

# NEWS RELEASE

Following the FDA Drug Safety Warning — the Hummingbird™ TTS enables a timely alternative to general anesthesia for ear tube procedures for children.

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Plymouth, MN. 6, 2017 - On December 14, 2016, the U.S. Food and Drug Administration (FDA) released a Drug Safety Communication warning providers, parents and caregivers that “repeated” use of general anesthetic and sedation drugs during surgeries in children younger than 3 years . . . may affect the development of children’s brains. To better inform the public, the FDA is requiring warning labels to be added to *specific* general anesthetic and sedation drugs.<sup>1</sup>

The Hummingbird TTS Ear Tube Delivery System by Preceptis Medical solves this safety concern for ear tube procedures for children—the most common pediatric procedure associated with repeated exposures to general anesthesia.<sup>2</sup> The Hummingbird device uses a One-Pass™ system to reduce pain and manipulations to the eardrum during ear tube placement, enabling a conscious sedation alternative that does not require general anesthesia or any of the drugs listed in FDA’s safety alert.<sup>1, 3</sup>

Per Steve Anderson, CEO of Preceptis Medical, “though general anesthesia is necessary for many pediatric surgeries, routine ear tube placement is a minor procedure that should not necessitate the use of general anesthesia. The FDA warning highlights the need for alternatives to general anesthesia for young children.” Mike Loushin M.D., pediatric anesthesiologist and founder of Preceptis Medical adds, “There are benefits to reduced anesthesia whenever possible. Preceptis was founded to bring these benefits to pediatric ear tube surgery by providing surgeons with new tools that enable it to be performed safely and effectively with less anesthesia.”

The Hummingbird TTS offers a solution for reducing the exposure to general anesthesia for ear tube procedures in children —providing parents, providers and caregivers with a choice.

Preceptis invites parents, providers and caregivers to JOIN THE MOVEMENT and log onto <https://www.facebook.com/preceptismedical> or [www.preceptismedical.com/parents](http://www.preceptismedical.com/parents) to learn more about safe alternatives for ear tube procedures for children.

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## References

1. [http://www.fda.gov/Drugs/DrugSafety/ucm532356.htm?source=govdelivery&utm\\_medium=email&utm\\_source=govdelivery](http://www.fda.gov/Drugs/DrugSafety/ucm532356.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery)
2. O’Niel, Mallory B., et al. "Tracking tympanostomy tube outcomes in pediatric patients with otitis media using an electronic database." *International journal of pediatric otorhinolaryngology* 79.8 (2015): 1275-1278
3. Preceptis Ear Tube Delivery Study and Preceptis data on file.

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