



snOO in the NEWS



FDA grants De Novo approval to the SNOO Smart Sleeper

Marking a significant advance in infant safety, the U.S. Food and Drug Administration (FDA) has granted De Novo approval to Happiest Baby's SNOO Smart Sleeper. SNOO is now the first medical device designed to keep sleeping babies safely positioned on the back during sleep. Babies who are positioned to sleep on the back are at a lower risk of sleep-related mortality.

For two decades, Happiest Baby's mission has been to help parents succeed at their most important job — raising healthy, happy children. SNOO was created specifically to improve infant sleep safety by ensuring babies are securely anchored on the back, one of the key safe sleep recommendations of the American Academy of Pediatrics.¹



Every year, 3,500 American babies die in their sleep from suffocation and unexplained causes, including SIDS (Sudden Infant Death Syndrome).² These deaths are collectively referred to as SUID (Sudden Unexpected Infant Death) and constitute the leading cause of death of healthy, full-term infants during the first year of life (90% of SUID cases occur in the first six months).³

Finally, there is a medical device designed to reduce the risk of non-supine infant sleep positioning. SNOO is approved for use by babies under 6 months of age or until they have demonstrated they can consistently roll — from stomach to back — during sleep. In a study of 1,012 infants, SNOO use was associated with a 91.5% reduction in unsafe stomach sleeping.⁴ However, SNOO has not directly demonstrated a reduction in the incidence of SIDS/SUID. For Indications, Safety and Warnings regarding SNOO, click [here](#).

What does this mean for healthcare providers?



Improving patient access

Based on the FDA's designation of SNOO as a De Novo medical device, SNOOs may now be eligible for tax-preferred accounts (i.e., FSAs, HSAs), increasing affordability and access for families using SNOO at home!

Modeling safe sleep in the hospital

In clinical settings, SNOO can model safe infant sleep to parents in the first days of their infant's life. The updated 2022 AAP guidelines call upon hospitals to model safe infant sleep, stating, "Sitting devices, such as car seats, strollers, swings, infant carriers, and infant slings, are not recommended for routine sleep in the hospital or at home."

References

1. Moon R, Carlin R, & Hand I. Sleep-Related Infant Deaths: Updated 2022 Recommendations for Reducing Infant Deaths in the Sleep Environment. *Pediatrics*. 2022. doi:10.1542/peds.2022-057990
2. Mortality for 1979–1998 with ICD 9 codes; Mortality for 1999–2016 with ICD 10 codes. Compressed Mortality File 1999-2016 on CDC WONDER Online Database. Centers for Disease Control and Prevention, National Center for Health Statistics. Published 2017. Accessed March 31, 2023 from <http://wonder.cdc.gov/cmfi-icd10.html>.
3. Trachtenberg FL, Haas EA, Kinney HC, Stanley C, & Krous HF. Risk factor changes for sudden infant death syndrome after initiation of Back-to-Sleep campaign. *Pediatrics*, 129(4), 630-638. 2012. doi: 10.1542/peds.2011-1419.
4. Karp H & Balasubramanian S. A Comparison of SIDS/SUID Behavioral Risk among Users of a Responsive Bassinet. *Sleep Medicine*, Vol100, S1. 2022. <https://doi.org/10.1016/j.sleep.2022.05.515>.