More control, less stress, throughout the GI tract

Evolution®
CONTROLLED-RELEASE STENT

Biliary

Duodenal

Colonic

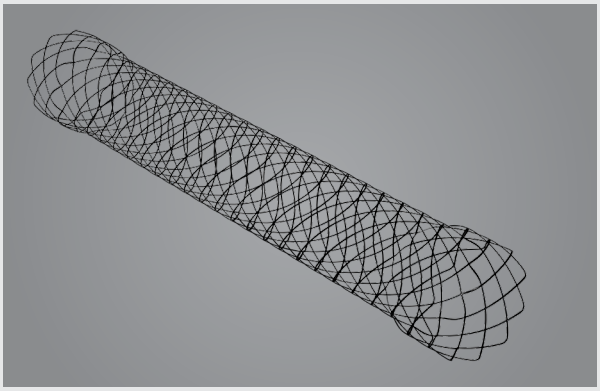
Esophageal

COOK MEDICAL

The Evolution family

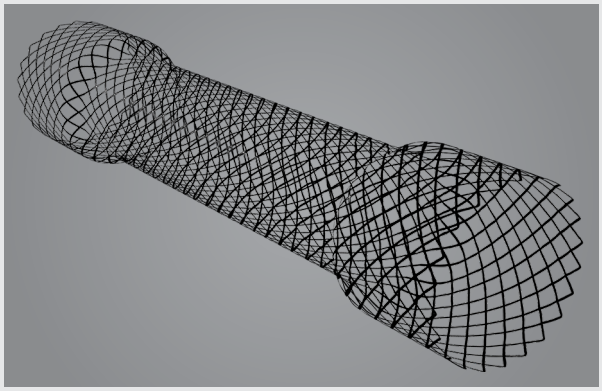
Evolution gives you the ability to deliver stents with more control and less stress. Now, no matter where you are stenting in the GI tract, you can focus even more on patient outcomes.

Biliary



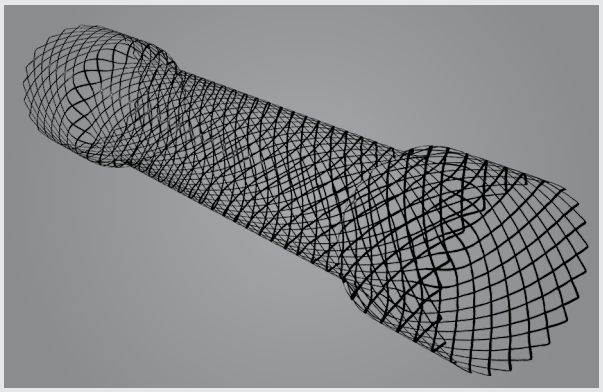
Uncovered

Duodenal



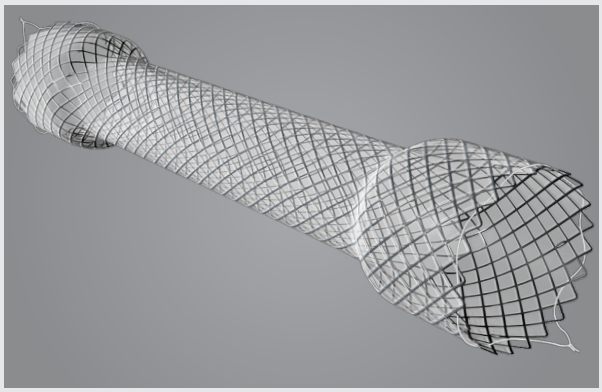
Uncovered

Colonic

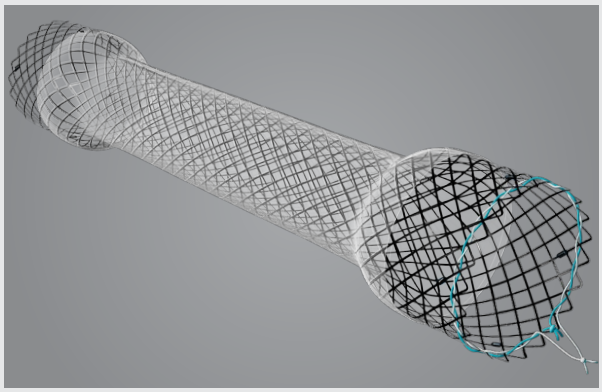


Uncovered

Esophageal



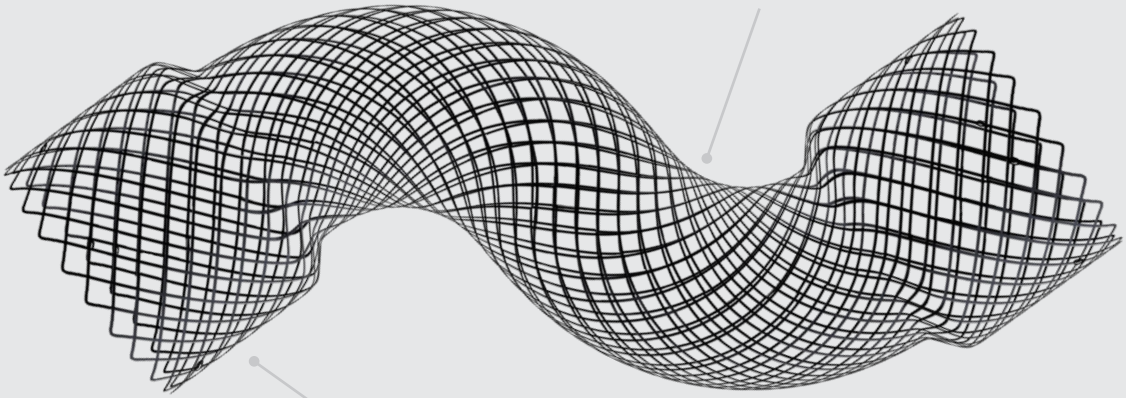
Fully Covered



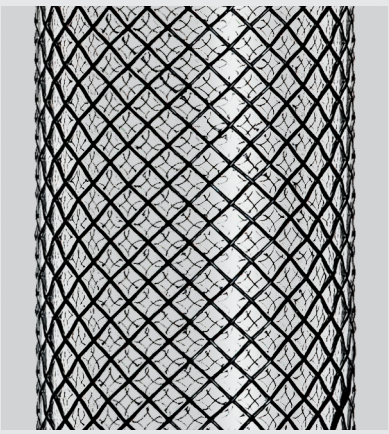
Partially Covered

Evolutionary stent

The stent, the most important component in the procedure, is meant to provide relief specific to the patient's disease state. That's the guiding concept behind all of our Evolution stents.

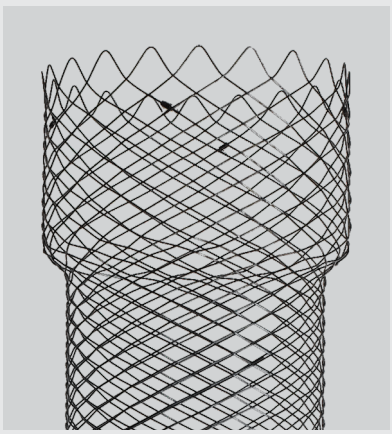


Esophageal



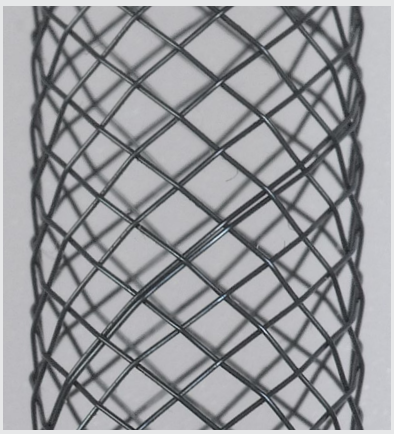
Silicone coating helps minimize the risk of tissue ingrowth and food impaction.

Colonic | **Duodenal**



The 18 crowns on the Evolution Duodenal and the 20 crowns on the Evolution Colonic are designed to deliver an even distribution of radial force to reduce pain and the risk of perforation.

Biliary

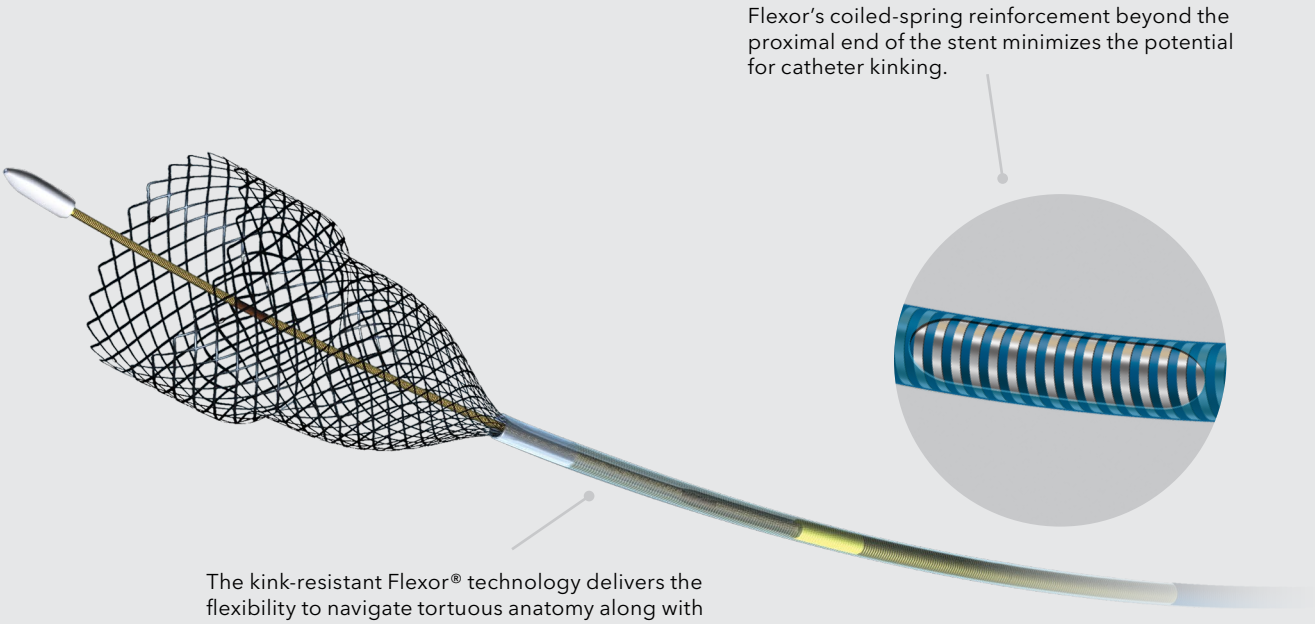


With its small-cell configuration, the uncovered weave design potentially improves patency.

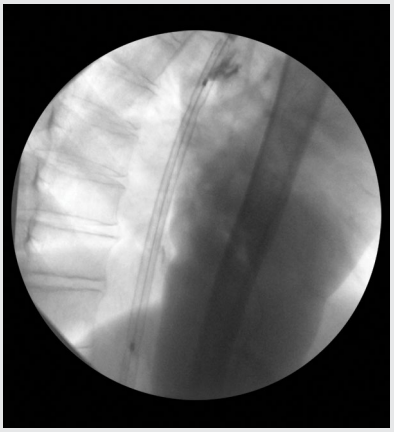
*Evolution Biliary has a nitinol wire with a platinum core.

Evolutionary precision

Precision is gaining access to your stenting position and then maintaining that position throughout the deployment process, even in complex and challenging anatomy.



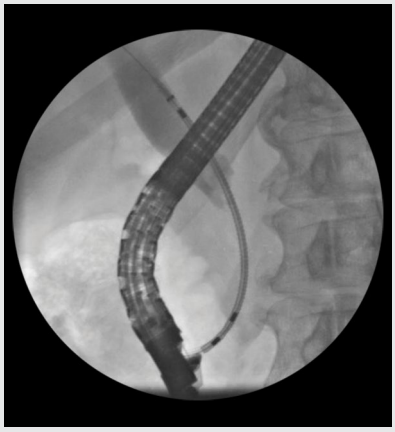
Esophageal



Radiopaque markers on the inner catheter assist in estimation of stent foreshortening and precise stent placement.

Image courtesy of Dr. Inder Mainie, Belfast City Hospital, Northern Ireland.

Biliary



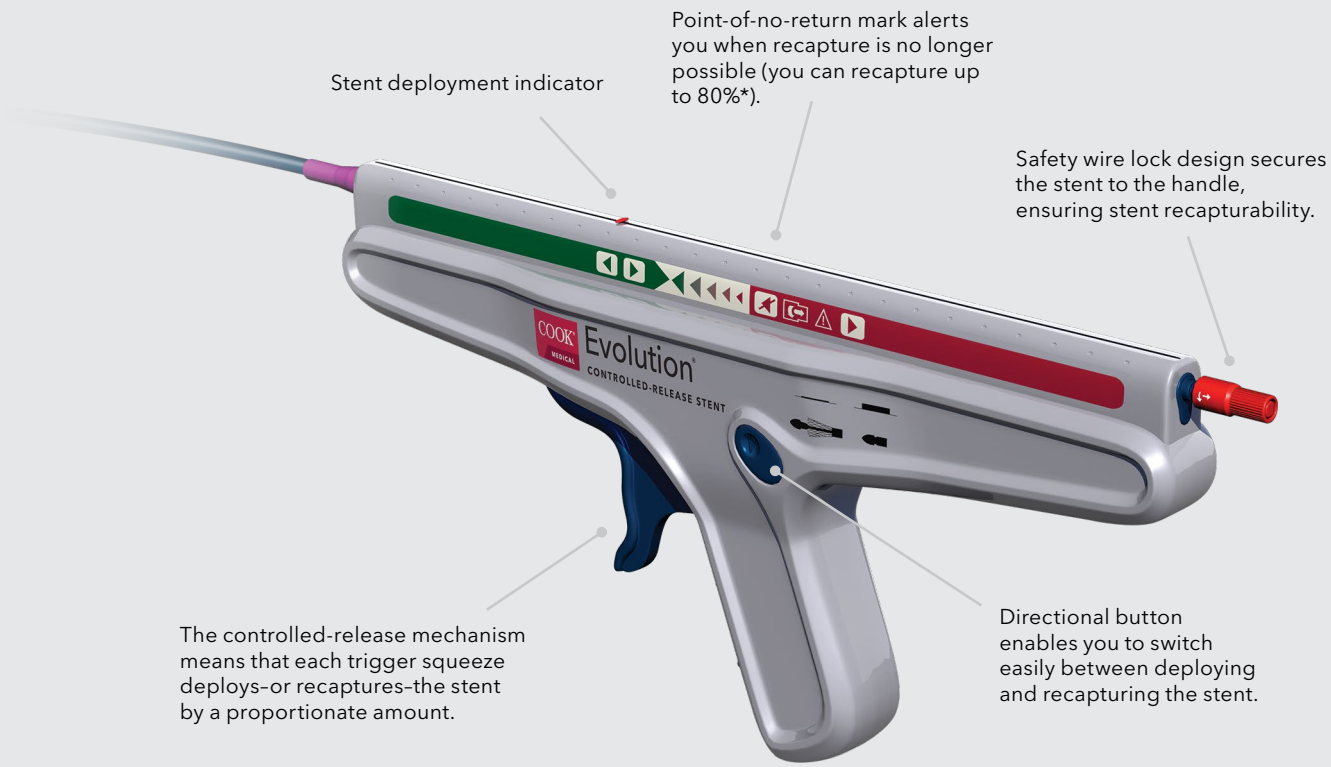
Radiopaque markers indicate precise stent location during introduction and deployment.

Image courtesy of Prof. Marco Bruno, Erasmus Medical Centre, Rotterdam, the Netherlands.

Evolutionary control

An intuitive, controlled-release system with the ability to recapture gives you and your assistant the confidence needed to remain in sync throughout the deployment process.

The controlled-release mechanism minimizes potential stent jumping, allowing for precise stent placement.



"Excellent controlled release and good pushability."

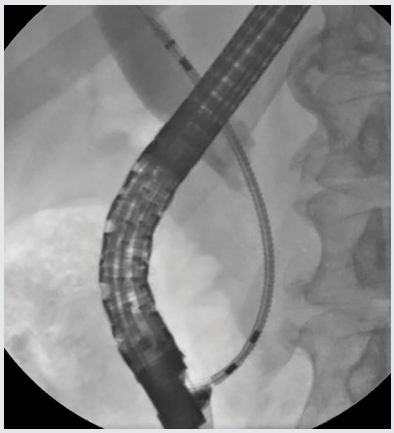
Dr. Martin James
Queen's Medical Centre
Nottingham, United Kingdom

*80% for Evolution Biliary and 50% for Evolution Colonic, Duodenal, and Esophageal.

Evolution Biliary

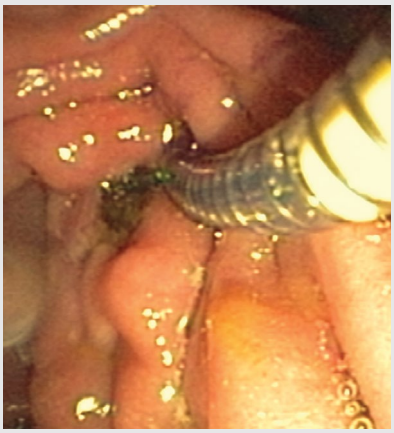
Even in a completely retroflexed position, you are able to effectively deploy a stent designed for prolonged patency.

- Evolution stents are woven with a single nitinol wire, with platinum core, which is designed to provide uniform radial force, optimal flexibility, and conformability.
- Every Evolution stent has both proximal and distal flanges, which are designed to aid in preventing migration.
- Flexor's coiled-spring reinforcement beyond the proximal end of the stent minimizes the potential for catheter kinking.
- The kink-resistant Flexor technology delivers the flexibility to navigate tortuous anatomy along with the pushability to traverse tight strictures.



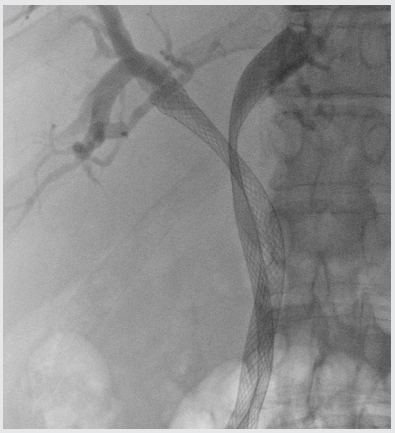
Radiopaque markers before deployment begins

Image courtesy of Prof. Marco Bruno, Erasmus Medical Centre, Rotterdam, the Netherlands.



Endoscopic yellow marker

Image courtesy of Prof. Horst Neuhaus, Evangelisches Krankenhaus, Düsseldorf, Germany.



Double stenting immediately after placement

Image courtesy of Prof. Guido Costamagna, Policlinico Universitario Agostino Gemelli, Rome, Italy.

Evolution Biliary

This device is used in palliation of malignant neoplasms in the biliary tree.
It is supplied sterile and is disposable (for single use only).

Order Number	Reference Part Number	Introducer Size Fr	Body Diameter mm	Stent Flange Diameter mm	Stent Length cm	Wire Guide Diameter inch	Minimum Accessory Channel Diameter mm
Uncovered							
G23123	**EVO-8-9-4-B**	8.5	8	9	4	0.035	3.2
G23124	**EVO-8-9-6-B**	8.5	8	9	6	0.035	3.2
G23125	**EVO-8-9-8-B**	8.5	8	9	8	0.035	3.2
G23126	**EVO-8-9-10-B**	8.5	8	9	10	0.035	3.2
G23127	**EVO-10-11-4-B**	8.5	10	11	4	0.035	3.2
G23128	**EVO-10-11-6-B**	8.5	10	11	6	0.035	3.2
G23129	**EVO-10-11-8-B**	8.5	10	11	8	0.035	3.2
G23130	**EVO-10-11-10-B**	8.5	10	11	10	0.035	3.2

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Support & Distribution for details regarding stock or nonstock status (expect longer lead time if nonstock), pricing, and/or availability.

Warning: *The safety and effectiveness of this device for use in the vascular system have not been established.*

MR Conditional

Evolution® Biliary Stent System – Uncovered

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

INTENDED USE: This device is used in palliation of malignant neoplasms in the biliary tree.

CONTRAINDICATIONS: Those specific to ERCP and any procedure to be performed in conjunction with stent placement. Additional contraindications include, but are not limited to: inability to pass the wire guide or stent through the obstructed area • biliary duct strictures of benign etiology • biliary obstruction preventing endoscopic cholangiography • concurrent perforated bile duct • those patients for whom endoscopic procedures are contraindicated • patients with coagulopathy, concurrent bile duct stones, very small intrahepatic ducts and any use other than those specifically outlined under Intended Use.

WARNINGS: The safety and effectiveness of this device for use in the vascular system has not been established. This device is not intended to be deployed through the wall of a previously placed or existing metal stent. Doing so could result in difficulty or inability to remove introducer. The stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity. This stent system is designed for single use only. Attempts to reprocess, resterilize and/or reuse may lead to device failure and/or transmission of disease. If the 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. After stent placement, additional methods of treatment such as chemotherapy and irradiation may increase the risk of stent migration due to tumor shrinkage, stent erosion, and/or mucosal bleeding. **This metal biliary stent is not intended to be repositioned or removed after stent placement** and is considered a permanent implant. Attempts to remove the stent after placement may cause damage to the surrounding mucosa. In case of accidental deployment or improper placement (immediately following deployment), stent should be left in place and placement of a second stent of the same diameter should be attempted to achieve desired result providing adequate overlapping (minimum 1cm).

PRECAUTIONS: Refer to the package label for the minimum channel size required for this device. A complete diagnostic evaluation should be performed prior to placement to measure the stricture length and determine the proper stent length. The stent length chosen should allow for additional length on either side of the stricture. **Note:** In the event a single stent will not adequately cover the stricture, a second stent of the same diameter should be placed providing adequate overlapping (minimum 1cm) of the initially placed stent to ensure a bridging of the stricture between the stents. If wire guide or stent cannot advance through obstructed area, do not attempt to place stent. Stent should be placed using fluoroscopic and endoscopic monitoring. The stent should only be placed with the Cook delivery system, which is provided with each stent. This stent is intended for palliative treatment only. Alternate methods of therapy should be investigated prior to placement. Long-term patency with this stent has not been established. Periodic evaluation of the stent is advised. Assessment must be made to determine the necessity of sphincterotomy or balloon dilation prior to stent placement. In the event sphincterotomy or balloon dilation is required, all appropriate cautions, warnings and contraindications must be observed. Stent cannot be recaptured after the deployment threshold has been passed. The position of the red marker on the top of the handle in relation to point-of-no-return position on the handle label indicates when threshold has been passed. Do not attempt to reload a deployed stent. Do not use this device for any other purpose than the stated intended use. Not compatible with THSF wire guide. Use of this device is restricted to a trained healthcare professional. Passing a delivery system through a just deployed stent may cause a previously placed stent to dislodge. To reduce the risk of stent dislodgement ensure that the delivery system is completely recaptured following stent deployment.

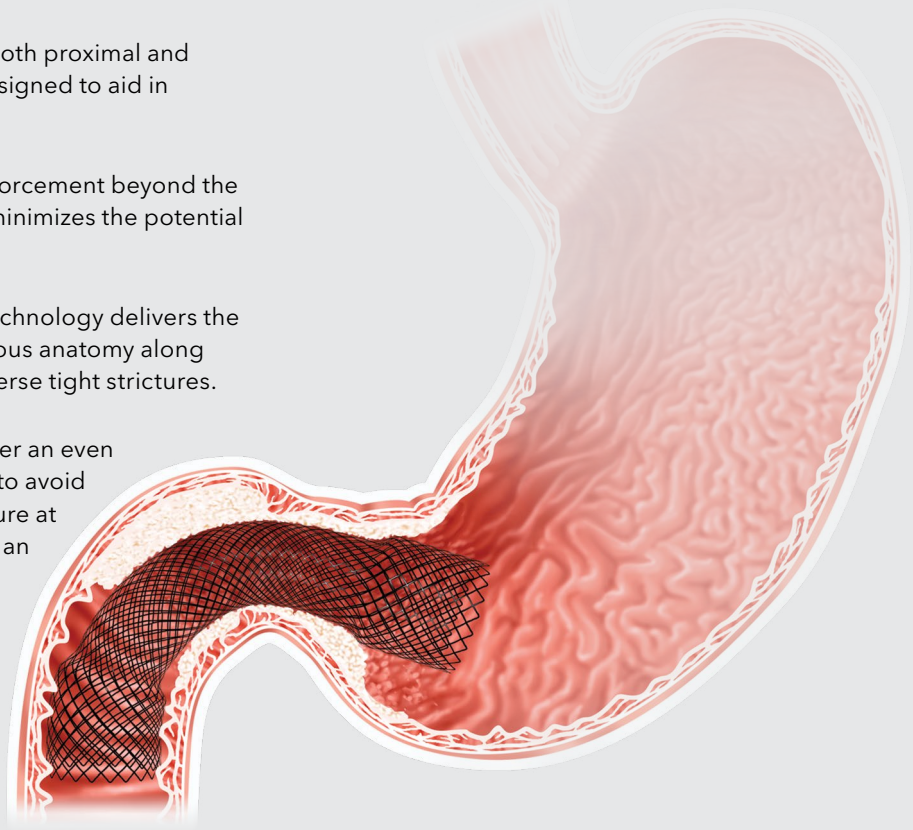
POTENTIAL ADVERSE EVENTS: Potential adverse events associated with ERCP include, but are not limited to: allergic reaction to contrast or medication • aspiration • cardiac arrhythmia or arrest • cholangitis • cholecystitis • cholestasis • hemorrhage • hypotension • infection • pancreatitis • perforation • respiratory depression or arrest • sepsis. Additional adverse events that can occur in conjunction with biliary stent placement include, but are not limited to: allergic reaction to nickel • bile duct ulceration • death (other than due to normal disease progression) • fever • inflammation • ingrowth due to tumor or excessive hyperplastic tissue • nausea • obstruction of the pancreatic duct • pain/discomfort • perforation • recurrent obstructive jaundice • stent migration • stent misplacement • stent occlusion • trauma to the biliary tract or duodenum • tumor overgrowth • vomiting.

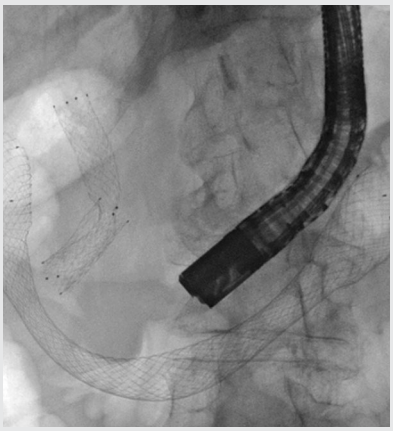
See Instructions for Use for full product information.

Evolution Duodenal

Maneuver through the duodenum's difficult angulations, and deploy a stent that conforms to the anatomy's particular curve, even in the complex third or fourth portions of the duodenum.

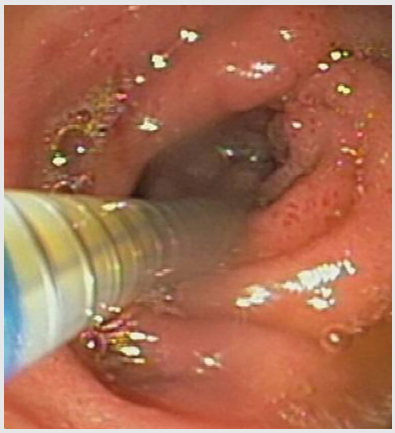
- Evolution stents are woven with a single nitinol wire, which is designed to provide uniform radial force, optimal flexibility, and conformability.
- Every Evolution stent has both proximal and distal flanges which are designed to aid in preventing migration.
- Flexor's coiled-spring reinforcement beyond the proximal end of the stent minimizes the potential for catheter kinking.
- The kink-resistant Flexor technology delivers the flexibility to navigate tortuous anatomy along with the pushability to traverse tight strictures.
- The stent's 18 crowns deliver an even distribution of radial force to avoid the concentration of pressure at any one point of contact in an effort to reduce pain and the risk of perforation.





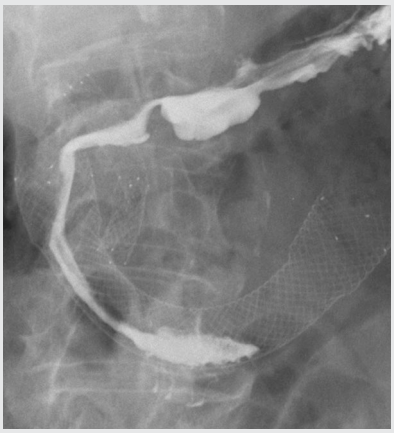
Stent position immediately after deployment

Image courtesy of Dr. Douglas A. Howell, Maine Medical Center, Portland, Maine, USA.



Endoscopic yellow marker

Image courtesy of Dr. Mario Traina, IsMeTT, Palermo, Italy.



Stent position 2 weeks after deployment

Image courtesy of Dr. Douglas A. Howell, Maine Medical Center, Portland, Maine, USA.

Evolution Duodenal

This device is used for palliative treatment of duodenal or gastric outlet obstruction and duodenal strictures caused by malignant neoplasms. It is supplied sterile and is disposable (for single use only).

Order Number	Reference Part Number	Stent Body Diameter mm	Stent Flange Diameter mm	Stent Length cm	Delivery System Diameter Fr	Delivery System Length cm	Wire Guide Diameter inch	Minimum Accessory Channel Diameter mm
G48025	**EVO-22-27-6-D**	22	27	6	10	230	0.035	3.7
G48026	**EVO-22-27-9-D**	22	27	9	10	230	0.035	3.7
G48027	**EVO-22-27-12-D**	22	27	12	10	230	0.035	3.7

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Support & Distribution for details regarding stock or nonstock status (expect longer lead time if nonstock), pricing, and/or availability.

MR Conditional

Evolution® Duodenal Stent System – Uncovered

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

INTENDED USE: This device is used for palliative treatment of duodenal or gastric outlet obstruction and duodenal strictures caused by malignant neoplasms.

CONTRAINDICATIONS: Those specific to GI endoscopy and any procedure to be performed in conjunction with stent placement. Additional contraindications include, but are not limited to: enteral ischemia • suspected or impending perforation • intra-abdominal abscess/perforation • inability to pass wire guide or stent through obstructed area • patients for whom endoscopic procedures are contraindicated • coagulopathy/patients with elevated bleeding times • benign disease.

WARNINGS: The stent is not intended to be removed or repositioned after stent placement and is intended to remain in the body permanently. Attempts to remove or reposition stent after placement may cause damage to surrounding tissue or mucosa. The stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity. 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. 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. After stent placement, alternative methods of treatment such as chemotherapy and radiation should not be administered as this may increase risk of stent migration due to tumor shrinkage, stent erosion, and/or mucosal bleeding.

PRECAUTIONS: Refer to product package label for the minimum channel size required for this device. A complete diagnostic evaluation must be performed prior to use to determine proper stent size. If wire guide or stent cannot advance through obstructed area, do not attempt to place stent. Stent should be placed using fluoroscopic monitoring with endoscopy. The stent should only be placed with the Cook delivery system, which is provided with each stent. This device is intended for palliative treatment only. Alternate methods of therapy should be investigated prior to placement. Long-term patency of this device has not been established. Periodic evaluation is advised. Stent cannot be retrieved after the deployment threshold has been passed. The position of the red marker on the top of the handle in relation to the point-of-no-return position on the handle label indicates when threshold has been passed. Do not use this device for any purpose other than stated intended use. Use of this device is restricted to a trained healthcare professional.

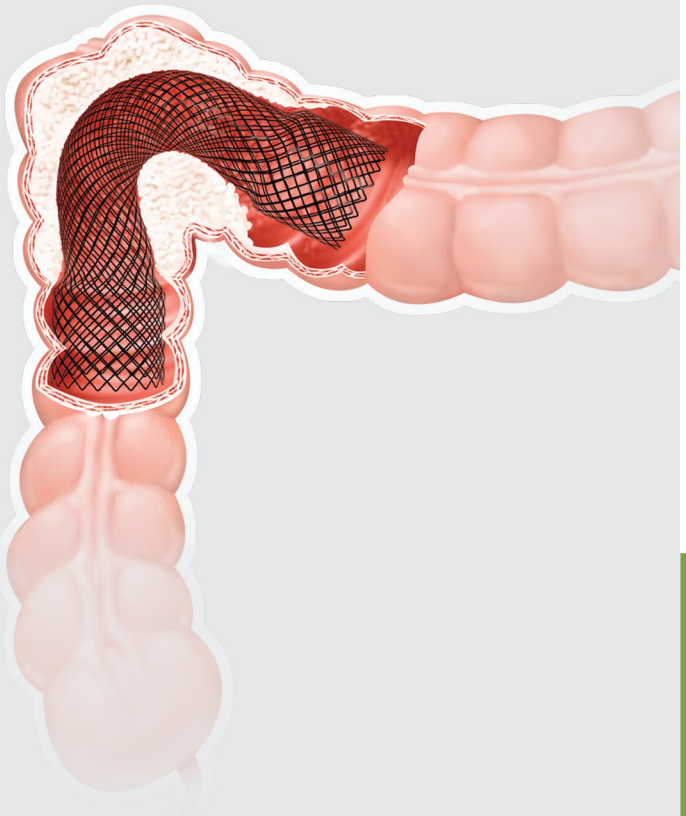
POTENTIAL ADVERSE EVENTS: Potential adverse events associated with GI endoscopy include, but are not limited to: airway obstruction • allergic reaction to contrast or medication • aspiration • biliary obstruction • cardiac arrhythmia or arrest • cholangitis • fever • hemorrhage • hypotension • infection • perforation • reflux • respiratory depression or arrest. Additional adverse events include, but are not limited to: allergic reaction to nickel • bowel impaction • death (other than due to normal disease progression) • erosion of the luminal mucosa • foreign body sensation • inadequate expansion • intestinal perforation • nausea/vomiting • pain/discomfort • pancreatitis • pressure necrosis • septicemia • stent misplacement and/or migration • stent occlusion • tumor ingrowth or overgrowth • ulcerations.

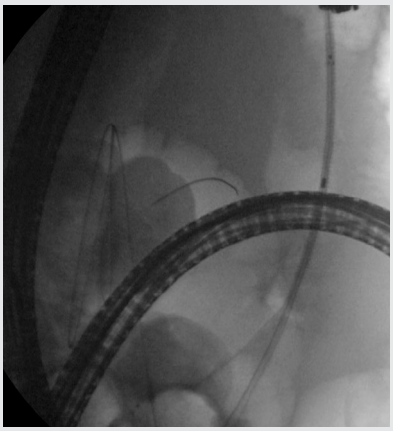
See Instructions for Use for full product information.

Evolution Colonic

Whether you do colonic stenting regularly or rarely, for palliation or as a bridge to surgery, Evolution stents are designed to give your patient relief and can be delivered confidently even in the most complex and tortuous environments.

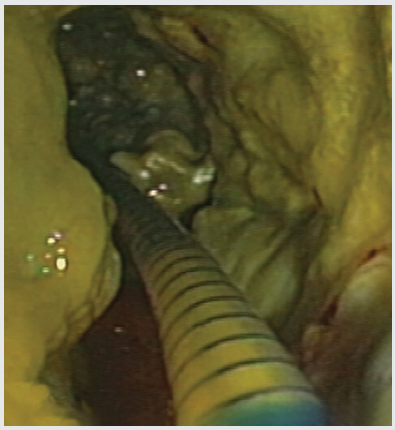
- Evolution stents are woven with a single nitinol wire, which is designed to provide uniform radial force, optimal flexibility, and conformability.
- Every Evolution stent has both proximal and distal flanges, which help reduce migration.
- Flexor's coiled-spring reinforcement beyond the proximal end of the stent minimizes the potential for catheter kinking.
- The kink-resistant Flexor technology delivers the flexibility to navigate tortuous anatomy along with the pushability to traverse tight strictures.
- The stent's 20 crowns deliver an even distribution of radial force to avoid the concentration of pressure at any one point of contact in an effort to reduce pain and the risk of perforation.





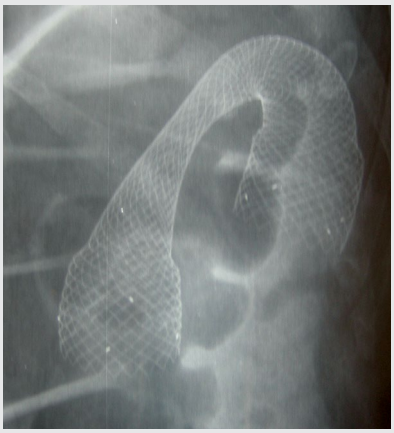
Partially deployed stent

Image courtesy of Dr. Julio Faria, McGill University, Jewish General Hospital, Montreal, Quebec, Canada.



Endoscopic yellow marker

Image courtesy of Dr. Mario Traina, IsMeTT, Palermo, Italy.



Stent position immediately after deployment

Image courtesy of Dr. Alessandro Repici, Istituto Clinico Humanitas, Rozzana (Milano), Italy.

Evolution Colonic

This device is used for palliative treatment of colonic obstruction or colonic strictures caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures. It is supplied sterile and is disposable (for single use only).

Order Number	Reference Part Number	Stent Body Diameter mm	Stent Flange Diameter mm	Stent Length cm	Delivery System Diameter Fr	Delivery System Length cm	Wire Guide Diameter inch	Minimum Accessory Channel Diameter mm
G48029	**EVO-25-30-6-C**	25	30	6	10	230	0.035	3.7
G48028	**EVO-25-30-8-C**	25	30	8	10	230	0.035	3.7
G48038	**EVO-25-30-10-C**	25	30	10	10	230	0.035	3.7

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Support & Distribution for details regarding stock or nonstock status (expect longer lead time if nonstock), pricing, and/or availability.

MR **MR Conditional**

Evolution® Colonic Stent System – Uncovered

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

INTENDED USE: This device is used for palliative treatment of colonic obstruction or colonic strictures caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

CONTRAINDICATIONS: Those specific to GI endoscopy and any procedure to be performed in conjunction with stent placement. Additional contraindications include, but are not limited to: enteral ischemia • suspected or impending perforation • intra-abdominal abscess/perforation • inability to pass wire guide or stent through obstructed area • patients for whom endoscopic procedures are contraindicated • significant coagulopathy • benign disease.

WARNINGS: The stent is not intended to be removed or repositioned after stent placement and is intended to remain in the body permanently. Attempts to remove or reposition stent after placement may cause damage to surrounding tissue or mucosa. This stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity. 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. To minimize pain and tenesmus, the stent end nearest to the anal canal/anus should be placed 2 cm above the anal canal or 6 cm from the anus. 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. After stent placement, alternative methods of treatment such as chemotherapy and radiation should not be administered as this may increase risk of stent migration due to tumor shrinkage, stent erosion, and/or mucosal bleeding. The device should be used with caution and only after careful consideration in patients with: • Patients with radiation colitis or proctitis. • Patients with elevated bleeding times, coagulopathies.

PRECAUTIONS: Refer to product package label for the minimum channel size required for this device. A complete diagnostic evaluation must be performed prior to use to determine proper stent size. If wire guide or stent cannot advance through obstructed area, do not attempt to place stent. Stent should be placed endoscopically with fluoroscopic monitoring. The stent should only be placed with the Cook delivery system, which is provided with each stent. This device is intended for palliative treatment only. Alternate methods of therapy should be investigated prior to placement. Long-term patency of this device has not been established. Periodic evaluation is advised. Use of this device is restricted to a trained healthcare professional. Do not use this device for any purpose other than stated intended use. Stent cannot be retrieved after the deployment threshold has been passed. The position of the red marker on the top of the handle in relation to the point-of-no-return position on the handle label indicates when threshold has been passed.

POTENTIAL ADVERSE EVENTS: Potential adverse events associated with GI endoscopy include, but are not limited to: allergic reaction to contrast or medication • aspiration • cardiac arrhythmia or arrest • fever • hemorrhage • hypotension • infection • perforation • respiratory depression or arrest. Additional adverse events include, but are not limited to: allergic reaction to nickel • bowel impaction • constipation • death (other than due to normal disease progression) • diarrhea • erosion of the luminal mucosa • foreign body sensation • inadequate stent expansion • intestinal perforation • nausea/vomiting • pain/discomfort • peritonitis • pressure necrosis • septicemia • stent misplacement and/or migration • stent occlusion • symptoms of tenesmus or urgency/incontinence • tumor ingrowth or overgrowth • ulcerations.

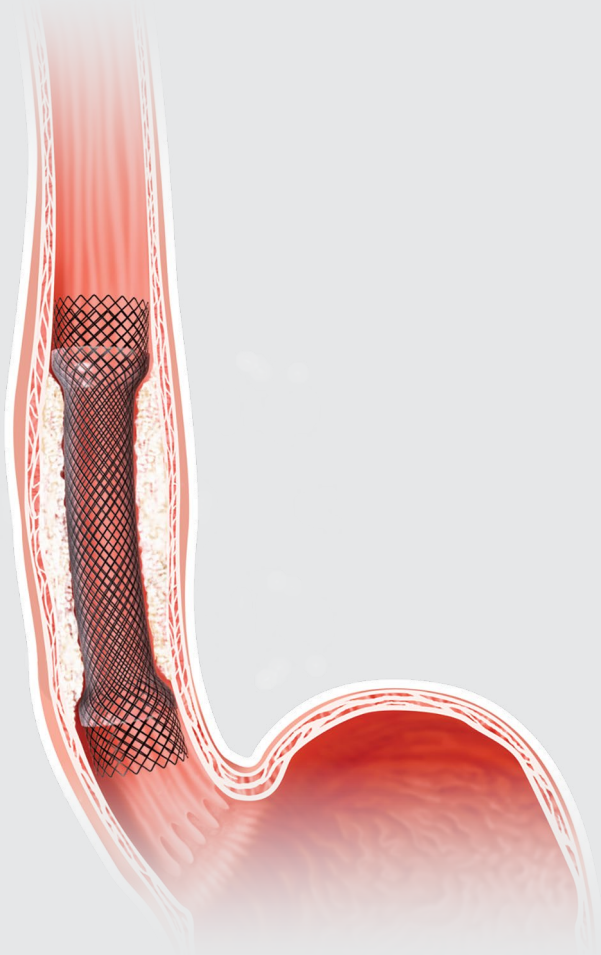
See Instructions for Use for full product information.

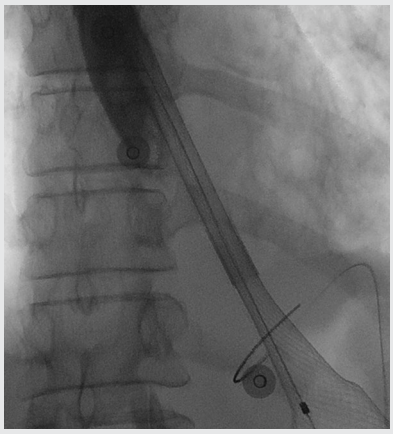
AB IFU0052 REV2

Evolution Esophageal

With the right balance of radial force to open the stricture, this stent is also durable enough to withstand the corrosive environment of the esophagus.

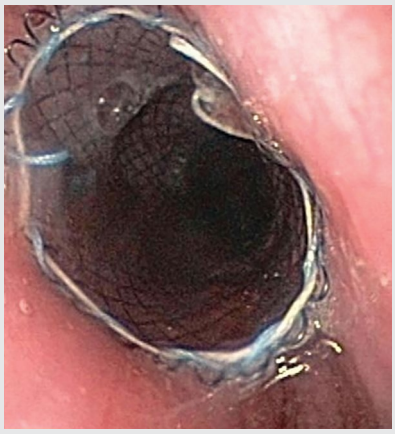
- Evolution stents are woven with a single nitinol wire, which is designed to provide uniform radial force, optimal flexibility, and conformability.
- Every Evolution stent has both proximal and distal flanges, which are designed to aid in preventing migration.
- Silicone coating helps minimize the risk of tissue ingrowth.





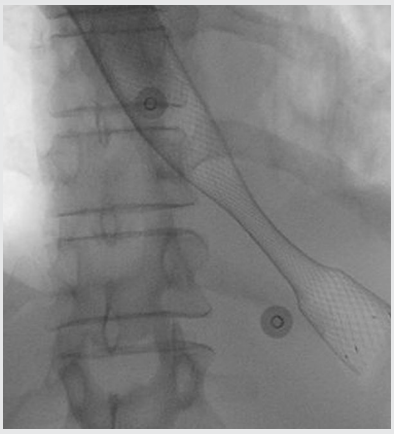
Partially deployed stent

Image courtesy of Dr. Marc Giovannini, Paoli-Calmettes Institute, Marseilles, France.



Lasso loop

Image courtesy of Dr. Mojtaba Olyaee, University of Kansas Medical Center, Kansas City, Kansas, USA.



Stent position immediately after deployment

Image courtesy of Dr. Marc Giovannini, Paoli-Calmettes Institute, Marseilles, France.

Evolution Esophageal

This device is used to maintain patency of malignant esophageal strictures and/or to seal tracheoesophageal fistulas. It is supplied sterile and is disposable (for single use only).

Order Number	Reference Part Number	Stent Body Diameter mm	Stent Flange Diameter mm	Stent Length cm	Delivery System Diameter mm	Delivery System Length cm	Wire Guide Diameter inch
Partially Covered							
G48030	EVO-20-25-8-E	20	25	8	8	78	0.035
G48031	EVO-20-25-10-E	20	25	10	8	78	0.035
G48032	EVO-20-25-12.5-E	20	25	12.5	8	78	0.035
G48033	EVO-20-25-15-E	20	25	15	8	78	0.035
Fully Covered							
G51181	EVO-FC-18-23-8-E	18	23	8	8	78	0.035
G51182	EVO-FC-18-23-10-E	18	23	10	8	78	0.035
G51183	EVO-FC-18-23-12-E	18	23	12	8	78	0.035
G52225	EVO-FC-20-25-8-E	20	25	8	8	78	0.035
G52227	EVO-FC-20-25-10-E	20	25	10	8	78	0.035
G52226	EVO-FC-20-25-12-E	20	25	12	8	78	0.035

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Support & Distribution for details regarding stock or nonstock status (expect longer lead time if nonstock), pricing, and/or availability.

MR Conditional

Evolution® Esophageal Stent System – Partially Covered / Fully Covered

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

INTENDED USE: This device is used to maintain patency of malignant esophageal strictures and/or to seal tracheoesophageal fistulas.

CONTRAINDICATIONS: Those specific to upper GI endoscopy and any procedure to be performed in conjunction with stent placement. Additional contraindications include, but are not limited to: total esophageal obstruction • strictures that cannot be dilated to a minimum size as outlined in the precautions section • placement requiring positioning of stent within 2 cm of the cricopharynx • surgical resection candidates • hiatal hernia and gastric prolapse in the esophageal area • patients with a perforated esophagus • placement in actively bleeding tumors • benign diseases. Relative contraindications include, but are not limited to: uncooperative patient • coagulopathy • tracheal compression • recent myocardial infarction • cervical arthritis with fixed cervical spine • large tumor mass occupying the mediastinum • nonobstructive tumor • gastric outlet obstruction • necrotic esophageal mucosa • acutely angled stenosis.

WARNINGS: The **stent is not intended to be removed** and is considered a permanent implant. Attempts to remove stent after placement may cause damage to esophageal mucosa. 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. If package is opened or damaged when received, do not use. Visually inspect product with particular attention to kinks, bends and breaks. If an abnormality is detected that would prohibit proper working conditions, do not use. Please notify Cook for return authorization. This stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity. Do not introduce the endoscope into the stent as displacement may occur. After stent placement, alternative methods of treatment such as chemotherapy and radiation should not be administered as this may increase risk of stent migration due to tumor shrinkage, stent erosion, and/or mucosal bleeding. The risk of perforation and erosion into adjacent vascular structures or aortoespohageal and arterioesophageal fistulas may be increased with pre- or post-operative chemotherapy and radiation, longer implantation times, aberrant anatomy, and/or mediastinal contamination or inflammation.

PRECAUTIONS: A complete diagnostic evaluation must be performed prior to use to determine proper stent size. Part numbers with the prefix EVO-FC are Fully Covered. Stent should be placed using fluoroscopic monitoring. Stent should only be placed with the Cook delivery system, which is provided with each stent. **Note:** Prior to advancing system, area to be stented should be dilated to: **For (18mm x 23mm) stent** – a minimum of 9 mm and a maximum of 11 mm. If area is dilated greater than 11 mm, stent may migrate. **For (20mm x 25mm) stent** – a minimum of 10 mm and a maximum of 14 mm. If area is dilated greater than 14 mm, stent may migrate. This device is intended for palliative treatment only. Alternate methods of therapy should be investigated prior to placement. Long-term patency of this device has not been established. Periodic evaluation is advised. This device shortens upon deployment. With proximal strictures near the upper esophageal sphincter, deployment should be performed under fluoroscopic visualization as this may enhance placement accuracy. Do not use this device for any purpose other than stated intended use. Stent cannot be retrieved after the deployment threshold has been passed. The position of the red marker on top of the handle in relation to the point-of-no-return position on the handle label indicates when the threshold has been passed. Use of this device is restricted to a trained healthcare professional.

POTENTIAL ADVERSE EVENTS: Those associated with upper GI endoscopy include, but are not limited to: allergic reaction to contrast or medication • aspiration • cardiac arrhythmia or arrest • fever • hemorrhage • hypotension • infection • perforation • reflux • respiratory depression or arrest • vomiting. Additional adverse events include, but are not limited to: airway compression • allergic reaction to nickel • aortoesophageal fistula and arterioesophageal fistula • chest or retrosternal pain • death (other than due to normal disease progression) • dysphagia • edema • erosion or perforation of stent into adjacent vascular structures • esophageal ulceration and erosion • esophagitis • fistula involving trachea, bronchi or pleural space • food bolus impaction • foreign body sensation or reaction • gas bloat • inadequate stent expansion • intestinal obstruction secondary to migration • mediastinitis or peritonitis • nausea • pain/discomfort • reocclusion • sensitivity to metal components • sepsis • stent misplacement and/or migration • tracheal obstruction • tumor ingrowth or overgrowth • wire entrapment.

See Instructions for Use for full product information.

AB_IFU0061_REV3

Clinical studies

van Boeckel PGA, Repici A, Vleggaar FP, et al. A new metal stent with a controlled-release system for palliation of malignant dysphagia: a prospective, multicenter study. *Gastrointest Endosc.* 2010;71(3):455–460.

van Heel NCM, Haringsma J, Boot H, et al. Comparison of 2 expandable stents for malignant esophageal disease: a randomized controlled trial. *Gastrointest Endosc.* 2012;76(1):52–58.

van den Berg MW, Haijtink S, Fockens P, et al. First data on the Evolution duodenal stent for palliation of malignant gastric outlet obstruction (DUOLUTION study): a prospective multicenter study. *Endoscopy.* 2013;45(3):174–181.

Tringali A, Didden P, Repici A, et al. Endoscopic treatment of malignant gastric and duodenal strictures: a prospective multicenter study. *Gastrointest Endosc.* 2014;79(1):66–75.

Collaborative education and training

We are always seeking to provide stimulating and productive educational opportunities for clinicians to enhance their knowledge of new technologies and learn about exciting new procedural techniques. Cook Medical's Vista programs encourage physician and industry collaboration to improve patient care by sharing best practices. Vista programs foster collaboration among the best and the brightest gastroenterologists in the world, who all share one common goal: improving patient care.

vista.cookmedical.com

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