning.

We wanted to find out:

- how long children usually spend in bed
- how often they need to be moved or turned during the night
- how often their parents check on them
- the main reasons for prescribing a sleep system
- the main function of night-time positioning ï is it supportive or correctional?
- the most common sleeping positions which need to be supported
- the most common postural reflexes which need to be inhibited during the night
- the requirements for temperature control/pressure relief
- what is acceptable in terms of appearance and aesthetics ï especially as this system would be used in childrenôs bedrooms

Once we had answers to these questions we had a sense of what children, families and therapists needed and wanted from a sleep system. From this we drafted a product design specification that outlined our main aims for the product.

Design aims

Our core aim was to develop a proximally supportive system that would ensure childrenôs comfort and help to inhibit abnormal postural reflexes. We wanted a system which allowed children and their parents / carers to have an uninterrupted nightôs sleep so they were fully rested for the day ahead.

In addition to this we knew that the system would need to:

- Accommodate supine, side and prone lying
- Reduce the risk of breathing issues or suffocation
- Reduce heat build & sweating
- Prevent scissoring and postures that the child cannot recover from during sleep
- Be quiet to set up minimizing disruption during sleep
- Allow easy re-positioning
- Be simple for parents to use

We then disregarded traditional thinking about sleep system design which was based on mechanical design solutions - typically on the support elements from seating systems. We felt that these mechanical solutions were too invasive for the children, families and carers, especially since the product was going to be mainly used in childrenôs bedrooms.

We wanted to start afresh, from first principles.

Thinking "outside the box"

We began to investigate other sectors where firm, contoured postural support was required. We found out that emergency rescue equipment also requires this level of postural support and discovered a Swedish company who made mouldable pillows used by accident and emergency teams to transport injured people to safety.

This pillow consisted of a PVC outer layer and an inner bag filled with polystyrene beads which could be moulded into any desired shape by extracting the air inside the pillow using a vacuum pump. The pillow would then retain this shape until air was re-introduced and the system could be re-moulded. This would provide us with the proximal support we were looking for without the need for any bespoke bed design, metal brackets, sliders, nuts or bolts. It could simply be used on the individualõs own bed.

We were excited by this product and its versatility, and although none of the products in production at the time were appropriate for our intended application, we were confident that this was the right starting point.

Developing our ideas

We knew from our initial research that our sleep system would require a specific design and some of the obvious issues for us to overcome included preventing heat build up and improving comfort. So alongside our clinical research we looked at the wide range of fabrics and cushioning used in other industries such as sports wear, outdoor clothing, furniture, and aircraft seating as well as the healthcare industry.

We sourced a polyester based filling which had been developed as an insulation material for the construction industry. Other forms of the material are used in the automotive industry for sound insulation, and more recently in car seat design as a cushioning material. By tweaking the properties of the material we were able to create a padded filling that allowed excellent air circulation and prevented heat build up and sweating. It also exhibited good mechanical properties and worked well as a cushioning layer.

We had found our airflow mattress for the re-mouldable pillow. The unique properties of this base material meant that we were able to use a simple cotton fabric for the outer layer - similar to that used in standard bed linen.

Prototype development

The next stage for us was to develop the range of components we felt were needed to position children during the night. After a number of component prototypes we felt we had an initial set of components that we could trial to see if we were on the right track.

Due to the mouldable characteristics of the system we called the product ñSleepformò

Sleepform Product Trials

Sleepform Trial - Prototype #1

This first prototype was designed for children between the ages of 5 and 18.

We assembled a kit of soft support components which included the re-mouldable pillow, the air flow mattress, a side lying pillow, various foam positioning rolls and some leg and chest positional guides.

We trialled this system with 2 children aged 10 and 12 ï David* and Nicola*. Both children have Cerebral Palsy (spastic quadriplegia) and were at risk of hip dislocation due to adopting harmful leg positions ï ñfroggingò (flexion and external rotation of the hips and flexion of the knees) and ñscissoringò (leg extension, and adduction where one leg crosses over the other) during the night.

David used the leg positional guides in a supine position for 20 weeks. Over this period there was an improvement in Davidôs ability to control his legs and recover from a scissored position.

Nicola had previously tried a night time positioning system but had found it too restrictive. Nicola prefers to sleep on her side and her mother turns her from one side to the other during the night. She used the side lying pillow with the leg positional guide on her uppermost leg. The system kept her in a comfortable position during the night and prevented her from frogging and scissoring her legs. Nicola used the system from October 2004 to July 2006 and continued to use the equipment when our field trial period had finished.

* names have been changed

Sleepform Trial – Prototype #2

As a result of feedback from the first trials we made some changes to the design of the system.

We added elastic to the straps of the leg and chest guides ï this allowed children to move when using these guides and brought them back to the desired symmetrical position when they relaxed. This eased the childrenôs acceptance of the product as they didnôt feel restricted or strapped down.

We made some changes to the specification of the material used in the air flow mattress to ensure improved air flow, pressure relief and comfort.

As the system was so versatile therapists requested we make a system for younger children aged 0-1 and 1 -5 years as other sleep systems available on the market were too big or cumbersome to use with these little ones.

These modified prototypes were then trialled with children throughout the UK and Ireland.

Case Histories

In all, 15 children with Cerebral Palsy and one child with Angelmanôs Syndrome participated in the trials for Prototype #2.

Our youngest participant was 6 months old and the oldest participant was 18 years old. These trials began in March 2005 and ended in June 2006 ï although some of the children continued to use the equipment when the trial ended.

There is a summary of the childôs postural issues and the components prescribed in the table below. The light shaded boxes indicate the components used by the child, the darker shaded boxes indicate the components tried by the child during initial set-up but which were not used in the trials.

We were present at the set-up of these systems and maintained contact with parents, children and therapists through visits to their homes and telephone conversations.

Patrick* (8) initially used a lot of support components but within a few weeks the only component he needed was the leg guide. These prevented his legs from scissoring which previously caused him to get into positions that he could not recover from himself.

Sam* (8) who had previously woken up during the night with hip pain due to ôfroggingôhis legs, was now sleeping soundly through the night using a knee roll and leg guides. As the trial progressed the leg guides were removed and he was using just the knee roll ï the destructive ôfroggingôpattern had been broken.

		Components Used					
	Postural Issues	**Leg Guide**	**Chest/Hip Guide**	**Knee Roll**	**Knee Pillow**	**Air Flow Mattress**	**Sleepform Mattress**
1	Assymmetry, contractures, dislocated hip						
2	Asymmetry, pelvic rotation, contractures						
3	Contractures, scoliosis, rib flaring L>R, deformity on head - left side due to side lying,abduction						
4	Legs/hips externally rotated, frogs legs						
5	Hypertonia, abduction, right windsweeping, left head turning, breathing difficulties						
6	Rare disorder-presents as CP, heat build up at night, pelvic/hip area of concern, tight hamstrings						
7	Fluctuating tone, floppy trunk						
8	Fluctuating tone, floppy trunk, left head turning						
9	Trunk/hips twisting in opposite directions, contractures at knees, external rotation hips/legs - frogs						
10	Visual difficulties, clonus, extension/thrusting,						
11	Right hip removed, windsweeps to left, knee contractures, hips/pelvis rotating to left						
12	High tone, trunk beginning to flex to side, pelvis beginning to twist, starting to windsweep						
13	Scoliosis, assymmetry, kyphosis, adduction, gastrostomy, breathing difficulties,						
14	Spastic CP pattern, scissors legs						
15	Extensor spasms, back of head flattened, has had bilateral psoas release, leg length discrepancy						
16	Dislocation of one hip, subluxation of the other, scissoring, temperature regulation issues						

Joe* (14 months) had been falling asleep on his side but during the night was moving himself into assymmetrical, unsafe sleeping positions. His parents had tried to use pillows and towels to keep Joe in a safe position but these weren't working. Joe's mother would sit with him until he fell asleep and would usually check on him 8-10 times during the night. Using the Sleepform mattress and the knee pillow Joe was getting a more restful night's sleep in a symmetrical, safe position and most importantly his mother and father did not have to worry about his safety – they could leave him to fall asleep on his own and only needed to get up once a night to turn him onto his other side. They even brought the system on holiday with them!

Ongoing learning…

We began to learn more about the postural issues which needed to be addressed during the night and which pieces of equipment were most effective in tackling these issues.

We found that for many of the children, whole body support was not what was needed. The children needed proximal support to target their main 'problem areas'- once these areas were supported the children were able to sleep in a more symmetrical, comfortable position. This also kept the amount of equipment in the bed to a minimum and ensured the system was as discreet as possible.

This meant that instead of making a full bed size re-mouldable pillow a smaller half-mattress size pillow was sufficient.

We realised that we didn't need to have specific head support for many of the older children - they were happier using their own pillow. However, for the younger children, being cradled in a cocoon which included head support was effective in giving them the proprioceptive feedback and midline position they needed. These children instantly felt safe, secure and comfortable in the system – two of the children even falling asleep in the system as we set it up for them.

We learned that as children grew more tolerant to the sleep system and their postural issues changed the equipment setup also changed.

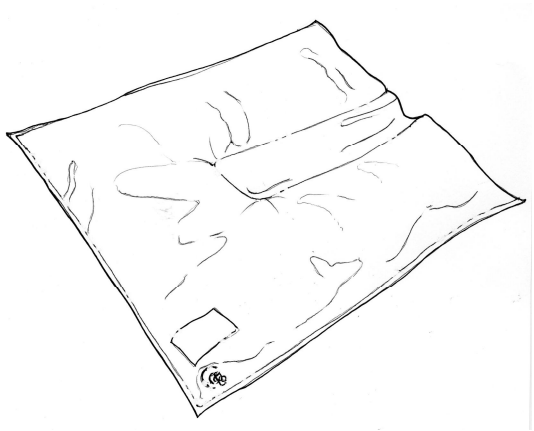
Some children, particularly the younger children, were immediately comfortable with the system, however a number of the older children had more difficulty adjusting to the new equipment as they already had a preferred sleeping position and routine. The children's parents and carers developed techniques in order to gradually introduce their children to the system including letting their child spend short periods of time in the system during the day or placing the supports on the child during storytime, then removing them – until the child was ready to fall asleep with the supports on. Some parents found it easier to place the supports on the child when they had fallen asleep and their tone had reduced.

For the younger children the Sleepform could be brought into the parentsô bed if necessary or could be used to provide comfortable support in other rooms of the house during the day.

Development of supporting material

As the product was being used in the home and therapists were relaying second hand information on how the prototypes were working we decided that we needed to provide parents with a means of capturing and feeding it back directly to us. We began to develop support material for the prototype trials ï a sleep diary, record card and assessment form. The assessment form was designed to assist the therapist in the component selection process; the record card enabled the therapist to record the desired set-up of the components so it could be communicated to the parents; and the sleep diary enabled therapists to monitor how the well the prototype met the childrenôs & parentsôneeds. These enabled parents and therapists to document their childôs experience with the system and also keep a record of components used and their position on the bed if the equipment was moved.

Following feedback from these trials we realised that the re-mouldable pillow needed to be redesigned to include a central section that had no beads in it. This was because in some cases it was difficult to move these beads to the areas where they were needed when positioning a child on the pillow. We went back to the Swedish company who made up another pillow to our new specific requirements. This also involved redesigning the inner bag that held the beads in place



Re-designed re-mouldable pillow with central channel

Sleepform Trial – Prototype #3
We now had our new re-mouldable pillow with a sealed off channel in the centre of the bag ï this prevented beads falling into the central section which not only made it easier to place the children on the pillow, but also easier to mould and readjust the pillow around them.

We left a section at one end of the pillow that did not have the channel and had a greater volume of beads. This enabled us to achieve better positioning around the pelvis and legs depending on where it was placed on the bed. We also could turn it the opposite way in the bed so this section was around the head and shoulders for a child who needed more support in this area.

Sleepform Trial – Final Prototype #4
Following the success of the modified re-mouldable pillow we felt confident that we were able to meet the needs of a large proportion of children with special needs. However we were also aware that there was a percentage of the population who did not need the degree of proximal support offered by our specifically designed re-mouldable pillow.

We experimented with simpler supports that work in a similar way to the leg/knee guide and designed a chest and hip positioning guide that could be used on its own or with the re-mouldable pillow.

These proved successful with specific children who required minimal support and in some cases were only used to address sleeping positions that could have led to further physical complications. We learned that once some children had overcome destructive patterns such as scissoring that the number of supports they needed could be reduced.

We felt that we now had the kit of components that would enable effective night time positioning. However, we knew that it had taken us almost 2 years of research, product trials and design iterations to get to this point and that the greatest challenge still lay ahead for us ï how would we pass on all this experience, learning and knowledge to those who would prescribe and use the product? The effectiveness and success of the system would not only be defined by the quality of the end product but also in how we would communicate the information we had gathered to parents and therapists.

The project entered its final stage which was divided into two strands:

1. The final design of all of the components so that they could be produced in greater quantities and would meet the necessary Quality Standards and Regulations

2. The generation of marketing and user information to communicate to parents & clinicians all we had learned throughout the productôs development.

1 Final Component Design

We were now able to define the full list of components that we felt was necessary to accommodate the range of children we had encountered in our field trials. Although we knew that this was not exhaustive we felt that we would be able to accommodate the majority of clients and for exceptional cases we already had a ñspecial designòprocedure in place.

The primary aim of the Sleepform system was to provide proximal support to children that would maximise their comfort and ensure they and their carers had as uninterrupted a nightôs sleep as possible. Our approach was more about passive positioning rather than aggressive repositioning. We realised during our trials that a sleep system was not a quick fix solution and just as in many cases postural issues had arisen over long periods of time, so too, the solutions to counteract these would take time.

The process of defining the final design of each component started with the selection of the raw materials to be used. Each component of the final prototypes was reviewed and a list of requirements drawn up. We had to consider how easy it was to clean, how it affected comfort, whether it needed to meet any flame retardancy or infection control requirements, as well as how durable it was.

We also spent a considerable amount of time ensuring the aesthetics of each component was appropriate for use in childrenôs bedrooms. Every childôs bedroom is very personal to them and usually decorated with their favourite colours, toys and cartoon characters. Although we wanted our system to be as óinvisibleôas possible we also wanted it to be desirable and attractive. We chose white as the main colour and where practical used natural fibres - soft brushed cotton. We complimented this with subtle but distinctive pastel-coloured cotton binding to finish the components. This trim was later to become the signature of the Sleepform system in the marketing material.

Once the materials were selected we reviewed the construction of each component so it met all our requirements. These patterns were transferred to CAD and the process of making the parts automated so that they could be produced in larger volumes.

Once we had verified the process then the task of training production staff and generating detailed working instructions had to be completed. As with all our other positional equipment we pride ourselves on producing the highest quality products and while Sleepform was not an engineering product it still need to reflect this commitment to quality.

2 Marketing and user information

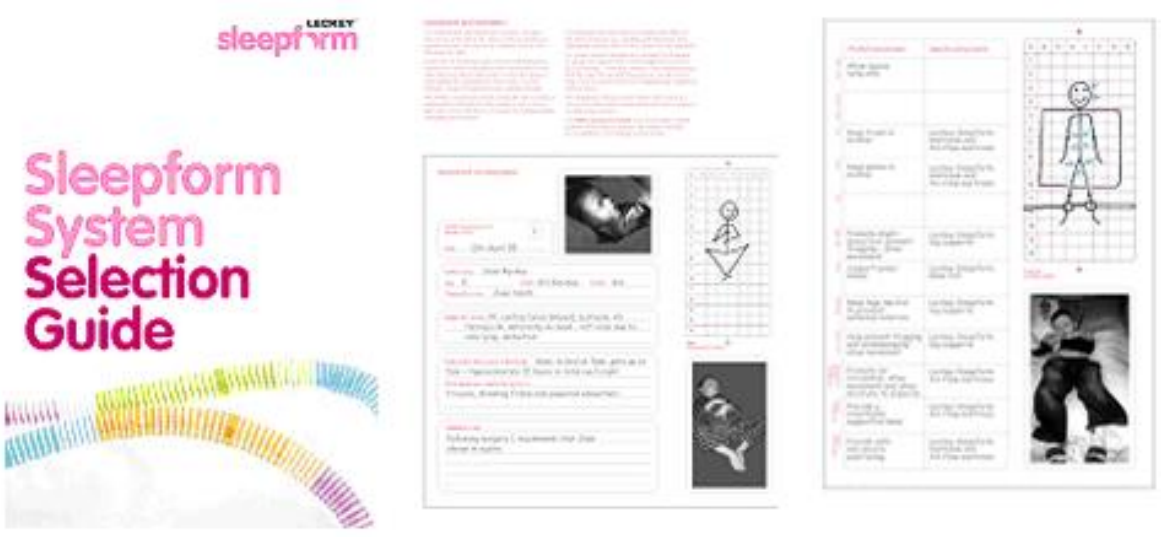
Role of Assessment - as our trials progressed we realised how important the assessment of the child was in selecting the most appropriate components for use in the sleep system. As night time positioning is such a new area and our approach is quite different we concentrated our efforts in designing our supporting documentation to communicate to parents and therapist not only how to use the product but also a selection guide to assist in the product prescription process. Each product is supplied with the following documents contained in the ìNight Night Sleep Tightôpack:

A. Sleepform Selection Guide
B. Sleepform Record Card
C. Sleep Diary
D. Sleepform User Instructions

A. Sleepform Selection Guide

Using information compiled during our trial period and working in collaboration with therapists we developed our own Sleepform Selection Guide. This contains sections for all the information needed to set up a sleep system ï it looks at the postural issues and also at temperature control and any medical issues which may affect the children. This document also records the therapistôs goals and objectives for the child using the system. It can be reviewed when the goals and objectives change and components need to be added or removed. The Guide takes therapists through a step by step process from initial assessment to goals and desired lying position. It defines the product characteristics needed to meet these goals, and in turn which components in the Sleepform system should be trialled.

In all our product support material we recommend that when prescribing a sleep system the childôs therapy team and parents should be present. This is crucial for the health and safety of the child and to ensure the system is successful in providing comfort and support.

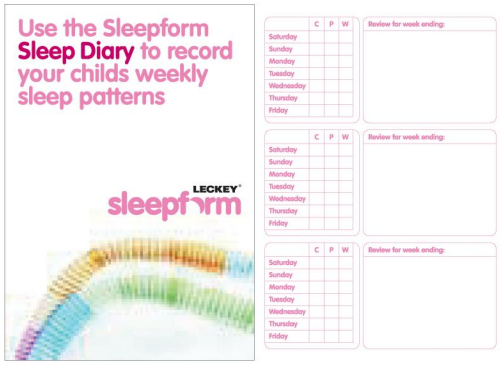


B. Sleepform Record Card

Once the components have been selected for the child, the Sleepform record card allows you to record the setup and position of each component exactly. If any of the components need to be removed for cleaning or the system needs to be moved to another location, then repositioning the components is made easier as the original position has been documented in the Record Card.

C. Sleep Diary

The sleep diary is an essential part of the Sleepform system as it enables parents and carers to monitor how the system is working for their child. Although completed by parents or carers, it should be reviewed periodically with the prescribing therapist to ensure the Sleepform system continues to meet the childôs needs. It is important that parents and carers are clear what the goals and objectives are. These need to be measurable so that progress can be tracked and changes made where necessary. We have suggested three different measures



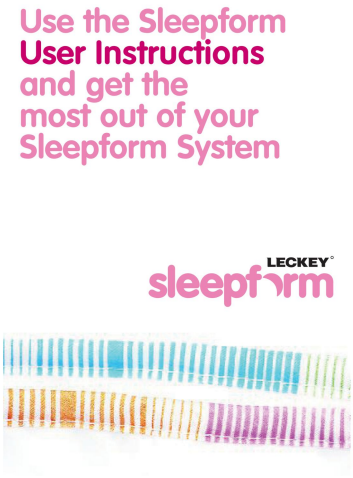
C ï How often the child is checked during the night

P ï How often the child has needed to be repositioned

W ï How many times the child has wakened

D. Sleepform User Instructions

As with all of our products we provide customers with technical details on how to setup and maintain the products, as well as safety information so that the product can continue to meet the needs of the users for as long as possible.



Further Developments

Since the Sleepform was launched in June 2006, we have been listening to feedback from our customers, our product advisors and learning more about night time positioning. This has led to several improvements and additions to the Sleepform system.

The Size 1 / Size 2 Airflow Mattress has been made thinner to provide proximal support to smaller and lighter children.

We now provide a waterproof mattress protector as part of the system.

We are currently developing other products in this area for premature babies, adults and also products that will meet the infection control guidelines for multiple users.

We have introduced a Temperature Control Sheet using Outlast fabric which was originally developed for use by NASA in space travel! This sheet can be placed under the childôs own topsheet and keeps the user at a constant comfortable temperature.

We continue to welcome feedback from parents and clinicians alike to improve the overall quality of the products and service we provide. Please do not hesitate to forward any suggestions or feedback to info@leckey.com.

Clinical Research

We are continuously monitoring the latest developments in clinical research, evidence based practice and assistive technology in the field of 24 hour postural management.

This ongoing research is extremely important to us in ensuring our products reflect the most up to date clinical thinking and our service continues to accommodate the needs of our users.

We also have an ongoing Case History Programme with therapists around the world ï follow this link to read these - http://www.leckey.com/template.asp?parent=308&pid=349&webArea=5 .

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