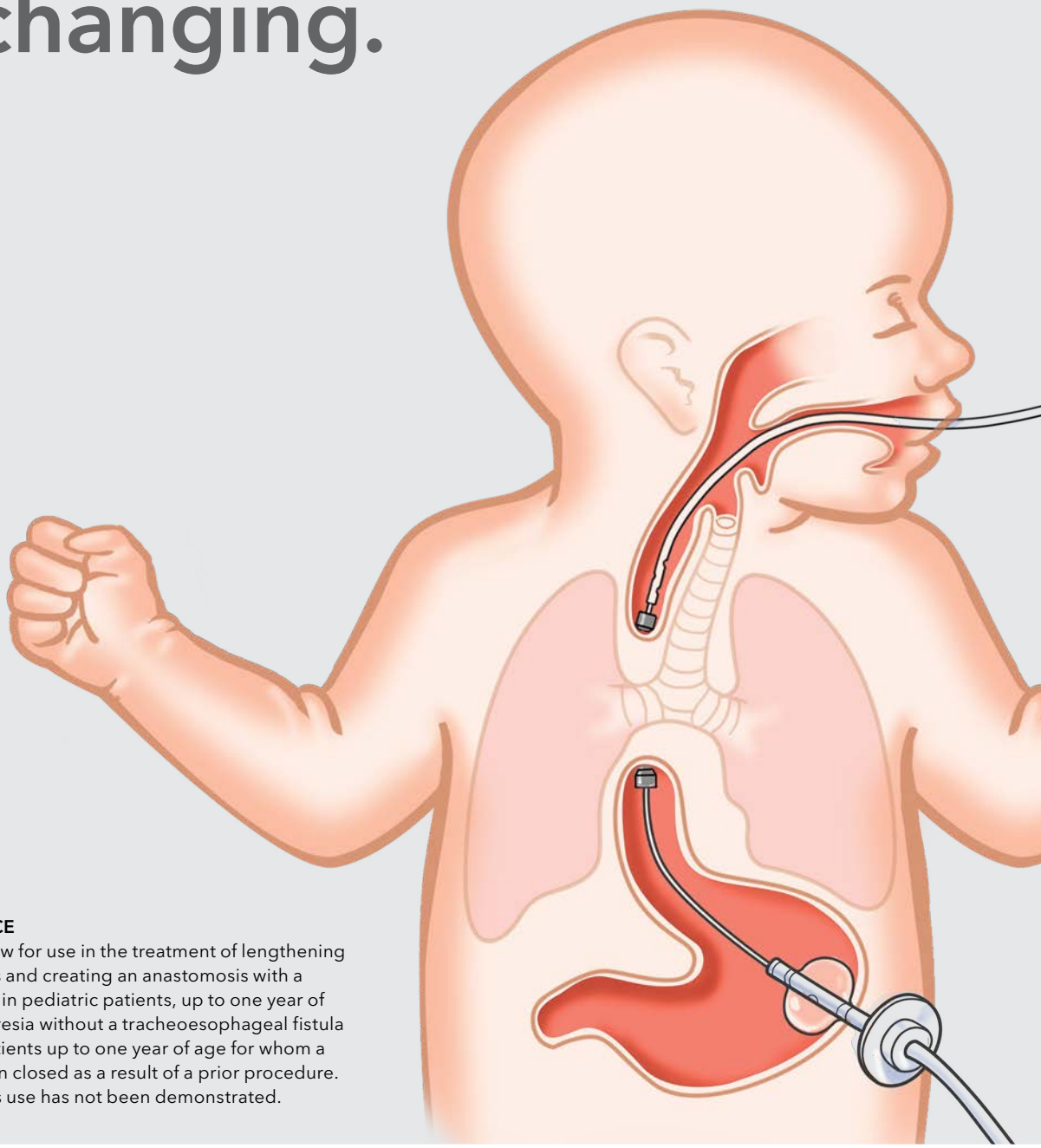
Life changing.



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.

Flourish®

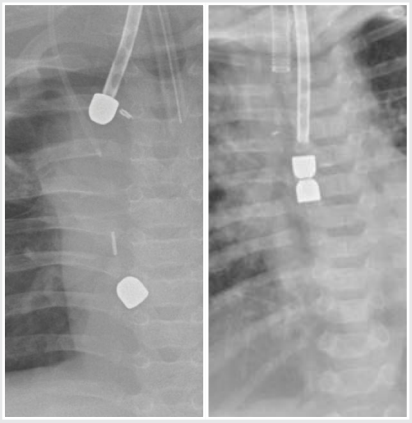
PEDIATRIC ESOPHAGEAL ATRESIA DEVICE

Flourish was created to give doctors a minimally invasive alternative to surgery when treating esophageal atresia, a congenital birth defect which occurs in about 1 in every 2,500 newborns.[1] Using rare earth magnets, Flourish gradually stretches both ends of the infant's esophageal pouches together to form a fully functioning esophagus.

COOK® MEDICAL

1. Spitz L. Oesophageal atresia. *Orphanet J Rare Dis.* 2007; 2:24. doi: 10.1186/1750-1172-2-24.

FOR SALE IN THE US ONLY.



Flourish®

PEDIATRIC ESOPHAGEAL ATRESIA DEVICE

H150003

The Flourish Pediatric Esophageal Atresia Device is indicated for use in 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. This device is indicated for atretic segments <4 cm apart.

This product is supplied sterile and is disposable. It is intended for single use only.

Order Number	Reference Part Number	Oral Catheter Fr	Oral Catheter Length cm	Gastric Catheter Fr	Gastric Catheter Length cm	Magnet Diameter inch	Wire Guide* Diameter inch
G47283	FLRSH-PEA	10	58	18	58	0.25	0.035

**Wire guide sold separately.*

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Support & Delivery for details.

Images courtesy of Dr. Mario Zaritzky, University of Chicago.

Flourish® Pediatric Esophageal Atresia

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

INDICATIONS FOR USE: The Flourish Pediatric Esophageal Atresia Device is indicated for use in 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. This device is indicated for atretic segments< 4cm apart.

CONTRAINDICATIONS: 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.

WARNINGS: **This device is MR unsafe due to the presence of magnets.** The Flourish device should be used only at institutions with pediatric thoracic surgery capabilities. The Flourish device should be used only at institutions with capabilities in catheter and wire guide manipulation; endoscopy and bronchoscopy techniques; collection and interpretation of relevant radiographic imaging; respiratory support; nutrition and hydration; and esophageal dilatation. **Do NOT** inject feed through the oral catheter assembly as doing so would be a misconnection and could result in aspiration of fluids into the patient's lungs if anastomosis has not completely formed. **Do NOT** insert the gastric catheter (also known as the 18 Fr feeding/gastric tube) into the lower esophageal pouch. Presence of the gastric catheter in the lower esophageal pouch may result in pressure on the magnet and subsequent perforation or tracheoesophageal fistula. **Do NOT** apply any force besides the magnetic pull onto the esophageal pouches to approximate them as this may result in perforation or tracheoesophageal fistula. Applying sustained force to the catheter in an effort to improve magnet advancement may increase the risk of perforation or tracheoesophageal fistula. **Do NOT** over-inflate the balloon. Feeding into an over-inflated balloon may result in tube migration and/or tube or balloon failure. The oral inner magnet catheter "Wire Guide Lumen" port is for wire guide insertion only. This connector is not for I.V. use. **Do NOT** inject enteral fluids into this connector since doing so would be a misconnection, which may result in aspiration or catheter blockage. The gastric inner magnet catheter "Wire Guide Lumen" port is for wire guide insertion only. This connector is not for I.V. use. **Do NOT** inject enteral fluids into this connector since doing so would be a misconnection that could lead to improper delivery of fluids and/or medications. The device has **KNOWN** misconnections with connectors found in the following medical devices/healthcare applications. **Do NOT** attempt to connect with these devices. • Intravascular devices • Hypodermic applications • Breathing systems and driving gas devices • Urethral/urinary devices • Limb cuff inflation devices • Neuraxial devices. **Do NOT** use this product in the vasculature as the device is only intended for esophageal atresia. Based on limited clinical data on this device, the rate of endoscopic dilation or surgical intervention for stenosis of the anastomosis is higher than that following surgery. Based on limited clinical data on this device, fibrosis from previous surgery may lead to a recalcitrant stricture.

PRECAUTIONS: During placement and use, care must be taken to avoid crimping or damaging components. **Do NOT** allow magnet to touch any metal objects. If magnet touches any metal objects, inspect for damage to the magnet. If damage is present, **do NOT** use the device. **Do NOT** remove magnet protective packaging cover until necessary for use. Balloon must be inflated with sterile or distilled water only. **Do NOT** use air, saline, feeding formula, medication, or radiopaque contrast for balloon inflation as they may cause premature deflation. The bolster should rest gently on skin surface. Excessive traction on gastric catheter may cause premature removal, damage to gastric mucosa and abdominal wall, fatigue or failure of device. **Do NOT** use petroleum jelly or mineral oil for tip lubrication as they may compromise the integrity of the balloon. Device should only be indwelling in a patient for a maximum of 13 days since implantation of the device has not been evaluated beyond 13 days.

POTENTIAL COMPLICATIONS: Potential complications during the device indwelling period include: • inability to approximate the atretic gap with the magnets • rupture of the balloon in the gastrostomy device • ulceration, tissue irritation, or necrotizing fasciitis around the stoma • trauma to the patient's gum due to constant oral catheter pressure • inflammation • bleeding • respiratory complications, including pleural effusion and pulmonary infections. Potential complications during the device indwelling period that may result in additional procedures and/or death include • magnet migration and/or tissue erosion • new or recurrent tracheoesophageal fistula • perforation and leak of one or both esophageal pouches • anastomotic leak. Potential complications after the device indwelling period include: • gastroesophageal reflux disease • esophageal dysmotility • respiratory complications, including tracheomalacia, recurrent asthma, and pulmonary infections • significant infection and leaks that may result in peritonitis and require surgical or medical interventions • tracheoesophageal fistula • stenosis that may require repeated endoscopic or surgical intervention(s). Death is also a potential complication of the procedure and survival is greatly influenced by risk factors. Spitz classification indicates that if a patient weighs greater than 1.5 kg or 3.3 lbs and does not have a major cardiac anomaly, survival rate is 98%, if the patient weighs less than 1.5 kg or 3.3 lbs or has a major cardiac anomaly, survival rate is 82%, and if the patient weighs less than 1.5 kg or 3.3 lbs and has a major cardiac anomaly, survival rate is 50%.

See Instructions for Use for full product information.

AB_10271_REV3

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