

Patient Information Booklet

Repairing My Baby's Esophagus with Magnets

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.

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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.

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.

Orogastric catheter: A soft plastic or rubber tube that is passed through the mouth to the stomach; typically for feeding.

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: An abnormal connection between the trachea (air tube) and esophagus (food tube).

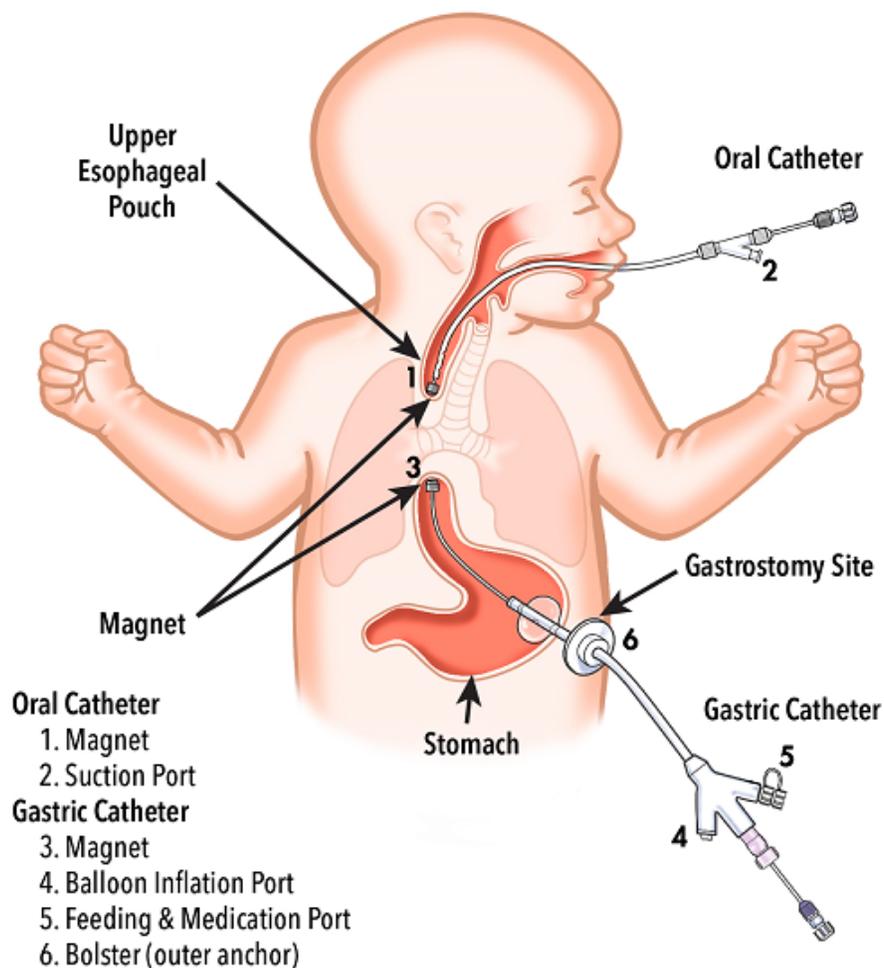
About the condition

Esophageal atresia (EA) is an in-born condition 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 eat or drink by mouth.

What is the Flourish™ Pediatric Esophageal Atresia Device?

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



How does the device work?

The magnets placed in each end of the esophagus attract each other. This causes the ends of the esophagus to stretch toward each other. Successful connection of the tissue of the upper and lower esophageal pouches is confirmed with x-ray imaging. 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 that typically occurs in 3 to 13 days.

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.

Who cannot have this procedure done? (Contraindications)

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 esophageal 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.

Risks of using the Flourish™ device

During the procedure, your 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 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 during the procedure 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.

Issues that could happen while the device is in place include tissue damage or trauma around the opening where the gastric catheter rests, and trauma to the infant's gums from oral catheter.

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.

Infants who do not have a successful connection of their esophagus may have to have an additional surgery.

Warnings

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 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 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.

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 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 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 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 doctor before making a decision.

What happens before the treatment?

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.

What happens during the treatment?

Your baby may be sedated or anesthetized at the doctor's discretion.

How is the device placed?

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 1).

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 1).

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. 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 Gastric Catheter.

How long is the device left in place?

Every baby is different, but typically, formation of the anastomosis is seen within 3 to 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.

What happens after the treatment?

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 doctor will determine how often your baby will return for visits.

What happens if the device does not work?

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, 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 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.

Relevant clinical results are summarized in the following table.

Short-Term Clinical Outcomes	Outcomes with Flourish™
Successful creation of an 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
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

Where you can find out more?

If your doctor cannot answer questions about your device, please call Cook Medical:

www.cookmedical.com

1-800-245-4707

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.