

Infant Sleep Positioners Pose Suffocation Risk

Advice for Consumers

- **STOP** using infant sleep positioning products. Using this type of product to hold an infant on his or her side or back is dangerous and unnecessary.
- **NEVER** put pillows, sleep positioners, comforters, or quilts under the baby or in the crib.
- **ALWAYS** place an infant on his or her back at night and during nap time.
- **REPORT** an incident or injury from an infant sleep positioner to the Consumer Product Safety Commission by visiting www.cpsc.gov/cgibin/incident.aspx or calling 800-638-2772, or to FDA's MedWatch program at www.fda.gov/Safety/MedWatch/HowToReport/default.htm.



Two government agencies are warning parents and other caregivers not to put babies in sleep positioning products as two recent deaths underscore concerns about suffocation.

The Food and Drug Administration (FDA) and the Consumer Product Safety Commission issued the warning after reviewing reports of 12 known infant deaths associated with the products.

The most common types of sleep positioners feature bolsters attached to each side of a thin mat and wedges to elevate the baby's head. The sleep positioners are intended to keep a baby in a desired position while sleeping. They are often used with infants under 6 months old.

To reduce the risk of Sudden Infant Death Syndrome (SIDS), the American Academy of Pediatrics recommends infants be placed to sleep on their backs on a firm surface free of soft objects, toys, and loose bedding.

Suffocation and Other Dangers

In the last 13 years, the federal government has received 12 reports of babies known to have died from suffocation associated with their sleep positioners. Most of the babies suffocated after rolling from the side to the stomach.

In addition to the deaths, the commission has received dozens of reports of babies who were placed on their back or side in the positioners only to be found later in hazardous positions within or next to the product.

"We urge parents and caregivers to take our warning seriously and stop using these sleep positioners so children can be assured of a safe sleep," says Inez Tenenbaum, chairman of the Consumer Product Safety Commission.

FDA pediatric expert Susan Cummins, M.D., M.P.H, says parents and caregivers can create a safe sleep environment for babies if they leave the crib free of pillows, comforters, quilts, toys, and other items.

"The safest crib is a bare crib," she says. "Always put your baby on his or her back to sleep. An easy way to remember this is to follow the ABC's of safe sleep—Alone on the Back in a Bare Crib."

Medical Claims

Some manufacturers have advertised that their products prevent SIDS, gastroesophageal reflux disease (GERD)—in which stomach acids back up into the esophagus—or flat head syndrome, a deformation caused by pressure on one part of the skull.

Although in the past FDA has approved a number of these products for GERD or flat head syndrome, new infor-

mation suggests the positioners pose a risk of suffocation.

As a result, FDA is requiring makers of FDA-cleared sleep positioners to submit data showing the products' benefits outweigh the risks. FDA is also requesting that these manufacturers stop marketing their devices while FDA reviews the data.

Infant sleep positioner manufacturers who are making medical claims without FDA clearance must stop marketing those products immediately, agency experts say, adding there's no evidence the devices have benefits that outweigh the risk of suffocation.

"At this time, there is no scientifically sound evidence to support the medical claims being made by the manufacturers of these infant sleep positioners," says Cummins. [FDA](#)

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