

...Someone at risk from Seizures, Convulsions or breathing difficulties?



Anti-Suffocation Pillows

Protects **THEM** while they sleep –
and gives **YOU** peace of mind!

From Don Alderton, Pharmacist
a Member of the Royal Pharmaceutical Society

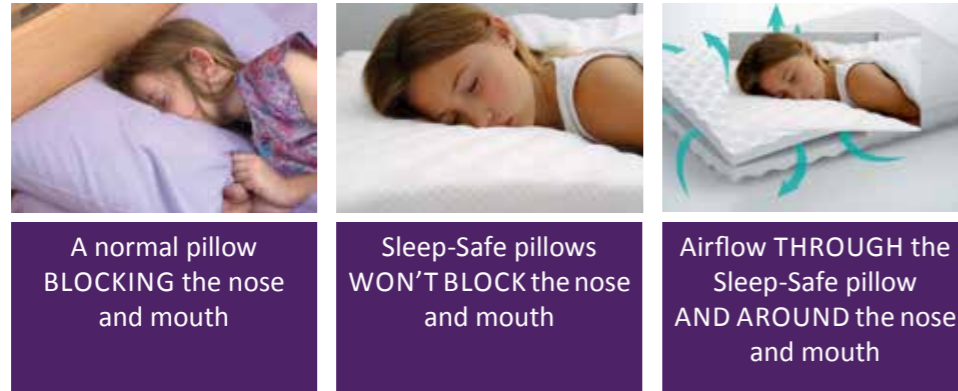
KEY CONTENTS:

- Quality Health Checks for people with learning disabilities
- Managing Sleep Seizure Suffocation Risk - A Harm Prevention Clinical Guideline
 - Evidence for the Effectiveness of Sleep-Safe Pillows
 - MHRA urges caution in switching epilepsy drugs

www.sleep-safe.co.uk

A Family Company,
run by Healthcare Professionals, focussed on Healthcare Integrity.

Connect with us!  @sleepsafepillows  #sleepsafepillows



Essential for anyone who is 'at risk'

For children and young people...
 For older people...
 For people of all ages with special needs...



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Here is your Sleep-Safe Pillow

Made in a workshop dedicated to providing products and services which help people with long-term medical conditions manage their lives more effectively.

The email shipping advice we sent you has many useful links to focussed information specially selected to 'signpost' you towards help in the day-to-day management of seizure conditions. These can all be viewed online at www.sleep-safe.co.uk/signposts

In the 30 years since Sleep-Safe were introduced they have been improved continually – much softer, a more gently rippled surface, a smoother micromesh cover, and the unique Aero-Matrix core. These developments originated mostly from ideas suggested by the users and carers, and mean increased comfort and breathability, and, of course, even greater safety.

The latest improvements provide significantly increased 'Breathability': "What you can See-Through, you can Breathe-Through" along with a 'Take-Apart' design: if a 'slimmer' pillow is preferred, perhaps for child or a smaller adult, the Aero-Matrix core can be removed easily; also, if the Sleep-Safe becomes heavily contaminated it can be taken apart and the components washed separately.

Do please pay particular attention to the washing and laundering instructions!

I enclose an overview of the NICE Clinical Guideline NG 217 'Epilepsies in children, young people and adults', which describes the recommendations for treating and coping with epilepsy that has been issued to the UK National Health Service by the National Institute for Health and Care Excellence. **NICE Guideline 217 emphasises** the importance of a comprehensive care plan, and gives recommendations for good practice in treating and managing the condition. It's a comprehensive 154 page document with information and guidance for everyone in the epilepsy treatment pathway: health and social care professionals, care commissioners and people with epilepsy.

If you live outside the UK it will give you some idea of what's happening in the UK with regard to managing epilepsy.

The credit-card sized 'I Have Epilepsy' fold-out leaflets describe what action to take in the event of a seizure and provide key first aid information. They should be filled out with personal details and an emergency contact and are designed to be carried at all times personally or given to a carer, a colleague, a child's teacher or to a health or social care professional.

There is also a 'Yellow Card' which describes how to report medicine side effects easily: people with epilepsy can sometimes experience unpleasant effects from their medicines, and every side effect that's notified may help to ensure more effective management of seizures for people with epilepsy.

There is now a 'Yellow Card' app: The Yellow Card Scheme, introduced in 1964 in the wake of the Thalidomide disaster, has now moved into the digital age. Among many other features it enables instant reporting of side effects directly to the Yellow Card Scheme. Full information and a download links here...

<https://yellowcard.mhra.gov.uk/>

A "Taking Medicines" leaflet is included, as well, which in a jargon-free question and answer format gives further information about drug side effects.

The information included with Sleep-Safe is based on the best available evidence but isn't a substitute for discussions with your neurologist, epilepsy nurse or specialist in the underlying condition which causes the seizures affecting you or the person for whom you care. This should result in better informed management of the condition, minimising the risk of harm and reducing stress, anxiety and emergency hospital admissions.

A Sleep-Safe Anti-Suffocation Pillow, replaced at appropriate intervals, amounts to a lifetime investment in safety and security for just a few pence a day, giving greater hope and a better life for people with epilepsy and their families.

Do please let me know if there is any further information that you need.

Best wishes,

Yours sincerely,



Don Alderton BSc (Hons) Pharmacy

P.S. If you find that you have a spare Sleep-Safe leaflet I should be grateful if you would pass it on to somebody who suffers from seizures, or to their carer, or to a health or social care worker - you may help to save a life. Many thanks!

Brief Biographies



Don Alderton is a pharmacist who has worked in health care since 1963, and served fourteen years in hospitals and field medical units of the Royal Army Medical Corps. After three years with the Trucial Oman Scouts, a Bedouin Arab force in the Trucial States, he left the army to go to university and then to qualify as a pharmacist.

He has managed and owned a number of pharmacies and has worked as the medical devices registration specialist for a leading surgical equipment manufacturer.

His experience in medical device regulation makes him well qualified to ensure that Sleep-Safe Anti-Suffocation pillows conform to the essential requirements of UK legislation and the relevant EU Directives.

Don is registered with the Royal Pharmaceutical Society of Great Britain and his vocation as a pharmacist ensures that he keeps well up to date with health care issues.

For six years Don was Secretary of the Chester Branch of Arthritis Care (400+ members) with overall responsibility for coordinating the group activities including hydrotherapy, holidays and branch meetings. During that time he negotiated a substantial 3-year National Lottery grant which enabled the introduction of new local initiatives aimed at reducing the problems of social isolation stemming from disability and low income.

Chris Alderton has worked in the NHS for over 40 years and is a qualified general nurse and midwife. She is also a health visitor, and

this additional qualification in public health enables her to work with families to give pre-school-age children the best possible start in life. She has wide-ranging knowledge and experience within health promotion and preventative care for families, especially children and their parents.

Chris is a trained psychotherapist and mindfulness teacher, with wide experience of providing outreach therapy in primary care settings and courses for health and education professionals and members of the general public, including carers.

Chris says, 'I'm very aware of the detrimental effects of long term stress and anxiety on the lives of families and especially on carers. I've witnessed the transformative effects and stress reduction that evidence-based practical medical solution can bring.

'It's a situation I experienced at first-hand: our infant son's seizures were extremely worrying, causing deep concerns about his night-time safety – the unpredictability of convulsions, possibly resulting in cessation of breathing, brain damage and even death due to lack of oxygen. We could minimise the risk with breathable bedding but standard domestic pillows were fundamentally unsafe.'

'This is why, personally and professionally, I endorse the use of Sleep-Safe Anti-Suffocation Pillows as an important aid to safe sleeping and alleviating the anxiety and concerns of parents and carers.'

The information that Don and Chris provide is based on the principle that patients, residents, service users and carers get the best support when there is inter-professional communication between colleagues from different health and social care disciplines.

Chris and Don's aim is to promote a sense of personal empowerment which will enable everyone affected by seizures - especially carers - to manage more effectively the underlying medical condition.

Quality health checks for people with learning disabilities

(from Public Health England, which exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It is an executive agency of the Department of Health, with operational autonomy to advise and support government, local authorities and the NHS in a professionally independent manner).

A way of finding out what is happening locally at your doctors' surgery...

Having a health check every year with the doctor can help people with learning disabilities find out if they have any health problems they need help with.

It is a good way of helping people to stay healthy.

The government has been paying doctors to do health checks for people with learning disabilities who are also known to social services. But we know that there are lots of people who still haven't had a health check.

We have written a quality checking tool.

This can be used to find out what is happening about health checks locally.

It can be used by parents and carers, learning disability nurses, doctors, health quality checkers, other staff and Partnership Boards, to:

- find out about the good things that are happening
- find out if health checks are happening in the same way locally
- find out if things are changing and getting better
- help family doctors and staff make changes so that people with learning disabilities can use services better.

These changes are called 'reasonable adjustments'.

There are 6 questions:

For 5 of the questions there are 3 'levels of success' – bronze, silver or gold.

If a service is marked as gold this means they are doing really well.

We have suggested some things that can be looked at to tell how well the surgery is doing at annual health checks.

You can read and download the Quality Health Checks Audit Tool here...

Google / search on 'People with learning disabilities: health checks audit tool'.

Annual health checks - Learning disabilities
Anyone aged 14 or over who is on their doctor's learning disability register can have a free annual health check once a year.

Google / search on 'Annual health checks - learning disabilities'.

Disability Rights – UK Government Services, Guidance, News:

Google / search on 'UK Government Disability Rights'

Citizens Advice – What Counts as a Disability:

Google / search on 'Citizens Advice – What Counts as a Disability'

The Management of Sleep-Seizure Suffocation Risk — A Harm Prevention Guideline

Introduction

This guideline provides a framework for the management of sleep-seizure suffocation risk in children and adults. Its objective is to limit the incidence of dangerous events by anticipatory provision of medical devices and by creating systems that are better able to eliminate the risk.

Breathing and adequate airflow is fundamental to a person's well-being. There is a positive duty at common law to care for and provide such treatment as is in the individuals' best interests, and this duty of care includes the provision of support to preserve life. The aim of sleep-seizure suffocation management is to ensure that airflow during a sleep-seizure is sufficient to maintain life.

Sleep-seizure suffocation occurs when a person becomes entrapped into bedding which obstructs the nose and mouth and results in oxygen deficiency. This can lead to death, or brain damage and subsequent lifelong disability and dependency.

Seizures are both a consequence and a cause of ill health, and increase a person's vulnerability to further disease and disability. In the UK each year there are about 1,100 seizure related deaths, and the 44,000 unplanned emergency admissions resulting from seizures cost Primary Care Organisations an estimated £150 million. Many of these result from the fear engendered by a sleep seizure – has a brain injury occurred? Is the individual near death?

Effective management of sleep-seizure suffocation risk has the potential to substantially contribute to key delivery

targets for social and healthcare organisations. It provides an opportunity to strengthen and improve performance in the following NHS Outcomes Framework Domains:

- Domain 1 – Preventing People from Dying Prematurely
- Domain 2 – Enhancing Quality of Life for People with Long-Term Conditions
- Domain 5 – Treating and caring for people in a safe environment and protecting them from avoidable harm.

This guideline focuses on the key recommendations for identifying people at risk and the indications for, and provision of, support in the community, whether that is supported housing, sheltered schemes, care homes or domestic settings.

An important aim of the guideline is to improve the understanding among care managers of the causes, management and consequences of sleep-seizure risk. It provides guidance on correctly identifying people across all social and healthcare settings who require support, and also on the means of delivering it.

It is recognised that 'person centred' care is essential and that individuals should have the opportunity to make informed decisions about their care and treatment in partnership with those who are responsible for their care. The importance of good communication and a coordinated approach between social and healthcare workers across departmental boundaries in community settings is also identified as being key.

At-risk groups include people who are at risk of having seizures:

- while they are asleep, or while they are not conscious as a result of medication and therefore unaware of personal danger
- while they are conscious but lack mental capacity to be aware of personal danger
- while they are conscious and aware of personal danger but do not have the physical ability to remove themselves from that danger.

Organisation of sleep-seizure suffocation management

Care managers should ensure that people at risk of sleep-seizure suffocation receive co-ordinated care from the multidisciplinary team in the community. All social and healthcare care workers who are directly

involved in care provision should be made aware of the importance of providing adequate sleep-seizure suffocation management.

The team should ensure that appropriate support in the form of medical devices and interventions is delivered in order to help prevent death or brain damage.

Protocols and care pathways for support should be developed, along with education and training initiatives to ensure that all health and social care workers understand the importance of the prevention of sleep-seizure suffocation in patient care.

Education and training should cover:

- Screening for sleep-seizure suffocation risk
- Indications for sleep-seizure suffocation management
- Sleep-seizure suffocation management in practice
- Monitoring
- Supporting people in the community
- Key priorities for implementation

Screening for sleep-seizure suffocation risk

Sleep-seizure suffocation management should be implemented for people who have a history of seizures, and also for people who have, or who have had, conditions that predispose them to seizure onset but who have not yet suffered seizures.

The Management of Sleep-Seizure Suffocation Risk — A Harm Prevention Guideline

Early identification of people who are at risk of sleep-seizure suffocation, or who are at risk of becoming so, is vital in order to provide timely help and prevention. This is not a stand-alone procedure, and should be used to provide a reliable baseline for future reference for further on-going episodes of care. The outcome of screening should be recorded in the individual's notes.

Sleep-seizure suffocation screening should be undertaken in patients on discharge from hospital into supported housing, sheltered schemes, care homes and domestic settings in the community. Screening should be repeated periodically, and should also be considered at other opportunities, for example, health checks, flu injections, and also when there is clinical concern, for example, stroke or head injury following a fall. All individuals with learning disabilities should have an annual medical examination.

Indications for sleep-seizure suffocation management

The aim of sleep-seizure suffocation management is to ensure that breathing and airflow during a sleep-seizure is sufficient to maintain life.

Care managers should ensure that people having sleep-seizure suffocation management, and their carers, are kept fully informed about the management of their condition. They should also have access to appropriate information and be given the opportunity to discuss diagnosis and treatment options.

Sleep-seizure suffocation management in practice

In order to achieve the aim of preventing death or brain damage by suffocation during sleep-seizures, a number of measures should be implemented:

- Sheets and blankets should be of the lightest possible weave
- blanket clips should be used to attach sheets and blankets to mattress welting or to a bed or cot frame to ensure that bedding remains in position during normal movement and seizures thus reducing the likelihood of entrapment and suffocation
- domestic pillows containing down, feathers or hollofibre all have extremely low breathability and should be replaced by registered medical devices such as anti-suffocation pillows. On no account should plastic, polythene or close weave cotton pillow cases be used.

Adaptations and medical devices are an aid in the management of medical conditions in which suffocation is a risk; they are not a substitute for the "duty of care". Standards of nursing and social care and vigilance appropriate to the individual's condition should be maintained.

Monitoring

Monitoring is important to ensure that sleep-seizure suffocation management is being provided safely and effectively, and to detect and manage clinical complications as early and effectively as possible. The type and frequency of monitoring will depend on the nature and severity of the seizures affecting the individual and the underlying disease state.

Supporting people in the community

The prevalence of sleep-seizure suffocation is increasing year on year, as more people survive congenital and developmental disabilities to live longer and as more elderly people survive strokes, falls and age-related disabilities.

All people in the community who have a history of seizures or who have conditions that pre-dispose to seizure onset should have sleep-seizure suffocation management, whether they live in supported housing, sheltered schemes, care homes or domestic settings, and should be supported by the multidisciplinary team of social and healthcare workers.

Key priorities for implementation

Training

There should be clear documentation that all staff caring for people who suffer from sleep-seizures have the necessary work competencies commensurate with their role in the caring process.

Screening and care plans

There should be evidence that a clear process for sleep-seizure suffocation screening is in place; that outcomes of screening are being documented, and that preventive care plans are developed for (a) people who have a history of seizures and (b) people who have, or who have had, conditions that pre-dispose to seizure onset but who have not yet suffered seizures.

Implementation of protective measures

People identified as having a history of seizures and also people who have conditions that pre-dispose to seizure onset but who have not yet suffered seizures should have protective measures implemented to ensure their clinical well-being in respect of maintaining sufficient breathing and airflow to maintain life during sleep-seizures.

Review

There should be evidence of periodic reviews undertaken to update procedures and protocols relating to the sleep-seizure care pathway and the process of sleep-seizure suffocation screening and management.

Review dates should be set for replacement of bedding and medical devices used in the management of the condition such as monitors and anti-suffocation pillows.

Endorsements for Anti-Suffocation Pillows

1. Personal

“My son was admitted to the Foothills Hospital Seizure Monitoring Unit here in Calgary.

They showed me a video one of the seizures in the middle of the night. My son turns his head to the right side at the onset of his seizures. I watched the video of my son laying on his right side, turning his head to the right, with his face directly in to the pillow. Of course, this was alarming! But even as I was watching, I knew he was OK because he was sleeping with Sleep-Safe pillows that I recently purchased from your company. When my son was admitted to hospital, I brought his Sleep-Safe pillows to the hospital, because now that I have them, I no longer feel comfortable with him sleeping with any other pillows.”



Richard E Appleton

Consultant Paediatric Neurologist
Alder Hey Children’s Hospital
Liverpool

MRCS LRCP, MB BS, DCH, MA
(Oxon) FRCP, FRCPC

2. Clinical

Richard E Appleton

“Anti-suffocation pillows are likely to significantly reduce the risk of suffocation in children (and even adults) who experience frequent nocturnal seizures and particularly if these nocturnal seizures are tonic-clonic (also called Grand Mal) seizures.

There is no evidence that the use of an anti-suffocation pillow will completely stop the possibility of a child (or adult) not suffocating during a tonic-clonic seizure, but it is likely these pillows will greatly reduce the risk of suffocation.

It would therefore be reasonable, if not wiser, to consider using an anti-suffocation pillow in any child (or adult) who is known to experience nocturnal tonic-clonic seizures.”

Provided to Sallieann Gould, Founder of the Epilepsy Sucks Charity and used with permission.

3. Academic

“In patients with recognized higher SUDEP risk, prevention measures should be suggested, such as the use of anti-suffocation pillows.” ‘Sudden unexpected death in epilepsy (SUDEP) and sleep’.

Published in Sleep Medicine Reviews, Volume 15, Issue 4, August 2011, Pages 237-246 Lino Nobili, Paola Proserpio, Guido Rubboli, Nicola Montano, Giuseppe Didato, Carlo A. Tassinari.

Evidence for the Effectiveness of Sleep-Safe Anti-Suffocation Pillows

Report Prepared for: DM Alderton BSc (Hons) Pharmacist

Report Prepared by: Dr Alison McConnell, Professor of Applied Physiology, Respiratory Physiology Research Group, Brunel University

Professor McConnell’s research group has published the most influential research on the ergogenic effects of inspiratory muscle training; she invented and commercialised the first ‘breathing training’ product for use by sports people and is widely credited as the creator of the ‘breathing training’ product category.

Summary:

To determine as a primary outcome the effectiveness of various domestic pillows in permitting respiratory airflow for patients experiencing breathing difficulties during a seizure.

Note: Sleep-Safe Products had no role in the test design, data collection, data interpretation or writing of this report.

Based on these test results, Sleep-Safe Pillows should be the choice in circumstances where breathing ability is compromised by disability, disease state, medication or age.

Test conditions: The products were tested under “blind” conditions with all identifying marks removed. This ensured that any variance in performance could be accepted as being due entirely to product difference rather than due to operator bias.

The flow rate selected to measure the resistance of each pillow was 0.3 l.sec⁻¹, which corresponds to the typical mean inspiratory flow rate during tidal breathing (approximately 500ml inhaled in 1.5 sec). For pillows B and D, this flow rate generated no measurable pressure load, so two higher flow rates were tested in order to produce a figure for the resistance of these pillows (1.0 l.sec⁻¹ and 3.0 l.sec⁻¹). These higher flow rates are not physiologically relevant for a resting human, but it is conceivable that a person experiencing a seizure might undergo an increased metabolic and ventilatory demand resulting in a mean inspiratory flow rate in the region of between 1.0 l.sec⁻¹ and 3.0 l.sec⁻¹.

Procedure: The equipment was set to generate the desired flow (measured with a flow meter at the exhaust) whilst drawing air through each pillow. The pressure load generated at the fixed flow rate was recorded on two occasions at 20 sites on each pillow. The resistance of the pillow was calculated as follows.

$$\text{Resistance (cmH}_2\text{O.l.sec)} = \frac{\text{pressure load generated (cmH}_2\text{O)}}{\text{flow rate through the pillow l.sec}^{-1}}$$

Summary data: Table 1 summarises the data collected. Each value is the mean of the twenty sites measured for each pillow on two occasions.

Evidence for the Effectiveness of Sleep-Safe Anti-Suffocation Pillows

Table 1

Resistance (cmH ₂ O.l.sec)			
Pillow	0.3 l.sec ⁻¹	1.0 l.sec ⁻¹	3.0 l.sec ⁻¹
A	53.3	-	-
B	0	3.6	18.7
C	16.7	-	-
D	0	0	1.12
D + non-woven cover	0	0	1.44

The resistance of the non-woven cover per sec, was circa 1 cmH₂O at 3.0 l.sec⁻¹.

There was a tendency for pillow resistance to increase with flow rate (see Pillow B). This effect would not be observed in, for example, a fixed orifice (pressure load would rise with flow rate, but the proportionality is preserved such that the resistance remains relatively constant). This increasing resistance is most likely due to the compressible nature of the test material, which is squeezed closer together at higher flow rates, thus increasing its resistance.

The site of measurement (1-20) did not influence the resistance systematically. However, there was a 'random' effect of site with pillow D, which was influenced by the location of the holes and bumps in the material. There was a tendency for resistance to be lower at sites where the 'airway' tube (the tube that was placed on the pillow surface and through which the air was drawn) was placed over a hole. The presence of the non-woven cover appeared to reduce this resistance even further.

Conclusions: Pillows A and C have a relatively high resistance at 0.3 l.sec⁻¹ (typical inspiratory flow rate for a resting human). The pressure load imposed would require breathing effort and inspiratory muscle force output to increase in the region of 3 and 10 times normal respectively (the pressure load imposed by the elastance and flow resistance of the respiratory system is in the region of 5cmH₂O). Pillow A would certainly impair resting breathing, and pillow B would very likely impair resting breathing, especially in those with inspiratory muscle weakness, and/or increased work of breathing due to disease. Both pillows A and C would impair breathing at raised inspiratory flow rates, e.g., during a seizure. It is clear that at resting tidal flow rates (0.3 l.sec⁻¹), pillows B and D have negligible resistance and the resistance of pillow D was not increased significantly by the addition of the non-woven cover. At the higher flow rates that might be associated with a seizure (1.0 – 3.0 l.sec⁻¹), the resistance of pillow B would increase the demand for inspiratory force output by 1 to 4 times, which, as stated above, may be sufficient to impair breathing in some patients. In contrast, the resistance of pillow D is negligible at both test conditions (with and without the non-woven cover), even at the highest flow rate tested. Indeed, it is unlikely that an additional load of less than 1.5 cmH₂O would even be detectable.

Evidence for the Effectiveness of Sleep-Safe Anti-Suffocation Pillows

Interpretation: Pillows A and C would present significant resistance to breathing in healthy adults, and would be unsuitable for use by people with breathing difficulties such as would occur during a seizure or convulsion.

Pillow B would present significant resistance to breathing in adults with medical conditions where breathing difficulties were of an intermittent or unpredictable nature such as would occur during a seizure or convulsion.

Pillow D would present no significant resistance to breathing in healthy adults and adults where breathing difficulties were of an intermittent or unpredictable nature. The use of a non-woven cover would not impede the effectiveness of pillow D.

Based on these test results, Pillow D should be the choice in circumstances where breathing ability is compromised by disability, disease state, medication or age.

Table 2

Pillow Identities (Revealed after the tests were completed)	
Pillow	Description
A	Domestic Feather + Down
B	Glued Foam (CP)
C	Domestic Hollowfibre
D	Sleep-Safe Pillow
D + non-woven cover	Sleep-Safe Pillow + non-woven cover

How Sleep-Safe Anti-Suffocation Pillows Work

See the 'How Sleep-Safe Pillows Work' video at www.sleep-safe.co.uk



A normal pillow
BLOCKING the
nose and mouth



Sleep-Safe
pillows WON'T
BLOCK the nose
and mouth



Airflow
THROUGH the
Sleep-Safe pillow
AND AROUND
the nose and
mouth

What a Canadian mother says...

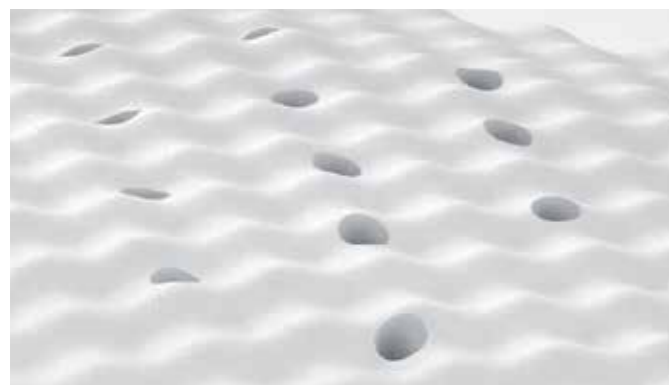
"My son was admitted to the Foothills Hospital Seizure Monitoring Unit here in Calgary.

They showed me a video one of the seizures in the middle of the night. My son turns his head to the right side at the onset of his seizures. I watched the video of my son laying on his right side, turning his head to the right, with his face directly in to the pillow. Of course, this was alarming!

But even as I was watching, I knew he was OK because he was sleeping with Sleep-Safe pillows that I recently purchased from your company.

When my son was admitted to hospital, I brought his Sleep-Safe pillows to the hospital, because now that I have them, I no longer feel comfortable with him sleeping with any other pillows."

- Sleep-Safe permits breathability through the entire pillow, not just through a mesh cover...
- Sleep-Safe does not contain fibre pads, memory foam, feathers, down or other fillings which impede breathability through the entire body of the pillow...
- Sleep-Safe is made from open cell materials with a gently rippled surface which enables maximum airflow and breathability...



You can 'see' the breathability:
hold a table light behind a Sleep-Safe pillow.

Hypoallergenic Open Cell Foam permits a very controlled diffusion of air and moisture vapour, which 'wicks' perspiration away from the skin.

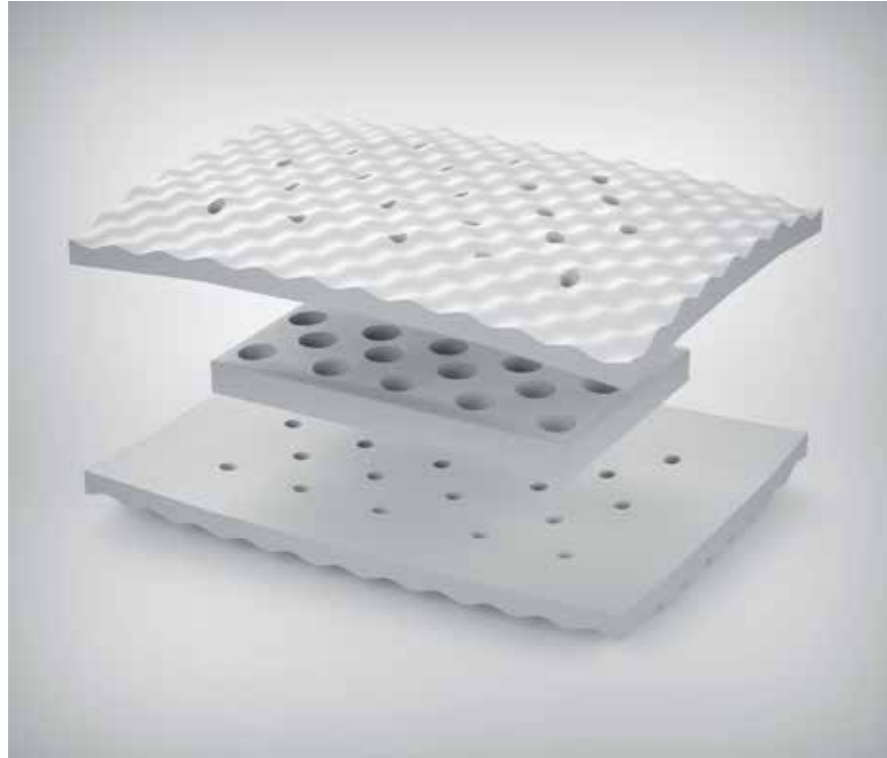
Hypoallergenic Micromesh Pillow Cases permit maximum breathability across the entire surface of the pillow.

'What you can See Through, you can Breathe Through'



Sleep-Safe is a 'dynamic' pillow with unique advantages

- Airflow and breathability through the whole depth, sides and ends of the pillow
- The built-in 'Aero-Matrix' pump construction eliminates exhaled breath and carbon dioxide



The Sleep-Safe pillow is made from soft, highly porous foam with an open-cell structure and has three components:

- A breathable, micromesh pillow case
- Two gently rippled Aero-Profile surfaces each with numerous Thru-Channels to facilitate plentiful airflow and breathability
- An inner core with multiple Aero-Matrix chambers

The outer micromesh pillow case and the rippled Aero-Profile pillow faces permit air flow across the entire surface of the pillow.

The rippled Aero-Profile pillow faces and inner core are held in proximity by a wide-mesh pillow case which permits maximum airflow and breathability.

This enables the Thru-Channelling of the pillow faces and the Aero-Matrix chambers to 'work together':

- Any head movement compresses and decompresses the core Aero-Matrix chambers, causing air to flow through the sides and ends of the pillow and the Thru-Channelling, and to pass around the face and help prevent suffocation
- Air is able to flow throughout the whole depth of the pillow, and through the sides and ends of the pillow
- This propels exhaled breath and carbon dioxide away from the user's nose and mouth

This means that Sleep-Safe is a 'Dynamic' pillow with unique advantages that help to prevent suffocation...

<p>Hypoallergenic Micromesh Pillow Cases – these are dye-free to minimise the risk of severe allergies which could trigger seizures in susceptible people.</p>	<p>UK made from UK sourced materials UK Hand-made in a disability workshop UK University lab tested for effectiveness UK Product Safety and Fire Regulations compliant UK Government Registered Class I Medical Device</p>
<p>Hypoallergenic Open Cell Foam - Not Latex Foam, which can cause allergies, Not Memory Foam, which can trap heat and also compress and impede airflow and breathability.</p>	<p>Hypoallergenic Manufacture - no adhesives or welding chemicals are used in making Sleep-Safe pillows, this means that there are no volatile 'leftovers' to cause allergic reactions, asthma attacks or breathing difficulties.</p>
<p>Easily washable - the 'Take-Apart' Benefit: Sleep-Safe can be washed and dried in one piece or taken apart and the components washed separately. This means that any soiling and house dust mites and airborne particles which cause allergic reactions or breathing difficulties can be washed out of the entire pillow in a single wash.</p>	
<p>Reduces stress and anxiety - Sleep-Safe help to reduce greatly the 'carer anxiety' of sleep seizures – the fear of suffocation. This helps to put people affected by seizures back in control of their lives by relieving a significant cause of family stress, so managing the condition which is causing the seizures becomes much less demanding.</p>	
<p>Not just for epilepsy, but also for the management of seizures caused by most conditions that disrupt the normal functioning of the brain. These include the ongoing effects of congenital and developmental conditions such as Down's syndrome, Dravet Syndrome, cerebral palsy and autism spectrum disorder, also acquired brain injury following falls, vehicle accidents and assaults and the aftermath of meningitis, stroke and brain tumour.</p>	

Protects **THEM** while they sleep –
and gives **YOU** peace of mind!

Some Frequently Asked Questions about Sleep-Safe

After you receive your Sleep-Safe, we may send you an email seeking your opinion and asking for any constructive criticism and suggestions for improvement. This is a part of our ongoing survey of users and carers. However, here are the answers to a few questions that crop up regularly:

Q. What influence do user and carer comments have on the design of Sleep-Safe?

A. During the past 28 years suggestions from users and carers has led to several complete re-designs of Sleep-Safe: a smoother surface to improve comfort, a large cell Aero-Matrix to lessen ‘flattening’ during intense-use situations, and the latest innovation – a Take-Apart design. In addition to these user-led improvements, we have integrated extra Thru-Channelling and progressively smoother micromesh covers. This unique blend of features - the micromesh cover, the profiled surface, the Thru-Channelling and the Aero-Matrix - permits air to pass between the surface of the pillow and the cover and through the body of the pillow itself to provide even greater breathability, comfort and, above all, user safety.

Q. Is a ‘firmer’ version of Sleep-Safe available?

A. In response to feedback the ‘firmness’ of Sleep-Safe has actually been reduced - they’ve been made softer - because most users wish for a pillow as similar to a ‘normal’ domestic pillow as possible. A latex version of Sleep-Safe has been trialled, however latex is a natural product derived from the *Hevea brasiliensis* tree and contains proteins to which some individuals develop an allergy. Other natural products such as grains and vegetable fillings can cause similar problems. The entirely synthetic nature of Sleep-Safe means that possible allergens can be eliminated more easily, thus reducing the likelihood of allergies, breathing difficulties and hypersensitivity reactions.

Q. Is a ‘softer’ version of Sleep-Safe available?

A. There has to be a ‘trade off’ between softness and breathability. The softer the pillow, the more likely it is to shape around the nose and mouth and to suffocate the user.

Q. What about the micromesh cover?

A. The micromesh cover is the same type of fabric used to line clothing that ‘wicks’ perspiration away from the skin - we always use materials which already have established uses in ‘next-to-skin’ applications. Over the years, the original net cover (which veteran Sleep-Safe users will remember) has been replaced by a succession of smoother materials. The textile we use currently is chemically inert and inherently flame retardant, and any replacement material must also possess these characteristics; in particular, it must not require any chemical treatments, which could cause allergies, breathing difficulties and hypersensitivity reactions.

Q. Are coloured pillow covers available?

A. No, because dyes may cause skin reactions resulting in high temperatures and a danger of seizures.

Q. Is Sleep-Safe suitable for use by vegans?

A. Yes. Sleep-Safe contains nothing created from the exploitation of living creatures.

MHRA urges caution in switching epilepsy drugs

Switching between different manufacturers’ epilepsy drugs could cause patients to have seizures or suffer other side effects, the Medicines and Healthcare Products Regulatory Agency has warned.

The MHRA split anti-epileptic drugs into three categories, based on the risk of harm from switching.

Patients on the four medicines that fall into category one – phenytoin, primidone, phenobarbital and carbamazepine – should be maintained on a specific manufacturer’s product, the MHRA said.

Clinicians should exercise caution when prescribing the drugs that fall into category two, which include valproate, rufinamide and clonazepam. The decision to switch patients on these drugs should be based on clinical judgement and consultation with the patient or carer, “taking into account factors such as seizure frequency and treatment history”, the MHRA advised.

It was “usually unnecessary” to stick to a particular manufacturer when prescribing the seven category three medicines such as gabapentin and lacosamide, the MHRA ruled. But it advised clinicians to be mindful of specific concerns such as patient anxiety and risk of confusion and dosing errors.

The medicines watchdog urged healthcare professionals to exercise caution when switching their patients between drugs, after a review by the Commission on Human Medicines found patient harm “could not be completely ruled out” in some cases.

A review by the Commission on Human Medicines found patient harm when switching patients between epilepsy drugs “could not be completely ruled out”.

Siu Ping Lam, the MHRA’s acting director of licensing, said: “The categories of anti-epileptic drugs are designed to help healthcare professionals decide upon whether it is necessary to maintain continuity of supply of a particular manufacturers’ product.”

“If patients have any concerns about, or problems with, their anti-epileptic medicine, they should speak to a healthcare professional such as a doctor, pharmacist or nurse.”

The three categories:

- **Category one medicines:** Phenytoin, Carbamazepine, Phenobarbital, Primidone
- **Category two medicines:** Valproate, Lamotrigine, Perampanel, Retigabine, Rufinamide, Clobazam, Clonazepam, Oxcarbazepine, Eslicarbazepine, Zonisamide, Topiramate
- **Category three medicines:** Levetiracetam, Lacosamide, Tiagabine, Gabapentin, Pregabalin, Ethosuximide, Vigabatrin

From Don Alderton

After I qualified as a pharmacist, and my wife as a health visitor...

...and we started a family I developed **Sleep-Safe pillows** because our son's seizures made me desperately concerned about his safety while he slept. I was **dismayed** that there were no specialist items of bedding designed to help keep him safe while he slept. During the seizures his breathing became spasmodic and laboured and for brief periods he would cease breathing entirely: I feared that becoming tightly entrapped during a sleep seizure could lead to brain injury - or even death - due to lack of oxygen. Sheets and blankets could be minimised, but all standard domestic pillows seemed fundamentally unsafe. A few years later I discovered that an 'anti-suffocation' pillow *had* been available, however, production ceased when the manufacturer closed down. I obtained a used sample of the pillow, re-designed it, and launched it as '**Sleep-Safe**'.

Because of the 'small demand' – only 1 in 140 people suffer from epilepsy – no established medical products company would consider manufacturing Sleep-Safe, so I started production myself. Sleep-Safe are still hand-made in the UK and supplied to thousands of people with seizures and to their carers, helping to relieve the constant anxiety that I know results from seizures.

Sleep-Safe are *not just* for people with epilepsy: Sleep-Safe can help protect against the adverse outcomes of seizures which result from a wide variety of medical conditions including the ongoing effects of congenital and developmental conditions such as Down's syndrome, cerebral palsy and autism spectrum disorder, and also acquired brain injury following falls, vehicle accidents, assaults and the aftermath of meningitis, stroke and brain tumour.

The figures quoted in the leaflet show that this is a matter of very real concern. In the UK, each year, epilepsy *alone* results in about **1,100 deaths** and **44,000 emergency hospital admissions**, and most of these are sudden and unexpected and occur usually at night.

However, no research has been conducted into the total deaths from all causes of seizures and convulsions, for example, diabetes, stroke and head injuries, so the actual mortality could be very much greater.

Worldwide, in general, the proportion of the population affected by epilepsy is much the same as in the UK – about 1 person in every 140.

The benefits of Sleep-Safe anti-suffocation pillows go beyond helping to prevent the death or injury of the person who is actually affected by seizures. **Sleep-Safe pillows also provide reassurance to parents and carers** by breaking the cycle of fear that can result in disturbed sleep patterns, anxiety and depression, often leading to a profound deterioration in the quality of life for the entire family.

Electronic alarms and monitors can provide valuable surveillance, but these are expected to function with 100% certainty for 100% of the time, and are limited by the availability of a nearby carer or caregiver who can respond. However, that kind of excellence is usually found only in specialised electro-medical monitoring equipment used in hospital settings, and 100% reliability shouldn't always be relied upon. **Sleep-Safe pillows don't require carer intervention in order to 'work properly'** – they are designed to help prevent fatal suffocation events during sleep seizures occurring in domestic or care settings where 24-hour continuous monitoring is not entirely feasible.

This means that **Sleep-Safe also help to reduce greatly the "carer anxiety" of sleep seizures** – the fear of the consequences of suffocation – helping to put carers and patients back in control of their lives by relieving a significant cause of family stress. As a result, management of the underlying medical condition becomes much less demanding.

Sleep-Safe pillows have been tested at a leading UK University which specialises in respiratory physiology. The tests compared the 'breathability' of a range of domestic and medical pillows, and established that only Sleep-Safe pillows – because of their very high breathability - would deliver benefits for adults and children with medical conditions where there is a risk of suffocation and breathing difficulties.

This evidence has been accepted by the UK Government's Medical and Healthcare products Regulatory Agency which has registered Sleep-Safe pillows as a Class I Medical Device. **Also, in an extremely rare decision**, the UK Customs & Excise has given written authority for Sleep-Safe pillows to be supplied VAT-free to eligible personal purchasers and charities. It's almost unheard of for the Government to stop collecting a tax, which will give you some idea of the quality of evidence that we had to present in order to obtain this tax concession.

The consistent demand for Sleep-Safe Anti-Suffocation Pillows reflects the benefits that Sleep-Safe deliver in terms of safety and effectiveness. Sleep-Safe is a registered medical device which many health and social care professionals judge to be essential in providing anticipatory, preventative care for people affected by seizure disorders, and which can make a real difference to their lives.

These professionals confidently recommend Sleep-Safe pillows as an evidence-based solution to help prevent fatal suffocation events, and also the non-fatal but often devastating life-long consequences of brain injury caused by suffocation oxygen deficiency.

Who Else is Using Sleep-Safe?

Leading health and social care providers in the UK and overseas which are providing Sleep-Safe Anti-Suffocation Pillows to protect their patients with epilepsy and other seizure disorders include:

Young Epilepsy (formerly The National Centre for Young People with Epilepsy) - the UK's leading provider for children and young people aged 5 to 25 with complex epilepsy and other neurological conditions

Charing Cross Hospital - referral centre for neurosurgery which houses the serious injuries centre for west London

Merseycare NHS Foundation Trust - 40 community units housing people with learning disabilities

Cornwall Partnership NHS Trust - 107 community units housing people with learning disabilities

United Response - 40+ community units supporting people with learning disabilities, mental health needs and physical disabilities

Also... (not a complete list) Herts Partnership NHS Foundation Trust, Solihull Care Trust, the States of Guernsey Health and Social Services, Bath & West Community NHS Trust, Central Lancashire PCT, Northgate & Prudhoe NHS Trust, Derbyshire County PCT, Hampshire Partnership NHS Trust, Northumberland Care Trust, Oldham Community Health Services, Hertfordshire County Council Adult Care Services, Somerset County Council, Barnardo's, BUPA, SENSE, the leading UK charity supporting deaf-blind people...

...and hundreds of individual private purchasers with seizure disorders.

USA: About 1 in 10 of all Sleep-Safe pillows are supplied to care provider organisations and individuals in the United States.

France: A further 1 in 10 of all Sleep-Safe pillows are supplied to the French Social Services and Epilepsy Societies.

400 Sleep-Safe Pillows supplied to Association ASPEC Le village du Perche
230 Sleep-Safe Pillows supplied to Centre Médical de La Teppe Specialising in Epilepsy
160 Sleep-Safe Pillows supplied to U G E C A M home for people with epilepsy
60 Sleep-Safe Pillows supplied to "Castelnouvel" home for children with epilepsy
60 Sleep-Safe Pillows supplied to Association EPI home for children with epilepsy
50 Sleep-Safe Pillows supplied to Maison d'Ulysse Order of Malta for adults with autism

European Union

200 Sleep-Safe Pillows supplied to the European Union Dravet Syndrome Foundation

Kenya

60 Sleep-Safe Pillows supplied to Children with Special Needs Support, Kisumu, Kenya

What Parents and Carers say about Sleep-Safe...



When my son was admitted to hospital, I brought his sleep-safe pillows to the hospital, as now that I have them, I no longer feel comfortable with him sleeping with any other pillows.

I think that it is a wonderful thing that your company is supplying. I have given your information to the Foothills Hospital Seizure Monitoring Unit here in Calgary, Alberta, Canada and they are very interested in advertising to future patients. It surprised me that they had not seen pillows like this before.

I hope that I can help you save lives!

Thank you for your wonderful product! I don't know how my son ever did without them.

Thank you very much for your prompt response to my order. It was very nice reading about you and your family and your son's positive achievements. It has made us feel more positive about our daughter, who is struggling with seizures at the moment. We have got 4 daughters - our 14 year old has never had any of the usual childhood ailments like tonsillitis, ear infections etc. and suddenly in April last year she started having seizures. She was diagnosed with epilepsy in December and has got progressively worse since April this year. We are in the process of changing her medicine and your letter has given us hope for her future. I suppose what has made it more difficult is that, apart from colds, she has never been ill and she really hates taking the medication - she says that her seizures have got worse since she has been taking it. Combine that with the usual teenage moods and you can imagine what we are going through!

Thank you again - I have recommended you on the parents' forum of the National Epilepsy Society's website.

Dear Don, Thank you for delivering my order for new pillows, the next day! I will continue to use your service, because of the excellent quality of your product and the prompt delivery. Regards JD.

Dear Don, I have just received my order. Thank you very much and wow!! What an improvement you've made on the pillow since the last two I bought! It feels much softer. My daughter is going to be so pleased. Once again, we can't thank you enough. We sleep with peace of mind, knowing our daughter won't suffocate if she has a seizure.

Thank you so much Don! I received my pillow yesterday, you're a lifesaver! My daughter used it last night. I actually slept a bit last night! God Bless U and your family!

What Parents and Carers say about Sleep-Safe...



Don, I just wanted to touch base with you and let you know that we got the pillow on Monday. My daughter absolutely loves it! It is the first pillow that I have ever allowed her to sleep on. I am so happy that you designed it. I know you know as a parent that you would do anything you could to make sure that your child is safe. When I get the chance to sign up at some of these epilepsy sites, I plan on telling people how much it put me at ease! Take care and God bless.

Hi Don I just had to say a huge THANK YOU for a fantastic product! WOW..... Not only can my child sleep safe now but SO CAN I, knowing he is safe... For 5 years now I cannot remember having a beautiful peaceful sleep until last night. My 5yr old slept soundly and so did I. He loves his new MAGIC PILLOW - he thinks it's quite cool... J suffers so many different types of seizures so this is a god send... I had to tell you about how this has changed our lives dramatically on the first night, people are so quick to complain but not so quick to say Brilliant and Thank You. Well a HUGE THANK YOU FROM US ALL. YOU WILL BE IN OUR THOUGHTS – M.

Dear Mr Alderton, Thank you for processing my order for 2 sleep safe pillows. I confirm that I have received your E mail and wish to apply for VAT exemption for this order. The service I have received from your company has been exemplary and thank you sincerely for the speed with which my order has been processed. The pillows have arrived safely! These are early days in the diagnosis for my son, and for us, and it is so reassuring that we have access to so much help and information regarding epilepsy. The information pack you also sent with the pillows has been very useful to read and my son has already ensured that the "I have epilepsy" card and first aid notes are tucked securely on his person whenever he goes out of the home! Maybe all this helps me not be so frightened when he is away from me. Thank you once again.

Mr. Alderton, Thanks for your swift arrangements for shipment and delivery of sleep-safe anti-suffocation pillow and pillow-cases for my daughter. I guessed that you have had a comprehensive understanding of seizure problems from inside out and your letter has proven correctness of my guess. You have done great job to keep thousands of people safe and protected during sudden occurrences of seizure while sleeping. Therefore you deserve to be blessed by The God. With best wishes, Giorgi and Family, United Arab Emirates.

Notes



Anti-Suffocation Pillows

Protects **THEM** while they sleep –
and gives **YOU** peace of mind!



A Family Company,
run by Healthcare Professionals, focussed on Healthcare Integrity.

www.sleep-safe.co.uk

Order online or phone **07773 619552** Email to enquiries@sleep-safe.co.uk

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