

Infant Sleep Positioning Products and Wedges*

Since the identification of prone (stomach) sleeping as a high risk factor for Sudden Infant Death Syndrome (SIDS) and the launch of the "Back to Sleep" campaign, there has been a proliferation of new products on the market developed in response to the AAP recommendation to place infants to sleep on their backs.

Product Types:

Currently there are two main types of infant sleep positioning products on the market; no safety or performance requirements exist for either product. The first group is sleep positioning products used to restrain infants during sleep, developed in response to the American Academy of Pediatrics' (AAP) recommendation to place infants to sleep on their backs. There are no current studies that show the effectiveness of such products in reducing the risk of SIDS. The products are composed of a base mat and a pair of lateral support blocks/wedges intended to restrain the infant in the position in which he/she is placed. The second group of products is wedges or products with an incline, some of which are equipped with a harness restraint. These products are used to relieve acid reflux and colic in infants, and are more likely to be recommended by physicians.

Concerns:

- There are no current studies that show the effectiveness of such products in reducing the risk of SIDS. The U.S. Consumer Product Safety Commission (CPSC) has not publically addressed these specific products, but recommends against the use of any kind of cushion or pillows in infant cribs and in the infant sleep environment. The AAP states that "...back sleeping is comfortable and does not require special equipment. Wedges to keep babies in place are not necessary and are not recommended, unless specified by a physician." See attachment A
- Although the intended function of these products is to keep an infant in a supine (back) position, and the products are likely purchased for this reason, CPSC data shows that parents and caregivers still have placed infants to sleep on their stomach in these products with fatal outcomes.
- The other major concern is use of the product to maintain an infant on its side, which is an unstable position. Infants placed on their sides are more likely to flip into a prone position because their backs are pressed against the side of the sleep positioning product.
- In 1996, the AAP reversed an earlier recommendation and warned against the side position as an alternative to prone sleeping because of stability concerns. Infants placed on their sides were flipping to the prone position. The AAP now recommends only the supine sleep position, to reduce the risks of SIDS and suffocation.
- It would seem unlikely that a parent or a caregiver who is aware of the intent of the product would place an infant on it in the prone position. However, misuse (placing infants on their stomachs) or improper placement of infants (on the side) in these products continues.

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CPSC Staff Data Analysis:

CPSC staff is aware of ten deaths associated with these products. The deaths occurred between the period of January 1, 1997 and August 20, 2009. (See attachment B)

- Nine of the deaths were associated with sleep positioning products.
 - In five of the nine deaths, the infants were placed on the side or stomach within the product.
 - In two of the incidents, it was not clear whether the product played a role in the death of the infant. In one case the cause of death according to the medical examiner “may have been SIDS.” In the second incident the medical examiner merely stated the cause of death as “accidental, infant improperly placed in sleep positioner device covered with blankets.”
 - The remaining two deaths occurred outside the product. The infants were found wedged in the space between the product and a component of the crib and/or other bedding products.
- The tenth fatality was associated with what seemed to be a positioning wedge intended for an infant with acid reflux. In this incident the infant slid off the restraint and was found dead lying along the crib railing. The cause of death as stated by the medical examiner was “positional asphyxia with history of bi-pulmonary dysplasia”.

Between January 1, 1997 and August 20, 2009, there was one knee abrasion injury reported through NEISS (National Electronic Injury Surveillance System) associated with these products. At least 33 non-injury incidents and consumer complaints have been reported to CPSC since 1997.

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Attachments:

- A. Front page and P. 45. of AAP reference document to sleep positioning devices and wedges on the AAP website, and corresponding link to the entire document.
<http://www.healthychildcare.org/pdf/SIDSfinal.pdf>.
- B. Table of Infant Sleep Positioner Fatalities ages 0- 23 months from January 1, 1997 to August 20, 2008 prepared by Epidemiology Hazard Analysis staff.

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Infant Sleep Positioner Fatalities 1/1/1997 to 8/20/2009*

Children 0 - 23 Months of Age

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Count	Docno	Tkno	Source	Inc_Date	Age/Sex	City and State	Narrative	Dt_ent
1	H0330162A		IPII	6/5/1997	2 MO M	██████████	A male infant, age 2 months, placed on his side in the crib, rolled forward & suffocated to death. His right arm had got wedged between his body & anti rollover protection device when he rolled & he was unable to push himself up.	4/3/2003
2	X9910147A	990119HCC3132	INDP	9/12/1998	2 MO F	██████████	A 2-month-old female suffered anoxia when her mother placed her in a prone position on a baby pad within a bassinet. The pad was designed to maintain the position of the infant during sleep. The incident resulted in the infant's death, ruled accidental, and caused by positional asphyxia.	8/31/1999
3	9953036188	001121HCC3062	INDP	10/2/1999	4 MO F	██████████	Due to health problems a four month old female was placed to sleep in a crib on wedge shaped foam product. Victim secured in place by a cloth harness that was secured around victim by Velcro straps. During the night the victim fell out of the harness. The next morning the victim's father found the victim lying face down along the crib's railings. Victim was cold to touch and unresponsive, CPR was initiated. Victim was transported to local hospital and pronounced dead....	1/17/2001

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4	I0350302A	030522CCC1566	INDP	1/8/2002	1 MO M	■■■■■	A 7-1/2-week-old-male asphyxiated in his crib following a routine feeding, after being placed on his side in a foam sleep positioning device. The victim was discovered unresponsive by his home-nurse 3-hours after the feeding, and was rushed to the hospital, where he was pronounced dead after all attempts to resuscitate failed. Following autopsy and investigation, the medical examiner's office concluded that the victim's nose and mouth had been obstructed by the device.....	6/23/2003
5	X03C6041A		IPII	10/6/2003	1 MO F	■■■■■	A female infant, age 6 weeks, was found unresponsive in her bassinet after being placed for a nap & may have died from SIDS. The bassinet had foam prop pillows for infants.	1/6/2004
6	G04B0137A	050113CCC2314	INDP	10/6/2004	3 MO F	■■■■■	A 15-week-old female was dropped off at a babysitter's house. A little while later, the babysitter put the baby down in a playpen for a nap (on her side in a foam wedge). She returned later to find that the baby was not breathing and called "911." Emergency personnel transported the baby to a local hospital where she was later pronounced dead. The cause of death was suffocation and the manner of death was accidental.	2/23/2005
7	N0660197A	060609CNE1101	INDP	6/7/2006	3 MO M	■■■■■	A three month old male victim died in his play yard after his mother placed him down to sleep on a foam sleep positioner and covered him with multiple blankets	7/5/2006
8	H0850078A	080717CCC1758	INDP	9/24/2006	3 MO M	■■■■■	A three-month-old boy was found not breathing and unresponsive in his crib by his father. It was reported that the father placed him on a 3-in-1 sleep positioner in his crib. The local fire rescue was called and the child was transported to an area hospital where he was pronounced dead. Local police department responded to the scene. The local medical examiner reported the manner of death as "positional asphyxia".	8/29/2008

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9	0837074968	090508HCC1698	DTHS	11/20/2008	3 MO M	██████	Accidental suffocation. Rolled over / wedged between wedge cushion and bassinet side. Autopsy-yes....	4/30/2009
10	N0920307A	090212CNE4184	INDP	1/11/2009	3 MO M	████████	A three-month-old male was placed to sleep stomach down on a sleep positioner in a bassinet. When his mother checked on him approximately six hours later, he was felt cold to the touch and rigid. A teen-ager in the home called 911. EMS personnel found no vitals and determined the victim had been deceased for several hours. An autopsy was performed the next day with the cause of death listed as position asphyxia due to a dangerous sleep environment.....	4/3/2009

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