

CPSC and FDA Warn Against Using Infant Sleep Positioners Because of Suffocation Risk: Initial Communication

U.S. Food & Drug Administration

Date Issued: Sept. 29, 2010

Audience:

- Parents of infants younger than 1 year old
- Health Care Providers: Pediatricians, Nurse Midwives, Pediatric Nurse Practitioners, Neonatal Nurses, Obstetricians, Obstetric Nurses, Family Nurse Practitioners, Family Physicians, Home Health Care Nurses, Maternal and Child Care Nurses, Children's Hospitals, Hospital Administrators, Lactation Consultants, Doulas, Childbirth Educators, Visiting Nurses, and Social Workers
- Educators of Health Care Providers
- Childcare Providers and Day Care Centers

Medical Specialty: Pediatrics, Family Medicine, Maternal and Child Health

On Sept. 29, 2010 the Food and Drug Administration (FDA) and the Consumer Product Safety Commission (CPSC) issued a joint press release ***urging parents and caregivers to stop using infant sleep positioners because of the risk of suffocation associated with their use.***

Device:

Infant sleep positioners are devices intended to keep a baby in a desired position while sleeping. Infant sleep positioners can be purchased over-the-counter at retail stores or on websites. They are marketed for use in homes and medical facilities.

The most common types of infant sleep positioners are:

- the sleeping bolster, usually a flat mat with round or triangular cushions on each side of a baby (See **Figure 1**) and
- the wedge-style positioner, which elevates a baby's head higher than its body, sometimes by placing the infant in an attached, diaper-like sling (See **Figure 2**).



Figure 1: Sleeping Bolster

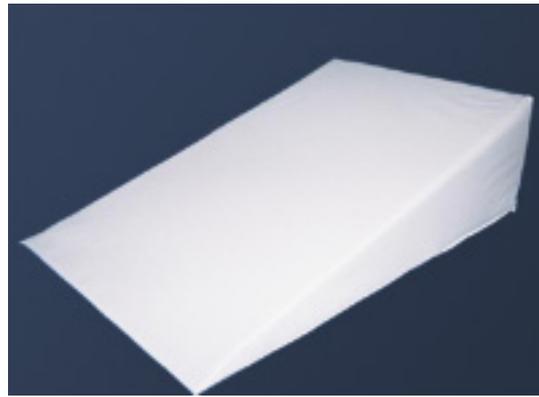


Figure 2: Wedge-Style

Suffocation Risk:

The FDA and the CPSC are aware of 12 infant deaths in the past 13 years associated with the use of infant sleep positioners. Deaths occurred after the baby rolled from its back onto its stomach and became trapped and suffocated between the device and side of the crib or bassinet. CPSC has also received dozens of reports of infants who were placed to sleep on their backs and sides in the sleep positioners, only to be found later in potentially hazardous positions within or next to the sleep positioner.

With bolster-style positioners, if a baby is placed on its stomach or if a baby rolls from its side to its stomach, his or her mouth and nose can become pressed against a bolster or other parts of the device. Even if placed on its back, a baby may move upward or downward in the positioner, entrapping its face against a bolster or becoming trapped between the positioner and the crib side or bassinet.

A baby placed on a wedge-style positioner can scoot upward so that its head falls off and hangs over the high edge of the positioner, or the baby may scoot or roll down the wedge so that its mouth and nose are pressed into the positioner. The baby's movement may also cause the positioner to flip on top of the baby, trapping the baby underneath the positioner or between the positioner and the side of the crib.

Medical Claims:

Many infant sleep positioners make medical claims that the device prevents Sudden Infant Death Syndrome (SIDS), prevents plagiocephaly (including flat head syndrome), or relieves the symptoms of gastroesophageal reflux disease (GERD) .

Here are some examples of medical claims that would cause an infant sleep positioner to be considered a medical device:

- "Minimize the risk of flat head syndrome"
- "Slight incline reduces acid reflux..."
- "...designed to address the dual risk of SIDS and sleep-related skull

flattening (deformational plagiocephaly)"

The FDA has never cleared an infant sleep positioner to prevent or reduce the risk of SIDS. Also, the FDA is unaware of any scientific study that shows infant positioners prevent SIDS or are proven to prevent suffocation or other life-threatening harm.

In the past, the FDA has cleared infant sleep positioners for the prevention of flat head syndrome and the treatment of GERD; however, in light of new safety data there is no evidence that any benefits of these devices outweigh the risk of suffocation.

Recommendations:

The FDA and CPSC warn parents, caregivers and health care professionals:

- **STOP** using infant sleep positioners. Using a device to hold an infant in a particular position is dangerous and unnecessary.
- **NEVER** put pillows, infant sleep positioners, comforters, or quilts under the baby or in the crib.
- **ALWAYS** place an infant to sleep on his/her back at night and during nap time. To reduce the risk of SIDS, the American Academy of Pediatrics (AAP) recommends placing infants to sleep on their backs and not their sides.

Child health care providers and professionals who educate parents about infant safety should advise the parents and caregivers of their infant patients to not use or stop using infant sleep positioners.

For more information on creating a safe sleep environment for infants, visit:

- NICHD- http://www.nichd.nih.gov/publications/pubs/safe_sleep_gen.cfm [1]
or "Safe Sleep for Your Baby: What Does a Safe Sleep Environment Look Like?"
http://www.nichd.nih.gov/publications/pubs/upload/Safe_Sleep_2009_Eng.pdf [2]
- AAP- <http://aappolicy.aappublications.org/cgi/content/full/pediatrics;105/3/650> [3]
 [4]

FDA and CPSC Activities:

The FDA is requesting all manufacturers of infant sleep positioners to stop marketing them until they submit and FDA reviews clinical safety and effectiveness data showing that the benefits of these devices outweigh the risk of suffocation.

If an infant positioner is marketed with medical claims but lacks FDA clearance, the FDA will take appropriate actions against the manufacturer if sales continue without clearance (see FDA's letter to manufacturers of infant sleep positioners without FDA-clearance) The FDA is also currently reviewing websites that make illegal medical claims related to infant sleep positioners and will be taking appropriate actions to stop this practice.

The FDA is contacting the manufacturers of FDA-cleared infant sleep positioners to request clinical safety and effectiveness data showing that the benefits of their products outweigh the risk of suffocation or other serious harm (see FDA's letter to manufacturers of FDA-cleared infant sleep positioners).

The FDA and CPSC will continue to monitor this issue and keep the public informed as new information becomes available.

Reporting Problems to FDA:

Prompt reporting of adverse events can help the FDA and CPSC identify and better understand the risks associated with these products. If you have had a problem with infant sleep positioners, we encourage you to file a voluntary report through MedWatch, at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> [5] or CPSC, at <http://www.cpsc.gov/cgi-bin/incident.aspx> [6] or call CPSC's Hotline at (800) 638-2772.

To help the FDA and CPSC learn as much as possible about the adverse events associated with infant sleep positioners, please include the following information in your reports, if available:

- Manufacturer's name
- Device name (brand name)
- Date device was manufactured
- Distributor's name or name of store where infant positioner was purchased
- Details of adverse event and medical and/or surgical interventions (if required)

Contact Information:

If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@FDA.HHS.GOV [7], 800-638-2041, or 301-796-7100.

Links for More Information:

[Joint FDA and CPSC Press Release](#) [8]

Consumer Product Safety Commission

- [CPSC](#) [9]
- [CPSC Consumer Blog](#) [10]
- [CPSC Accident Reports](#) [11]
- [CPSC FLICKR](#) [12]

Food and Drug Administration

- [FDA Consumer Update](#) [13]
- [CDRH Initial Communication](#) [14]
- [Letter to Manufacturers with FDA 510\(k\) clearance](#) [15]
- [Letter to Manufacturers without FDA clearance](#) [16]
- [FDA Facebook](#) [17]

SIDS and Safe Sleep Information

- [AAP Policy Statement on SIDS](#) [18]
- [NIH Back to Sleep Campaign](#) [1]
- [NIH: Preventing Sudden Infant Death Syndrome and Suffocation](#) [19]

[SOURCE](#) [14]

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Links:

- [1] http://www.nichd.nih.gov/publications/pubs/safe_sleep_gen.cfm
- [2] http://www.nichd.nih.gov/publications/pubs/upload/Safe_Sleep_2009_Eng.pdf
- [3] <http://aappolicy.aappublications.org/cgi/content/full/pediatrics;105/3/650>
- [4] <http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>
- [5] <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>
- [6] <http://www.cpsc.gov/cgibin/incident.aspx>
- [7] <mailto://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/DSMICA@FDA.HHS.GOV>
- [8] <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm227654.htm>
- [9] <http://www.cpsc.gov/>
- [10] <http://www.cpsc.gov/onsafety/2010/09/sleep-positioners-a-suffocation-risk/>
- [11] <https://www.cpsc.gov/cgibin/incident.aspx>
- [12] <http://www.flickr.com/photos/uscpsc>
- [13] <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm227575.htm>
- [14] <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm227301.htm>
- [15] <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm227303.htm>
- [16] <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm227302.htm>
- [17] <http://www.facebook.com/fda>
- [18] <http://aappolicy.aappublications.org/cgi/reprint/pediatrics;116/5/1245.pdf>

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[19] http://www.nichd.nih.gov/health/topics/Sudden_Infant_Death_Syndrome.cfm