

Pool neck floats are a danger to babies, FDA warns

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Neck floats marketed for babies to use in water can lead to serious



injury or death, the U.S. Food and Drug Administration warned this week.

The inflatable plastic rings are especially dangerous for infants who have developmental delays or special needs, such as those with spina bifida, spinal muscular atrophy (SMA) type 1, Down syndrome or cerebral palsy, the agency said in its news release.

The neck floats can increase the risk of neck strain and injury, according to the agency.

"The FDA is aware that some manufacturers are claiming these products support water therapy interventions in <u>babies</u> with developmental delays or special needs and that the benefits of these products include increased <u>muscle tone</u>, greater flexibility and range of motion, increased lung capacity, better sleep quality, and increased brain and nervous system stimulation," the statement noted.

Yet the safety and effectiveness of neck floats to build strength, to promote motor development or as a physical therapy tool have not been established, according to the FDA.

The agency encouraged parents and providers to report any injuries that have happened using the pint-sized swim aids to the FDA, so it can identify and better understand the risks associated with <u>medical devices</u>.

The FDA said it knows of one baby death and another baby who was hospitalized with injuries related to neck floats. Both babies were injured when their caregivers were not directly monitoring them, and it is possible some cases have not been reported to the FDA.

The rings are worn around babies' necks, allowing them to float freely in water. Some are marketed to babies as young as 2 weeks old or to



premature babies, the FDA said. They are designed to cradle a baby's head while their body moves in the water.

In addition to water therapy, they are sometimes used for swimming and bath time.

The announcement was made after the agency became aware of companies marketing neck floats for use as a water therapy tool without FDA clearance or approval.

Those who have experienced adverse events with neck floats can file a report through <u>MedWatch</u>, the FDA Safety Information and Adverse Event Reporting program. Health care personnel whose facilities are subject to the FDA's user facility reporting requirements should follow their facility's reporting procedures.

Reports should include the device brand name; manufacturer's, importer's and/or distributor's name, and details about what happened and any medical or surgical interventions.

More information: The American Academy of Pediatrics has more on <u>infant water safety</u>.

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