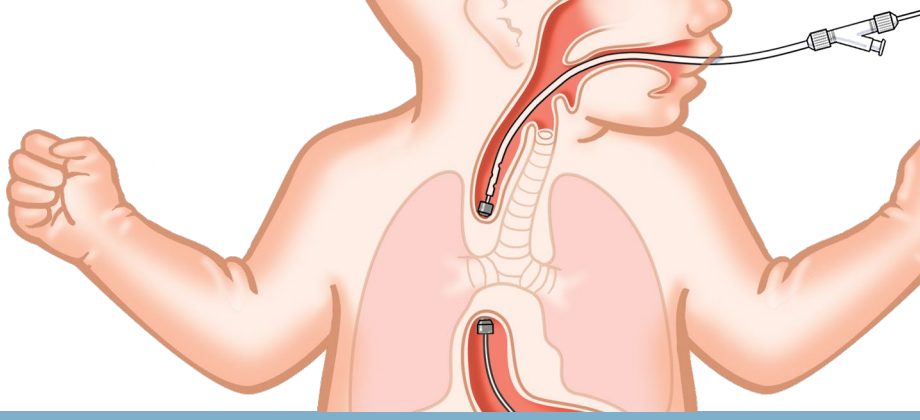


Flourish® FAQs

What condition indicates the use of this device?

Esophageal atresia.

What is esophageal atresia?

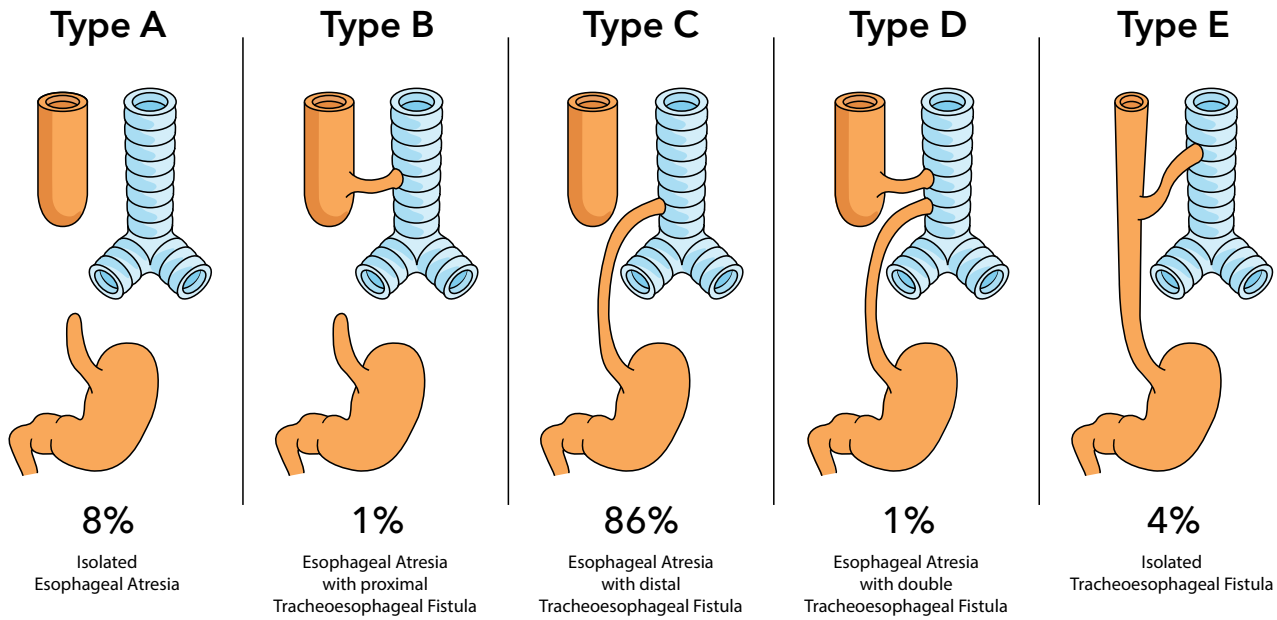
Esophageal atresia is a medical condition in which an infant is born with an upper esophagus that ends in a pouch rather than connecting normally to the stomach. This means that food cannot pass from the mouth to the stomach and can also lead to the accumulation of saliva in the upper pouch.

Are there any 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, infants are also born with concurrent cardiac and renal conditions.

What are some other types of esophageal atresia?

The most common type of esophageal atresia is Type C (Fig. 1), which occurs when the infant is born with a distal tracheoesophageal fistula. However, it is Type A—isolated esophageal atresia—for which the Flourish device is most often used. The Flourish can be used for Types B, D and E but only when the fistula has been repaired.



Adapted from: Bowder AN, Lal DR. Advances in the surgical management of esophageal atresia. *Adv Pediatr.* 2021;68:245-259.

Fig. 1

HUMANITARIAN DEVICE

Authorized by federal law for use in the treatment of lengthening atretic esophageal ends and creating an anastomosis with a non-surgical procedure in pediatric patients, up to one year of age with esophageal atresia 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. The effectiveness of this use has not been demonstrated.

COOK® MEDICAL

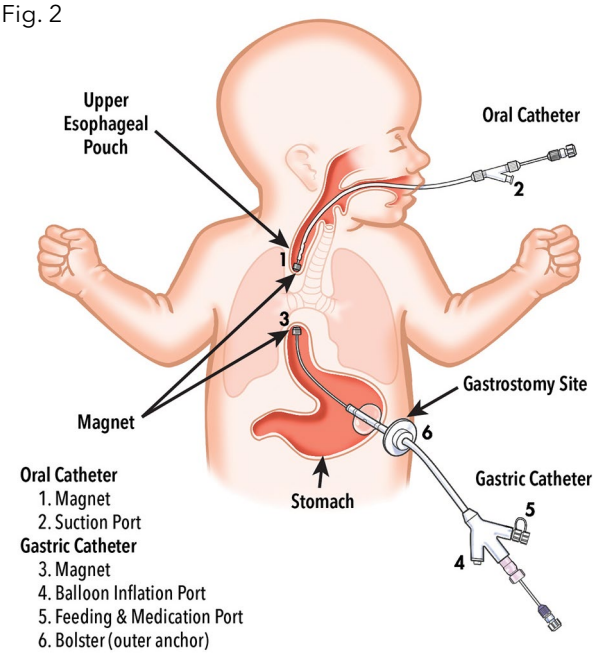
What is the normal treatment for esophageal atresia?

Various surgical procedures are available depending on the gap length between the disconnected ends of the esophagus. Short gaps can usually be sutured together. For longer gaps (> 3 cm), the stomach may be pulled up to connect the lower esophagus to the upper esophagus. In another surgical method, called the Foker technique, the two ends of esophagus are pulled toward each other by external traction over time to ultimately be linked by anastomosis.

What is Flourish?

The Flourish is an humanitarian use device (HUD) (Fig. 2) used to treat pediatric esophageal atresia.

Fig. 2



What is an HUD device?

A Humanitarian Use Device (HUD) is a medical device intended to benefit patients in the treatment or diagnosis of diseases or conditions that affect fewer than 8,000 individuals in the United States per year.

What is an HDE device?

The Humanitarian Device Exemption (HDE) was established to make it possible for products to be developed and sold to treat small patient populations with rare conditions.

How does the Flourish device work?

An oral catheter and gastric catheter are used to deliver a rare earth magnet into each of the disconnected ends of the infant's esophagus (Fig. 2). The magnets gradually stretch both ends of the esophagus toward each other, after which the tissue connects to form an anastomosis and an intact esophagus. Early clinical experience shows anastomosis typically occurs within 13 days.

Who can benefit from Flourish?

Infants up to one year of age with esophageal atresia without a tracheoesophageal fistula (TEF) or for whom a concurrent TEF has been closed by a prior procedure. Flourish can only be used if the gap between the esophageal pouches is 4 cm or less.

What are some of the contraindications for Flourish?

Contraindications include: Patients older than one year of age or with teeth as it may damage the oral catheter. Patients who have an existing TEF. For creation of an anastomosis other than in the esophagus. For atretic segments >4cm apart. Patients without an established and appropriately sized gastrostomy tract. Patients having gastrostomy site signs of significant infection. Patients who cannot be intubated or administered sedative or paralytic drugs during the device indwelling period.

How can the Flourish device be obtained?

Because Flourish is a device that has received approval to market via H150003, interested physicians will need to get approval from their facility's Institutional Review Board (IRB). Once IRB approval has been granted, the device can be ordered through that facility's normal procedure. Flourish has a GPN (G47283) and RPN (FLRSH-PEA) and will be distributed through Cook's normal process.

What training is required for this procedure?

The MDM team will be conducting the nurse and physician training on the Flourish because of the low number of cases.

How can Flourish be obtained outside of the US?

The Flourish device is not available outside of the US. The acquisition pathway from country to country varies. If you receive a request for the Flourish, please consult with your product manager to determine feasibility.