

Flourish™

Pediatric Esophageal Atresia Device

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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.

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.

NOTES



This device is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device failure and/or transmission of disease.

RxOnly

Caution: Federal law restricts this device to sale by or on the order of a physician.

Do not use this device for any purpose other than the stated intended use.

If package is opened or damaged when received, do not use. Visually inspect with particular attention to kinks, bends, and breaks. If an abnormality is detected that would prohibit proper working condition, do not use. Please notify Cook for return authorization.

Store in a dry location, away from temperature extremes. Do not remove device from box until ready for use.

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.

POTENTIAL COMPLICATIONS

Potential complications during the procedure include inability to approximate the atretic gap with the magnets or rupture of the balloon in the gastrostomy device.

Potential complications during the device indwelling period include ulceration or tissue irritation around the stoma, and trauma to the patient's gum due to constant catheter pressure.

Potential complications also include recurrent tracheoesophageal-fistula and inflammation.

WARNINGS:



This device is MR unsafe due to the presence of magnets.

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 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.

Potential late complications following successful anastomosis include gastroesophageal reflux, tracheomalacia, esophageal dysmotility, recurrent asthma, and pulmonary infections.

Potential complications post-anastomosis include significant infection and leaks that may result in peritonitis and require surgical or medical interventions, and stenosis that may require repeated endoscopic or surgical intervention(s).

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.

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%.¹

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

PRECAUTIONS

During certain steps of the procedure the usage of fluoroscopy is required.

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.

The Balloon Replacement Gastrostomy Tube is radiopaque. Proper location and integrity of any internal component can be visualized by x-ray.

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 feeding tube may cause premature removal, damage to gastric mucosa and abdominal wall, fatigue or failure of device.

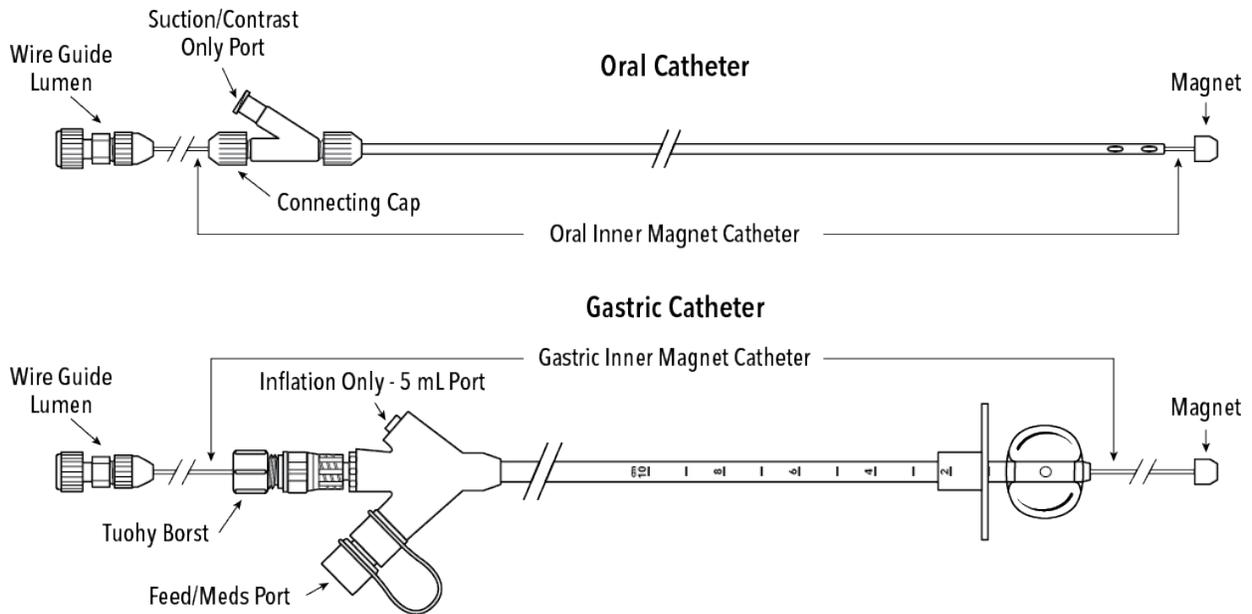
Do not use petroleum jelly or mineral oil for tip lubrication as they may compromise the integrity of the balloon.

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.

DEVICE DESCRIPTION

The Flourish Pediatric Esophageal Atresia Device is a device that consists of an esophageal catheter and a gastric catheter. The esophageal catheter is a 10 Fr catheter with an inner magnet catheter. The inner catheter is fitted with bullet-shaped neodymium iron boron (NdFeB) magnet, which features a central hole for insertion of a wire guide. The “Suction/Contrast Only” port is for suction of saliva, and for injection of contrast to confirm anastomosis.

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 magnet catheter, essentially creating a lumen within a lumen. This modified arrangement allows for initial placement of a wire to guide introduction of the gastric magnet catheter assembly. Feed is delivered through the accessory” Feed/Meds” port adjacent to the adapted central port. The inflated balloon holds 5 mL of liquid. The distal end of the internal catheters is fitted with bullet-shaped neodymium iron boron (NdFeB) magnet, which features a central hole for insertion of a wire guide. When the two catheters are aligned tip to tip the magnets have opposite polarities; thus attracting each other. They are cylindrically shaped. The oral catheter is fitted with a Connecting Cap to allow locking and unlocking of the inner magnet catheter. The gastric catheter is fitted with a Tuohy-Borst adapter to allow locking/unlocking of the inner magnet catheter.



EQUIPMENT REQUIRED

- Fluoroscopy system
- Multi-purpose angio catheter
- Non-magnetic wire guide

PROCEDURE PREPARATION

- Before starting the catheter placement procedure, the distance between upper and lower esophageal pouches must be measured and determined to be less than 4 cm in length, without exerting pressure to the pouches in AP and lateral fluoroscopic views.
- Sedation/anesthesia should be used at the physician's discretion.
- Refer to manufacturer's instructions for removal of currently placed oral catheter and gastrostomy device.

INSTRUCTIONS FOR USE

1. Remove device from packaging box and pouch, inspect contents for damage. Do not use if contents are damaged.
2. Inflate the gastric catheter balloon with 5 mL of sterile or distilled water through the "Inflation Only 5 mL" port.
Caution: Only use sterile or distilled water for balloon inflation. Do not use air, saline, feeding formula, medication, or radiopaque contrast for balloon inflation.
3. Verify balloon integrity by visually inspecting inflated balloon and gently squeezing the balloon to determine if the balloon is leaking. Do not use device if any damages that may affect the performance of the balloon are noted.
4. Deflate balloon by reattaching syringe and removing all water from balloon. Do not attempt to use device if balloon cannot be deflated.
5. Remove protective cover from the magnet at distal end of the gastric catheter.
6. Place gastric catheter through established stoma over pre-positioned wire guide as instructed below:
 - Evaluate existing stoma tract to ensure well-established gastrostomy tract into stomach.
 - a. This device uses an 18 Fr gastric catheter. Ensure established gastrostomy tract is compatible with this size.
 - Push external bolster above 10 cm mark.
 - Locate the distal end of the lower esophageal pouch under fluoroscopy with a multipurpose angio catheter, then pass a non-magnetic wire guide and remove the catheter.
 - Generously lubricate replacement tube and stoma site with water soluble lubricant.
Note: Do not use petroleum jelly or mineral oil for tip lubrication as they may compromise the integrity of the balloon.
 - Ensure the gastric inner magnetic catheter is unlocked.
 - Remove the cap from the white luer lock on the proximal end of the gastric inner magnet catheter. Retain the cap for later usage.
 - Gently pull the gastric inner magnet catheter proximally until the magnet is flush with the balloon catheter.
 - Gently advance gastric tube over the pre-positioned wire guide into stoma site until balloon is completely in stomach. **Note:** Maintain insertion angle perpendicular to the surface of the skin.
 - Advance gastric inner magnet catheter over wire guide to the most distal portion of the lower esophageal pouch.
 - **Caution:** Confirm that the balloon of the gastric catheter assembly will not occlude pylorus when inflated.
 - Securely attach sterile syringe filled with 5 mL sterile or distilled water to "Inflation Only 5 mL" port on gastric catheter and inflate balloon. **Caution:** Only use sterile or distilled water for balloon inflation. Do not use air.
 - Withdraw balloon catheter gently until tension is felt as balloon rests against stomach wall.

- Slide external bolster down shaft of tube until bolster rests gently against abdominal wall.
 - Note centimeter marking on balloon catheter that is closest to bolster in order to monitor balloon catheter location.
 - Remove pre-positioned wire guide through the white luer lock on the proximal end of the gastric inner magnet catheter. Place the retained cap over the white luer lock port.
7. Place oral catheter through mouth as instructed below:
- Remove protective cover from the magnet at the distal end of oral catheter assembly.
 - a. If magnet touches any metal objects, inspect for damage to the magnet. If damage is present, do not use the device.
 - Ensure the oral inner magnetic catheter is unlocked.
 - Gently pull the oral inner magnet catheter proximally until the magnet is flush with the outer oral catheter.
 - Advance oral inner magnet catheter to most distal portion of the esophageal pouch along with the outer oral catheter. Ensure that the outer oral catheter is very close to the most distal end of the upper esophageal pouch to ensure proper suction of saliva.
 - Alternate method: A wire guide may be used with a multi-purpose angio catheter. To use this method remove the cap from the white luer lock on the proximal end of the oral inner magnet catheter. Retain the cap for later use. Advance multi-purpose angio catheter to the distal end of the upper esophageal pouch under fluoroscopy. Pass a non-magnetic wire guide through multipurpose catheter. Remove the multipurpose angio catheter leaving the wire guide in place. Advance the oral inner magnet catheter over the wire guide to the distal end of the upper esophageal pouch. After wire guide is removed place the cap back over the luer lock port.
8. Tape excess oral catheter to infant's cheek to secure catheter position.
9. Using either fluoroscopy or chest x-ray, verify magnet placement and alignment is correct.
10. During approximation, always ensure that at least one of the inner magnet catheters is left in the unlocked position so that the magnets can continue to slowly move towards each other. It is recommended that the gastric inner magnet catheter is left in the unlocked position using the gastric catheter Tuohy-Borst adapter to allow catheter movement and the oral inner magnet catheter is locked using the oral Catheter Connecting cap.
- Movement of the infant should be minimized, and when necessary done with care so as not to disturb the position of the magnets.
- Excess saliva can be continuously or intermittently aspirated through the oral catheter's "Suction/Contrast" port.
- To properly aspirate, the Connecting Cap of the oral catheter must be tightened to lock the oral inner magnet catheter in place and allow proper suction. Prior to locking, ensure that the outer oral catheter is advanced to the most distal part of the pouch so that the outer oral catheter is positioned against the magnet.
 - a. If no aspirate is being collected, verify again that the position of the outer oral catheter is at the most distal portion of the upper esophageal pouch and that the Connecting Cap is tightened to lock the oral inner magnet catheter in place.
 - If aspirate shows signs of milk/nutrition or gastric fluid, this is an indirect indication that an anastomosis may have formed.
 - After aspiration, always ensure that at least one of the inner magnet catheters is left in the unlocked position so that the magnets can continue to slowly move towards each other. If continuous aspiration is prescribed, keep the oral inner magnet catheter locked.
11. Daily X-rays may be used to verify that magnets are attracting and proper alignment is maintained throughout anastomosis formation.

12. Before feeding, the following steps should be taken:
 - Ensure that the Tuohy Borst adapter is tightened to lock the gastric inner magnet catheter in place; failure to lock the Tuohy Borst adapter could result in leakage during injection of feeds.
 - Ensure the length of the tube from the stoma to the end of the tube has not changed by recording centimeter marking on tube that is closest to bolster.
 - Verify the proper placement of tube prior to feeding:
 - a. Remove plug from “Feed/Meds” port.
 - b. Draw 10 mL of water into a syringe and insert into “Feed/Meds” port. Gently pull back on syringe plunger until stomach contents are aspirated and visible in the feeding lumen. **Note:** The presence of gastric contents in the feeding lumen confirms correct positioning and that feeding tube is inside the stomach lumen.
 - c. Flush contents with the 10 mL of water in the syringe.
 - d. Remove syringe.
13. Infant can be fed through the “Feed/Meds” port of the gastrostomy tube after confirmation of device placement.
 - Insert the tip of the filled feeding syringe into the port and slowly inject.
 - Continue the process until the prescribed amount of formula has been delivered to the patient.
 - Upon completion of feeding, flush the tube with 5-10 mL of water to prevent clogging.
 - After feeding, unlock one inner magnet catheter so that the magnets can continue to slowly move towards each other.
14. The stoma site should be inspected and cleaned regularly. Cleaning should be performed with mild soap and water. Remove moisture afterwards.
15. Clean residual contents from the external area of the feeding tube with mild soap and water as needed. Remove moisture afterwards.
16. In order to prevent feeding tube clogging, always flush lumen with prescribed amount of water after nutrition administration every 4-6 hours during continuous feedings, before administering medication, and after medication administration is complete. **Note:** The amount of water used for flushing will depend on patient’s need and clinical condition.
17. Assess the feeding tube daily for damage, clogging or abnormal discoloration.
18. Esophageal anastomosis is anticipated within 3 to 13 days post magnet placement. Daily repositioning maybe required.
19. Inject a small amount of contrast through outer oral catheter “Suction/Contrast only” port verifying that contrast moves into stomach to confirm anastomosis formation prior to removing magnet catheters. After confirmation of anastomosis, wait one day to remove magnets.
20. To remove magnet catheters:
 - Untape the oral catheter from the patient’s cheek.
 - Ensure that both the oral catheter assembly and the gastric catheter assembly are in the unlocked position so that the inner magnet catheters can move freely.
 - Cut the oral inner magnet catheter at proximal end to remove adapter assembly. Discard clipped section.
 - Remove the cap from the white luer lock on the proximal end of the gastric inner magnet catheter.
 - Under fluoroscopic guidance, introduce a non-magnetic wire guide through the oral inner magnet catheter to pass through newly formed anastomosis and exit through the gastrostomy port. Some resistance may be encountered as wire guide is introduced through the proximal magnet into the distal magnet due to tissue trapped between the magnets or slight misalignment of magnets; slight pressure may help to manipulate the wire guide appropriately through the magnets. If significant resistance is encountered, verify proper magnet alignment with fluoroscopy before proceeding.

- Attach syringe to “Inflation Only 5 mL” port on gastric catheter and deflate balloon completely. If balloon does not deflate, cut gastric catheter below “Inflation Only 5 ml” port. This will deflate balloon completely.
 - Push the oral catheter distally toward stomach until magnets are in the stomach, below the anastomosis. Then, gently push the oral inner magnet catheter and pull the gastric catheter until the system exits from gastrostomy site, thus removing the gastrostomy tube, oral and gastric inner magnet catheters and the magnet pair as a unit. Follow institutional standard for covering the gastrostomy and check periodically for normal healing at the site.
 - Remove orogastric (OG) tube.
 - Place a new similarly sized OG or nasogastric tube over the wire guide to facilitate feeding through the anastomosis for 1-3 days.
 - Follow institutional standard for covering the gastrostomy and check periodically for normal healing at the site.
21. If significant difficulties are encountered when attempting to remove the assembly through the gastrostomy port, removal through the patient’s mouth may be attempted:
- Cut the gastric inner magnet catheter at the proximal end to remove adapter assembly. Discard clipped section.
 - Under fluoroscopic guidance, introduce a non-magnetic wire guide through the gastric inner magnet catheter to pass through the newly formed anastomosis and exit through the oral catheter. Some resistance may be encountered as wire guide is introduced through the proximal magnet into the distal magnet due to tissue trapped between the magnets or slight misalignment of magnets; slight pressure may help to manipulate the wire guide appropriately through the magnets. If significant resistance is encountered, verify proper magnet alignment with fluoroscopy before proceeding.
 - Push the gastric inner magnet catheter toward the mouth while gently pulling the oral catheter assembly until the system exits from the mouth, thus removing the gastric inner magnet catheter, inner oral magnet catheter and outer oral catheter as a unit.
 - Place a new OG or nasogastric tube over the wire guide to facilitate feeding through the anastomosis for 1-3 days.
 - Remove feeding tube.
 - Follow institutional standard for covering the gastrostomy and check periodically for normal healing at the site.
 - Monitor infant for anastomotic leak, stricture formation, and adequate nutritional support via OG tube.

Dispose of device per institutional guidelines for biohazardous medical waste.

CLINICAL RESULTS

Clinical results supporting product approval were derived from a case series in Argentina² (n=9) and cases performed as emergency use in the U.S. (n=7; three (3) of these cases were reported in references 3 and 4) for a total of 16 cases.

The product was used for 1st line therapy, as well as in patients with previous thoracotomy or thoracoscopy in which an anastomosis was unable to be achieved.

In the described cases, patient ages have ranged from 23 days to 8 months when the product was used. Anastomosis was achieved in all patients with times that ranged from 3 to 13 days.

Post-procedure, none of the patients experienced an anastomotic leak. Thirteen (13) of 16 patients (81.3%) developed stenosis that required dilatation of the anastomotic site with serial balloon dilation and/or esophageal stenting. One patient (who underwent several dilatations and stent placement) ultimately required surgical re-anastomosis.

One patient developed sepsis 48 hours after magnet placement. In this case, the catheter-based magnets were removed, the patient was treated with antibiotics, and the catheter-based magnets were replaced to complete the magnetic treatment.

Regarding oral capabilities, six (6) patients from the Argentinian series with long-term follow-up data were reported to be ingesting normal residue diets for their age. For the emergency cases, one patient was reported to be swallowing salivary secretions well and progressing with oral feedings at 8 months post-procedure. One was reported to be swallowing oral secretions well at 4 months post-procedure, and one patient was ingesting foods normally at 1.5 years of age. Relevant data was not available on the remaining 7 subjects.

Regarding other conditions, of the six (6) subjects with longer term follow-up from the Argentinian series, two (2) patients were diagnosed with gastroesophageal reflux disease (GERD) and tracheomalacia. Three (3) patients were diagnosed as having esophageal dysmotility requiring treatment and three (3) patients developed asthma or recurrent pulmonary infections. None of the patients have scoliosis or rib deformities.

Principal clinical results are summarized in the following table:

Short Term Clinical Outcomes with Flourish™	Percent	N
Successful creation of an anastomosis	100%	16/16
Death	0%	0/16
Anastomotic leak	0%	0/16
Stricture at anastomosis site requiring endoscopic dilation	81.3.%	13/16
Stricture at anastomosis site requiring surgical intervention	6.3%	1/16
Long Term Clinical Outcomes with Flourish™		
Gastroesophageal reflux disease	33%	2/6*
Tracheomalacia	33%	2/6*
Esophageal dysmotility requiring treatment	50%	3/6*
Asthma	50%	3/6*
Recurrent pulmonary infections	50%	3/6*

* Patients from the Argentinian series having longer term follow up

For additional information:

1. Spitz L. Esophageal atresia. Lessons I have learned in a 40-year experience. J Pediatr Surg. 2006 Oct; 41(10):1635-40.
2. Zaritzky M, Ben R, Johnston K. Magnetic gastrointestinal anastomosis in pediatric patients. J Pediatr Surg. 2014 Jul; 49(7):1131-1137.
3. 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.
4. 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.

Note: Publications 2-4 contain fluoroscopic procedure-related images

Image	Standard	Symbol Ref #	Symbol Title (from Standard)	Symbol Definition (from Standard)
	ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information to be Supplied	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC

	ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information to be Supplied	5.2.3	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide
	ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information to be Supplied	5.4.2	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
	ASTM F2503-13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Fig. 9	MR Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment
RxOnly	CFR Title 21 Part 801.109	801.109	Prescription Only	Prescription only. U.S. federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner.
Image	Standard N/A	Symbol Ref #	Symbol Title (from Cook Medical)	Symbol Definition (from Cook Medical)
	Cook Medical	N/A	Wire guide compatibility	If symbol appears on product label, X = wire guide compatibility
	Cook Medical	N/A	Minimum accessory channel	If symbol appears on product label, X = minimum accessory channel
	Cook Medical	N/A	Maximum insertion portion width	If symbol appears on product label, X = maximum insertion portion width
	Cook Medical	N/A	Quantity per box	If symbol appears on product label, X = quantity per box