Insertion of Lengthening Device for Esophageal Atresia

Flourish® Pediatric Esophageal Atresia Device

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Background

- The **Flourish® Pediatric Esophageal Atresia Device** is a humanitarian device indicated for use in lengthening atretic esophageal ends and creating an anastomosis with a nonsurgical procedure in pediatric patients under one year of age, with a gap less than 4cm, without a tracheoesophageal fistula (TEF), or in pediatric patients up to one year of age for whom a concurrent TEF has been closed as a result of a prior procedure.
- **What is esophageal atresia?**
  - Esophageal atresia is a medical condition in which an infant is born with an upper esophagus that ends in a pouch rather than connecting normally to the stomach. This means that food cannot pass from the mouth to the stomach and can also lead to the accumulation of saliva in the upper pouch.
- **Other relevant conditions:**
  - Esophageal atresia is often accompanied by a tracheoesophageal fistula (TEF), a condition in which there is an abnormal connection between the esophagus and the trachea. This can complicate breathing and can sometimes allow fluids from the esophagus and/or gastric contents to reach the lungs.
  - In some instances, there may be other conditions associated with these patients which include vertebral defects, anal atresia, cardiac defects, renal anomalies, and limb abnormalities also know as VACTERL Association.

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Flourish® Pediatric Esophageal Atresia Device

- **HUD**
  - The Flourish® is an FDA designated Humanitarian Use Device (HUD). For use of this device, the requesting physician is required Institutional Review Board (IRB) approval before the device can be used.
- The Flourish® device is used in the inpatient setting only, as patients must be interned throughout the indwelling days. The use of Flourish will be dictated into the procedure section of the provider/operative notes in the medical record.
- The procedure in which the Flourish® device is used is called: Esophageal Magnetic Anastomosis.
- The device is indicated for use in the treatment of Atresia of esophagus without fistula (ICD-10-CM: Q39.0) in patients up to one year of age.
- Only one device is used for each procedure.
  - The Flourish® device is not permanent, as it is indwelling for 3-13 days, until the anastomosis has matured.
- The procedure is not performed in conjunction with another procedure. Typically, fluoroscopy is used to place the magnets in the esophageal pouches. In addition, sedation and/or anesthesia is used to keep the pediatric patient comfortable.

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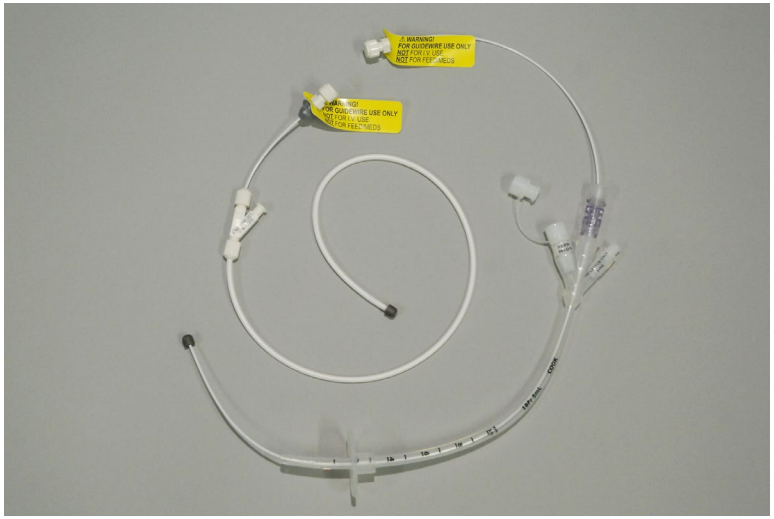
Flourish® Pediatric Esophageal Atresia Device

- The Flourish® Pediatric Esophageal Atresia Device consists of an esophageal catheter and a gastric catheter (Fig.1). The esophageal catheter is a 10 Fr two-lumen catheter with an inner magnet catheter.
- The gastric catheter is a modified two-lumen 18 FR/5 mL balloon retention catheter. One lumen is for balloon inflation/deflation. The second lumen is modified by the addition of the gastric (lower esophageal pouch) magnet catheter.
- The distal ends of the internal catheters are fitted with bullet-shaped neodymium iron boron (NdFeB) magnets, which feature a central hole for insertion of a wire guide.
- When aligned, the two catheter magnets, having opposite polarities, attract each other.



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Procedure Description

- **Insertion**
  - After identification of the pouches, the gastric catheter is inserted over a wire guide, under fluoroscopy through a mature stoma and advanced until the magnet is located at the distal end of the lower pouch. The gastric catheter is secured to the stomach wall internally with a balloon and externally with a bolster. The oral catheter is inserted orally and advanced until the magnet is located at the distal end of the upper pouch. Within 3 to 13 days, the traction caused by the magnets allows the esophageal sacs to approximate.
  - Daily x-rays are taken to assess the distance between magnets. Once approximated, the surrounding tissues grow together while the tissue between the magnets undergoes necroses, causing development of an anastomosis, thereby creating a connected passage from mouth to stomach.
- **Removal**
  - Once an anastomosis has been confirmed through fluoroscopy, the magnets are removed. The proximal end of the oral/esophageal inner magnet catheter is cut. A new wire is introduced through the oral/esophageal inner magnet catheter through the newly formed anastomosis and exits through the gastrostomy port. The oral/esophageal catheter is pushed distally toward the stomach until magnets are in the stomach, below the anastomosis. Then, the oral/esophageal inner magnet catheter is gently pushed and the gastric catheter is pulled until the system exits from gastrostomy site, thus removing the gastrostomy tube, oral/esophageal and gastric inner magnet catheters and the magnet pair as a unit. A new orogastric tube or nasogastric tube is placed over the indwelling wire for one to three days.

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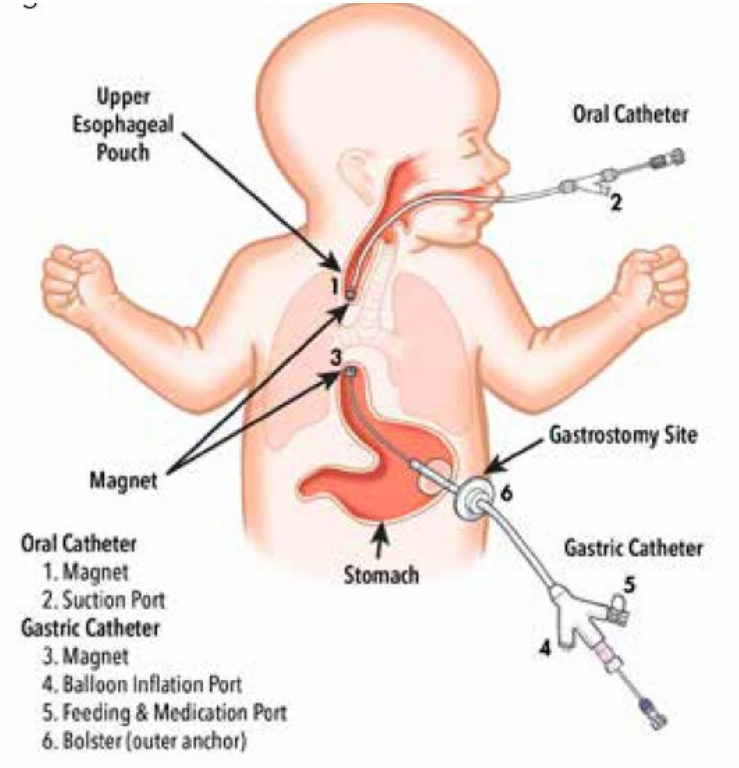
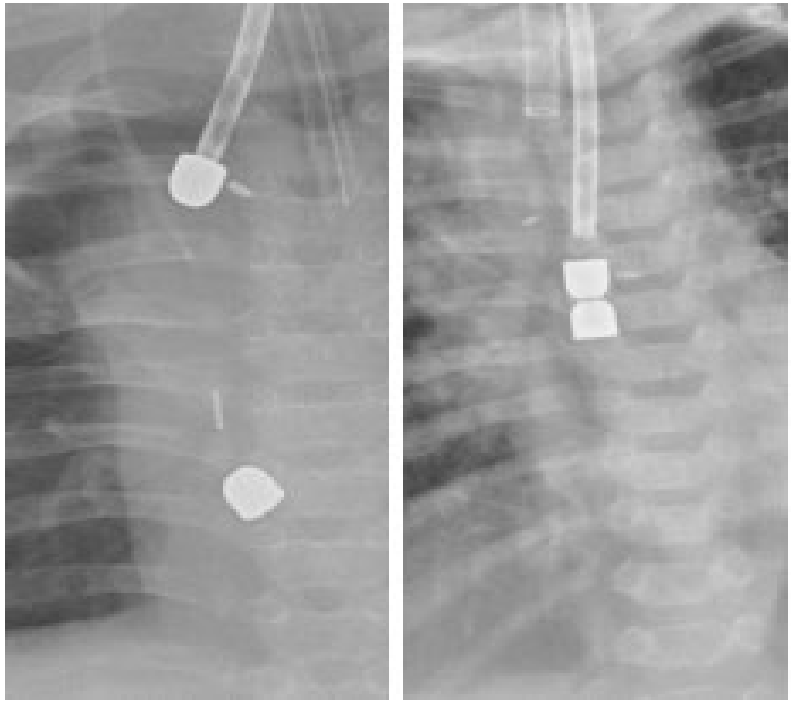
Flourish® Procedure Description- Illustration

An oral catheter and gastric catheter are used to deliver a rare earth magnet into each of the disconnected ends of the patient's esophagus.



How does Flourish® work?



Before anastomosis

After anastomosis

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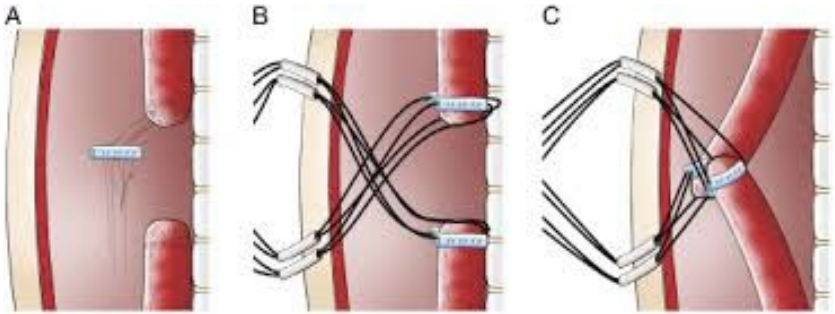
Current Treatments

- **Open chest surgery**
  - Incision is performed on the side of the patient's chest between the ribs to access the esophageal pouches.
  - If the length is short enough (short gap atresia), the surgeon will dissect and stretch the esophageal ends and perform a surgical anastomosis. If the separation is too long (long gap atresia) the Foker technique/procedure will be performed.
- **Foker Technique/Procedure**
  - Traction sutures are placed on the end of each pouch, then the sutures exit the patient's chest cavity.
  - Externally the medical staff will be applying tension to the sutures until the esophageal ends meet. This can take days.
  - After the esophageal ends meet, the patient will require subsequent surgery to create the surgical anastomosis.



Flourish® Additional Notes and Adverse Events

- Since the designation of the HUD/HDE in 2017 we have performed 42 procedures with a 60% success rate.
- We are actively running an FDA mandated Post Approval Study in which we are following 20 patients for a 2-year period.
- Failures reported are heavily associated with gaps longer than 4cm on the day of the procedure.
- Complications associated with the Flourish® device are similar to those of open surgical anastomosis, which include multiple dilations and stenosis.
- The standard of care for these patients until now has been open chest surgery.
- The Flourish® device offers a minimally invasive approach to treat pediatric patients with esophageal atresia. If the device fails, there are no complications, and the patient can have surgical repair if needed.

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Summary

- The Flourish® Pediatric Esophageal Atresia Device is indicated for use in lengthening atretic esophageal ends and creating an anastomosis with a nonsurgical procedure in pediatric patients up to one year of age.
- Flourish® is an FDA designated Humanitarian Use Device (HUD).
- Currently, there is no coding convention for the technology, only the procedure. This does not allow for accurate reporting and outcomes-tracking when utilizing this device.

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