

access

ENHANCING PATIENT OUTCOMES. DELIVERING TOTAL VALUE.™

The Acquire™ EUS Fine Needle Biopsy Device

Bringing Precision and
Control to Histology

Working with caregivers
to bring screenings to remote
regions of Brazil





Art Butcher

A Message From Art Butcher

Many of you know Dave Pierce and his passion for the field of endoscopy. Over the past 15 years, his vision and drive have resulted in the development of innovative technologies and services that are enabling less invasive treatment alternatives and allowing physicians to focus on what matters most, their patients. In May, Dave was named president of Boston Scientific's urology and pelvic health business, a new role that recognizes his leadership and the success of the endoscopy business. We wish him all the best and thank him for his remarkable service to the field of endoscopy.

I now have the honor and challenge of leading this organization. My most recent role as general manager of the endoscopy business in Japan was an amazing opportunity to see our business in a new light. As president of the endoscopy business, I am committed to incorporating a global perspective in everything we do. Whether it's advocating for the practice of endoscopy, developing new technologies or improving access to care, we are committed to "advancing science for life."

In June, Boston Scientific received an expanded indication in the U.S. for its WallFlex™ Biliary RX Fully Covered Stent System RMV for indwell up to 12 months in the treatment of benign biliary strictures caused by chronic pancreatitis. The expanded indication could change a physician's protocol for placing plastic stents, meaning fewer procedures for a patient and helping reduce a hospital's overall costs for treating the patient (p. 4). Indications like this are critical to the practice of endoscopy and to improving patient care.

It's why we innovate. The new Acquire™ Endoscopic Ultrasound Fine Needle Biopsy Device is designed to obtain larger tissue samples, a critical first step in diagnosing and staging malignancies. Obtaining an inadequate sample may mean a repeat procedure, which is certainly difficult for the patient and will also increase overall treatment costs (p. 6).

Innovating is also about working with our customers in new ways and being able to utilize feedback quickly to develop new products. Read about our team that did just that to enhance our biliary and esophageal metal stents (p. 9). At a recent physician forum hosted by our team in Galway, we heard from some of Ireland's top EUS physicians on our Expect Needle and impact of the AXIOS™ Stent System (p. 3).

The SpyGlass™ DS System continues to receive favorable reviews. At this year's annual Digestive Disease Week™ Conference, several studies highlighted compelling data on a physician's ability to alter patient management and potentially enable earlier treatment using the SpyGlass DS System (p. 7).

Innovation isn't restricted to our devices. Through web-based platforms and mobile broadcasting, we are enabling physician-led education and training, and piloting telemedicine initiatives. By expanding our global connectivity, we will be able to help physicians bring care to remote regions throughout the world (p. 10). In addition, we are donating \$1M to the American Society for Gastrointestinal Endoscopy in support of its campaign to bring high-quality educational content to physicians regardless of where they practice. Earlier this year in India, we opened Boston Scientific's ninth Institute for Advancing Science that will enhance our ability to support global customers.

Geography has its challenges and for countries such as Brazil that are working to address health issues for large populations, getting to patients in remote areas is a significant undertaking. Since 2014, working in conjunction with the Hospital Sírio-Libanês, Boston Scientific has helped support a population health initiative to bring GI screenings to people located in villages along the Amazon. To date, over 1,200 patients have been screened (p. 2).

In 2015, we managed 13 active clinical trials with over 2,600 patients enrolled at 170 hospitals across 21 countries, building evidence for the benefits of our technologies. Through clinical studies, developing new products and bringing physician education and care to remote regions of the world, we are working to advance the practice of endoscopy and improve patient care, worldwide.

Art Butcher

Senior Vice President, Boston Scientific
President, Endoscopy Division

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Foundation Pancreatic
Cancer Research
Walk/Run Events**

- New England (Boston),
Mass, October 1
- Long Island, New York,
October 9
- Denver, Colorado,
November 6

► **Cincinnati First Ladies
For Health**

- Boston Scientific is
supporting health screenings
at over 20 locations

► **Sign up for news, product
updates and more at
[www.bostonscientific.com/
endo-access-subscribe](http://www.bostonscientific.com/endo-access-subscribe)**

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Screening for GI Cancer in the Amazon:

Bringing Care to Underserved Populations

Since the end of 2014, a gastrointestinal (GI) cancer screening program has been taking place in Belterra, a city founded by Henry Ford in the early 1900s in Pará state in the middle of the Brazilian rain forest. Belterra is a poor city where some of its American characteristics remain.



GASTROENTEROLOGY PROCEDURES ARE BEING CONDUCTED AT A SMALL HOSPITAL with little to no equipment and on a boat (Abaré) where a two-room endoscopic unit was created in order to attend to the remote population that lives along the beautiful and large Tapajós River. The total city population is approximately 18,000. Per international guidelines for upper and lower GI endoscopy, the goal is to screen those between the ages of 50 and 70, which equates to 2,000 people in this region.

The project is conducted by Hospital Sírío-Libanês (Sao Paulo, Brazil) with support from Boston Scientific to deliver a mass-population prevention initiative. Such pilot projects are being evaluated to determine effective methods for screenings of large populations in the region. Screenings are held every two months and conducted over a four-day period. Boston Scientific funded the project, providing equipment and devices for the procedures in addition to covering costs for travel, lodging, food and supplies.

To date, **11 screening events** have taken place with an average of **110 patients screened** in each round by a team consisting of four physicians, two nurses, one nurse technician and two medical students. Additional support from five local nurses, five nurse assistants and 50 local community health agents is provided on site.

Screenings have resulted in several polyps being found and endoscopically resected when possible, four patients diagnosed with colorectal cancer and four with gastric cancer, one of whom was at an early stage. All patients found with cancer, including the one at an early stage, have been referred to surgery.



Dr. Angelo Ferrari conducts a colonoscopy at one of the screening locations.



11 SCREENING EVENTS



110 PEOPLE, ON AVERAGE,
AT EACH EVENT



OVER 1,200 PEOPLE SCREENED
TO DATE

AN ABSTRACT RELATED TO THIS SCREENING PROGRAM WAS PRESENTED AT THE 2016 ANNUAL DIGESTIVE DISEASE WEEK™ CONFERENCE.

TITLE: Screening for Colorectal Cancer: Results of a Pilot Population-Based Screening Program in the Brazilian Amazon Region

AUTHORS: Ferrari, Angelo P.; Martins, Fernanda P.; Abrantes, Eduardo F.; Fresca, Aldenir; Toscano, Cristiana M.; Averbach, Marcelo



A banner is displayed at one of the village hospitals to promote the screening event.

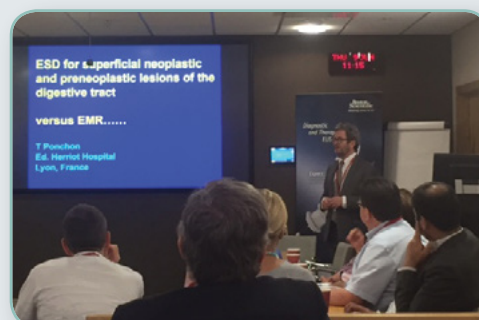
BOSTON SCIENTIFIC HOSTS PHYSICIAN FORUM IN GALWAY

Advancements in biliary and endoscopic ultrasound (EUS) treatment options

were the topics of discussion at a gathering of more than 18 of Ireland's top EUS physicians, held June 9 at Boston Scientific's facility in Galway, Ireland. Two of Europe's key opinion-leader physicians, Professor Thierry Ponchon of Edouard Herriot Hospital in Lyon, France, and Professor Laurent Palazzo of the Clinique Du Trocadero in Paris, France, presented and facilitated discussions. Professor Palazzo presented on managing superficial digestive neoplasms and talked about his clinical experience using the Expect™ Needle and its benefits over a leading competitor needle. The Expect Needle was recently selected for clinical trials in Portiuncula Hospital in Galway. Members of the Irish Society of Gastroenterology also participated in the meeting.

In addition, prior to the meeting, physicians were given a tour of the company's AXIOS™ Stent System manufacturing line. The feedback on the stent has been extremely positive. Dr. Barbara Ryan spoke on the experiences at the Adelaide and Meath Hospitals in relation to the AXIOS Stent System as well as the paper currently being published. Dr. Ryan was the first to place an AXIOS Stent in Ireland.

Of particular note was one physician's statement that the new stent technology was a true "game changer."



Professor Thierry Ponchon of Edouard Herriot Hospital in Lyon, France presents at the physician forum.

WallFlex Biliary RX Fully Covered Stent System RMV

The current standard of care used by about 80 percent of physicians in the United States when treating benign biliary strictures due to chronic pancreatitis is to place multiple plastic stents. These plastic stents often require replacement an average of five times per year due to clogging¹. Multiple stent procedures not only impact patients, who may undergo multiple endoscopic retrograde cholangiopancreatography (ERCP) procedures in a year, but may also impact time and care workflows for physicians.

The treatment of benign biliary strictures secondary to chronic pancreatitis, however, is evolving in the United States. Boston Scientific was the first and is currently the only company to receive U.S. FDA clearance for an indication of a metal stent, the WallFlex™ Biliary RX Fully Covered Stent System RMV, to treat benign biliary strictures due to chronic pancreatitis. This is a significant clinical milestone and demonstrates Boston Scientific's commitment to advancing endoscopic GI therapies.

Ali A. Siddiqui, M.D., professor at Thomas Jefferson University in Philadelphia, has changed his protocol for determining which stent to place. *“In the past, I would place plastic stents. However, now for any patient who has a stricture of the bile duct from chronic pancreatitis, I do not bother using plastic stents. I opt for the WallFlex Biliary RX Fully Covered Metal Stent.”*

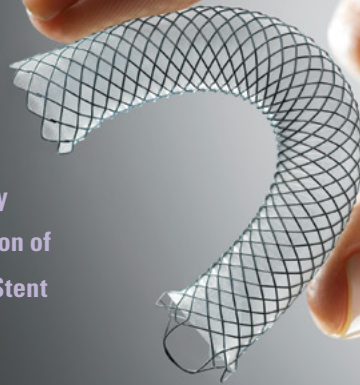
How does the metal stent compare to plastic stents when resolving benign strictures due to chronic pancreatitis? Designed with an integrated retrieval loop, the WallFlex Biliary RX Fully Covered Stent System RMV, with its larger diameter, may be left in place for up to 12 months before it needs to be removed, unlike most plastic stents that may require replacement every few months due to clogging. In fact, this fully covered self-expanding metal stent has the radial dilation equivalent to that of at least three side-by-side plastic stents². Therefore, placing the WallFlex Biliary RX Fully Covered Stent from Boston Scientific may reduce the number of reinterventions, potentially contributing to quality of life improvements for patients.

This reduction in repeat procedures each year may also yield economic benefits. In fact, initial placement of a fully covered self-expanding metal stent for benign biliary strictures secondary to chronic pancreatitis may help to avoid the cost of multiple ERCP with stent placement procedures.

“If you look at the overall economic value, it's clearly been shown that the fully covered stents are most cost effective because they can potentially save patients from having recurrent endoscopic procedures. It also may help to improve the patient's overall quality of life as they undergo treatment for resolving strictures,” said **Prof. Siddiqui**.

In the United States, the WallFlex Biliary RX Fully Covered Stent System RMV is also cleared for use in the palliative treatment of biliary strictures produced by malignant neoplasms, and relief of malignant biliary obstruction prior to surgery.





Boston Scientific was the first and is currently the only company to receive U.S. FDA clearance for an indication of a metal stent, the WallFlex™ Biliary RX Fully Covered Stent System RMV, to treat benign biliary strictures due to chronic pancreatitis.

A large prospective, multinational study sponsored by Boston Scientific is currently underway. The study includes 11 centers in 10 countries in Europe, Asia, Australia and North America.

Marco J. Bruno, professor of Gastroenterology and Hepatology and head of the department of gastroenterology and hepatology at the Erasmus Medical Centre in Rotterdam, Netherlands, an investigator in the study says, "The results after one year of stent indwelling in patients with chronic pancreatitis, was that we were able to resolve the stricture in 80 percent of cases. This is very high compared with historical results obtained with plastic stents, where the maximum success rate would be 30 or 40 percent."

An abstract highlighting the three-year follow-up data ("Self-expanding metal stents for treatment of benign biliary strictures secondary to chronic pancreatitis – long-term results in a multi-center study"³) was presented at Digestive Disease Week™ in May 2016. The abstract noted that "[i]n patients with symptomatic chronic pancreatitis associated bile duct strictures treated with a single fully covered self-expanding metal stent for one year, stricture resolution obtained at the time of stent removal (80% of patients) is maintained without relapsing symptoms in 83% of patients at a median follow-up of 3 years³."

References:

1. Deviere J., Nageshwar Reddy D, Puspok A, et al. Successful management of benign biliary strictures with fully covered self-expanding metal stents. *Gastroenterology* 2014; 147:385-395.
2. Cote G., et al. Effect of Covered Metallic Stents Compared With Plastic Stents on Benign Biliary Stricture Resolution: A Randomized Clinical Trial. *JAMA*. 2016;315(12):1250-1257.
3. **Abstract:** Self-expanding metal stents for treatment of benign biliary strictures secondary to chronic pancreatitis – long term results in a multi-center study. Jacques Deviere, D. Nageshwar Reddy, Andreas Püspök, Thierry Ponchon, Marco J. Bruno, Michael J. Bourke, Horst Neuhaus, André Roy, Ferrán González-Huix Lladó, Paul Kortan, Joyce Peetermans, Sundeep Lakhtakia, Daniel Blero, Werner Dolak, and Guido Costamagna.

INDICATIONS FOR USE in the United States:

The WallFlex Biliary RX Fully Covered Stent System RMV is indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms, relief of malignant biliary obstruction prior to surgery and for indwell up to 12 months in the treatment of benign biliary strictures secondary to chronic pancreatitis.

LIMITATIONS

The sale, distribution, and use of the device are restricted to prescription use in accordance with 21 CFR 801.109

Contraindications:

- The WallFlex Biliary RX Fully Covered Stent should not be placed in strictures that cannot be dilated enough to pass the delivery system, in a perforated duct, or in very small intrahepatic ducts.
- The WallFlex Biliary RX Fully Covered Stent System RMV should not be used in patients for whom endoscopic techniques are contraindicated.

Warnings: The safety and effectiveness of the stent has not been established for indwell periods exceeding 12 months. The WallFlex Biliary RX Fully Covered Stent System RMV is for single-use only. The safety and effectiveness of the WallFlex Biliary RX Fully Covered Stent System RMV for use in the vascular system has not been established.

The safety and effectiveness of the WallFlex Biliary RX Fully Covered Stent System RMV has not been established in the treatment of benign biliary anastomotic strictures in liver transplant patients and benign biliary post abdominal surgery strictures. Testing of overlapped stents has not been conducted. The stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.

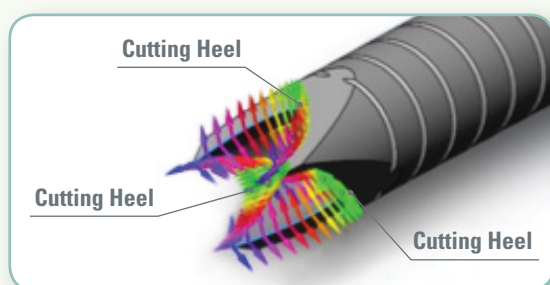
PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

The Acquire Fine Needle Helps Bring *Precision and Control to Histology*

▶ Learn about this new device.

The Boston Scientific Acquire™ Fine Needle Biopsy (FNB) Device is a new product designed for the sampling of larger tissue specimens within submucosal and extramural lesions in the gastrointestinal tract.

For physicians without an onsite pathologist to provide rapid onsite evaluation (ROSE), obtaining tissue samples that are large enough is one of the first steps in a successful histological assessment to diagnose and stage malignancies. Often, physicians are told by the pathology or cytopathology departments that they have an inadequate sample due to the quality of the tissue produced from a biopsy, requiring patients to undergo repeat procedures.



Although there are no standard biopsy requirements or evaluation criteria, recent double-blinded research shows that more than half of physicians opted to use FNB (Boston Scientific market research

2016*) to help aid in improving the quality of the biopsy. In fact, they agree that larger tissue samples enable them to give a more accurate diagnosis in the absence of any ROSE.

What makes the Acquire FNB needle stand out among the others? The cutting surfaces. While other needles may only aspirate cells and perform minimal tissue cutting, the Acquire FNB design, made up of three symmetrical fully formed cutting heels, delivers multiple cutting surfaces for easier penetration, greater control at the puncture site, and the greater chance of obtaining good tissue samples for histological assessment.

Along with an optimized tip design, the Acquire FNB is made of cobalt chromium, which is more durable and leads to less needle deformation than stainless steel alloys¹. The heels are fully formed to maximize sharpness and cutting capabilities. In addition, the design helps cut tissue from three different angles, making a more circular cut before it is pushed into the needle, promoting stability in the tissue and reduce the possibility of problems that may occur during multiple passes.

“The Acquire FNB Needle is changing how we conduct biopsies,”
says Dr. Jose Nieto of Borland-Groover Clinic, Jacksonville, Florida.

“Now we are able to answer questions we could not answer before based on histology and, more importantly, we are making it easier for patients to get better treatments faster. In fact, there is a strong potential for this technology to help physicians diagnose diseases earlier, stage more cancers more accurately and overall, ensure a much more personalized approach by obtaining key genetic information.”

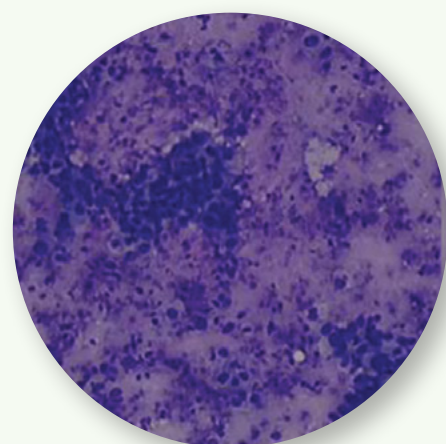


Image courtesy of Dr. Shyam Varadarajulu.

References:

1. Keehan E, Gergely L. 2009. Catheter and Specialty Needle Alloys. Poster session presented at: Materials & Processes for Medical Devices Conference & Exposition; Minneapolis.

*This research was performed by or on behalf of BSC. Data on file.



Compelling Clinical Data Presented on Cholangioscopy at Digestive Disease Week

Learn about
cholangioscopy on
EndoSuite.com.

This year at Digestive Disease Week™ (DDW 2016), more than 30 abstracts were presented on cholangioscopy with a combined total of more than 1,000 patients. Many of the presented abstracts featured one of the newest innovations in endoscopic retrograde cholangiopancreatography (ERCP) technology, the Boston Scientific SpyGlass™ DS Direct Visualization System. An advanced, single-use visualization technology, the SpyGlass DS System offers high-resolution imaging and therapy during ERCP procedures.

Two studies, in particular, stood out.

1 A retrospective, multicenter study (**“Digital Single Operator Cholangioscopy (DSOC): Multicenter Experience in 237 Patients”**) presented by Dr. Isaac Raijman of Baylor St. Luke’s Medical Center in Houston, TX, USA, examined the diagnostic and therapeutic effectiveness of DSOC. “We found that direct visualization using the SpyGlass DS System enabled us to perform multiple tests during a single procedure, providing us with better intelligence about a patient’s pathology and improving our ability to guide treatment decisions,” explained Dr. Raijman. “In fact, in 30 percent of cases, we modified the patient’s diagnosis from malignant to benign, a change that allowed these patients to avoid additional and unnecessary intervention. The key takeaway here is that if we use the best available technology and perform procedures like cholangioscopy in a systematic and methodical way, we have the ability to markedly enhance the patient experience and improve outcomes.”

2 Another notable abstract included a retrospective, multicenter study (**“SPYGLASS DS Cholangioscopy for Difficult Stones: Early Experiences of Two UK Centres”**) presented by Dr. Richard Sturgess of The Digestive Disease Centre at Aintree University Hospital in Liverpool, UK, and Dr. George Webster of University College Hospital in London, UK. The abstract reports on the early use of the SpyGlass DS System using electrohydraulic lithotripsy (EHL) in patients who have undergone multiple failed ERCPs to attempt stone clearance. “In these complex cases, we were able to achieve definitive stone clearance in 81 percent of patients without any complications or the need for additional or repeat procedures,” explained Dr. Webster. “We found that cholangioscopy and intraductal lithotripsy have had a specific role in treating patients with difficult stones due to stone location, size or number. Using the SpyGlass DS System in these procedures significantly increased our ability to reduce the number of repeat ERCPs.” Webster added, “The SpyGlass DS System enabled us to more efficiently diagnose and treat difficult stones with or without intervention. When we use the SpyGlass DS System, we are taking preventative measures to help reduce repeat procedures, therefore improving the overall quality of care for the patient.”

Since its launch last year, the SpyGlass DS System has **impacted more than 18,000 patient lives in 43 countries**. For case studies, presentations and programs on cholangioscopy, please visit www.EndoSuite.com.

Industry Accolades for the SpyGlass DS System

In November 2015, the SpyGlass DS System won an R&D 100 Award in the Analytical and Test category.

Boston Scientific recently won a Silver 2016 Medical Design Excellence Award



(MDEA) for the SpyGlass DS System in the **“Radiological and Electromechanical Devices”** category.

The MDEA recognizes significant achievements in medical product design and engineering that improve the quality of healthcare delivery and accessibility.

In addition, the Galien Foundation named the SpyGlass DS System as a finalist for the 2016 Prix Galien USA award in the **“Best Medical Technology”** category. The Prix Galien Award is among the health-innovation industry’s most prized honors, and is widely regarded as the equivalent of the Nobel Prize in biopharmaceutical and medical technology research. Winners, selected by a committee of world-renowned leaders from industry and academia, will be announced at a ceremony in October 2016.

Blue Hope Program Helps the Underserved Get Free Screening Colonoscopies



Boston Scientific is a proud partner of the Colon Cancer Alliance (CCA) and is a founding sponsor of the Blue Hope Financial Assistance program.* In 2016, as part of its colon cancer awareness initiatives, Boston Scientific donated over \$75,000 to the CCA in support of the program. The program provides qualifying individuals with access to lower cost screenings or stipends to reduce the costs associated with screening.

▶ **Learn more about the Blue Hope program.**

2015 FINANCIAL SUPPORT HIGHLIGHTS

2,618
APPLICANTS

41
SCREENED

216
AWARDS GIVEN

OVER \$100,000
GIVEN TO PATIENTS

As of March 2016, since the program's inception, 331 patients from across the U.S. have been referred to receive screening assistance as a result of the Blue Hope Financial Assistance program. Since the program began, 3 patients have been diagnosed with colon and/or rectal cancer.

WORKING WITH HOSPITALS TO BETTER SERVE THEIR COMMUNITIES

As part of the **Blue Hope Financial Assistance** program, the Colon Cancer Alliance can work with hospitals to refer qualified individuals in need of screening. Learn how your hospital can help underserved members of your community. Speak with your Boston Scientific representative or email us at closethegap@bsci.com.

COLON
CANCER
ALLIANCE

BLUE HOPE
FINANCIAL ASSISTANCE

“Receiving the Blue Hope Prevention Award is hopefully going to save my life. Because of my colonoscopy, I found out I have colon cancer. My recent surgery went well and greatest news ever. I'm cancer free! It's like a miracle! If your organization had not provided this gift of a colonoscopy for me, my life would be very different. I'm unemployed so there was no insurance to cover the test. How can I begin to thank you?”

— Colon Cancer Survivor, Jessica Lee. Read Jessica's blog and learn more about the Blue Hope Financial Assistance program at <http://ccalliance.org/blog/jessica-lee/>.

▶ **Read a survivor's story.**

Close the Gap is a Boston Scientific health equity program dedicated to raising awareness and increasing access to care for underserved patient communities across the U.S. at high risk of suffering from gastrointestinal and pulmonary diseases.

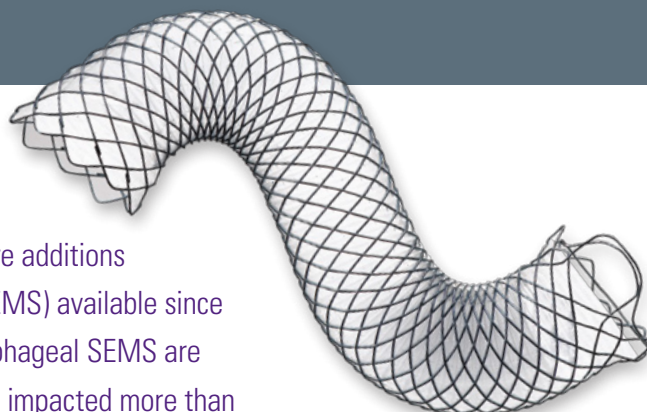
CLOSE THE GAP
Health Equity for Life

▶ **More about Close the Gap.**

*Blue Hope Prevention Awards are funded in part by Boston Scientific, The Tony Elliot Memorial Event and Steph's Fall 5k.

Taking a New Approach to Product Development through *Innovation and Collaboration*

Boston Scientific received CE Marks for its WallFlex™ Biliary RX 6mm Stent and its WallFlex Esophageal Fully Covered RMV Stent System Longer Loop. These stents are additions to the WallFlex family of Self-expanding Metal Stents (SEMS) available since 2008. Boston Scientific biliary, colonic, duodenal and esophageal SEMS are recognized for supporting procedural excellence and have impacted more than one million patient lives in the U.S., Europe and other regions of the world.



“With regard to the WallFlex Biliary RX 6mm stent, the decision to add to our existing product line was our desire to respond to physicians’ need for a smaller size but with the same features and capabilities they have come to value in our WallFlex Biliary RX Stent,” said Astrid Monteau, director of marketing for Europe, Boston Scientific Endoscopy. “This particular size is not a high-volume demand product but still an important one for treating patients with pancreatobiliary diseases.”

As important as it was to meet the clinical needs of physicians by delivering these smaller diameter stents, so too was the approach used to develop the products. Boston Scientific assembled a multinational cross-functional team focused on development of these stents. The team was also tasked with streamlining processes and making innovation a priority. Leveraging Boston Scientific’s expertise and learnings as a long-time stent manufacturer, the team took the projects from concept to delivery in six months. By delivering outcomes quickly, the team earned the nickname “Road Runner.”

More than simply focusing on internal processes, customer input was paramount to the projects. “Innovation goes beyond technology,” explained Gary Jordan, director of research and development, Boston Scientific Endoscopy. “It’s about collaborating with our customers in a new way so we are getting the feedback we need and making decisions and adjustments in real time.”

The team continues to work with physicians from all regions of the world to evaluate new product development projects.

“It’s about collaborating with our customers in a new way so we are getting the feedback we need and making decisions and adjustments in real time.”

— Gary Jordan

Director of Research and Development, Boston Scientific Endoscopy

The WallFlex Biliary RX 6mm Stent System is CE Marked and available in the European Union, but has not been FDA cleared for sale in the United States.

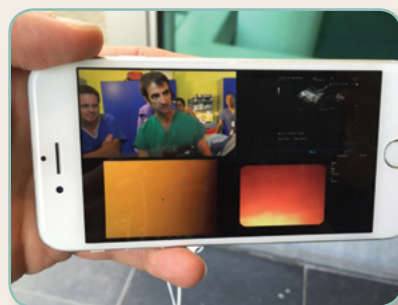
Warning: The safety and effectiveness of the WallFlex Biliary RX Stent System for use in the vascular system has not been established.

Boston Scientific Expands its Global Reach through *Virtual Education*

As technological advances in diagnostic and therapeutic endoscopy continue to evolve, the need for global clinician education and training is increasing. Education on disease management, new procedures and the proper use of medical devices can have a positive impact on clinical outcomes as well as efficiencies. Physicians particularly value learning from other physicians, but access to programs such as preceptorships is limited due to geographic availability, travel costs and time away from a physician's busy practice. Recognizing these challenges, **Boston Scientific is investing in new approaches and platforms designed to enable clinicians to learn from KOL experts in live, interactive or virtual settings — anytime, anywhere.**



Dr. Arnelo conducts a remote e-proctorship from the Karolinska Institute.



A viewer watches the broadcast of Dr. Farrell (left) and Dr. Arcidiacono via smartphone.

IN ITALY, a new e-preceptorship program (currently being piloted in three facilities) is enabling physicians to view live endoscopy procedures with commentary provided by KOL experts. Trainees are notified when procedures of interest will be broadcast and they can log in to view the live case or review a podcast at a later time. Remote viewers can see multiple video streams or select the view they prefer on their laptop or mobile device and can ask real-time questions at the end of the procedure. To date, these broadcasts have reached more than 500 clinicians worldwide.

Dr. Alberto Larghi who participated in the first two e-preceptorship programs said, “I strongly believe this is a highly valuable method to teach endoscopy by enabling easy-to-access training for the next generation of gastroenterologists as well as the dissemination of widespread clinical knowledge and training throughout the world.”

IN SWEDEN at the Karolinska Institute, a teleguided e-proctorship pilot program funded by Boston Scientific was established in 2014 to provide guidance and support to endoscopists performing complex ERCP procedures at low-volume centers. Today, the program has grown to include five remote hospitals with over 200 e-proctored ERCPs performed to date.

“Telemedicine programs such as the one at our Karolinska Institute may improve the quality of care for patients by enabling access to medical procedures that might not otherwise be available and by improving the quality of complex procedures by less experienced physicians,” said **Urban Arnelo, M.D., PH.D.** “Based on our experience over the last five years, I believe this type of technology and approach is now ready for more widespread use.”

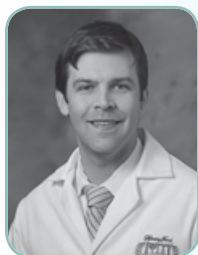
IN THE U.S., small portable units are enabling live broadcasts to be conducted from virtually any location, with participants able to view live cases or physician lectures remotely via a website log-in. The units can accommodate live, two-way interaction with individuals or small groups as well as broadcasts to large, global audiences. Programs can also be archived for later viewing.

“Boston Scientific has been developing and delivering high-quality education programs for decades,” said **Art Butcher, president of the Endoscopy Division.** “Building on that tradition, our web-based education platforms are now enabling clinicians from virtually anywhere to access learning from KOL experts. With these programs we are opening up new pathways for physicians — especially those living in remote regions — to bring more advanced skills and technologies to the care and management of their patient populations.”

To learn more, visit: www.EndoSuite.com (US and EU); and www.BronchSuite.com (US and EU); and VirtualTrainingInstitute.com (AMEA).

Boston Scientific is donating \$1M to the American Society for Gastrointestinal Endoscopy (ASGE) in support of the foundation's “Beyond our Walls: The Future of Endoscopic Education and Practice” campaign. The campaign seeks to build upon the success of the ASGE's Interactive Training and Technology Center, and to deliver visionary and innovative clinical education and practice management resources to meet the need of its members. Webinars, videos and other mechanisms that enable physicians to attend courses virtually will help ensure that high-quality educational content is reaching a greater number of physicians. In addition, Boston Scientific and the ASGE will partner on clinical education and practice management education programs for advanced fellows.

Less Invasive Diagnosis Achieved Using a Fine Needle Biopsy Device



CASE PRESENTED BY:
RALPH BROOKS VANCE, M.D.
Advanced Endoscopy Fellow
Henry Ford Health System
Detroit, Michigan, USA



KRISHNAVEL V. CHATHADI, M.D.
Director of Endoscopic Services
Henry Ford Health System
Detroit, Michigan, USA

[▶ Learn about the
new Acquire
FNB Needle.](#)

PATIENT HISTORY

A 60-year-old woman was evaluated with upper endoscopy for persistent nausea and vomiting at an outside hospital. On this exam, an apparent subepithelial lesion was discovered in the duodenal bulb (**Figure 1**). "Bite-on-bite" biopsies were obtained and the final pathology report reported normal duodenal mucosa. The patient was referred to our institution for endoscopic ultrasound (EUS) for diagnostic fine-needle aspiration (FNA) to make a conclusive diagnosis. Endoscopic ultrasound confirmed a 15x7mm hypoechoic subepithelial lesion within the submucosal layer in the duodenal bulb. The lesion was very difficult to evaluate due to a challenging position in the proximal duodenal bulb. Fine-needle aspiration was performed using an Expect™ 22G FNA Needle (three passes). Cytology was non-diagnostic, only showing gastric epithelial cells. Repeat "bite-on-bite" biopsies revealed normal duodenal mucosa again. Due to concern about a possible carcinoid tumor, another EUS was performed in hopes of better yield on repeat sampling.

PROCEDURE

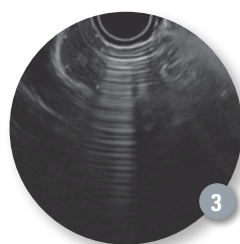
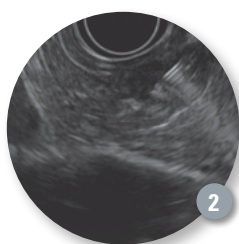
Repeat EUS was performed after the new 22G Acquire™ FNB was released (**Figure 2**). The duodenal bulb submucosal lesion was sampled four times with the FNB needle. Visible core tissue was noted to be obtained. On-site cytology service was not utilized on either EUS procedure.

OUTCOME / POST-PROCEDURE

The patient tolerated the procedure well. The final cytology using the Acquire fine needle biopsy was positive for malignant cells, consistent with carcinoid tumor. An adequate amount of tissue obtained in this case with an FNB needle allowed for immunochemical staining that was positive for synaptophysin and negative for chromogranin and LCA, helping make a conclusive diagnosis of carcinoid tumor. The patient elected to have definitive surgical resection of her duodenal carcinoid tumor. A definitive diagnosis influenced the management of this patient.

CONCLUSION

Definitive diagnosis of a malignant condition was made possible with this newer Acquire FNB (fine needle biopsy) device in this difficult-to-diagnose subepithelial lesion (Figure 3). It likely provided a higher yield specimen as it is designed to obtain more tissue compared to a standard FNA needle. The diagnosis was achieved relatively less invasively without having to attempt resection, which would have been challenging and risky in this location with a thin wall.



EUS-Guided Fine Needle Biopsy Allows for Extensive Tissue Acquisition Leading to Diagnosis



CASE PRESENTED BY:
DOUGLAS GRAHAM ADLER, M.D.
Salt Lake City, Utah, USA

PATIENT HISTORY

The patient is a 75-year-old female who was transferred to our institution after being diagnosed with acute pancreatitis and cholecystitis at an outside hospital. An ERCP at the outside hospital resulted in stone clearance from the common bile duct, but the patient failed to improve clinically and developed hypoxic respiratory failure warranting transfer. At our institution, the patient underwent a CT scan that showed diffuse changes of interstitial pancreatitis and a hypodense lesion in the pancreatic body suspicious for a mass lesion. The radiologist felt this was consistent with a pancreatic adenocarcinoma. After stabilization and improvement in respiratory status, the patient was referred for endoscopic ultrasound (EUS)-guided fine-needle biopsy (FNB).

PROCEDURE

Linear EUS was performed at 7.5MHz with Doppler imaging. There was mild diffuse peripancreatic edema seen consistent with a history of resolving pancreatitis. An irregular solid mass was identified in the pancreatic body. The mass was hypoechoic and measured 37.6mm in maximal cross-sectional diameter (**Figure 1**). The lesion was somewhat vascular with an appearance that was not typical for a pancreatic adenocarcinoma. The endosonographic borders were well-defined. Fine needle biopsy was performed using a 22 gauge Acquire™ Needle. Color Doppler imaging was utilized to confirm a lack of significant vascular structures within the needle path. Three passes were made using a transgastric approach using the slow-pull technique of stylet withdrawal during needle actuations (**Figure 2**). Several tissue cores were obtained.

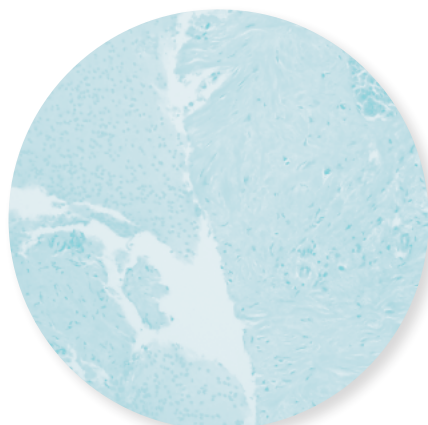
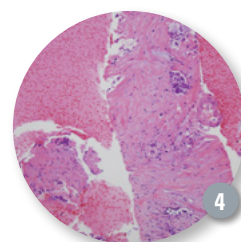
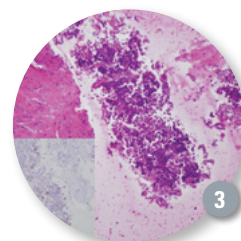
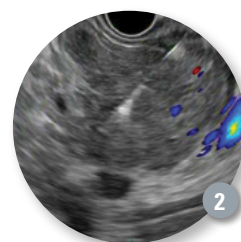
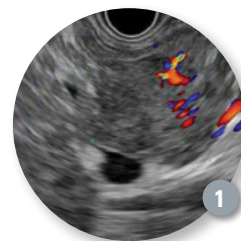
Note: Boston Scientific Product Acquire EUS-FNB device uses syringe and stopcock to create and maintain suction during a standard operational procedure. Methods of providing suction other than the supplied syringe are not recommended with this device. Several tissue cores were obtained.

OUTCOME / POST PROCEDURE

The patient tolerated the procedure well with no adverse events. The patient was diagnosed with a neuroendocrine tumor (**Figures 3 and 4**). It is not fully clear if this lesion was truly incidental or if it also played a role in the development of the patient's acute pancreatitis. The patient was referred to surgery for resection of this lesion.

CONCLUSION

This case illustrates several key points. First, cross-sectional imaging allowed identification of a mass lesion that might have been missed. Second, the lesion in the CT scan was suggestive of an adenocarcinoma, but EUS findings suggested a different type of tumor. Third, EUS-guided FNB allowed for extensive tissue to be acquired that allowed for histologic analysis and staining that led to the true diagnosis of neuroendocrine tumor and a surgical referral.



[▶ Learn about the new Acquire FNB Needle.](#)

Images provided courtesy of Dr Adler.

(Images courtesy Dr. Barbara Chadwick, Pathology, University of Utah)

Acquire Fine Needle Biopsy (FNB) Device Provides Diagnosis



PATIENT HISTORY

A 63-year-old female presented to our office as a referral for a second opinion by her oncologist. She presented to a physician four months prior to seeing us for complaints of 40-pound weight loss over a few months with persistent nausea and vague upper abdominal pain.

Imaging initially revealed a 4cm mass encasing the celiac trunk. Endoscopic ultrasound (EUS) was performed by another provider and the mass was felt to not affect the celiac trunk. Fine needle aspiration was performed using a 22 gauge Expect™ Needle and 7 passes of the mass were obtained. Rapid on-site evaluation (ROSE) with cytology as well as stains were inconclusive and the patient was sent to an oncologist for further options. A PET CT revealed a soft-tissue abnormality at the level of the celiac trunk with mild increased metabolic activity. In addition, there was a 1.5cm mass of the adrenal gland with hypervascularity concerning for a metastatic lesion.

PROCEDURE

An EUS was scheduled in our Ambulatory Surgical Center (ASC). The mass was felt to involve the trunk, and fine needle biopsy (FNB) was performed using a 22 gauge Acquire™ Needle. Two passes using the slow pull method and dry suction were sent on a slide and in a fixative and sent for analysis. (Figure 1). A third pass, using wet suction, was sent in formalin (Figure 2). Rapid on-site evaluation is not available in the ASC, where the procedure was performed, and therefore was not used.

The biopsies came back positive for adenocarcinoma (Figures 3 and 4).

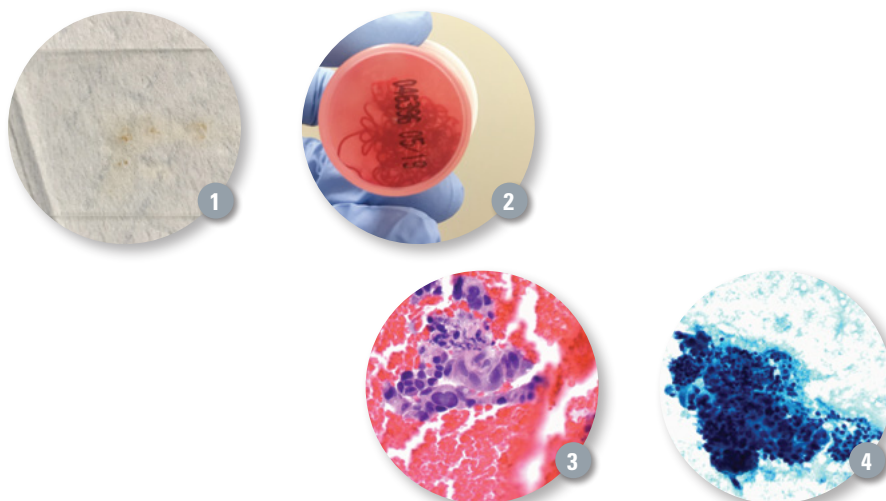
POST PROCEDURE

The patient had no pain post procedure and was discharged home. She was informed of the results as they became available.

DISCUSSION

This case demonstrates that FNB using the Acquire needle:

1. Should be considered as an alternative when FNA is unsuccessful
2. May be utilized safely in appropriate cases in an ASC
3. May be effective when ROSE is not available



Images provided courtesy of Drs. Sachdev, Das, Khosravi.



CASE PRESENTED BY:

MANKANWAL SINGH SACHDEV, M.D.

Medical Director Endoscopy
St. Joseph's Hospital, Phoenix
Arizona Center for Digestive Health
Assistant Professor of Medicine,
Creighton University
Gilbert, Arizona, USA



ANANYA DAS, M.D., FACC, FASGE

Chair of Gastroenterology
St. Joseph's Hospital and Medical Center
Professor of Medicine
Creighton University
Director Arizona Center for Digestive Health
Gilbert, Arizona, USA



FARHOUD KHOSRAVI, D.O.

Advanced Endoscopy Fellow
Arizona Center for Digestive Health
Gilbert, Arizona, USA

[▶ Learn about the new
Acquire FNB Needle.](#)

Mechanical Clipping in a Challenging Case



CASE PRESENTED BY:

CARMELO LUIGIANO, M.D. (Far Left)

GIUSEPPE IABICHINO, M.D.

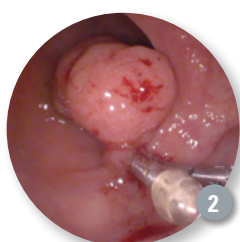
Unit of Digestive Endoscopy
San Paolo University Hospital
Milan, ITALY



PATIENT HISTORY

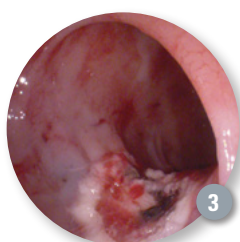
A 58-year-old man with hepatitis C virus-related cirrhosis (Child Pugh classification B, MELD score 10, INR 0.9, platelet count 85000) underwent a colonoscopy due to rectal bleeding.

During the colonoscopy, a large sessile lesion (diameter 3.5cm) was found 5cm from the anal verge and in proximity of a rectal varix (**Figure 1**). Biopsies of the lesion were consistent with a villous adenoma. The patient was referred to our endoscopy unit for endoscopic resection (ER).



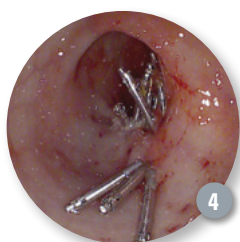
PROCEDURE

Patient underwent a diagnostic and hemodynamic evaluation using a linear endoscopic ultrasound scope. With the aid of color Doppler imaging, hemodynamic evaluation helped in clipping closer to the feeder vessel near the inflow area at the highest point. Endoscopic clipping of the varix was performed using two Resolution 360° Clips (**Figure 2**). Subsequently, the lesion was lifted with submucosal injection of saline and epinephrine, 1:20000, and en bloc resection was performed using a 33mm Captivator™ Snare (**Figure 3**). This resulted in a large mucosal defect of 25mm in diameter, which was closed using five Resolution 360 Clips. Finally, another clip was placed prophylactically in the varix (**Figure 4**).



POST PROCEDURE

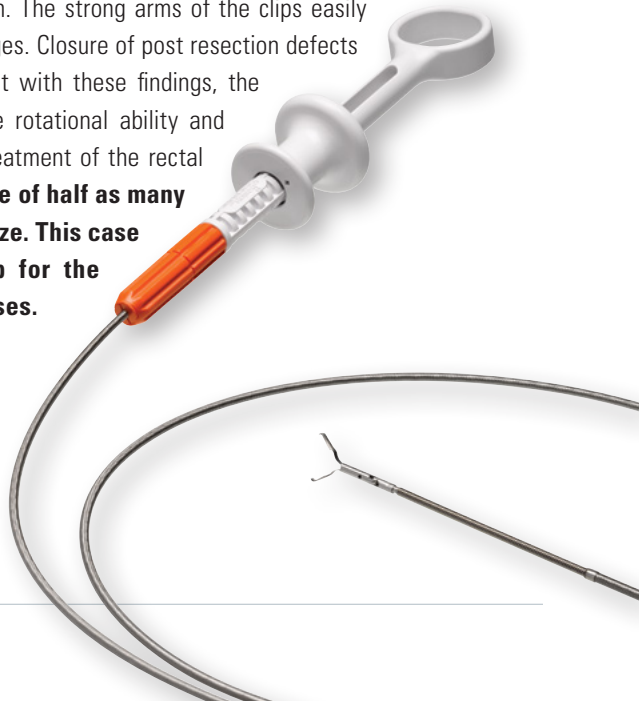
The patient reported no pain or complaints and was discharged home after the procedure. No late post-procedure complications occurred. The pathological diagnosis of the lesion revealed villous adenoma with high-grade dysplasia.



CONCLUSION

This case presented a pre-cancerous lesion that was large and in proximity of a rectal varix in a patient with advanced cirrhosis, all of which contribute to a challenging procedure. Patients with clinical risk factors, such as cirrhosis or coagulopathy, and with a large defect post endoscopic resection, are usually admitted to the hospital for several days of inpatient observation due to risk of delayed post-procedural complications, such as bleeding and perforation. Instead, five Resolution 360 Clips were used to completely close the defect, allowing the patient to be discharged home the same day. The rotation of the Resolution 360 Clip allowed for precise positioning to adequately approximate and close the edges of the mucosal defect post resection. The strong arms of the clips easily approximated the large diastasis between the defect's edges. Closure of post resection defects may reduce the risk of delayed complications. Consistent with these findings, the patient had no immediate or delayed complications. The rotational ability and gripping strength of device allowed for the successful treatment of the rectal varix. **The use of Resolution 360 Clips allowed for use of half as many clips as typically required to close a defect of this size. This case confirmed the versatility of Resolution 360 Clip for the treatment of a wide range of gastrointestinal diseases.**

[▶ Learn about the
Resolution 360 Clip.](#)



Clinical Efficacy and Efficiency of the Resolution 360 Clip



CASE PRESENTED BY:

JONH PINEDA, M.D.

LewisGale Medical Center
Salem, Virginia, USA

INTRODUCTION

A 68-year-old woman with a history of constipation and intermittent diarrhea underwent surveillance colonoscopy. During the colonoscopy, a large, laterally spreading flat polyp consistent with a sessile serrated adenoma was seen in the cecum.

PROCEDURE

The polyp was lifted and demarcated with a 20 ml mixture of hetastarch, methylene blue and epinephrine. The lesion was removed by endoscopic mucosal resection (EMR) technique, piecemeal fashion, with a Captivator™ Single-Use Stiff Snare. The edges of the lesion were ablated with soft coagulation using the tip of the snare. Visible vessels and a bleeding spot were ablated with a coagulation grasper (**Figure 1**).

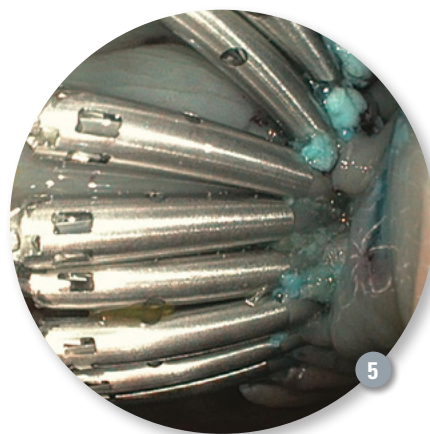
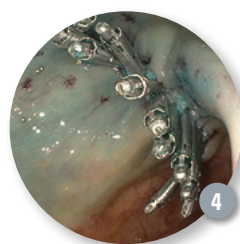
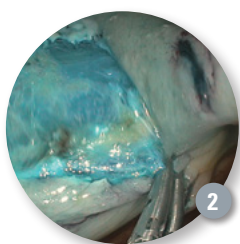
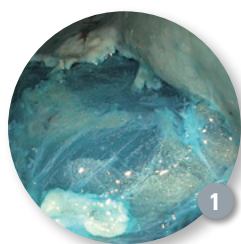
The 2.9cm defect was closed with placement of 12 Resolution 360™ Clips (**Figures 2 through 5**).

POST PROCEDURE

The patient tolerated the procedure well. The polyp was a sessile serrated adenoma without high-grade dysplasia. A surveillance colonoscopy will be done in six months.

DISCUSSION

This case demonstrated the ability to effectively close a large post EMR defect using the new Resolution 360 Clip. The one-to-one physician control to rotate the clip afforded fast and easy placement of the clips in the exact alignment needed to close the defect. The jaw strength of the clip allowed for the edges of the lesion to be brought together reliably. There were no clip misplacements, contributing to a shorter procedure time and cost-effectiveness.



[▶ Learn about the Resolution 360 Clip.](#)

EMR vs. Surgery for Esophageal Adenocarcinoma



CASE PRESENTED BY:

BRIAN RAJCA, M.D.

Associates in Digestive Health
Cape Coral Hospital
Cape Coral, Florida, USA

BACKGROUND

Esophageal cancer remains a disease plagued with high morbidity and mortality. Barrett's esophagus is a precursor to esophageal cancer and is a central step on the disease continuum from GERD to esophageal cancer. In Barrett's esophagus, the normal esophageal mucosa transforms into a cell more adapted to tolerate an acidic environment in a process termed intestinal metaplasia¹. While only 10-15% of individuals with GERD develop Barrett's esophagus, this metaplasia change has the potential to progress to dysplasia and ultimately esophageal adenocarcinoma.^{2,3}

Endoscopic resection has evolved to become a crucial treatment option in the endoscopic management not only of esophageal nodules arising in the setting of high grade dysplasia but also in the resection of early esophageal cancer.² Endoscopic resection not only provides histologic staging but also offers the potential for an endoscopic cure when combined with radiofrequency ablation.^{2,4}

CASE REPORT

An 82-year-old male with a history of non-dysplastic Barrett's esophagus presented with confirmed esophageal adenocarcinoma arising in an esophageal nodule in the setting of Barrett's with high-grade dysplasia. Due to multiple co-morbidities, the patient was deemed not to be a surgical candidate. After an endoscopic ultrasound confirmed superficial mucosal involvement and a lack of

region lymphadenopathy, the decision was made to perform an endoscopic mucosal resection (**Figure 1**). Using the Captivator™ EMR Device, the nodule was gently suctioned into the cap and a single ligating band was deployed. This adequately captured the nodule with a small margin. Resection was performed with a hexagonal snare positioned below the band with cautery. Resection and retrieval were complete (**Figures 2 and 3**). The patient tolerated the procedure well, without complications, and was discharged home the same day.

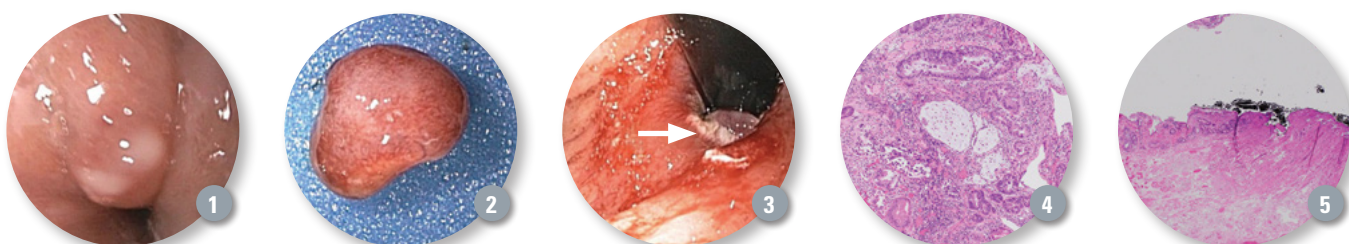
PATHOLOGY RESULTS

Diagnosis: Gastroesophageal tissue with intestinal metaplasia with high-grade dysplasia and intramucosal adenocarcinoma (**Figure 4**).

Comment: The resection margin appears free of intramucosal adenocarcinoma. Intestinal metaplasia with probable dysplasia is present at the inked margin (**Figure 5**).

CONCLUSION:

Endoscopic therapy is a safe, effective therapy in the management of Barrett's esophagus. For early stage esophageal adenocarcinoma, endoscopic mucosal resection offers the potential for cure with low morbidity and mortality when compared to surgical resection. In the case presented above, endoscopic resection was performed with the Captivator EMR Device.



[Learn about tissue resection on EndoSuite.com.](https://www.endsuite.com)

References:

- 1) Absi, A., Adelstein, D. J., & Rice, T. (2010). Esophageal Cancer. *Current Clinical Medicine*, 643-648. doi:10.1016/b978-1-4160-6643-9.00097-7
 - 2) Shaheen, N. J., Falk, G. W., Iyer, P. G., & Gerson, L. B. (2015). ACG Clinical Guideline: Diagnosis and Management of Barrett's Esophagus. *Am J Gastroenterol The American Journal of Gastroenterology*, 111(1), 30-50. doi:10.1038/ajg.2015.322
 - 3) Vilsteren, F. V., Pouw, R., Herrero, L., Peters, F., Bisschops, R., Houben, M., Bergman, J. (2011). Learning to perform endoscopic resection of esophageal neoplasia is associated with significant complications even within a structured training program. *Endoscopy*, 44(01), 4-14. doi:10.1055/s-0031-1291384
 - 4) Namasivayam, V., Wang, K. K., & Prasad, G. A. (2010). Endoscopic Mucosal Resection in the Management of Esophageal Neoplasia: Current Status and Future Directions. *Clinical Gastroenterology and Hepatology*, 8(9), 743-754. doi:10.1016/j.cgh.2010.05.030
- Images provided courtesy of Dr. Rajca.

Exceptional Pathfinding Ability for the NovaGold High Performance Guidewire



CASE PRESENTED BY:

FRÉDÉRIC PRAT, M.D., PH.D

Diagnostic Interventional Endoscopy Unit
Cochin Hospital, Paris, FRANCE

INTRODUCTION

ERCP can be a complex and demanding procedure, and passing a difficult stricture can be one of the trickiest moments during ERCP procedures. Thanks to improvements in coating materials — especially hydrophilic ones — and metals forming the core of guidewires as well as cannulae and dilators, only a few strictures still resist the efforts of the expert endoscopist. However, the slim remaining fraction of untractable obstacles means that those patients, conditions will worsen or that more invasive interventions may be necessary. The NovaGold™ High Performance Guidewire is a recently launched guidewire, .018" in diameter with a stiff body and a 6cm long gold tip, providing high flexibility, alpha-loop-forming capacity and a pretty good shape memory.

PATIENT HISTORY

The patient was a 60-year-old man, who presented with a history of alcohol and tobacco abuse, professional asbestos exposure and esophageal carcinoma. The patient previously underwent an esophagectomy with esogastric anastomosis. He then presented in August of 2015 with degraded general condition, severe weight loss and large volume ascites. The ascites was rich in amylase, suggesting a ruptured main pancreatic duct.

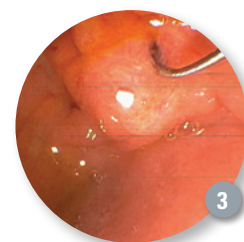
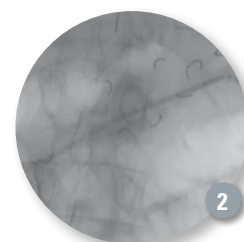
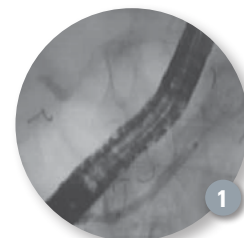
PROCEDURE

A CT scan and pancreatic MRI showed no sign of chronic pancreatitis, but revealed a large 2cm cystic formation in the head of the pancreas. After recovery from septic shock resulting from the ascites infection, the patient was referred to Cochin Hospital for further investigation. An endoscopic ultrasound (EUS) found a hypoechoic 2cm cephalic nodule, and fine needle aspiration (FNA) yielded inflammatory and dystrophic acinar cells suggestive of focal pancreatitis. The same day, a first attempt at ERCP was unsuccessful because the papilla was difficult to cannulate as a consequence of previous esogastric surgery. A biliary sphincterotomy was performed to facilitate further attempts.

Three weeks later, another ERCP enabled finding the pancreatic duct in the anterior rim of the sphincterotomy. Contrast injection showed a short hook-shaped, tight and angulated stricture in the right part of the pancreatic body, with some contrast runoff above the stricture corresponding to the ductal rupture (**Figure 1**). Despite using a slim 0.025" guidewire and fully hydrophilic straight and angulated 0.035" wires, the stricture remained impassable. A NovaGold High Performance Guidewire was tried after more than one hour of unsuccessful attempts, and it almost immediately found the path through the stricture by forming an alpha-loop (**Figure 2**). Since the stricture was short, it wasn't necessary to change for a thicker wire before inserting a 7F, 12cm-long stent (**Figure 3**). The patient has done well following the procedure. A scheduled stent exchange was performed four months later, showing no residual stricture or leak. A CT scan showed no residual peri-pancreatic collection. The present stent will be definitively removed.

CONCLUSION

The NovaGold High Performance Guidewire represents a significant breakthrough in wire-guided pathfinding during ERCP, as demonstrated by this case report in which repeat attempts by an expert endoscopist with all the previously available tools had remained unsuccessful.



[▶ Learn about the
NovaGold Guidewire.](#)

Using Cholangioscopy to Provide a Diagnosis of Benign Hepatobiliary Cystadenoma



CASE PRESENTED BY:

ABHIJIT KULKARNI, M.D., FASGE

Associate Professor, Department of Medicine
Temple University School of Medicine
Director, Therapeutic Endoscopy
Medical Director, GI Laboratory
Allegheny General Hospital
Pennsylvania, USA

PATIENT HISTORY

A 68-year-old female with a past medical history of cholelithiasis presented to us with right upper quadrant pain and intermittent dark urine after eating a heavy, fatty meal. A right upper quadrant ultrasonogram revealed a cystic mass causing extrinsic compression on the common hepatic duct, and bilateral intrahepatic dilation in addition to the patient's known history of cholelithiasis. Subsequently, a CT scan showed a thin-walled cystic lesion encompassing almost the entire caudate lobe.

PROCEDURE

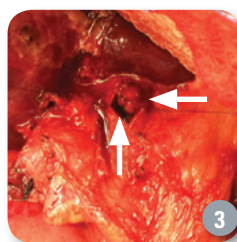
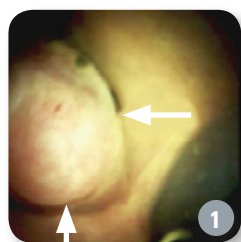
Endoscopic retrograde cholangiopancreatography revealed a large, fixed filling defect at the bifurcation. In order to better determine the nature of this obstruction, cholangioscopy using a single-operator digital cholangioscope (SpyGlass™ DS System) was performed, which revealed a 2cm cystic lesion with its stalk in the proximal right main hepatic duct (**Figures 1 and 2**). Detailed visualization with high-quality imaging and targeted manipulation of the mass showed that it was mobile, causing an obstruction to the right and, intermittently, to the left system. It appeared to be a benign, pedunculated lesion. Endoscopic resection was not performed due to the inability to control potential intraductal post-polypectomy hemorrhage. Surgical resection was subsequently performed with pathology consistent with benign hepatobiliary cystadenoma (**Figure 3**). The preoperative staging of the lesion permitted the removal of the lesion via a choledochotomy. This avoided the need for a larger surgical resection of the liver, with subsequently a quicker postoperative recovery.

OUTCOME

A follow-up ERCP was performed which revealed resolution of the filling defect on cholangiography. However, a repeat cholangioscopy procedure was performed which revealed persistent mucosal irregularity which was felt to be postoperative scarring. A follow-up MRI of the liver unfortunately demonstrated a recurrence of the cystic lesion and a larger surgical excision is now being planned.

SUMMARY

Right upper quadrant abdominal pain and obstructive jaundice are the most common symptoms of cystadenomas. Much as a pendulum swings back and forth, this mass appeared to swing from the right main hepatic duct into the left, causing intermittent obstruction of the left system as well, ultimately leading to the patient's presentation of jaundice. Biliary cystadenomas, while extremely rare, should be considered in the differential for obstructive jaundice. Complete surgical excision is required as these tumors have a high rate of recurrence and potential for malignant transformation.



[▶ Learn about the SpyGlass DS System.](#)

Endoscopic Management of a Benign Biliary Stricture Due to Chronic Pancreatitis by Inserting a Fully Covered Self-expanding Metal Stent



CASE PRESENTED BY:

GIANFRANCO DONATELLI, M.D.

Unité d'Endoscopie Interventionnelle
Hôpital Privé des Peupliers
Paris, FRANCE

PATIENT HISTORY

A 39-year-old man with a history of chronic alcoholism was admitted to the hospital, in an emergency, for abdominal pain and jaundice. A CT scan showed an obstructive chronic calcifying pancreatitis (chronic pancreatitis) with dilatation of the common bile duct above the head of the pancreas. The pancreatic duct was obstructed by the stricture. Possible treatments were surgery or endotherapy. Endoscopic stenting was chosen in order to treat biliary and pancreatic stenosis.

PROCEDURE

Under general anesthesia, the papilla was visualized and appeared normal, as there was no ampulloma or any other disease. Primary cannulation of the main pancreatic duct was successfully attempted and pacification showed a canal stricture at the level of the junction body-tails (**Figure 1**). A pancreatic sphincterotomy was performed, and after a 6mm hydrostatic dilation using a Hurricane™ RX Biliary Balloon Dilation Catheter (**Figure 2**), a multi-perforated 10Fr Advanix™ Pancreatic Stent was placed.

Using a standard three-lumen Ultratome™ Sphincterotome loaded with a straight guidewire, cannulation of the common bile duct was accomplished. Injection of medium contrast showed a long, benign extrinsic biliary stenosis evaluated at 3cm in length (**Figure 3**) with dilation of the common bile duct. The guidewire was inserted deeply in the intrahepatic ducts and a biliary sphincterotomy was performed. Then, in order to treat the stenosis, the decision was made to place a WallFlex™ Biliary RX Fully Covered Stent. Under fluoroscopy, a 6cm long x 10mm in diameter WallFlex Biliary RX Fully Covered Stent System RMV was placed. The 10mm x 60mm stent was chosen based on the length of stenosis and considering at least 1cm of extension at both extremities to prevent migration, being careful to position the stent

below the hilar region (**Figures 4a-b-c, Figure 5**). Following stent placement, we observed immediate biliary flow following deployment of the WallFlex Biliary RX Fully Covered Stent. The patient was discharged 48 hours later, with antibiotic therapy for five days in order to prevent cholecystitis and improved liver function test results.

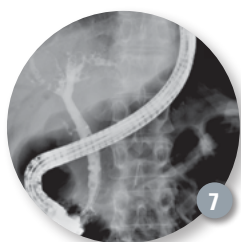
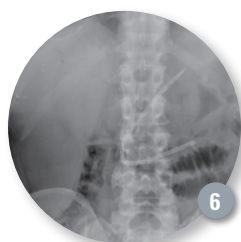
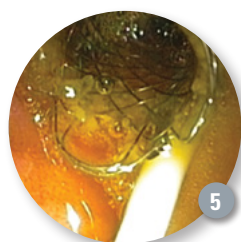
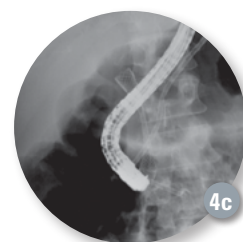
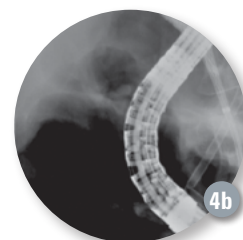
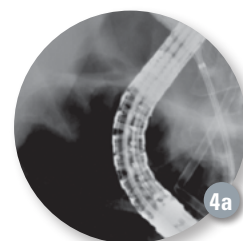
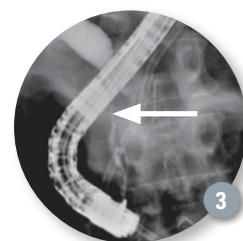
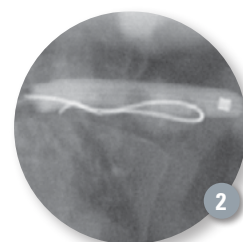
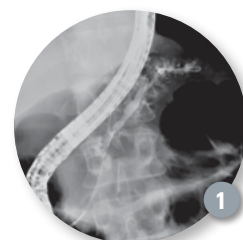
OUTCOME

Six months after stent implantation, the patient was scheduled for removal. Blood chemistry was normal. An abdominal x-ray was taken of the bile duct, which showed that the covered biliary stent was still in place and well positioned despite the partial migration of the plastic pancreatic stent into the duodenum (**Figure 6**). Both stents were removed and occlusive retrograde cholangiography indicated that the biliary stricture was resolved (**Figure 7**). Main pancreatic duct contrast injection was achieved and showed improvement of the duct stricture. Nevertheless, a second plastic pancreatic stent placement was performed for another period of six months. At the time of pancreatic stent removal (one year since first ERCP), the common bile duct was free of stenosis. At 18-month follow-up, the patient is doing well, is completely asymptomatic and liver function tests are normal.

CONCLUSION

In conclusion, use of the WallFlex Biliary RX Fully Covered Stent System RMV can be a successful therapy option for management of benign biliary strictures secondary to chronic pancreatitis. It is a valid alternative to multiple plastic stenting and surgery.

Migration may occur spontaneously and can be treated by delivering longer stents; however, particular attention should also be paid during stent deployment to avoid obstruction of hilum biliary side branches.



[Learn about this device.](#)

Providing a Definitive Diagnosis of Cholangiocarcinoma for a Patient Who Underwent Four Failed Diagnostic Tests



CASE PRESENTED BY:
FARHOUD KHOSRAVI, D.O.

Advanced Endoscopy
Fellow, Arizona Center
for Digestive Health
Gilbert, Arizona, USA



MANKANWAL SINGH SACHDEV, M.D.

Medical Director
Endoscopy, St. Joseph's
Hospital, Phoenix,
Arizona Center for
Digestive Health, Asst.
Professor of Medicine
Creighton University
Gilbert, Arizona, USA



ANANYA DAS, M.D., FACC, FASGE

Chair, Gastroenterology
St. Joseph's Hospital
and Medical Center
Professor of Medicine
Creighton University
Dir. Arizona Center for
Digestive Health
Gilbert, Arizona, USA

PATIENT HISTORY AND ASSESSMENT

A 64-year-old female presented with jaundice, chills and progressive fatigue. The patient was well until three months earlier when she was diagnosed with a hilar mass, causing suspicion of cholangiocarcinoma. An ERCP at that time revealed right and left hepatic duct strictures (**Figure 1**). She was successfully decompressed with the placement of two plastic biliary stents into the left and right hepatic systems. She then underwent an extensive work-up including biliary brushings via ERCP, two EUS procedures with FNA, and an exploratory laparotomy with hepatic wedge resection of suspected metastatic disease. Unfortunately, pathology from the above examinations failed to yield a diagnosis. Given the suspicion for cholangitis, an ERCP was recommended for biliary decompression via stent removal. In addition, cholangioscopy with biopsy using the SpyGlass™ DS System and SpyBite™ Biopsy Forceps was recommended to aid in establishing a diagnosis.

PROCEDURE

An ERCP was performed and two occluded biliary plastic stents were noted with no bile flow into the duodenum. The stents were removed and deep cannulation of the CBD into the right hepatic duct was achieved over an 0.035" guidewire using a sphincterotome. Once the wire was in place, a retrieval balloon was used and copious purulent fluid was drained from the bile duct. Next, a cholangiogram was performed (**Figure 1**), which revealed a 15mm stricture of the right hepatic duct and a very tight ~15mm stricture of the left hepatic duct. At this point, the balloon was exchanged for the SpyGlass DS System's SpyScope™ DS Access and Delivery Catheter, which was

used to directly examine the right and left hepatic duct strictures. The right hepatic stricture was easier to access and revealed significant narrowing, loss of vascular pattern with congested, erythematous and friable mucosa (**Figure 2**). Next, the SpyBite Biopsy Forceps were introduced and a direct biopsy of the right hepatic stricture was performed. The patient was then decompressed with successful placement of a 10Fr x 12cm Advanix™ Biliary Stent into the right hepatic duct and a 7Fr x 15cm Advanix Biliary Stent into the left hepatic duct (**Figure 3**).

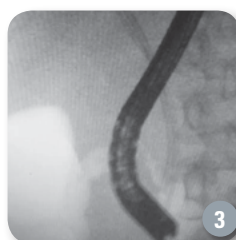
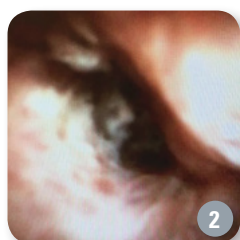
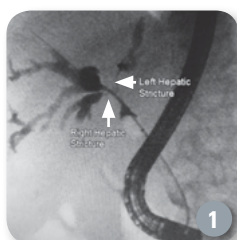
POST-PROCEDURE

The patient did very well and did not experience any complications. Her liver biochemistry completely normalized within four days, and her jaundice and fever were resolved. Biopsies of the right hepatic duct stricture taken under direct visualization with SpyBite™ Biopsy Forceps confirmed adenocarcinoma, consistent with cholangiocarcinoma.

DISCUSSION

This case demonstrates the utility of the SpyGlass™ DS System using SpyBite Biopsy Forceps in achieving tissue diagnosis in an otherwise elusive case. The patient underwent four modalities (biliary brushing, two EUS with FNA and exploratory laparotomy) for obtaining tissue from this hilar mass prior to our examination, all of which were non-diagnostic. **Fortunately, the SpyGlass DS System with SpyBite Biopsy Forceps helped provide a definitive diagnosis and helped provide her oncologic management.**

(Continued on next page.)



[▶ Learn about the SpyGlass DS System.](#)

Potential Economic Impact (U.S. Only) of the SpyGlass DS System

Earlier use of the SpyGlass™ DS System may have helped to avoid an exploratory laparotomy with hepatic wedge resection, potentially saving the hospital system \$20,111 in surgical costs.

ICD-9 Principal Procedure Code	Code Description	Costs, \$ (median)
50.22	Partial hepatectomy	\$20,111

Source: 2013 HCUP National Inpatient (NIS)- all payer inpatient health care database in the United States

Earlier use of the SpyGlass DS System may have helped to avoid several outpatient procedures costing between \$1,689 and \$2,187.*

CPT® Code	Code Description	2015 Medicare Geometric Mean Cost - Outpatient
43260	Endoscopic retrograde cholangiopancreatography (ERCP); diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	\$2,187
43242	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/ biopsy(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)	\$1,689

***Source:** Medicare's CY 2017 OPPS Cost Statistic File

The potential economic impact identified in this case only takes into account surgical and/or procedural costs avoided and does not take into account reimbursement.

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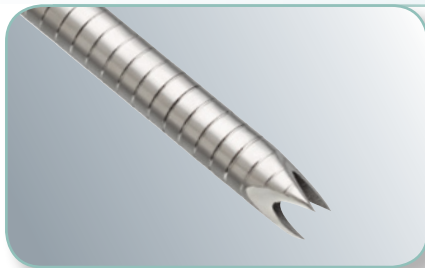
News and New Devices

➤ Boston Scientific Opens New Physician Training Facility in India

In March, Boston Scientific opened the Institute for Advancing Science (IAS) in Gurugram, India. The new facility will allow Boston Scientific to provide more in-depth training to a greater number of healthcare professionals in the region. The facility is equipped with simulators for hands-on training of devices, new technologies and procedures. The facility will also be home to Boston Scientific employees focused on innovation and product development. This is the ninth IAS facility, with others located in the U.S., China, France, Japan, South Africa and Turkey. For details, visit the About Us section of www.bostonscientific.com.



➤ See the complete list of IAS facilities.



➤ Learn more.

➤ The new **Acquire™ Endoscopic Ultrasound Fine Needle Biopsy Device** is designed to obtain larger tissue specimens. More than half of gastroenterologists surveyed agreed that a larger tissue sample would give them greater confidence that the samples obtained have the potential to improve diagnostic yield and may be sufficient to support further oncology research.* The Acquire FNB Device has the following features:

- **High-quality cutting surfaces** that allow for a circumferential cut
- **Three points** that provide stability at puncture
- **Echogenicity** that allows for visibility of the needle under EUS
- **Construction** with highly durable cobalt chromium material

The needle is made from cobalt chromium, a durable material, offering the potential for using fewer needles when more samples or more passes are required. This could potentially save the hospital material costs within the procedure.

*Data on file: PDM

For product information visit www.bostonscientific.com/gastro
For services and solutions visit www.bostonscientific.com/gastroservices

Information Related to the WallFlex™ Biliary RX Fully Covered Stent System RMV:

Warning: Use caution when placing stent near ductal branches to avoid obstruction of duct. Placement of a fully covered biliary stent across a branch duct or major bifurcation may result in complications due to blockage of flow from the branch duct and prevent endoscopic or transhepatic access for future procedures.

Warning: The safety and effectiveness of the stent for benign stricture treatment has not been established for indwell periods exceeding 12 months.

Information related to the WallFlex Biliary Stents.

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

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