

FDA Advises Parents Not to Use Head Shaping Pillows While **Turtle Beanies Stay Safe.**

Turtle Corrective Beanies Remain FDA-Cleared Class-I Medical Devices



as FDA issues official warning instructing parents to avoid using non-cleared head shaping pillows.

GREENWOOD VILLAGE, CO – On November 3, 2022, the **U.S. Drug and Food Administration (FDA)** issued a **warning** advising parents not to use infant head shaping pillows. Turtle Corrective Beanies, on the other hand, remain a safe and effective method for correcting infant head shapes.

Having been cleared and categorized by the FDA as a Class-I Medical Device—**completely separate from head shaping pillows**—the Turtle Lucky Elephant (available in Medium and Large sizes) is not classified as a hat, but a cap device—a **different category, cleared by the FDA.**

[You can read the full FDA Safety Communication here](#)

Turtle Corrective Beanies are the original FDA-cleared, pediatrician-designed solution aimed at Preventing and eliminating flat head syndrome, and its associated medical problems, in infants. Turtle creator and founder, Dr. Jane Scott, designed the first Turtle Beanie to function as a medical device that provides care to the smallest patients, giving infants the best chance at **a normal healthy development of their head shape** and balance of neck muscles.



- ✓ FDA-Cleared Class-I Medical Device
- ✓ Follows the American Academy of Pediatrics for Safe Sleep Practices
- ✓ Pediatrician-Designed
- ✓ Eliminates Flat Head Syndrome & Its Associated Medical Problems - Now Supported with Research

Head Shaping Pillows

- ✗ Not FDA-Approved
- ✗ Creates an Unsafe Sleep Environment
- ✗ Built on False Marketing Claims
- ✗ Not Proven Effective or Safe in Treating Flat Head Syndrome



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Having spent over **35 years in Pediatrics and Neonatology** across the world, Dr. Scott, a mother of four and best-selling author of *The Confident Parent: A Pediatrician's Guide to Caring for Your Little One—Without Losing Your Joy, Your Mind, or Yourself*, was inspired to create a **user-friendly device** that provided better outcomes for babies, peace of mind for parents, and the necessary data and quality assurances to earn FDA clearance, stating, “My experience with infants began when I completed both a residency in Pediatrics and a fellowship in Neonatology. Through first-hand knowledge I discovered the unprecedented need, yet lacking availability for better quality infant positioning. Today, the Turtle is the only medical repositioning device available that **actively addresses the root cause of flat head syndrome**, while also providing a simple, at-home care for babies that helps in achieving/maintaining normal head shape while still **allowing back-to-sleep practices and a worry-free experience for parents.**”

Unlike head shaping pillows, the FDA has cleared caps, helmets, and head bands for use as **cranial orthotic devices** intended to improve cranial symmetry or **head shape in infants ages birth to six months, with mild-moderate nonsynostotic positional plagiocephaly**. Flat head syndrome can take several forms including plagiocephaly, a flattening between the back and the side of the baby's skull; brachycephaly, a flattening of the back of the baby's skull; and Torticollis, the unbalancing of neck muscles that can cause the baby to tilt its head to one side.

“There are no FDA-Approved head shaping pillow options currently on the market.”



Turtle Beanie FAQs

Is the Turtle Corrective Beanie a head shaping pillow?

No. The FDA has acknowledged the fact that Turtle Beanies fit into the category of 'cap devices', which are FDA-cleared. The Turtle Lucky Elephant is NOT a loose pillow.

Loose head shaping pillows do not help flat head syndrome, but rather pose a risk of suffocation.

Has the Turtle Corrective Beanie been recalled or rescinded?

No. Turtle Corrective Beanies have been and remain in a different FDA category, separate from infant head shaping pillows. Turtle medical devices **status remains unchanged by the FDA.**

What size should I order if my baby's head is on the cusp?

Always size up as opposed to down. These little guys are experiencing rapid head growth at this time in their lives, so even **if the beanie is slightly large, they will grow into it quickly. It is possible to tighten it up with the side straps.**

What are your recommendations for wear during nap and overnight sleep?

You will be able to safely allow the baby to wear the Turtle during your waking hours morning till night whenever **baby is lying** against a firm surface. **Leave your infant to sleep without the Turtle at night and allow them to sleep without trying to reposition,** as it is healthier for the infant to be able to turn to both sides each day. This helps to prevent getting a flat spot on the other side while keeping your baby's neck muscles healthy and symmetrical.



Infant head shaping pillows are typically small pillows, with an indent or hole in the center designed to cradle the back of an infant's head while it's lying flat on its back, and were believed to treat flat head syndrome—until this most recent FDA warning. These pillows create an unsafe sleep environment with increased risks of suffocation and even death. Despite what false marketing claims may state, there are **no FDA-approved head shaping pillow options currently on the market.**

Information regarding flat head syndrome:

Flat head syndrome typically develops in the first six weeks of life as babies' heads are very soft and malleable, and their necks are weak. **Babies tend to rapidly develop** preferences for how they like to sleep, and because of this their head can develop a flat spot due to constant pressure on a specific area.

Due in part to the "Back to Sleep" response to SIDS in 1992, which advised parents to always place babies on their backs while sleeping, **flat head syndrome diagnoses have increased greatly.** Today, flat head syndrome affects nearly half of all babies under the age of three months in the United States. But Dr. Scott says with early intervention, there's no cause to sound the alarm for parents.

“Though the thought of any baby being anything other than a bright-eyed, healthy infant is worrisome, we are here to help parents/caretakers with sound education and assistance in using good infant positioning to eliminate all aspects of flat head syndrome, and to avoid other medical issues which can be a secondary effect.”

In addition to Turtle Beanies being cleared by the FDA, Turtle also adheres to the recommendations of **the American Academy of Pediatrics for Safe Sleep practices** and the **prevention of SIDs.** The American Academy of Pediatrics recommends that infants sleep on their backs in a bare crib, on a flat surface, without pillows, toys, soft objects, or loose bedding. Turtle instructs parents to remove the Corrective Beanie when the baby is unsupervised **at night when parents/caretakers are sleeping.**

For more information on our Turtle Beanies (FDA Registration Number 3007842980), visit **turtle.com.**