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FDA approves use of new Flourish device to treat infants born with esophageal atresia

May 12, 2017

The U.S. Food and Drug Administration today authorized use of the Flourish Pediatric Esophageal Atresia Anastomosis, a first-of-its-kind medical device to treat infants up to one year old for a birth defect that causes a gap in their esophagus, called esophageal atresia.

An estimated 1 in every 2,500 babies in the U.S. is born with esophageal atresia. Babies with this condition cannot feed normally, and they require a feeding tube until surgery can be performed to attach the esophagus to the stomach. Most babies born with esophageal atresia also have a tracheoesophageal fistula, which also needs to be repaired surgically, since fluids from the esophagus can get into the airways and interfere with breathing.

"This new device provides a non-surgical option for doctors to treat esophageal atresia in babies born with this condition," said William Maisel, M.D., M.P.H., acting director of the Office of Device Evaluation in the FDA's Center for Devices and Radiological Health. "But it is only intended for infants who do not have a tracheoesophageal fistula or who have had the fistula repaired in a prior surgery."

The device uses magnets to pull the upper and lower esophagus together, closing the gap and allowing food to enter the stomach. It is not for use in infants who also have a tracheoesophageal fistula, an abnormal connection between the esophagus and the windpipe (trachea).

During the procedure to insert the Flourish device, doctors insert two catheters, one through the mouth and one through the stomach. The magnetic ends of the two catheters attract each other, and this attraction pulls the two ends of the esophagus together over several days, closing the gap and forming a connection. Once the catheters are removed, the infant can begin to feed by mouth.

The FDA reviewed data for the Flourish device through the humanitarian device exemption (HDE) process. A Humanitarian Use Device (HUD) is a device that is

intended to benefit patients by treating or diagnosing a disease or condition that affects not more than 8,000 individuals in the U.S. per year.

Data supporting the safety and probable benefit of the Flourish device include results from 16 patients who had the Flourish device implanted. In the limited data provided, all of the infants had a successful joining of their esophagus, with no remaining gap, within three to 10 days after receiving the device. However, 13 of the 16 patients developed a complication which caused a narrowing in their esophagus (anastomotic stricture) that required a balloon dilation procedure, a stent or both to repair. Anastomotic strictures also occur from traditional surgery to repair the condition.

The Flourish device should not be used in patients older than one year, or who have teeth, which may damage the oral catheter. The device is also contraindicated in infants who have an existing tracheoesophageal fistula or who have esophageal segments that are more than 4 centimeters apart. Potential complications that may occur when the device is in place include ulceration or tissue irritation around the catheter implanted in the stomach and gum irritation due to pressure from the oral catheter.

Potential long-term complications include gastroesophageal reflux.

The FDA authorized use of the Flourish device to Cook Medical.

Source:

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm558241.htm

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