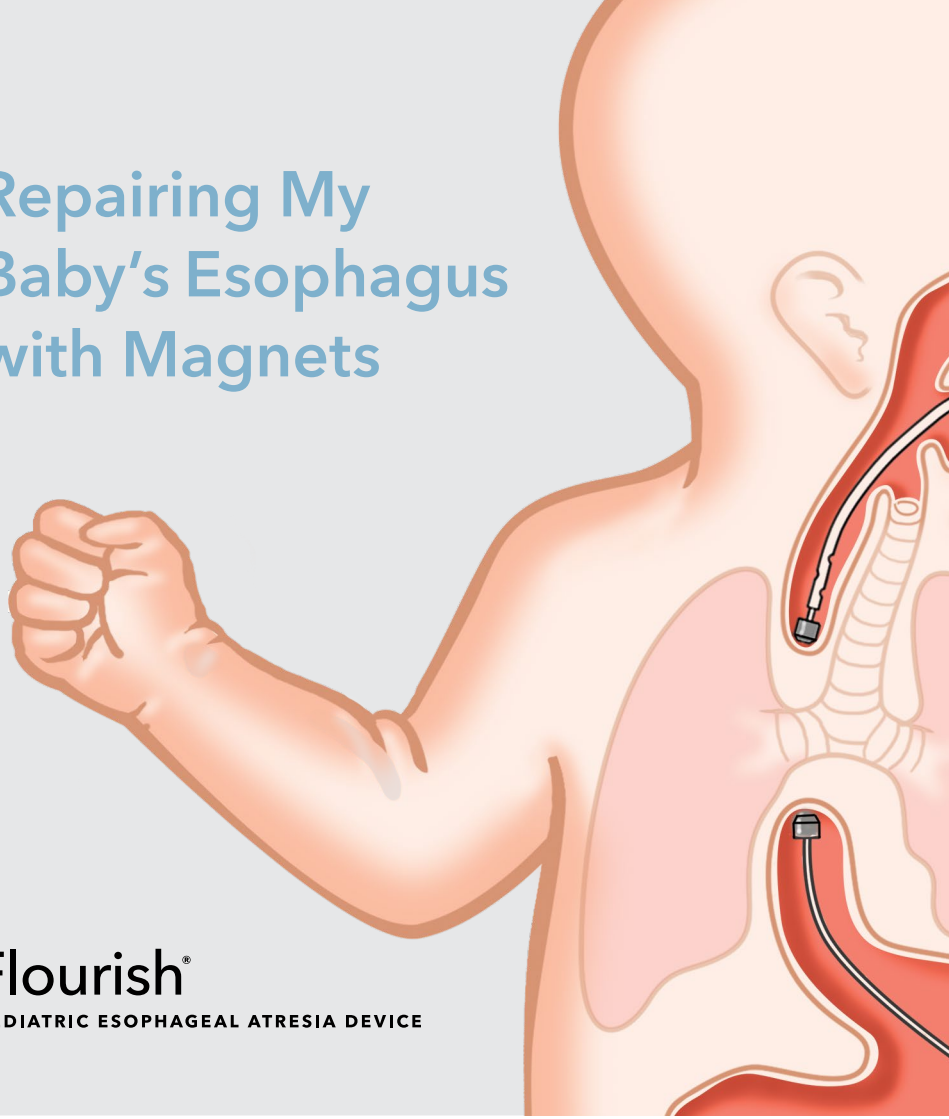
Repairing My Baby's Esophagus with Magnets



Flourish®

PEDIATRIC ESOPHAGEAL ATRESIA DEVICE

Caution: Federal (USA) Law restricts this device to sale by or on the order of a trained healthcare professional.

Humanitarian Device: Authorized by federal law to treat esophageal atresia in pediatric patients by creating an anastomosis using a non-surgical procedure. The effectiveness of this use has not been demonstrated.

COOK® MEDICAL

Table of Contents

Glossary

Anastomosis: An opening created between two hollow organs to connect them.

Atresia: A condition in which a tubular passage in the body is closed or absent.

Atretic Gap: The space between the ends of the Upper Esophageal Pouch and the Lower Gastric Esophageal Pouch. (See **A** on diagram on next page).

Gastroesophageal Reflux: When stomach contents come back up into the esophagus.

Gastrostomy: An opening into the stomach from the abdominal wall, made surgically for the introduction of food. (See **B** on diagram on next page).

G-Tube: (Also called a gastrostomy tube) is a tube inserted through the abdomen that delivers nutrition directly to the stomach. It's one of the ways doctors can make sure kids with trouble eating get the fluid and calories they need to grow.

Orogastric Catheter: A soft plastic or rubber tube that is passed through the mouth to the stomach; typically for feeding. (See **C** on diagram on next page).

Necrosis: Localized destruction of tissue due to loss of blood supply.

Slough: To remove an outer layer (as of skin or tissue).

Stenosis/Stricture: A narrowing of a tube, duct, or hollow organ such as the esophagus.

Sepsis: A severe infection (usually bacterial) that has spread via the blood stream.

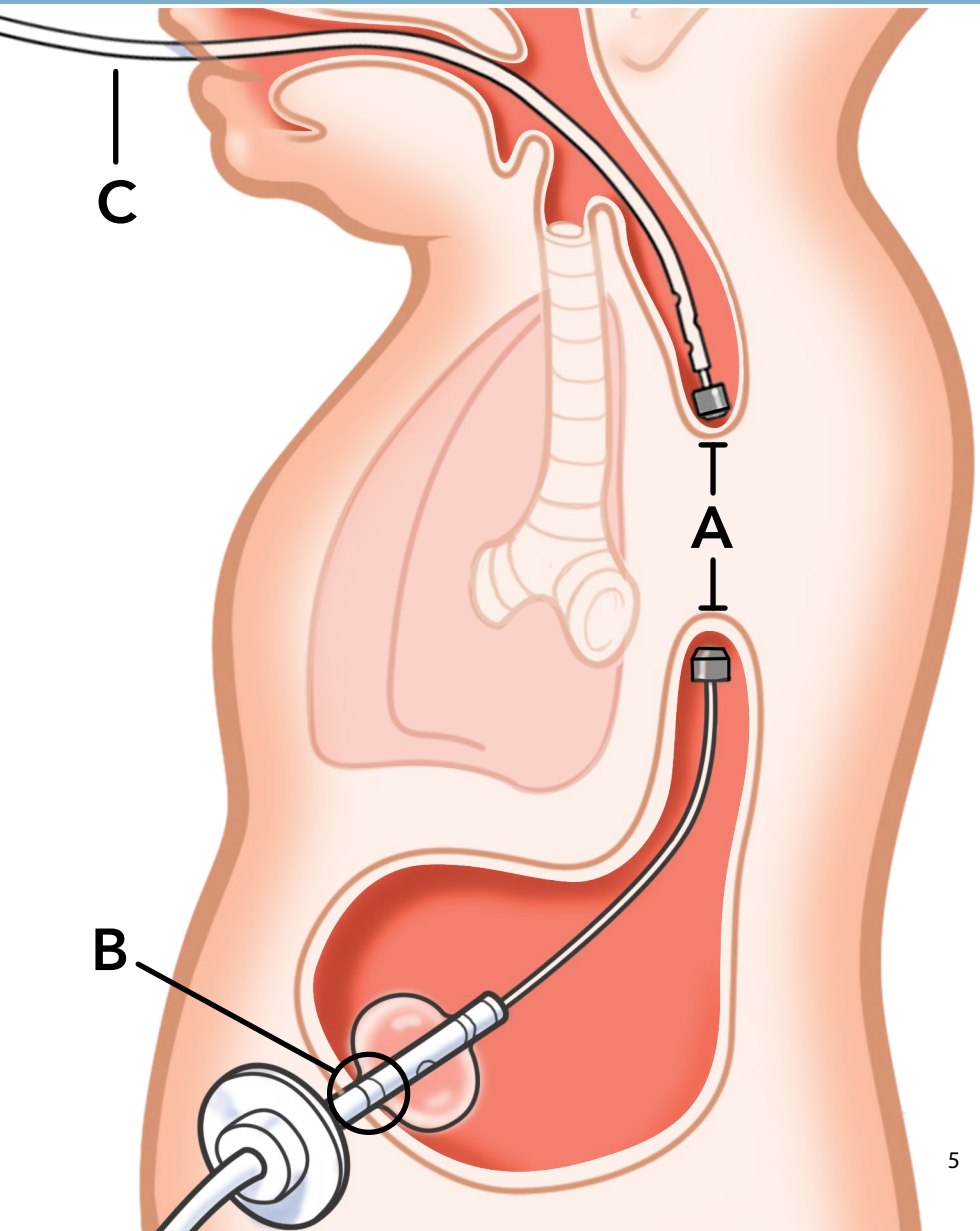
Peritonitis: Inflammation of the lining of the abdominal cavity.

Fistula: Opening that occurs naturally or surgically between hollow organs.

Tracheoesophageal Fistula: Is an abnormal connection in one or more places between the esophagus (the tube that leads from the throat to the stomach) and the trachea (the tube that leads from the throat to the windpipe and lungs).

About the condition

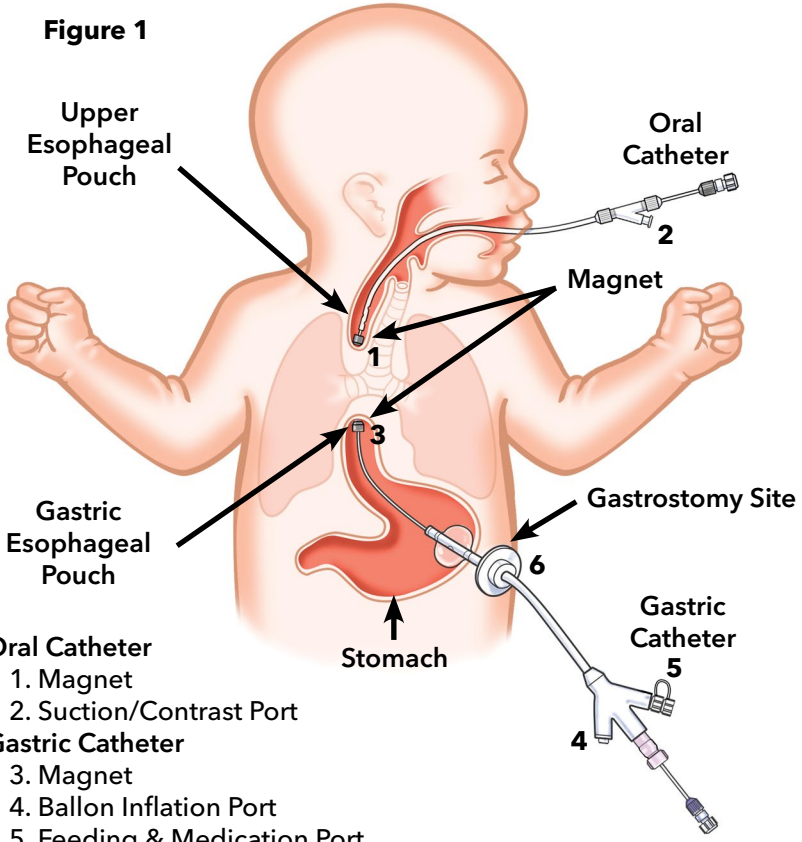
Esophageal atresia (EA) is a condition present at birth in which the upper esophagus does not connect with the lower esophagus. Infants with EA must be fed intravenously (via the vein), or through a feeding tube in the stomach. If not treated, EA is life threatening and can lead to serious nutritional complications. However, if the EA is diagnosed early and treated successfully, most children with the condition may be able to eat or drink by mouth.



Q. What is the Flourish® Pediatric Esophageal Atresia Device?

A. The Flourish Device consists of two (2) catheters. Each catheter has a magnet at its tip. The oral catheter passes through the mouth and into the esophagus so that the magnet reaches the bottom of the upper esophageal pouch. The gastric catheter replaces the current gastric feeding tube which is removed. The gastric catheter passes into the stomach through the existing gastrostomy site and upward through the stomach so that the magnet on the far end reaches the top of the gastric esophageal pouch. **(Figure 1)**

Figure 1



Oral Catheter
1. Magnet
2. Suction/Contrast Port

Gastric Catheter
3. Magnet
4. Ballon Inflation Port
5. Feeding & Medication Port
6. Bolster (outer anchor)

Q. How does the device work?

A. The magnets placed in each end of the esophagus attract each other **(Fig. 2)**. This causes the ends of the esophagus to stretch toward each other **(Fig. 3)**. Successful connection of the tissue of the upper and lower esophageal pouches is confirmed with x-ray imaging **(Fig. 4)**. Magnets may take more time to connect when the initial gap between them is farther apart. The surrounding tissues will grow together while the tissue trapped between the magnets will necrose and slough away. This creates an open passage from the mouth to the stomach. Early experience shows that the open passage typically occurs within 13 days **(Fig. 5)**.

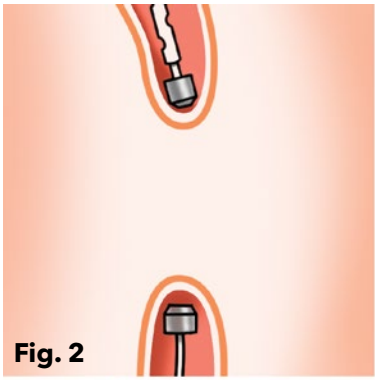


Fig. 2

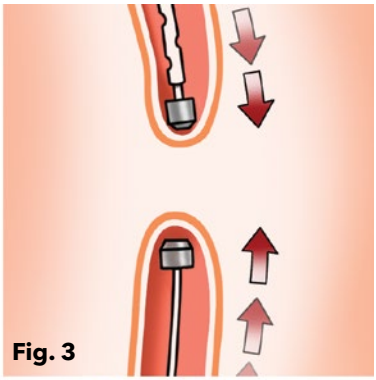


Fig. 3

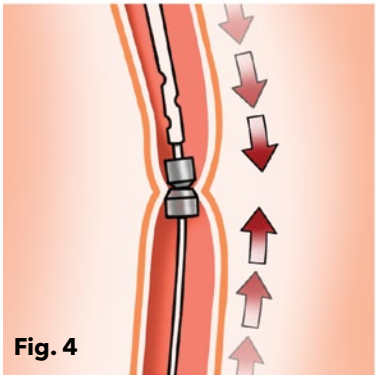


Fig. 4

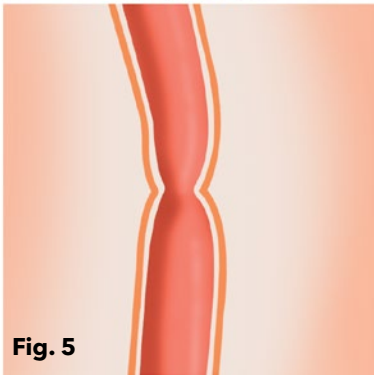


Fig. 5

Why doctors use the Flourish® device

Your baby's doctor can use this device to connect the two (2) ends of your baby's esophagus. This may allow your baby to be fed by mouth like a normal baby and to eat normal food. Your baby's doctor may like this non-surgical method better than open surgery.

Approved Indications for Use (From Physician Labeling)

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.

Q. Who cannot have this procedure done? (Contraindications)

A.

This device should not to be used in the following:

- Infants older than one year of age.
- Infants with teeth, as it may damage the oral catheter.
- Infants who have an existing tracheoesophageal fistula (an abnormal opening between their air tube and their food tube).
- This device should not be used to create an anastomosis other than in the esophagus.
- Infants with a gap of more than 4 centimeters (about 1½ inches) between the esophagus ends.
- Infants without an established and appropriately sized gastrostomy tract (opening from stomach to abdominal wall).
- Infants with signs of serious infection at the gastrostomy site.
- Infants who cannot be intubated (placement of tube into the airway) or given sedative drugs (drugs that calm) or paralytic drugs (drugs that limit movement) while the device is used.

Risks of using the Flourish® device

During the procedure, your baby's doctor may use a special type of x-ray called fluoroscopy to help place the device. This may expose your baby to small amounts of radiation. In addition, your baby's doctor may choose to sedate your baby during the procedure and there are risks to those medications which you should discuss with him or her.

Issues that could happen while the device is in place include the failed connection of the magnets of the esophagus and gastric pouch, or rupture of the balloon of the gastric catheter. These may require additional procedures or replacement of parts of the device.

Additional issues that could happen while the device is in place include tissue damage, infection or trauma around the opening where the gastric catheter rests, and trauma to the infant's gums from oral catheter. Bleeding, lung infection, or fluid on the lungs may also occur.

For infants who had tracheoesophageal-fistula (an abnormal opening between the air tube and the food tube) repaired, there is the possibility that the fistula may return. There is also a possibility that the device may cause a tracheoesophageal-fistula.

Infants who do not have a successful connection of their esophagus may have to have an additional surgery. Issues could happen while the device is in place, including perforation (tear)/leak in one or both ends of the esophagus or anastomosis, magnet migration (movement) and/or tissue erosion (trauma at site of device placement), which could result in additional procedures and/or death.

Events that could occur after the procedure is over and the device has been removed may include persistent or recurrent acid reflux, partial collapse of the airway when breathing out, difficulty swallowing or spitting-up of food, recurrent asthma, or lung infections.

Events that could occur after the procedure include significant infection and leaks at the junction where the two (2) pouches joined (anastomotic leak) that may result in inflammation (reddening and swelling) of that area and may require surgical or medical intervention. Narrowing where the two (2) pouches joined (stenosis) may require one or more endoscopic or surgical intervention such as using a balloon to stretch the narrowing and/or using a tube (stent) to open up the narrowing.

Limited clinical data on this device suggests that the rate of endoscopic dilation or surgical intervention to treat narrowing of the anastomosis (stenosis) is higher for this procedure than for traditional surgery. In the 16 infants in whom the device was used, it was found that 13 infants developed narrowing post-procedure. Treatments as described above (balloon stretching and/or stent placement), were performed from 12 days to 12 weeks after the procedure. One infant required surgery to create a new open passage.

Death is also a possible complication of the procedure and is greatly influenced by these additional risk factors:

- Survival of 98 out of 100 infants if the infant weighs more than 3.3 pounds and does not have significant heart problems,
- Survival of 82 out of 100 infants if the infant weighs less than 3.3 pounds, or has a significant heart problem, or
- Survival of 50 out of 100 infants if the infant weighs less than 3.3 pounds and has a significant heart problem.

Severe complications due to perforation or anastomotic leakage can also result in death.

All risks should be discussed with the attending medical team and weighed against the potential benefits of using the device.

Potential benefits of using the Flourish® device (see references 1-3)

In the limited number of cases using this device, the following benefits have been observed:

- Baby can eat a normal diet by mouth.
- Faster recovery time when compared to surgery.
- No surgical trauma because the device is placed through existing openings.
- Fewer complications such as wound infection or bleeding which are typically associated with surgery.
- Most other complications of surgery are reduced or eliminated.
- Your baby's doctor may choose not to use sedation/anesthesia during the placement of the Flourish® device. However,

surgical approaches will always require general anesthesia. Due to the tendency of these babies to have breathing and heart problems, general anesthesia poses a greater threat to the stability of the baby throughout the procedure.

How to decide about this treatment

Is my baby a candidate for this procedure?

Yes. Your baby's doctor is recommending the Flourish® device because your baby meets all of the criteria for treatment with this device and has none of the issues that would exclude its use.

What other options are available to treat my baby's condition?

The current standard of care for infants with an unconnected esophagus depends on their other medical problems. Infants with an unconnected esophagus and heart or breathing problems will have a feeding tube placed so the other medical problems can be treated first. Esophageal repair is attempted only after the other medical issues have been dealt with. Current surgical repair may include some combination of stretching the esophageal ends and connecting them. Preserving original esophageal tissue is preferred. When preservation is not possible, other methods of surgery to repair the atretic (gap), or to attach the upper end of the esophagus directly to the upper stomach, are attempted. It should be noted, all current surgical methods are invasive and require general anesthesia. As with any medical procedure, possible risks and benefits associated with the procedure must be carefully considered and should be discussed with your baby's doctor before making a decision.

Q. What happens before the treatment?

A. The doctor will use x-ray imaging to measure the distance between the two unconnected ends of the esophagus. If the gap between the ends is no more than 4 cm, your baby will be eligible to be treated with the Flourish® device.

Q. What happens during the treatment?

A. Your baby may be sedated or anesthetized at the doctor's discretion. Your baby's doctor is a pediatric surgeon. He/she may be helped by another doctor, such as an interventional radiologist, who places catheters and wire guides.

Q. How is the device placed?

A. First, the doctor removes the existing feeding tube and replaces it with the Gastric Catheter. The Gastric Catheter will be placed through the existing gastrostomy site (the pathway from the outside stomach wall through to the stomach) so that the magnet on the far end reaches the top of the gastric esophageal pouch **(Figure 6)**.

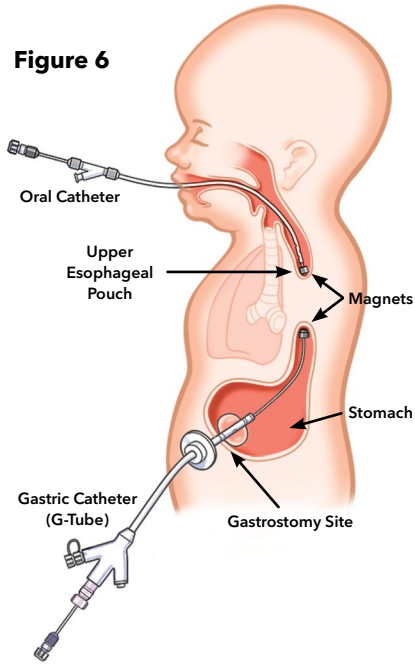
The Oral Catheter will be placed through the mouth into the esophagus so that the magnet reaches the bottom of the upper esophageal pouch **(Figure 6)**.

Once both magnets are in place, the doctor will use x-ray imaging to verify magnetic attraction by gently moving one of the magnets and watching for the other magnet to move in response. This is important because if the magnets do not attract each other, they may not be close enough to bring the two ends of the esophagus together, and the procedure will fail.

Over the next several days, the position of the magnets is checked by x-ray and the magnets may be repositioned, as needed. Once the magnets have successfully connected, the tissue of the upper and lower esophageal pouches grows together and the tissue trapped between the magnets sloughs away, creating an open passage from mouth to stomach.

During this time, your baby will be fed through the G-Tube.

Figure 6



Q. How long is the device left in place?

A. Every baby is different, but typically, formation of the anastomosis is seen within 13 days of placing the magnets. X-ray will be used to view the injection of contrast (a fluid used to increase the visibility of the gastrointestinal tract) into the esophagus. When a successful anastomosis is made, the contrast will flow through the esophagus and to the stomach with no leakage.

Both the gastric and oral catheters with their magnets will be removed through the hole in your baby's stomach and the gastrostomy port will be allowed to heal. To protect the sensitive newly-formed anastomosis, a new orogastric catheter will be placed to feed your baby. Feeding by mouth may begin slowly and your medical team will work with you to find out how quickly your baby is beginning to take nourishment and mimic normal eating behaviors (like swallowing) and when the orogastric tube can be removed.

- Movement of the infant should be **minimized**, and when necessary done with care so as not to disturb the position of the magnets. Your baby's doctor may choose to intubate or give your baby sedative or paralytic drugs while the device is in the body.
- Excess saliva can be continuously or intermittently suctioned through the oral catheter. Your baby's doctor may also decide to place another catheter alongside the oral catheter to suction excess saliva.

Q. What happens after the device is removed?

A. After the device is removed, your baby will stay in the hospital under supervision of their care team to be sure that oral feeding is being accepted. Vital signs and feeding behaviors (swallowing, spitting up, and bowel movements) will be watched closely to make sure that your baby is adjusting to oral feeding without discomfort or complications. Your baby will be watched to make sure there is no sign of leakage or narrowing at the anastomosis site after beginning to eat by mouth. Before discharge, your baby's doctor will determine how often your baby will return for visits.

Q. What happens if the device does not work?

A. If a connection between the two (2) esophageal ends is not made by the device, surgery may be needed. If a connection is made, it is likely that your baby will experience a narrowing of the newly created passage (stenosis) due to inflammation. Your medical team may elect to stretch the narrowing with a balloon (dilation), or may choose to place a removable stent across the site of the new anastomosis until the inflammation subsides. These procedures may need to be done more than once to widen the narrowing. If the stenosis remains a surgical procedure may need to be considered.

Things parents and caregivers must do to avoid other harm (Precautions):

Parents or caregivers should watch for signs or symptoms of narrowing or leakage at the anastomosis site, such as:

- Watch for signs or symptoms of narrowing or leakage at the anastomosis site (for example, fussiness, grimacing, crying, refusal to eat).
- Watch for symptoms of spitting up food, trouble swallowing, or fever.
- Watch for choking during feeding, indicating aspiration of food (going into the lungs instead of the stomach).
- Watch for signs of infection in the baby's abdomen such as abdominal tenderness and fever.

Call your baby's doctor immediately to discuss any concerns.

Clinical Results

Clinical data were obtained from procedures performed in Argentina (9 infants, reference 1) and cases performed for emergency use in the U.S. (7 infants, three of which were published in references 2 and 3) for a total of 16 cases.

In the cases described, infant ages have ranged from 23 days to 8 months when the product was used. A connection was achieved in all patients within 3 to 13 days. After the procedure, none of the infants experienced a leak at the connection site. Thirteen (13) of 16 infants (81.3%) developed narrowing of the food tube that required widening (either expansion with a balloon, or surgery). One infant developed a serious infection after use of the device. The infant was treated with antibiotics, and the device was replaced to complete the magnetic treatment. Nine (9) of the 16 infants had available follow up information showing they were able to swallow and eat normal diets. Long-term data was not available for the remaining infants.

Regarding other conditions which might appear later on after the procedure, data was available for six (6) of the infants. Two (2) of the infants were diagnosed with gastroesophageal reflux disease and partial collapse of the airway while breathing out. Three (3) infants were diagnosed as having abnormal movement of the muscles in their food tube affecting their swallowing, and three (3) infants developed asthma or infections in the lung. Most of the infants had more than one issue.

(*continued on next page*)

Relevant clinical results are summarized in the following table.

Short-Term Clinical Outcomes	Outcomes with Flourish®
Successful creation of a connection	16 out of 16 infants
Death	0 out of 16 infants
Connection leak	0 out of 16 infants
Narrowing at the connection requiring another procedure	13 out of 16 infants
Narrowing at the connection requiring surgery	1 out of 16 infants
Serious infection (Sepsis)	1 out of 16 infants
Long-Term Clinical Outcomes	
Reflux	2 out of 6 infants
Partial collapse of airway while breathing out	2 out of 6 infants
Problems swallowing	3 out of 6 infants
Asthma	3 out of 6 infants
Lung infections	3 out of 6 infants

The clinical results in the table are for pre-approval uses of the Flourish® device (before it was available to your baby's doctor). More results are now available. As of October 2022, 22 of 39 infants (56%) had successful creation of a connection.

You may also look at these papers:

1. Zaritzky M, Ben R, Johnston K. Magnetic gastrointestinal anastomosis in pediatric patients. J Pediatr Surg. 2014 Jul;49(7):1131-1137.
2. Dorman RM, Vali K, Harmon CM, Zaritzky M, Bass KD. Repair of esophageal atresia with proximal fistula using endoscopic magnetic compression anastomosis (magnamosis) after staged lengthening. Pediatr Surg Int. 2016 May;32(5):525-528.
3. Lovvorn III HN, Baron CM, Danko ME, Novotny NM, Bucher BT, Johnston KK, Zaritzky MF. Staged repair of esophageal atresia: pouch approximation and catheter-based magnetic anastomosis. J Ped Surg Case Reports. 2014;2(4):170-175.

Where you can find out more.

If your baby's doctor cannot answer questions about the device, please call Cook Medical: **1-800-245-4707** or Visit: **www.cookmedical.com**

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.

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