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What’s New

- Endoscopy Channel Launched on YouTube – back cover
Technology Innovation, Yes. But Our Value Goes Far Beyond.

Recently, Forbes magazine named Boston Scientific to its annual list of the “World’s Most Innovative Companies.” In healthcare, innovation is truly meaningful when focused on delivering value to patients and healthcare providers alike. That’s what we strive for every day at Boston Scientific Endoscopy.

We start with a clinical excellence mindset and data discipline. Over the past five years alone, Boston Scientific Endoscopy conducted clinical trials in 21 countries at 110 medical centers with enrollment of nearly 1,400 patients. These studies vigorously tested the performance, safety, and effectiveness of our products in standard practice or in novel procedures, paving the way for expanded indications. We also support physicians globally with data needed for their scientific studies, presentations, and publications. To further advance Endoscopy procedure efficiencies and knowledge of the latest patient treatment options, we became the first corporate sponsor of the American Society for Gastrointestinal Endoscopy’s (ASGE) planned global Institute for Training and Technology, a state-of-the-art version of its current facility.

We further add value through continuing education on healthcare economics. In the U.S., our presentations on coding and reimbursement pack conference rooms with healthcare administrators and lab managers such as at the annual meeting of the Society of Gastroenterology Nurses and Associates. Year round, our reimbursement support team is in demand at tertiary centers as well as in community hospitals. During a recent speaking tour of university-affiliated institutions, GI reimbursement trends and hospital benchmarking data were hot topics. One health program operations specialist in the audience commented, “I can’t believe Boston Scientific has a dedicated team that specializes in reimbursement and coding. I’ll be contacting them directly with questions. I’m planning on pulling all my data to understand our numbers better.”

At this year’s Digestive Disease Week, we introduced the Boston Scientific Endoscopy Channel (BSCEC) on YouTube® featuring physician practices. This alternative learning environment is already having an impact on practices worldwide while saving healthcare organizations and physicians travel time and money. Soon after the channel’s debut, a U.S. biliary stent case presented on BSCEC provided real-time decision support to a gastroenterologist at Lilavati Hospital in Bandra, India. A strong area of interest among top GI societies such as the ASGE and the United European Gastroenterology Federation, e-communications is paving the way for both improved patient care and operational efficiencies.

We hope you’ll find the cases in this publication valuable and look forward to connecting with many of you in person this fall at GI congresses worldwide.

▶ Tune in to the Boston Scientific Endoscopy Channel at www.youtube.com/bostonscientificendo.
▶ Learn more about healthcare economics and reimbursement support in the U.S., call 800-876-9960, extension 4145.
PATIENT HISTORY

This patient is a 71-year-old female who initially sought consultation with a general surgeon for rectal prolapse. Her complaint was complicated by significant constipation and straining with bowel movements. A colonoscopy was performed by the surgeon at an outlying facility. A 4.5 cm polypoid mass with a broad base was described in the rectum approximately 5 cm from the anal verge. Multiple biopsies were obtained, however the mass was left in-situ. The pathology report from the biopsies diagnosed a villous adenoma. On follow up, the surgeon recommended a trans-anal resection of the lesion in the operating room under general anesthesia.

The patient presented to me for a second opinion consultation regarding the management of the mass. A repeat colonoscopy was recommended.

PROCEDURE

A standard colonoscopy was undertaken and the cecum was intubated without difficulty. Along the anterior rectal wall, a 4.5 cm polypoid mass was encountered. The mass had a moderate sized base. There were no surface ulcerations or depressions to suggest dysplastic transformation. A Captivator II Snare was used to grasp the lesion, and it was removed en-bloc with one pass of electrocautery. Using the TWISTER® Rotatable Polyp Retrieval Device the polyp specimen was retrieved and delivered to a formalin jar for pathologic analysis. The polypectomy defect was then re-approximated with clips.

POST PROCEDURE

Pathological diagnosis of the polyp revealed a large villous adenoma without high-grade dysplasia. One month post procedure, the patient was doing well. Her complaints of rectal prolapse, constipation, and straining with bowel movements have resolved. A repeat surveillance colonoscopy is planned in one year.

DISCUSSION

Rectal prolapse occurs when part or all of the wall of the rectum slides out of place, sometimes protruding out of the anus. A variety of risk factors for prolapse exist, including weakening of the pelvic floor muscles with advanced age, chronic constipation and straining. Rectal polyps are an uncommon cause of prolapse, serving as a lead point for rectal mucosal intussusception.

This case demonstrates the importance of skilled endoscopists with cutting edge support equipment in the management of large polyps. The Captivator® II Snare was pivotal in this case. The snare’s large diameter aperture allowed for complete en-bloc resection of the polyp with one pass. The stiff braided metal filament achieved a clean-cut mucosal resection without the need for excess cautery. The TWISTER® Rotatable Polyp Retrieval Device, with its large aperture and capacity, allowed for easy retrieval of a large intact polyp specimen from the rectum with minimal manipulation. Although the post-EMR defect was not actively bleeding, it is my practice to employ the principle of improved wound healing with primary closure over that of secondary intent. The clip of choice is the Resolution® Clip, capable of opening, closing, and repositioning. The deployment apparatus is also less prone to technician error and failed deployments than other clips on the market. A repeat colonoscopy spared the patient the expense and risks of surgical resection, while achieving complete resolution of her complaints.
A 54-year-old woman presented with nausea and abdominal distention. She had no particular past history. Blood laboratory revealed diabetes mellitus; therefore, an abdominal ultrasound was done for screening the pancreas, showing a small mass 15 mm in diameter on the pancreatic body. Upon Endoscopic Ultrasound (EUS) examination, the mass was visualized as hypoechoic with unclear border from the normal pancreatic parenchyma. The mass led to dilation of the pancreatic duct in the tail (Figure 1). To make a diagnosis, EUS FNA was done with the transgastric approach.

A 22 gauge Expect™ Needle was deployed. Even though the strong angulation of the tip of the EUS scope was manipulated, the needle tip punctured the gastric wall and entered the small pancreatic mass easily. After three passes, an adequate amount of material was obtained for diagnosis. Next, we used the 25 gauge Expect Needle to puncture precisely the location of the pancreatic duct obstruction due to the mass. The 25 gauge needle easily and precisely entered into the small mass and target point (Figure 2).

The Expect Needle was very impressive with high operability and visibility of the needle tip. In particular, the 22 gauge Expect Needle handled as if it were a 25 gauge needle device. Therefore, a 22 gauge needle may be used for a wide variety of lesions.

A 75-year-old male presented with two months of jaundice, weight loss, and intermittent fevers. A CT scan (Figure 1) showed multiple peri-pancreatic and celiac nodes, with a large heterogenous pancreatic head mass measuring to 7 x 8 cm. The patient was not a candidate for surgery; an Endoscopic Ultrasound-Fine Aspiration Needle (EUS-FNA) was planned, to be followed by ERCP and biliary metal stenting for palliation.

EUS showed a large cystic solid mass arising from the head of the pancreas with involvement of the portal vein and surrounding vascular structures, and multiple large peripancreatic, perihepatic and celiac nodes. As the patient’s INR was 1.6, I targeted the lymph nodes using a 22 gauge Expect Needle. Adequate tissue was acquired after three passes. Specimens were sent for histopathology and cytology analysis. An ERCP was then performed and cholangiogram (Figure 2) revealed a long distal stricture with proximal bile duct dilation. A 10 mm x 6 cm WallFlex® Biliary RX Metal Stent was placed. The FNA showed abnormal lymphocyte aggregates, which on further staining with B cell marker (Figures 3 and 4), was strongly supportive of B-cell lymphoma.

This case further supports the algorithm for tissue sampling in unresectable pancreatic masses as the patient can now receive the appropriate palliative chemotherapy. The Expect Needle showed good visibility by ultrasound at all times, and it was easy to remove and replace the stylet on all three passes. It was also encouraging that using a 22 gauge needle, adequate tissue was obtained, making the diagnosis of lymphoma by using the appropriate stains.
**A Challenging Diagnosis of Duodenal GIST by Transgastric EUS-FNA Confirmed After Surgical Resection**

**INTRODUCTION**
A 61-year-old female patient with a history of kidney stones underwent an abdominal ultrasound, showing a new-onset solid mass near the body of the pancreas. An abdominal CT scan showed a solid mass of about 3 cm near the aorta, just above the fourth portion of the duodenum, while the pancreatic parenchyma was deemed normal.

**PROCEDURE**
Endoscopic Ultrasound (EUS) was performed, which confirmed the mass. It was not possible to find the lesion with EUS scanning from the duodenum, but the mass was clearly visible from the stomach, roughly oval hypoechoic, with high vascularity, most probably originating from the duodenal wall (Figure 1). This EUS finding led to the diagnostic hypothesis of a Gastrointestinal Stromal Tumor (GIST) of the fourth portion of the duodenum. Fine Needle Aspiration (FNA) was performed with the 22 gauge and 25 gauge Expect™ Needles (Figure 2), with 3 and 2 passes respectively in the lesion, through the stomach wall. Cytopathological examination showed spindle cells, with positive reactions with vimentine and anti-CD117 antibodies (Figure 3), supporting the diagnosis of GIST. FNA samples were of good cellularity so that we could also have information about the cellular proliferation index of the lesion: immunostaining with Ki67 antibodies was <1%. Such diagnosis was eventually confirmed after surgical resection of the lesion, with total agreement between FNA cytopathology and histology on the surgical specimen (Figure 4).

**CONCLUSION**
Trans-gastric FNA of abdominal lesions can be challenging, due to the extreme mobility of the gastric wall: Sometimes it can be hard to carry out wide needle movements within the lesion in order to obtain samples with good cellularity (Figure 5). In this case we believe that the sharpness of the Expect Needle was helpful in easily penetrating the gastric wall and moving within the hard structure of the stromal tumor. The excellent agreement between cytology on FNA samples and histology on surgical specimen suggests that samples obtained by the Expect Needle have optimal cellularity and allow us to obtain information of prognostic value before surgery.

**EUS FNA of a Mediastinal Lymph Node: 19 Gauge Expect Needle Procures a Larger Sample to Diagnose Lymphoma**

An 84-year-old male was referred for an evaluation for possible lymphoma. A CT scan demonstrated mediastinal, retroperitoneal and mesenteric lymphadenopathy. Endoscopic Ultrasound (EUS) revealed a malignant-appearing sub-carinal lymph node measuring 2.0 x 1.5 cm, in addition to several abnormal lymph nodes in the celiac, peripancreatic and porta hepatis region. A 19 gauge Expect Needle was used to make one pass (Figure 1) into the sub-carinal lymph node to get a larger sample after two prior passes with a 22 gauge needle. The sample was also sent for flow cytometry in addition to cytology review. Cytology was consistent with a non small-cell carcinoma and flow cytometry identified a monoclonal B-cell population consistent with involvement by B-cell non-Hodgkin’s lymphoma, favoring chronic lymphocytic leukemia. The patient tolerated the procedure well without any complications. The 19 gauge Expect Needle entered the lesion easily and its tip and tract was well visualized during the pass.
Tubercular Biliary Stricture Visualized with the SpyGlass System

CASE PRESENTED BY:
Randhir Sud, MD
Chairman
Institute of Digestive & Hepatobiliary Sciences
Medanta, The Medicity
Gurgaon, New Delhi, INDIA

PATIENT HISTORY
A 35-year-old woman presented with central abdominal pain radiating to the back, and weight loss occurring for one month. She developed cholestatic jaundice two weeks prior to presentation. Lab parameter suggested extra hepatic biliary obstruction.

A contrast-enhanced computed tomography of the abdomen revealed a mass in relation to the pancreatic body with a common bile duct obstruction. An endoscopic ultrasound (EUS) examination showed a heteroechoic mass lesion in the retropancreatic area — pushing the pancreatic parenchyma up and causing narrowing of the common bile duct (CBD) in the middle part, with upstream dilatation. Fine needle aspiration (FNA) from the mass was done and cytopathology confirmed a granulomatous lesion that stained positive for an AFB smear. In view of obstructive jaundice, the plan was to proceed for CBD stenting and evaluate the stricture with the SpyGlass® Direct Visualization System.

PROCEDURE
Wire-guided CBD cannulation was achieved, revealing a smooth stricture in the distal third of the CBD. A cholangioscopy using the SpyGlass System was performed after a papillotomy, which revealed an extrinsic bulge (Figure 1) with inflamed-appearing mucosa, causing luminal stenosis in the mid CBD for 1.5 cm. The proximal CBD, common hepatic duct (CHD) and intrahepatic bile duct were normal. A straight 10 French, 10 cm plastic stent was passed across the stricture to alleviate jaundice (Figure 2). In view of AFB +ve granulomas on EUS FNA, the patient was put on anti-tuberculosis treatment simultaneously. A diagnosis of tubercular peripancreatic lymphadenitis with biliary stricture causing jaundice was made.

CONCLUSION
The SpyGlass System is a useful modality for imaging the biliary tree, and to know the nature of an obstruction. The SpyGlass System has definitely added value to my practice.

IN MEMORIAM

PETER DUNSMORE STEVENS, MD
Director of Endoscopy, New York Presbyterian Hospital
Associate Professor of Clinical Medicine, Columbia University, New York, New York

November 1, 1961 – August 13, 2011

For years, many of us at Boston Scientific had the privilege to know and work with Dr. Peter D. Stevens, a gifted physician with a passion for patient care. Dr. Stevens demonstrated a deep commitment to clinical research and advancing the field of interventional endoscopy. He was recognized and respected throughout the worldwide GI community for his vision, leadership and dedication as a teacher and mentor who never lost his own love of learning.

Dr. Stevens was a leader in developing minimally invasive techniques for treating pancreatic and biliary disease including his pioneering work with single operator cholangioscopy to gain its acceptance as a standard of care. Dr. Stevens touched the lives of so many and we mourn the loss of this beloved physician and extraordinary man.
PATIENT HISTORY

A 58-year-old man was waiting for “urgent” orthotopic liver transplantation (OLT), due to alcoholic liver cirrhosis (MELD: 26) complicated by esophageal varices (F2) and splenomegaly. Because of increasing jaundice, the patient underwent blood tests showing high levels of cholestatic liver enzymes (AST: 149 U/L; ALT: 90 U/L; total bilirubin: 12.6 mg/dl; direct bilirubin: 4.8 mg/dl), Ca 19-9: 230 U/L and anemia (Hb: 8.1 gr/dl). Abdominal ultrasound (US) diagnosed a mild left intra-hepatic biliary duct dilatation with normal common bile duct (CBD) and incomplete portal vein thrombosis; a CT scan confirmed the US diagnosis and showed the absence of focal lesions in the liver parenchyma. Cholangio-magnetic resonance imaging (MRI) underlined the dilatation of left intrahepatic ducts without stenosis of the CBD; a mild stenosis of the right intrahepatic biliary duct at hilum bifurcation with no contrast medium signal in the homolateral biliary tract 2 cm above the stenosis that was suspected for malignancy (Figure 1).

PROCEDURE

The patient’s surgeons strongly required biopsy specimens by biliary brushing from the stenotic tract during ERCP.

Contrast medium selective cholangiography obtained during ERCP confirmed the dilatation of left intra-hepatic ducts without lesions into the extrahepatic ducts lumen and showed a right intrahepatic biliary duct substenosis at the hilar bifurcation with stenosis estimated in the left biliary tract, 2 cm above the hilum (Figure 2).

On suspicion of malignancy at previous ERCP, and because of anamnestic portal hypertension signs secondary to incomplete portal thrombosis, we performed peroral cholangioscopy with the SpyGlass® System to directly visualize the lumen of the biliary ducts. The SpyGlass System revealed four choledocal veins-ectasia/varices with red mucosal spots localized at medium part of CBD (not known at previous ERCP) and a substenosis of the right intra-hepatic duct at hilar bifurcation without wall lesions.

Under cholangioscopic view, a Jagwire® Guidewire was inserted into the right intra-hepatic duct; the direct visualization of the lumen with the SpyGlass System was achieved. Two cm above the hepatic hilum showed the stenotic tract secondary to biliary varix that did not allow the guidewire to go through.

CONCLUSION

The SpyGlass System plays a fundamental role in the differential diagnosis between benign and malignant biliary stenosis not performed by either contrast medium cholangiography at previous ERCP and/or others nor invasive radiological imaging techniques. The SpyGlass System provided direct visualization of the biliary lumen, allowed the correct diagnosis of biliary disease, avoided the invasive and dangerous endoscopic procedures (biliary brushing) with high risk of adverse events and it heavily changed the therapeutic approach and clinical outcome of the patient.

Two days later the patient successfully underwent an OLT; no OLT related complications were found at six months clinical follow up.

COMMENT

Biliary ducts varices are a rare complication secondary to portal hypertension and it is very difficult to distinguish them from other biliary tract diseases. Common non-invasive imaging techniques (US, CT, MRI) and endoscopic ultrasonography (EUS) are the first diagnostic tools to study the portal flow system. The SpyGlass Direct Visualization System is the most accurate tool to diagnose biliary complications secondary to portal hypertension.
PATIENT HISTORY

A 43-year-old male with acquired immune deficiency syndrome (AIDS) with biopsy-proven invasive squamous cell carcinoma of the distal esophagus was admitted for recurrent aspiration pneumonia. A CT scan of the chest demonstrated that the distal esophageal mass had eroded into the lower lobe of the right lung. Barium swallow confirmed the presence of a large esophagobronchial fistula (Figure 1).

PROCEDURE

The procedure was performed using a standard upper endoscope and revealed a large, circumferential, partially obstructing, fungating and ulcerating mass in the lower esophagus extending to the level of the gastric cardia measuring 16 cm in length. A large oval opening measuring approximately 3 cm was noted in the mid esophagus (Figure 2) consistent with the opening of an esophagobronchial fistula. A 0.035 inch Jagwire® Guidewire was placed into the stomach and a 23 mm by 150 mm WallFlex Esophageal Partially Covered Stent was placed under endoscopic visualization ensuring that the covered portion of the stent clearly overlapped the area of fistulization (Figure 3).

POST PROCEDURE

The patient did well following the procedure. A barium swallow was repeated on the following day, which demonstrated no extravasation of contrast through the fistula (Figure 4). The patient tolerated a soft diet and was discharged home with palliative care.

DISCUSSION

Malignant esophagorespiratory fistulae develop due to infiltration of esophageal carcinoma into the respiratory tract (trachea or bronchi); a condition associated with high morbidity and mortality rates. Case series using self-expanding metal stents (SEMS) for esophagorespiratory fistulae have reported occlusion rates of 70-100% and complication rates of 10-30%. A covered or partially covered SEMS is used to achieve occlusion of the fistula; the latter allows proximal and distal ends to embed into the tumor while the covered portion allows occlusion of the fistula. Endoscopic placement of SEMS is now the treatment of choice for definitive palliative treatment of esophagorespiratory fistulae caused by advanced esophageal cancer.

REFERENCES:
**Treatment of Malignant Stenoses with the WallFlex Biliary RX Fully Covered Stent**

**PATIENT HISTORY**

A 42-year-old male was admitted for recurrent right upper quadrant abdominal pain for more than twenty years. Cholecystectomy was performed ten years ago, diagnosed as “gallstones” at a local hospital. The symptoms were recurrent after his cholecystectomy. He was subsequently diagnosed with a hilar and common bile duct (CBD) stenosis (Figure 1) three years ago. He underwent plastic stent exchange during ERCP eight times; however, the symptoms did not palliate until a covered metal stent was placed during ERCP. There was no symptom recurrence after a six-month follow up.

**PROCEDURE**

The first ERCP showed the bottom stenosis with moderate expansion of the CBD, hilar bile duct stenosis with intrahepatic biliary dilatation; plastic stents were then placed into the left and right hepatic ducts. Six ERCPs were performed for stent replacement every 4-6 months, but the symptoms continued to recur until a 10 mm x 6 mm WallFlex® Biliary RX Fully Covered Stent (Figure 2) was placed. The stricture was significantly improved (Figure 3), the stent was removed using the integrated retrieval loop and another 10 mm x 6 mm WallFlex Biliary RX Fully Covered Stent was placed.

**OUTCOME**

ERCP showed stenosis of inferior CBD with moderate expansion. A WallFlex Biliary RX Fully Covered Stent was placed in the bile duct stricture during an ERCP. The stricture was significantly improved after being treated with a WallFlex Biliary RX Fully Covered Stent.

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**Note:** Use of the WallFlex Biliary RX Fully Covered Stent for the treatment of benign strictures or stenoses have not been cleared for use in the United States.
Clinical Research Updates

**WALLFLEX STUDY COMPLETES ENROLLMENT**

Enrollment was completed in a clinical trial evaluating the WallFlex® Biliary RX Fully Covered Stent for the treatment of benign bile duct strictures. One hundred and eighty-seven (187) patients were enrolled at 13 centers including 7 in Europe, 3 in Canada, and 1 each in India, Australia and Chile. The trial will evaluate removability of these stents following temporary indwell (5-11 months) as well as the effectiveness of temporary stenting for long-term stricture resolution assessed to five years after stent removal. The trial is sponsored by Boston Scientific and guided by Professor Guido Costamagna (Rome, Italy) and Professor Jacques Deviere (Brussels, Belgium).

**PEER-REVIEWED MEDICAL JOURNALS TO PUBLISH STUDY RESULTS**

Final results from four post-market clinical registries sponsored by Boston Scientific were accepted for publication and will be in print shortly.

Soren Meisner et al. will publish in *Gastrointestinal Endoscopy* the combined results of two registries documenting performance of the WallFlex Colonic Stent conducted at 39 centers in 13 countries. The article entitled, “Self-expanding metallic stent for relieving malignant colorectal obstruction: Short term safety and efficacy within 30 days of stent procedure in 447 patients” represents the largest multi-center prospective study to date of colonic self expanding metal stents (SEMS) placement in palliative care or bridge-to-surgery settings. The authors conclude that colonic (SEMS) are safe and highly effective for the treatment of malignant colorectal obstruction, allowing most curable patients to have a one-step resection without stoma and providing most incurable patients minimally invasive palliation instead of surgery. They also conclude that risk of complications, including perforation, was low.

Javier Jimenez-Perez et al. will publish in the *American Journal of Gastroenterology* the complete follow up of 182 patients treated with the WallFlex Colonic Stent as a bridge-to-surgery in the same two registries. The authors of the article entitled, “Colonic stenting as a bridge-to-surgery in malignant large bowel obstruction — a report from two large multi-national registries” conclude that colonic SEMS provide an effective bridge-to-surgery treatment with an acceptable complication rate in patients with acute malignant colonic obstruction, restoring luminal patency and allowing elective surgery with primary anastomosis in most patients.

Guido Costamagna et al. will publish in *Digestive and Liver Disease* the complete results of a WallFlex Duodenal Stent registry conducted at 12 centers in 10 countries. The article entitled “Treatment of malignant gastroduodenal obstruction with a Nitinol self-expanding metal stent: An international prospective multicentre registry” reports on 202 patients. The authors conclude that safety and effectiveness of duodenal stenting for palliation of malignant gastroduodenal obstruction was confirmed in the largest international prospective series to date.

Yang Chen† et al. will publish in *Gastrointestinal Endoscopy* the complete results from a 15-center, 297 patient study, the largest to date prospective series on peroral cholangioscopy. The article is entitled “Single-operator cholangioscopy in patients requiring evaluation of bile duct disease or therapy of biliary stones”. The authors conclude that evaluation of bile duct disease and biliary stone therapy can be safely performed with a high success rate by using the single-operator cholangioscopy (SpyGlass®) System.

“Over the past five years, we have invested millions of dollars in clinical research conducting trials in more than 110 centers in 21 countries, and enrolling nearly 1,400 patients,” said Joyce Peetermans, PhD, Director of Clinical Programs, Boston Scientific. “We are honored to partner with worldwide experts in gastrointestinal endoscopy to design and conduct trials with high ethical standards, inclusive of complete transparency of results and a commitment to publishing all study findings. We focus on research that has the potential to expand treatment options and positively impact patient care, with integrity every step of the way.”

† deceased
WallFlex® Biliary RX Fully Covered Stent Approved in Canada for Use in Treating Benign Biliary Strictures

Health Canada has approved the WallFlex® Biliary RX Fully Covered Stent for the treatment of benign biliary strictures, which supplements its current indication for management of malignant biliary strictures.

“Benign biliary strictures related to an injury, anastomosis or chronic pancreatitis may be challenging to resolve,” said André Roy, M.D., FRCSC, Director of the Liver Transplantation Program at Hôpital Saint-Luc du Centre Hospitalier de l’Université de Montréal. “The WallFlex Stent incorporates the latest innovations in self-expanding metal stent technology and may provide significant benefits as a less-invasive alternative to surgery in these patients.”

“Current management of benign biliary strictures typically includes repeated dilation with balloons and plastic stents. However, this new approval allows me to offer a one-step alternative, which may help to reduce the number of procedures my patients must undergo, while providing the best possible care and containing costs,” said Paul Kortan, M.D., Gastroenterologist at St. Michaels Hospital in Toronto.

The WallFlex Biliary RX Fully Covered Stent is constructed of braided, Platino™ (platinum-cored Nitinol) wire and features three key attributes: radial force to help maintain duct patency and resist migration, flexibility to aid in conforming to tortuous anatures and full-length radiopacity to enhance stent visibility under fluoroscopy. The WallFlex Biliary RX family of stents is available in fully covered, partially covered and uncovered versions. The covered stents have a silicone polymer Permalume® coating designed to reduce the potential for tumor/tissue ingrowth, and an integrated retrieval loop for removing or repositioning the stent in the event of incorrect placement during the initial procedure or for removal up to 12 months following initial placement in benign strictures.

The complete line of WallFlex Biliary RX Stents has previously received Health Canada, CE Mark and FDA clearance for the palliative treatment of malignant biliary strictures. The WallFlex Stent is the most frequently implanted biliary metal stent in the U.S., Canada and Europe.

In the U.S., the WallFlex Biliary RX Fully Covered Stent is not approved for the treatment of benign biliary strictures. The safety and effectiveness of the WallFlex Biliary RX Stent System for use in the vascular system have not been established.

CRE Wireguided Balloon Dilatation Catheter

The CRE™ Wireguided Balloon Dilatation Catheter has been CE Marked for endoscopic dilatation of strictures of the biliary tree and the Sphincter of Oddi following sphincterotomy.

The CRE Wireguided Balloon Dilator is constructed of Pebax® material and uses a Three-in-One Technology, designed for successive, gradual dilation of strictures, helping to eliminate the need for multiple balloons to employ multi-size dilation therapy. The rounded shoulder design is engineered to help facilitate Balloon Endoscopy and to provide visualization during dilation. The preloaded guidewire is designed to facilitate placement within tight strictures and tortuous anatomy.

The CRE Wireguided Dilatation Balloon is pending 510(k) clearance in the United States for “endoscopic dilatation of strictures of the biliary tree and the Sphincter of Oddi following Sphincterotomy;” it is not available for sale in the United States for this indication.
Boston Scientific Endoscopy Launches YouTube Channel

Educational Videos Now Available to Physicians Worldwide

The Boston Scientific Endoscopy Channel on YouTube®, launched during Digestive Disease Week (Chicago, Ill.) earlier this year, has received over 16,000 visitors from 101 countries. With more than 70 videos and a steady stream of new arrivals, the site features select physician presentations, animations, and case studies on ERCP, endoscopic ultrasound-fine needle aspiration, cholangioscopy/pancreatotmoscopy, stricture management, tissue acquisition, and more using Boston Scientific technologies to treat a variety of digestive and pulmonary conditions.

A global platform for peer-to-peer physician best practices, this web-based program is intended to support learning on demand. “Boston Scientific has been a long-standing industry leader in providing hands-on clinical training and education programs for physicians and hospital staff,” said Art Butcher, Global Vice President of Marketing, Boston Scientific Endoscopy. “The Endoscopy Channel offers an efficient and effective complement for physicians and nurses to keep current on emerging practices from around the world anytime, anywhere.”

Visit the Boston Scientific Endoscopy Channel by using your Smartphone to scan this code or go to www.YouTube.com/BostonScientificEndo.

Warning: The safety and effectiveness of biliary metal stents for use in the vascular system has not been established.

The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

ACCESS Magazine was produced in cooperation with several physicians. The procedures discussed in this document are those of the physicians and do not necessarily reflect the opinion, policies or recommendations of Boston Scientific Corporation or any of its employees.

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