

Do Not Use Infant Sleep Positioners Due to the Risk of Suffocation

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The U.S. Food and Drug Administration is reminding parents and caregivers not to put babies in sleep positioners. These products—sometimes also called “nests” or “anti-roll” products—can cause suffocation (a struggle to breathe) that can lead to death.

The two most common types of sleep positioners feature raised supports or pillows (called “bolsters”) that are attached to each side of a mat, or a wedge to raise a baby’s head. The positioners are intended to keep a baby in a specific position while sleeping and are intended for infants under 6 months old.

To reduce the risk of sleep-related infant deaths, including accidental suffocation and [**Sudden Infant Death Syndrome \(SIDS\)**](#) (<https://www.nichd.nih.gov/sts/about/SIDS/Pages/default.aspx>), the American Academy of Pediatrics recommends that infants sleep on their backs, positioned on a firm, empty surface. This surface *should not* contain soft objects, toys, pillows, or loose bedding.

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Safety Advice for Putting Babies to Sleep

- **NEVER** use infant sleep positioners. Using this type of product to hold an infant on his or her side or back is dangerous.
- **NEVER** put pillows, blankets, loose sheets, comforters, or quilts under a baby or in a crib. These products also can be dangerous. Babies don’t need pillows and adequate clothing—instead of blankets—can keep them warm.
- **ALWAYS** keep cribs and sleeping areas bare. That means you should also never put soft objects or toys in sleeping areas.
- **ALWAYS** place a baby on his or her back at night and during nap time. An easy way to remember this is to follow the ABCs of safe sleep: “**A**lone on the **B**ack in a bare **C**rib.”

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About Infant Suffocation and Other Dangers

Each year, about 4,000 infants die unexpectedly during sleep time from accidental suffocation, SIDS, or unknown causes, according to the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD).

The federal government has received reports about babies who have died from suffocation associated with their sleep positioners. In most of these cases, the babies suffocated after rolling from their sides to their stomachs.

In addition to reports about deaths, the federal government also has received reports about babies who were placed on their backs or sides in positioners—but were later found in other, dangerous positions within or next to these products.

To avoid these dangers, remember:

- The safest crib is a bare crib.
- Always put babies on their backs to sleep.

You can **[learn more about safe sleeping environments on NICHD's website](https://www.nichd.nih.gov/sts/about/environment/Pages/look.aspx)** (<https://www.nichd.nih.gov/sts/about/environment/Pages/look.aspx>).

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Beware of Medical Claims About Sleep Positioners

The FDA regulates baby products as medical devices if the manufacturer claims that the product will cure, treat, prevent, or reduce a disease or condition in its labeling, packaging, or advertising.

Sleep positioners that do not meet the definition of a medical device may be regulated by the Consumer Product Safety Commission.

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

Here are the facts:

- The FDA has *never* cleared an infant sleep positioner that claims to prevent or reduce the risk of SIDS. And, there is no scientifically sound evidence to support medical claims about sleep positioners.
- The FDA had previously approved some of these products for GERD or flat head syndrome. But because the agency learned in 2010 that these products have a risk of suffocation, the FDA then required manufacturers of FDA-cleared sleep positioners to submit data showing that the products' benefits outweigh the risks. **[In 2010, the FDA asked manufacturers to stop marketing these products](#)** ([/MedicalDevices/ResourcesforYou/Industry/ucm227302.htm](#)).

The FDA can continue to take action against manufacturers who make unproven medical claims about their products. You can do your part to keep your baby safe by not using sleep positioners.

You can report an incident or injury from an infant sleep positioner to the **[FDA's MedWatch program](#)** ([/Safety/MedWatch/default.htm](#)).

And you can find **[more advice about baby products on the FDA's website](#)** ([/MedicalDevices/ProductsandMedicalProcedures/SIDSPreventionClaims/ucm275782.htm](#)).

Finally, if you have questions about how to safely put a baby to sleep, or how to avoid or treat certain health issues, talk to your health care provider.

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