



## NEWS from CPSC and FDA



U.S. Consumer Product  
Safety Commission  
[www.cpsc.gov](http://www.cpsc.gov)

U.S. Food and  
Drug Administration  
[www.fda.gov](http://www.fda.gov)

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### Deaths prompt CPSC, FDA warning on infant sleep positioners

WASHINGTON, D.C. - The U.S. Consumer Product Safety Commission (CPSC) and the U.S. Food and Drug Administration (FDA) today warned consumers to stop using infant sleep positioners. Over the past 13 years, CPSC and the FDA have received 12 reports of infants between the ages of 1 month and 4 four months who died when they suffocated in sleep positioners or became trapped and suffocated between a sleep positioner and the side of a crib or bassinet.

Most of the infants suffocated after rolling from a side to stomach position. In addition to the reported deaths, CPSC has received dozens of reports of infants who were placed on their backs or sides in sleep positioners, only to be found later in potentially hazardous positions within or next to the sleep positioners.

"The deaths and dangerous situations resulting from the use of infant sleep positioners are a serious concern to CPSC," said CPSC Chairman Inez Tenenbaum. "We urge parents and caregivers to take our warning seriously and stop using these sleep positioners, so that children can have a safer sleep."

The two main types of infant sleep positioners are flat mats with side bolsters or inclined (wedge) mats with side bolsters.



**Flat Mat**



**Inclined/Wedge**

Both types of sleep positioners typically claim to help keep infants on their backs and reduce the risk of Sudden Infant Death Syndrome (SIDS). The FDA has never cleared an infant sleep positioner to prevent or reduce the risk of SIDS. In addition, CPSC and the FDA are unaware of any scientific studies demonstrating that infant positioners prevent SIDS or are proven to prevent suffocation or other life-threatening harm.

“To date, there is no scientifically sound evidence that infant sleep positioners prevent SIDS,” said Dr. Joshua Sharfstein, FDA Principal Deputy Commissioner and a pediatrician. “We want to make sure parents, health care professionals, and childcare providers understand the potential risk of suffocation and stop using infant sleep positioners.”

Sleep positioners also typically claim to do one or all of the following: aid in food digestion to ease colic or the symptoms of gastroesophageal reflux disease (GERD); and prevent flat head syndrome (plagiocephaly). In light of the new safety data, FDA believes any benefit from using these devices to ease GERD or prevent plagiocephaly is outweighed by the risk of suffocation.

CPSC and the FDA are warning parents and child care providers to:

- **STOP** using sleep positioners. Using a positioner to hold an infant on his or her back or side for sleep is dangerous and unnecessary.
- **NEVER** put pillows, infant sleep positioners, comforters, or quilts under a baby or in a crib.

- **ALWAYS** place an infant on his or her back at night and during nap time. To reduce the risk of SIDS, the American Academy of Pediatrics recommends placing infants to sleep on their backs and not their sides.

The American Academy of Pediatrics does not support the use of any sleep positioner to prevent SIDS.

Manufacturers of infant sleep positioners with medical claims that have not been reviewed by the FDA should stop marketing those products until they submit, and the FDA clears, appropriate premarket review submissions, including necessary safety and effectiveness data.

FDA has informed manufacturers of cleared devices of the agency's serious concern and has requested that they submit clinical data showing the benefits of their products outweigh the risk of suffocation or other serious harm.

Prompt reporting of adverse events can help the FDA and CPSC identify and better understand the risks associated with infant sleep positioners. If you have had a problem with an infant sleep positioner, the agencies encourage you to file a report through FDA's MedWatch program, at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>

CPSC is interested in receiving incident or injury reports related to these products. Please visit <https://www.cpsc.gov/cgi-bin/incident.aspx> to file a report.

For more information:

CPSC: Consumer Blog <http://www.cpsc.gov/onsafety/2010/09/sleep-positioners-a-suffocation-risk/>

FDA: Infant Sleep Positioners Pose Suffocation Risk (Consumer article)  
<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm227575.htm>

FDA: Infant Positioner Initial Communication  
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm227301.htm>

FDA: Letter to Manufacturers Concerning Medical Claims About Infant Sleep Positioners  
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm227302.htm>

FDA: Letter to Manufacturers of 510(k)-cleared Infant Positioners  
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm227303.htm>

NIH: Back to Sleep Campaign [http://www.nichd.nih.gov/publications/pubs/safe\\_sleep\\_gen.cfm](http://www.nichd.nih.gov/publications/pubs/safe_sleep_gen.cfm)

NIH: Preventing Sudden Infant Death Syndrome and Suffocation  
[www.nichd.nih.gov/health/topics/Sudden\\_Infant\\_Death\\_Syndrome.cfm](http://www.nichd.nih.gov/health/topics/Sudden_Infant_Death_Syndrome.cfm)

AAP: Policy Statement on SIDS <http://aappolicy.aappublications.org/cgi/content/full/pediatrics;116/5/1245>



**Hazard**

### **About CPSC**

The U.S. Consumer Product Safety Commission is charged with protecting the public from unreasonable risks of injury or death associated with the use of the thousands of types of consumer products under the agency's jurisdiction. Deaths, injuries, and property damage from consumer product incidents cost the nation more than \$800 billion annually. The CPSC is committed to protecting consumers and families from products that pose a fire, electrical, chemical, or mechanical hazard. CPSC's work to ensure the safety of consumer products—such as toys, cribs, power tools, cigarette lighters, and household chemicals—contributed to a significant decline in the rate of deaths and injuries associated with consumer products over the past 30 years.

To report a dangerous product or a product-related injury, call CPSC's Hotline at (800) 638-2772, teletypewriter at 800-638-8270, or visit [www.cpsc.gov/talk.html](http://www.cpsc.gov/talk.html). Consumers can obtain this press release and recall information at <http://www.cpsc.gov/index.html>. To join a free email subscription list, go to [www.cpsc.gov/cpsclist.aspx](http://www.cpsc.gov/cpsclist.aspx)

### **About FDA**

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and quality of human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation. The agency works to advance public health through initiatives that drive innovation in drug, medical device, and food science. The FDA is committed to providing accurate, science-based information to the public on the products it regulates. For more information, visit <http://www.fda.gov/>

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