The Evolution of SEMS

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Introduction

The word "stent" originates from the name of Dr. Charles Stent, an English dentist who developed a "prosthesis" made from natural latex (Gutta-percha, a tropical tree native to Southeast Asia) to fill in the empty space inside the tooth after root canal work (1, 2). The word "stent" was then adopted by many specialties and at present it is used to describe any implant inserted into a structure that has a lumen to maintain its patency (1, 2). Dr. Charters J. Symonds was the first to record the placement of a rigid esophageal tube for palliating malignant esophageal stricture (3). Since then tubes or stents have been used to palliate almost any gastrointestinal (GI) luminal malignancy (4, 5).

Due to their modern shape and design, the use of stents has expanded to treat and palliate many other conditions, including GI leaks, perforations and fistulas (6). Moreover, the indications, delivery methods and techniques to place stents continue to expand (7-10). Self-expanding metal stents (SEMS) are now used to access cavities such as pseudocysts, enter the stomach through the skin, drain retroperitoneal collections percutaneously and even create anastomosis of the gallbladder to the stomach or duodenum (7-10). In this review we will focus on SEMS and its use to treat and palliate endoluminal GI and pancreatobiliary disorders in clinical practice.

Esophagus

SEMS are one of the pillars for palliative therapy for patients with malignant and some forms of esophageal stenosis (4, 5). In addition, SEMS are an essential tool to palliate and treat esophageal leaks, fistulas and perforations (6). SEMS have become increasingly popular as a result of improvement in design and the availability of different models.

When choosing stents as palliative therapy several aspects need to be taken into consideration such as patient condition, tumor location and characteristics, presence of fistula and previous or planned treatments such as chemotherapy or radiation therapy. The presence of leak, fistula or perforation mandates the use of a partially or fully-covered SEMS. The success of esophageal SEMS placement requires precise knowledge of the location and length of the anatomical disruption to be palliated.

Case: A 65-year-old patient presented with dysphagia to solids and liquids as well as massive weight loss. Esophagogastroduodenoscopy (EGD) and CT demonstrated an ulcerating, stenosing adenocarcinoma of the esophagus (*Figures 1A and B*). The stricture was 5 cm long

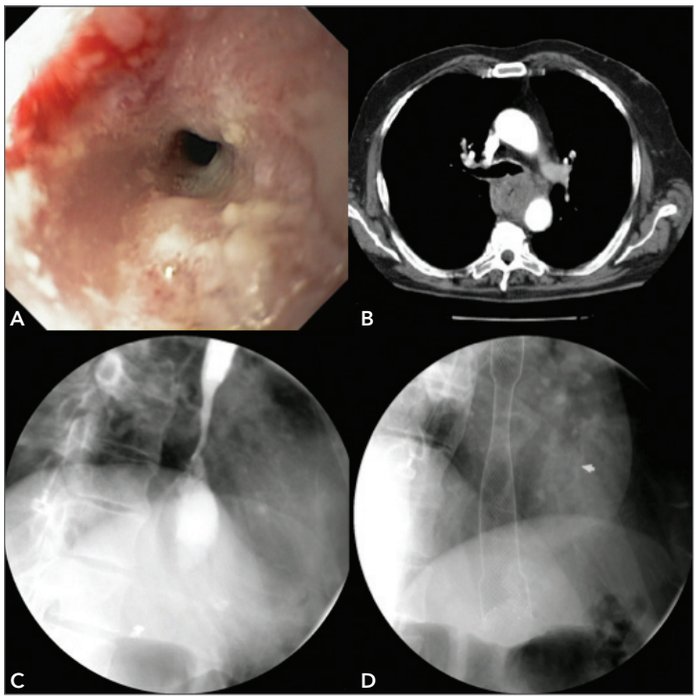

Figure 1

(*Figure 1C*). Therefore, a 120 mm long Evolution stent was inserted to bridge the stenosis (*Figure 1D*). The patient was able to resume oral intake and was also given palliative radiation therapy. On follow-up three months later, the patient's condition has improved and the patient is able to eat.

Stomach

SEMS are now a key palliative option for patients with malignant gastric outlet obstruction due to various types of cancers. Current delivery systems allow placing palliative SEMS through the scope, making a targeted delivery more feasible. However, only scopes with large (i.e. > 3.2 mm) working channels can be used (colonoscope, duodenoscope, therapeutic gastroscope).

Case: A 60-year-old patient with advanced gastric cancer presented with pyloric obstruction. Stent placement at another hospital had failed. The stricture could only be defined by injection of water-soluble contrast using a biliary catheter (*Figure 2A*). A guide wire was advanced into the upper jejunum (*Figure 2B*). The Evolution duodenal stent could be delivered through the working channel of a therapeutic gastroscope (*Figure 2C*).

The braided-to-coiled construction of the Flexor delivery catheter allowed for excellent trackability and maneuverability in this difficult angulation (*Figures 2B and C*). The tight stricture was well bridged (*Figure 2D*). The proximal and distal radiopaque markers of the Evolution SEMS provide excellent visualization for stent placement and localization. The patient has been able to eat since the stent insertion and is stable on follow-up two months later.

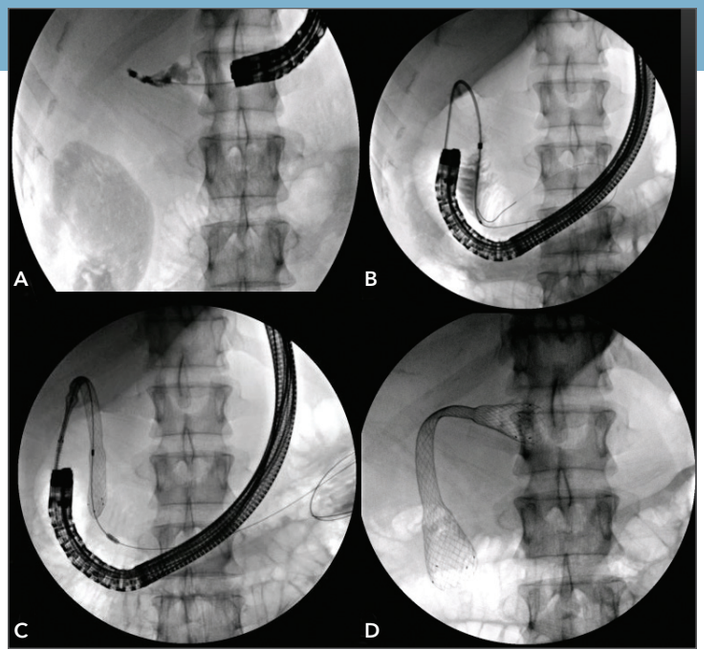

Figure 2

Duodenum and Small Bowel

The advent of deep enteroscopy methods has improved our diagnostic and therapeutic approach to small bowel disorders, including the palliation of malignant and benign stenosis. Whereas placement of SEMS is relatively easy in patients with malignant pyloric obstruction, delivery of a SEMS to the distal duodenum and small bowel may be fraught by difficulties, as the anatomy may be distorted due to massive stomach dilation and the wire may not provide enough tensile force for the stent to be delivered passed the stricture. A useful trick to deliver SEMS to the distal duodenal or small bowel strictures is using the overtube technique (6) (*Figure 3A*).

After localizing, interrogating and determining the length of the stricture using endoscopy and fluoroscopy, a guide wire is advanced through the stricture (*Figure 3B*), the scope is removed and the SEMS is the advanced over the wire and through the overtube, which serves a large "working-channel" (*Figure 3C*). The overtube's shape and strength allow for the SEMS to travel through it smoothly towards and through the stricture. This process is performed under fluoroscopy.

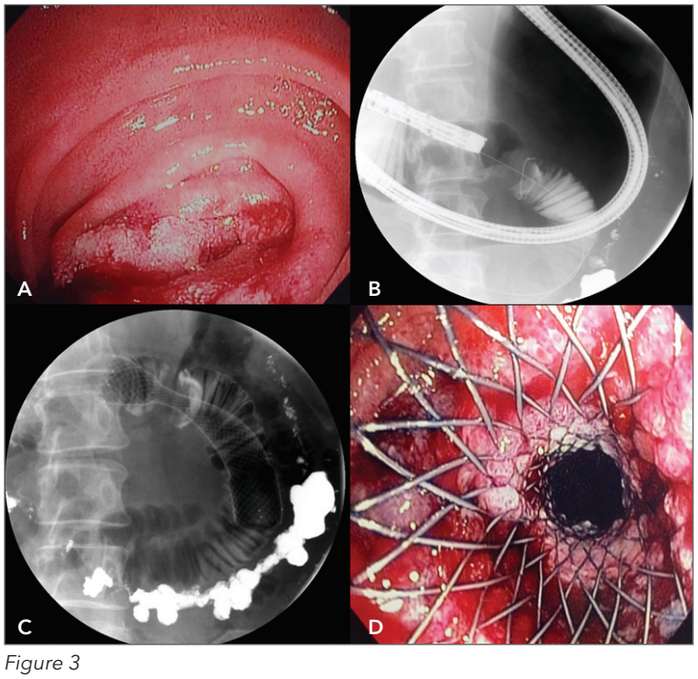

Figure 3

Once the stent is delivered, the scope can be reintroduced and a visual inspection of the proximal stent expansion can be performed (*Figure 3D*).

Colon

A large percentage of patients with colon cancer present with bowel obstruction. In addition, many other malignancies can result in bowel obstruction due to external compression. Thus, placement of a colorectal stent is indicated for preoperative decompression or for palliative purposes.

Case: A 65-year-old patient presented with sigmoid colon obstruction due to metastatic ovarian cancer (*Figure 4A*). Because the patient had almost complete bowel obstruction, a SEMS was placed to decompress the colon and serve as a "bridge to surgery." The Evolution Colonic SEMS was easily inserted using combined

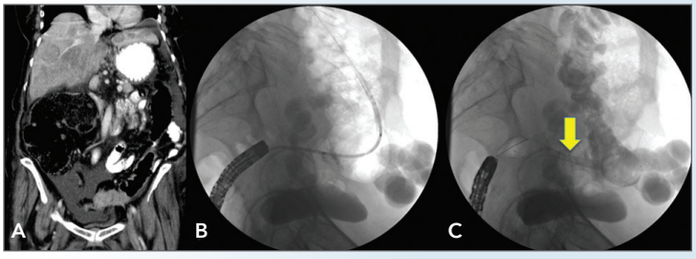

Figure 4

endoscopic-fluoroscopic technique (*Figures 4B and C, yellow arrow*). Once the colon was decompressed and the patient's condition had improved, the patient underwent exploratory laparotomy with resection of the cancerous mass, including the involved colon and SEMS. An end-to-end anastomosis of the colon was possible.

Pancreatobiliary

The two most common causes of malignant bile duct obstruction are pancreatic cancer and cholangiocellular carcinoma. Decompression of bile duct obstruction relieves jaundice, pruritus, improves appetite and reduces fat malabsorption (4). Decompression may be palliative in poor surgical candidates or only temporary in those patients undergoing potential curative resection (4).

The data clearly shows that SEMS are more cost effective for patients who survive longer than three to six months, whereas a single ERCP with placement of a plastic stent may suffice in patients with shorter life expectancy (4). Regardless of the indication, SEMS should be well selected and placed. In my practice, I prefer the Evolution Controlled-Release Stent, as it has excellent radiopaque markers and has an excellent delivery mechanism, making it a secure, safe and efficient stent. The role of SEMS to treat benign biliary conditions has been expanding. When using SEMS to treat benign conditions, a fully covered SEMS should be employed.

Case: An 88-year-old patient was referred to us for palliation of a T4N1MX pancreatic head cancer leading to biliary obstruction (*Figure 5A*). The tight, irregular, tortuous, 2 cm long, distal common bile duct stricture was palliated using an Evolution SEMS (Figure 5B). This SEMS has various radiopaque markers at its end, which facilitate the fluoroscopy placement and visualization (*Figures 5B and C*). The SEMS expanded nicely after deployment, relieving this patient's jaundice within few days (Figure 5D). The smaller diameter Evolution biliary SEMS are also excellent to provide bilateral intrahepatic bile duct drainage (*Figure 6*).

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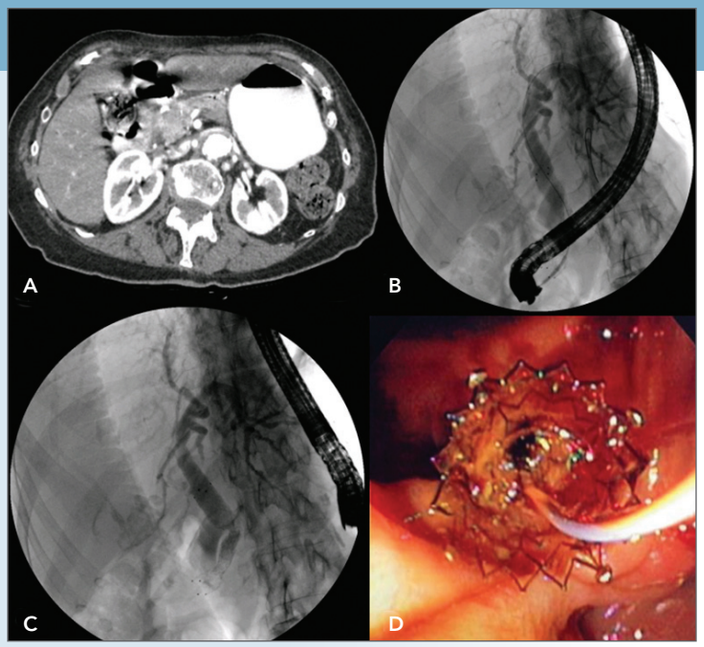

Figure 5

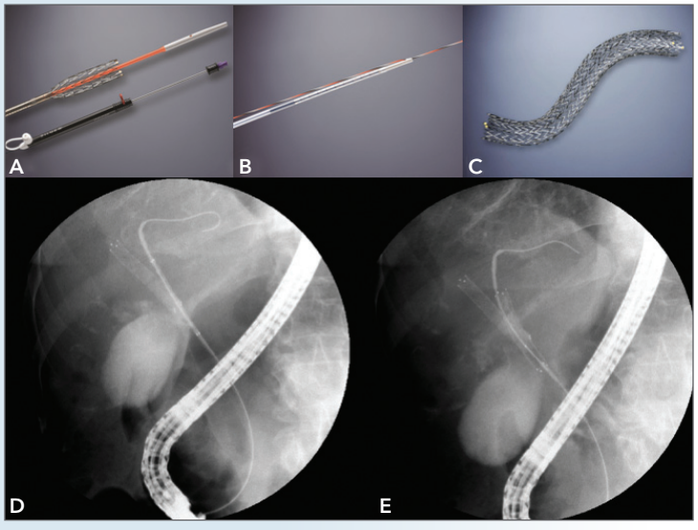

Figure 6

The Evolution of SEMS, continued from page 15

Future Directions

Additional clinical applications of SEMS in the future will likely include palliation and treatment of various other GI disease processes (7-10). The use of fully or partially covered SEMS to drain pancreatic fluid collections is being performed more frequently. This makes sense, as the thick and complex material within the cavity may not exit through small diameter plastic stents. SEMS utilization can create anastomosis within the gallbladder and stomach or duodenum (7). This palliative treatment option offers a great alternative to percutaneous drainage of the gallbladder in poor surgical candidates.

The use of SEMS to create percutaneous access to cavities (e.g. pancreatic necrosis) or luminal organs (e.g. stomach) to provide endoscopic access is expanding (9). Because current enteroscopes do not have a large-diameter channel to deliver SEMS into the bile duct of patients with surgically altered upper GI anatomy, we have developed overtube-assisted methods to place SEMS into the bile duct or perform direct cholangioscopy (8, 10). Therefore, further research into the development of small caliber delivery devices and/or specific overtubes to master difficult anatomical situations is mandatory.

Finally, fully covered SEMS may provide an excellent option to control esophageal variceal hemorrhage. The radial expansile forces of a fully covered SEMS may cause enough compression of the bleeding varices, leading to hemostasis, coagulum and fibrosis formation of the esophageal wall.

In summary, I have presented a brief description of modern uses of SEMS. The key aspects emphasized were the advances in shapes, delivery methods and techniques used to place these stents into various luminal cavities of the body thus permitting to palliate and treat a myriad of GI conditions. ■

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Evolution® Colonic Stent System – Uncovered

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a 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 considered a permanent implant. Attempts to remove or reposition stent after placement may cause damage to surrounding tissue or mucosa. Stent cannot be retrieved after the deployment threshold has been passed. Corresponding marks on outer catheter and delivery handle indicate when threshold has been passed. • This stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity. • 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. • 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. • 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. • Long-term patency of this device has not been established. Periodic evaluation is advised.

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

See instructions for use for full product information.

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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 a 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 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. • Stent cannot be retrieved after the deployment threshold has been passed. Corresponding marks on outer catheter and delivery handle indicate when threshold has been passed.

PRECAUTIONS: A complete diagnostic evaluation must be performed prior to use to determine proper stent size. • 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 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. • 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. • Long-term patency of this device has not been established. Periodic evaluation is advised. • After stent placement, patients should be instructed to chew food well or eat soft or pureed food. • 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.

POTENTIAL COMPLICATIONS: Those associated with upper GI endoscopy include, but are not limited to: perforation, hemorrhage, aspiration, reflux, fever, infection, allergic reaction to medication, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest. • Additional complications include, but are not limited to: stent misplacement and/or migration; tumor ingrowth or overgrowth; esophageal ulceration and erosion; nausea; chest or retrosternal pain; foreign body sensation; food bolus impaction; gasbloat; sensitivity to metal components; fistula involving trachea, bronchi or pleural space; intestinal obstruction secondary to migration; mediastinitis or peritonitis; airway compression; tracheal obstruction.

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Evolution® Duodenal Stent System – Uncovered

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a 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 considered a permanent implant. Attempts to remove or reposition stent after placement may cause damage to surrounding tissue or mucosa. • Stent cannot be retrieved after the deployment threshold has been passed. Corresponding marks on outer catheter and delivery handle indicate when threshold has been passed. • The stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.

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. • 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. • Long-term patency of this device has not been established. Periodic evaluation is advised.

POTENTIAL COMPLICATIONS: Those associated with GI endoscopy include, but are not limited to: perforation, hemorrhage, aspiration, reflux, fever, infection, allergic reaction to medication, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest. • Additional complications include, but are not limited to: intestinal perforation, pain, inadequate expansion, stent misplacement and/or migration, tumor ingrowth or overgrowth, stent occlusion, ulcerations, pressure necrosis, erosion of the luminal mucosa, septicemia, foreign body sensation, bowel impaction, death (other than due to normal disease progression).

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Evolution® Biliary Stent System – Uncovered

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a 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: This stent is **not intended to be removed** and is considered a permanent implant. Attempts to remove the stent after placement may cause damage to the surrounding mucosa. • Stent cannot be recaptured after the deployment threshold has been passed. Corresponding marks on outer catheter and delivery handle indicate when threshold has been passed. • 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 safety and effectiveness of this device for use in the vascular system has not been established. • The stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.

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. • 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. • 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.

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

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