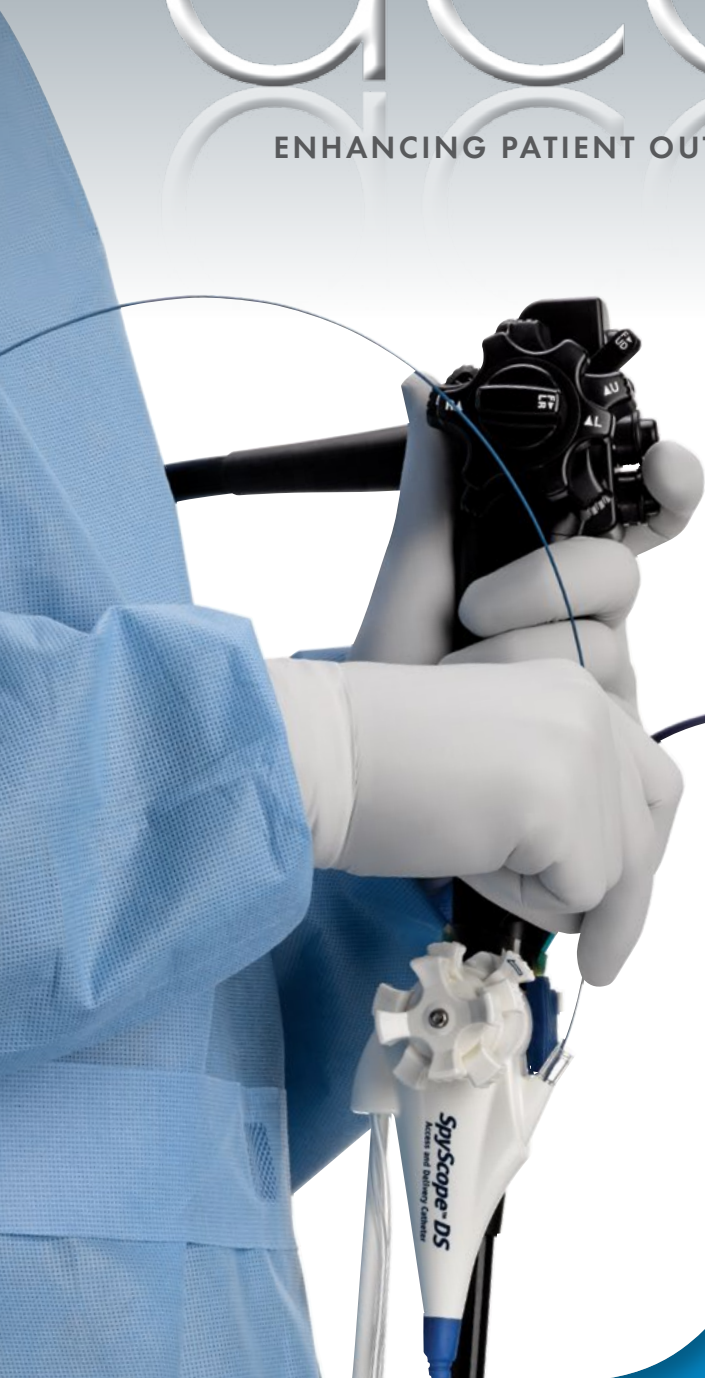


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Close the Gap

Employees Wear Blue
in Support of
Colon Cancer Awareness



A Message From Art Butcher

To say the field of healthcare is undergoing significant change is a major understatement. Around the world, healthcare providers are reassessing their care delivery models and cost structures with the common goals of improving outcomes, reducing costs, and simultaneously increasing access to care for patients. We share those goals. Today, our customers are taking a more holistic approach to healthcare and to every aspect of the care continuum. At Boston Scientific, we are focused on improving the quality of patient care by delivering new technologies, new

services, and new approaches to support our customers. More than ever before, we are helping providers deliver a more comprehensive approach to GI patient care.

bosc.endoscopy@bosc_endoscopy Mar 3
Boston Scientific employees around the world are wearing blue today to support March's [#coloncancerawarenessmonth](#) [#dressinblueday](#)



Tweet featured employees from around the world in support of colon cancer awareness.

To support this comprehensive approach, Boston Scientific acquired EndoChoice, a medical device and diagnostics company headquartered in Alpharetta, Georgia. The addition of EndoChoice

brings new core GI devices, infection control products, and GI-specialized pathology services to our portfolio, providing physicians with treatment options from detection to diagnosis.

Thinking beyond devices, we introduced our ADVANTICS™ Innovative Healthcare Solutions. The goal of ADVANTICS is to work collaboratively with our customers to address their immediate needs and their evolving challenges. A great example is how we worked with Wesley Hospital in Wichita, Kansas, to help them improve their inventory management and reduce expired products (p. 2).

In response to our ambulatory surgical center customers' desire to improve operations as well as patient satisfaction, we recently introduced the Patient Navigator powered by Vocera®. This pre-arrival patient navigation solution is designed to reduce no-shows, and create an engaging and informative experience for the patient undergoing a colonoscopy or an upper GI endoscopy procedure (p. 10).

Since 2012, our Close the Gap Health Equity for Life programs have engaged patients through awareness, education and access initiatives. We have funded screening colonoscopies for underserved patients, and we've lent our support to numerous colon cancer and pancreatic awareness activities (p. 21). Our donations have funded important research and third-party educational websites such as the [animatedpancreaspatient.com](#) and [youandcolonoscopy.com](#).

Training and development for clinicians is critical to patient care and it has always been a priority for us. Our EDUCARE programs have delivered numerous preceptorships, proctorships and hands-on device training. Our virtual education platforms, including EndoSuite and BronchSuite, are providing on-demand physician lectures, webcasts and more (p. 11). And we are helping fund education through physician societies. In 2016, we made a \$1,000,000 donation to the ASGE in support of the Beyond our Walls campaign to deliver a high-quality virtual training environment anywhere, anytime (p. 11).

The healthcare environment has changed dramatically over the past decade and going forward we can expect that change will only accelerate. Regardless of policies or regional challenges, healthcare is about making a difference and improving patients' lives. Boston Scientific is about advancing science for life and, as healthcare continues to change, we will continue to innovate with our customers to meet their challenges, and partner in their mission to provide better care for patients.

Art Butcher

Senior Vice President, Boston Scientific
President, Endoscopy Division

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Improving Inventory Management Yields More than 'Bottom-line' Results

Wesley Medical Center, a Wichita, Kansas, hospital, took the challenge to minimize expired endoscopy supplies and improve overall inventory management head-on. Working with Boston Scientific, the facility improved their ordering processes and met both goals.



Wesley Medical Center, Wichita, Kansas.
Photo provided by Wesley Hospital.

THE 700-BED WESLEY MEDICAL CENTER in Wichita, Kansas, is growing and currently building a children's hospital. The facility treats 24,000 patients each year. It boasts a rich century-plus old history, and this year entered its fourth decade as a Healthcare Corporation of America (HCA) hospital. The facility's endoscopy department performs 400 to 500 procedures each month, mainly outpatient.

As such, the facility does not have time, bandwidth or budget to allow for expired endoscopy supplies, or to carry nearly \$200,000 worth of endoscopy inventory at any given time to avoid supply shortages.

Assistant Nurse Manager Lindy Clingan, in the endoscopy department, decided to take on a new supply chain workflow that moved the process from paper to digital. In addition, Clingan consolidated the endoscopy department's ordering processes and inventory tracking. By doing so, the department decreased the total number of orders and reduced inventory on hand from roughly \$180,000 to \$120,000. Wesley Hospital expects to see more reductions to come as the new workflow process tracks more closely the ordering and use of endoscopy supplies.

IMPROVING SUPPLY CHAIN IMPACTS PATIENT CARE

The genesis of Wesley's endoscopy supply chain process improvements came out of conversations between Boston Scientific account representative Jonathan Gutierrez and the endoscopy staff last year, in which he heard complaints about expired inventory ranging from inexpensive supplies up to higher-cost medical devices. They were overstocked on some items, running out of others, and making do with substitute items at times.

Gutierrez and Clingan collaborated late in 2015 through early 2016 on the project. As a first step, Boston Scientific worked with a third-party to conduct an initial count of Boston Scientific endoscopy products. From the inventory count, order history data and knowing what items frequently run low, Boston Scientific was able to recommend "par levels" for each category of Boston Scientific products ordered. The par levels were then used to determine order amounts for each supply based on procedure mix estimates. Going forward, weekly counts are necessary to determine order quantities and track expirations.

Clingan went on to implement additional streamlining of ordering processes to the point where Wesley has now halved its number of orders per week.

“It's not just the hospital's bottom line that benefits from projects like these,” Clingan explained. “Having the right supplies at the right time in the workflow directly impacts patient care and satisfaction. When substitute supplies aren't being used or procedures don't have to be rescheduled due to lack of on-hand supplies, patients get the best experience possible. It also helps increase staff efficiency and satisfaction, because they're not hunting through expired product to find one that's usable for the next patient case.”



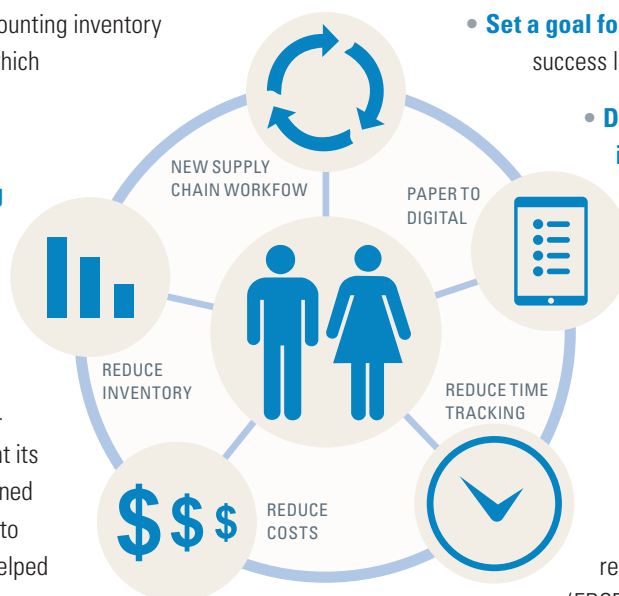
“You don’t realize, until you don’t have to do inventory counts anymore, how much time it takes,” Clingan said, who now relies on Boston Scientific to do the counting of Boston Scientific products. “With that type of support, department managers should be able to implement this type of workflow process in any facility.”

REPLICATING INVENTORY PROCESSES FOR IMPROVEMENTS IN YOUR DEPARTMENT

The improvements have made such an impact that Clingan reports the endoscopy inventory project may be replicated at other HCA hospitals. Facilities outside the HCA network can also benefit from examining their endoscopy ordering processes. Clingan offers a few tips to get started:

- **Get your vendors involved** in counting inventory and checking for expired items, which reduces staff overhead and frees up time for patient care.

- **Show the hospital accrediting organization The Joint Commission** – whose surveys determine whether or not you can take Medicare patients – what you’re doing. In the midst of the endoscopy inventory management makeover, Wesley underwent its accreditation survey. Clingan outlined to surveyors what she was doing to improve her department, which helped earn high marks.



- **Set a goal for improvement**, so you know what success looks like.

- **Divide and conquer unwieldy inventory and ordering processes**

by assigning different categories of supplies or subspecialty supplies to different staffers within the department, and making them accountable for items in stock, expired or out of stock. In Clingan’s department, that means one nurse handles pulmonary supplies, another takes care of general supplies, another endoscopic retrograde cholangiopancreatography (ERCP), etc.

When a product expires, not only is that a loss, but the department has to order a replacement and pay for it, too. Stopping instances of expired product becomes a powerful tool to stem department costs, explained a member of the Boston Scientific Endoscopy services and solutions team.

Interested in learning more about how Boston Scientific can help your department avoid expired supplies and better manage overall inventory? Email us at endoscopysolutions@bsci.com.

Transforming Biliary Stone Management

➤ [View this case on Endosuite.com](#)

CASE STUDY

Managing a Difficult Cystic Duct Stone (Mirizzi Syndrome) Using Cholangioscopy and EHL

Presented by Dr. George Webster,
University College London Hospitals, London, U.K.

A 58-year-old patient underwent a previous ERCP and bile duct stone clearance. She also underwent uncomplicated laparoscopic cholecystectomy, but represented with further jaundice three months later. An MRCP confirmed a dilated biliary tree down to an obstructing 8mm stone in the lower duct. Despite undergoing two additional ERCP procedures, the stone could not be removed.

The patient was then referred for ERCP with cholangioscopy. Direct visualization using the SpyGlass™ DS System confirmed that the stone was entirely within the distal cystic duct, explaining the difficulty of stone removal with conventional ERCP. Using electrohydraulic lithotripsy (EHL) the stone was fragmented during a single session and the fragments removed with flushing and subsequent balloon trawls.

The patient did well post-procedure, experiencing no further problems with biliary obstruction.

Endoscopic retrograde cholangiopancreatography (ERCP) with basket or balloon extraction is often used for the initial treatment of most bile duct stones, with **more than 1 million people worldwide undergoing ERCP procedures annually**. While stones can be removed with standard ERCP techniques, approximately ten to fifteen percent are considered difficult and cannot be treated effectively.¹ An obstructed duct left untreated may result in significant infection, particularly in the elderly.²

ELECTROHYDRAULIC LITHOTRIPSY (EHL) is one option to remove these difficult stones. The American Society of Gastrointestinal Endoscopy finds EHL not only to be effective, “but relatively inexpensive” compared to other modalities, such as laser lithotripsy.³ The EHL catheter must be passed through a cholangioscope for effective direct visualization and treatment. The SpyGlass DS System is used in an increasing number of EHL procedures, further enabling an increased stone clearance success rate in a single session.¹

THE SPYGLASS DS SYSTEM AND EHL IN PRACTICE

Dr. George Webster of University College London Hospitals (UCLH) in the United Kingdom has been using the SpyGlass System with EHL for stone management since 2007. He treats patients referred from a large region throughout and outside the city who have difficult-to-treat biliary stones. “Since obtaining the SpyGlass DS System,” said Dr. Webster, “EHL referrals have increased 70 to 80 percent.”

“By the time we see patients, nearly all have already undergone at least one, if not more, ERCPs,” he said. In fact, a multi-center, Boston Scientific-sponsored registry demonstrated that 86 percent of patients undergoing an EHL procedure using the SpyGlass System had a previous ERCP, and one-third of those had more than three previous ERCPs.¹

“We typically use the SpyGlass DS System with EHL for patients who have stones above strictures, Mirizzi Syndrome, stones in the intrahepatic ducts, and stones larger than 15 mm,” Dr. Webster said. “I am an advocate for the technique and the benefits it offers. It is a highly effective advancement in the management of particularly large and difficult-to-treat stones without having to perform multiple procedures. That is a great value to both the patient and hospital systems.”





Boston Scientific and Northgate Technologies

Despite the fact that EHL is an effective option for treating difficult stones,⁴ many hospitals around the world using the SpyGlass™ DS System have not had an EHL solution widely available to them.

That should change given the recent co-exclusive agreement between Boston Scientific and Northgate Technologies to distribute the Autolith™ Touch EHL System and EHL accessories designed for use with the SpyGlass DS System.

The Autolith Touch EHL System and accessories may now be ordered directly from Boston Scientific sales representatives or distributors, delivering a more efficient ordering process and expanded options for cholangioscopy and stone management.

Srinadh Komanduri, M.D., who practices at Northwestern University in Chicago, typically uses ERCP with papillary balloon dilation as a first-line treatment for patients with difficult-to-remove stones. If that fails, either due to the size of the stone or the angulation of the bile duct, cholangioscopy using the SpyGlass DS System with EHL is often performed next. "Cholangioscopy with EHL has nearly replaced mechanical lithotripsy in my practice given its effectiveness and ease of use," said Dr. Komanduri.

“The ability to better visualize the biliary duct and the extent of the stone burden with the SpyGlass DS System during EHL is critical,” said **Dr. Komanduri**. “The ease and use of the SpyGlass DS System helps makes it a much faster and more efficient procedure.”

“The success of EHL also helps avoid surgery for difficult stones which cannot be removed by standard ERCP techniques,” Dr. Komanduri continued. “That’s why it is so high in our stone management algorithm. It is clearly effective, and it’s rare that the patient requires another procedure.” In fact, data shows that direct visualization and stone clearance with EHL has a demonstrated procedural success in 90% of patients, with single-session stone clearance rates of 76%.³

The ability to reduce the need for repeat procedures, said Drs. Webster and Komanduri, may help provide greater patient satisfaction as well as help reduce costs for hospitals and payers.

“If, as is often the case with the SpyGlass DS System using EHL, it results in a high rate of stone clearance with one procedure, then clearly there is a good argument to say if that if the procedure had been performed earlier, there may have been significant cost savings,” said **Dr. Webster**.

References:

- 1) Chen YK, Parsi MA, Binmoeller KF, et al. Single-operator cholangioscopy in patients requiring evaluation of bile duct disease or therapy of biliary stones (with videos). *Gastrointest Endosc*. 2011;74(4):805-814.
- 2) Trikudanathan G, Navaneethan U, Parsi MA. Endoscopic management of difficult common bile duct stones. *World J Gastroenterol*. 2013;19(2):165-173.
- 3) American Society for Gastrointestinal Endoscopy. *Biliary and pancreatic lithotripsy devices, ASGE technology status evaluation report*. 2007.
- 4) American Society for Gastrointestinal Endoscopy. *ASGE Endoscopic Operations Trends*. 2013.



AN INTERVIEW WITH

*Bob Kwech, Executive Director, GI Associates & Legislative Committee Chair,
Association of Wisconsin Surgery Centers.*

Endoscopy Procedures at ASCs: **How Times Have Changed**

Q How would you say the ambulatory surgical center (ASC) landscape has changed in the past several years?

Nationwide, there has been significant growth in ambulatory care. We are seeing this growth because, oftentimes, we're able to provide higher-quality care at a lower cost, and with a better patient experience.

Surgery centers offer a very efficient model. Operating expenses are typically lower than many acute care facilities, therefore, we're able to charge less for procedures conducted in the ASC. The federal government reimburses ASCs 50% of what they reimburse a hospital for the same service. Procedures at an ASC cost between **33 to 50% less than at a hospital**, in part because we are specialized in the services we offer.

Q Describe the focus on and increase in endoscopy / colonoscopy procedures at ASCs.

Having these procedures done in an ASC setting is a more positive experience for both the patient and the family member or care provider responsible for transporting the patient. For example, in an ASC setting, colonoscopy patients need to arrive 30 minutes prior to the scheduled procedure time and will be done within a two-hour time frame. When this procedure is done at a hospital, the patient must arrive 1.5 hours before the treatment is scheduled, and the recovery times are longer due to the discharge process. This means the hospital procedure is approximately two hours longer than the same procedure performed at an ASC.

With advances in technology and devices now available, over 90% of GI procedures can be done in an ASC setting. For otherwise healthy adults not at risk for comorbidities, an ASC setting is much more efficient and provides a better overall patient experience.

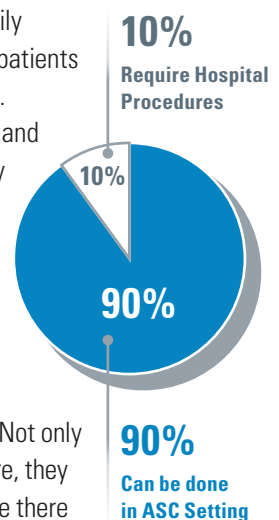
Having a GI-specific approach enables us to improve communication among our team of nurses, physicians and administrators, and we are able to have better communication with the patients before and after the procedure. Not only do we get them in and out in a shorter amount of time, but we make sure they are fully prepared for the procedure, they know how to check in, and we follow up with them post-procedure to answer any questions they have and ensure there are no issues. By being more efficient with our patients and making sure they are prepped for the procedure, we lower our cancellation and no-show rates, therefore lowering our overall costs savings, which ultimately get passed on to the patients.

Q What role can a supplier play in helping an ASC achieve its goals?

For years now, we've been talking with Boston Scientific, among other organizations, about transforming from a supplier/vendor transactional arrangement to a truly collaborative relationship.

What we've come to realize is that it's not just about the unit cost. All centers are under pressure to lower the cost of care, so you have to find ways to evaluate the total cost of care and use equipment to get the best outcome at the right cost. Boston Scientific really serves as a listener and partner on the front lines in the delivery of patient care.

For example, when you consider the effective use of a technology, you take input from physicians on the front lines and consider all aspects of the patient experience including wait time, sedation, pathology workload, etc. It's important to collaborate to understand the full scope of how a technology is being used and the ripple effects. When you do that, you find ways to improve outcomes for the patient and lower the total cost of care.



Dr. Jeremy S. Miller, Pathology Medical Director at Boston Scientific, specializes in GI pathology in Alpharetta, Georgia.

Dr. Miller has over 14 years of experience in the field of medicine. He graduated from the Medical College of Georgia with his medical degree in 2003, and completed fellowships in both gastrointestinal and genitourinary surgical pathology from Ameripath and Johns Hopkins Hospital, respectively.



Sessile Serrated Adenomas: The Role of the GI Pathologist

The majority of sporadically arising colorectal cancers develop through the adenoma pathway, beginning as tubular adenomas, progressing to pre-cancers before becoming metastatic. This process underlies current recommendations for screening colonoscopies, which have dramatically reduced the incidence of colorectal cancers.¹

However, approximately a third of sporadic cancers arise without any precursor adenomas, developing through the serrated pathway. Research in the past decade has identified molecular changes in certain colonic lesions that provide a surrogate marker for patients at risk for these cancers. These lesions have traditionally been grouped as hyperplastic polyps (HPP), but are now recognized as histologically and genetically unique, and identified as HPPs, sessile serrated adenomas (SSAs), or traditional serrated adenomas (TSAs).²

Sessile serrated adenomas tend to be larger than HPPs, (often >9mm) are typically located in the proximal colon; are more likely to arise in women, and exhibit a mucinous cap. They can significantly increase the risk of colorectal cancer.^{2,3}

“However, they are often misdiagnosed as HPPs by pathologists who remain unaware or uncertain of the differences between SSAs and HPPs”

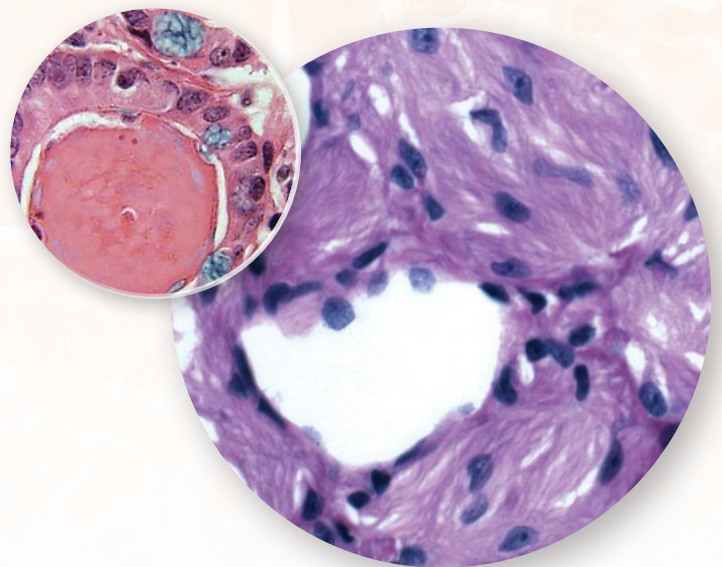
— **Jeremy S. Miller, MD,**
Director of Pathology Services at Boston Scientific

An internet survey of 168 pathologists found considerable variability in the diagnosis of 20 colorectal polyps provided on three representative images, including HPPs, TSAs, SSAs and tubulovillous adenomas (TVAs). About a third (34.5%) of the SSAs were diagnosed correctly, with GI-trained pathologists and fellows exhibiting the greatest accuracy.⁴

“The accurate diagnosis of serrated precursor lesions affects surveillance and management of the patient and thus requires consistent classification in the pathology lab,”
Dr. Miller stressed.

“Misdiagnosing an SSA may expose the patient to an increased risk of a malignancy, although the extent of that risk is not clear,” Miller continued. “Patients with two or fewer HPPs are considered low risk for cancer and given a 10-year interval between screenings. Current guidelines, however, recommend screening patients with an SSA <10 mm with no dysplasia every five years, and those with an SSA ≥10 mm or associated with dysplasia every three years.”⁵

“The potential clinical risk associated with a missed diagnosis is that if the patient doesn’t get a correct diagnosis, they have a 10-year wait for rescreening versus a five-year interval,” said Miller. “While some clinicians may rescreen patients with a diagnosed HPP that they suspect is an SSA, they may run into insurance issues because it differs from the standard of care and clinical guidelines.” Miller explained, “It is incumbent on the GI pathologist to diagnosis the polyp appropriately so it can be followed up appropriately.”



References:

- 1) American Cancer Society. Cancer Facts and Figures 2015.
- 2) Rosty C, Hewett DG, Brown IS, Leggett BA, Whitehall VL. Serrated polyps of the large intestine: current understanding of diagnosis, pathogenesis, and clinical management. J Gastroenterol. 2013;48(3):287-302.
- 3) Hiraoka S, Kato J, Fujiki S, et al. The presence of large serrated polyps increases risk for colorectal cancer. Gastroenterology. 2010;139(5):1503-1510. e1501-1503.
- 4) Glatz K, Pritt B, Glatz D, Hartmann A, O'Brien MJ, Blaszyk H. A multinational, internet-based assessment of observer variability in the diagnosis of serrated colorectal polyps. Am J Clin Pathol. 2007;127(6):938-945.
- 5) Lieberman DA, Rex DK, Winawer SJ, Giardiello FM, Johnson DA, Levin TR. Guidelines for colonoscopy surveillance after screening and polypectomy: a consensus update by the US Multi-Society Task Force on Colorectal Cancer. Gastroenterology. 2012;143(3):844-857.

Endoscopy Stent Tracker App for the AXIOS™ Stent

Assists Physicians with Tracking Patients

➤ Download the app from Google Play, the Apple Store or www.visiblehealth.com.

The new Endoscopy Stent Tracker app, developed through a partnership between Boston Scientific and Visible Health, Inc., supplements the current medical record-keeping process used for monitoring patients with an AXIOS Stent. Monitoring patients who have indwelling AXIOS stents is not an easy task for a busy practice. Each patient has their own treatment plan for AXIOS Stent placement and removal, and this plan can be fluid. It can be a time-consuming, labor-intensive task for clinicians and staff monitoring patients with stents to ensure they are removed upon resolution of the pseudocyst or walled-off Necrosis ($\geq 70\%$ fluid content).



"We worry about stents being left in place for too long, because as the cavity collapses it can come in contact with the stent. With time, the stent can abrade the adjacent wall and may be associated with delayed bleeding," said Dr. Christopher Thompson, director of therapeutic endoscopy at Brigham & Women's Hospital, associate professor at Harvard Medical School. "As such, we had concerns regarding patient monitoring and the potential for delay in scheduling follow-up procedures."

Boston Scientific has developed the Endoscopy Stent Tracker to provide a more convenient tool for stent tracking of the AXIOS Stent, which is now available to AXIOS physician customers. The Endoscopy Stent Tracker app was developed using feedback from physicians, including Dr. Thompson, to help address some of the challenges associated with tracking patients. The Endoscopy Stent Tracker app for the AXIOS Stent is HIPAA-compliant and can be used on Android and iPhone platforms.

"The app has helped my team tremendously. The app is a consolidated information source accessible to our entire care team at any time, which assists in the development of a timely and appropriate plan for a patient's AXIOS Stent removal," said Dr. Thompson. "The Endoscopy Stent Tracker app is well organized and helps my staff to efficiently schedule, prioritize and adjust cases as needed. Before, despite having a state-of-the-art electronic medical record, we didn't have this kind of detailed visibility into patient records at our fingertips."

In addition to improving scheduling efficiencies, the Endoscopy Stent Tracker app for the AXIOS Stent helps standardize data collection and automate the export process into files for easy analysis. Dr. Thompson explained, "The app is easy to use and provides a comprehensive view of all indwelling AXIOS stents, which supports my clinical research by providing structured data options for analysis."

The Endoscopy Stent Tracker app is now available for download and use to track indwelling AXIOS stents. In the future, Boston Scientific intends to expand the app's functionality, where appropriate, to include the tracking of patients with Boston Scientific fully covered biliary metal stents and plastic stents.

To access the Endoscopy Stent Tracker for the AXIOS Stent, download the app from the App Store, and send an email to: endostenttracker@bsci.com to request an account.

To learn more about therapeutic EUS and to watch programs and cases, please visit www.EndoSuite.com.

US: The AXIOS Stent is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6 cm in size, and symptomatic Walled Off Necrosis ≥ 6 cm in size, with $\geq 70\%$ fluid content, that are adherent to the gastric or bowel wall. Once placed, the AXIOS stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst or Walled Off Necrosis resolution.

EU: The Hot AXIOS Stent and Electrocautery Enhanced Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of a pancreatic pseudocyst, walled-off necrosis ($\geq 70\%$ fluid content) or the biliary tract.

The Boston Scientific Endoscopy Stent Tracker is a supplemental informational tool that does not substitute for or replace existing patient record keeping by the physician. The Boston Scientific Endoscopy Stent Tracker does not constitute professional medical recommendations, treatment, or advice. It is not intended to be used to diagnose, cure, treat, or prevent any condition or disease.

Q&A with Michael Cangelosi

Cost-effectiveness of Initial Placement of Metal Biliary Stents in Pancreatic Cancer Patients with Obstructive Jaundice

Learn about stricture management on EndoSuite.com.



About Michael Cangelosi

Michael Cangelosi joined the Boston Scientific Health Economics and Market Access (HEMA) team in 2014. He is currently on staff with Boston Scientific HEMA Center of Excellence, and has published several manuscripts and abstracts articulating the projected, estimated economic benefits of several Boston Scientific projects and products.

How did you and the other authors assess the need to perform a cost-effectiveness analysis of placing biliary metal stents versus biliary plastic stents in metastatic pancreatic cancer patients with biliary obstruction?

Treating pancreatic cancer is an incredibly large cost burden on the U.S. healthcare system. The ASGE and ESGE both recommend the placement of biliary metal stents for pancreatic cancer patients experiencing jaundice, and who are expected to live beyond six months. While we also know that biliary metal stents have clinical benefits to the patient, we were unsure of the savings that could be anticipated by placing metal versus plastic stents.

As providers move to a more value-centric framework, in some instances considering benefits in a lump sum payment for pancreatic cancer treatment, they realized the potential increase in healthcare costs related to having to replace plastic stents over time, along with subsequent costs that may arise from complications stemming from those procedures. All of these costs are today considered by all payers, and will be in the near-future by more providers as they pivot to value-based care systems. These broader trends, combined with the unanswered questions around the degree of the potential cost savings of placing biliary metal stents, led to this study. We wanted to better understand these savings.

Please describe the method used in this study.

We used the Markov cohort model to estimate the projected lifetime costs, quality-adjusted life years, and the overall cost-effectiveness of metal biliary stents compared with plastic biliary stents. We looked at a hypothetical patient on their treatment path to see how they would flow through the healthcare system, and the anticipated costs, quality of life, and potential adverse events that could take place. We ran the model based on the best available evidence from a detailed and highly targeted literature search; this data describes each point through the healthcare system to determine the cost-effectiveness.

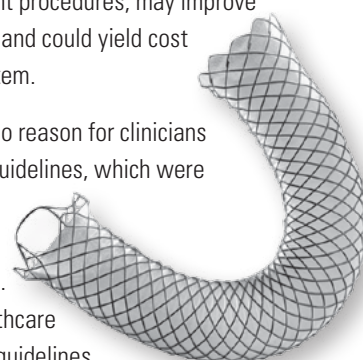
Please describe the results of the study.

The model estimated that newly diagnosed, locally advanced pancreatic carcinoma patients with initial placement of biliary metal stents saved \$1,453 in total costs over a lifetime when compared with patients who initially received plastic stents. The delta of cost savings between metal and plastic stents is small compared with the total cost of overall cancer care, but the quality-adjusted life months and number of stent replacement procedures yield the more significant savings. Even with the advances in the patency of plastic stents, they are often replaced after about three months. The data showed that fully covered biliary metal stents will be replaced on average 1.4 times over the course of a life versus just over 2.8 times for biliary plastic stents. This essentially avoids an average of 1.5 procedures per patient, which may be correlated to improved quality-adjusted life. These results indicate that when clinicians follow the ASGE and ESGE guidelines, they can be assured that they are providing the highest standard of care and may help to enhance their patients' quality of life.

What implications do these results have for physicians, payers and patients?

The results demonstrate that placement of metal biliary stents, rather than plastic biliary stents, at the onset of obstructive jaundice in patients with locally advanced pancreatic carcinoma may help to reduce the need for stent-replacement procedures, may improve overall and quality-adjusted survival, and could yield cost savings to the overall healthcare system.

These findings suggest that there is no reason for clinicians not to espouse the ASGE and ESGE guidelines, which were developed using the best available evidence demonstrating the clinical benefit of placing biliary metal stents. There are benefits to the overall healthcare system when clinicians follow these guidelines.



See back cover for Warnings and information.

Focus on the Overall Experience is *Key to Improving Patient Satisfaction*

Patient satisfaction is an increasingly important metric for hospitals and ambulatory surgical centers (ASCs). By 2018, ASCs will have to meet patient satisfaction quality measures that will have a direct impact on Medicare reimbursement.¹ Based on robust voice-of-customer interviews by Boston Scientific with administrators from ASCs across the country, it was clear that the patient experience was beginning to play an increasingly important role in how ASCs are doing business.²



In particular, for ASCs performing screening colonoscopies that require preparation ahead of time by the patient, there are clear challenges.

SOME OF THE ISSUES INCLUDE PATIENTS WHO

- ▶ **Neglect to stop taking medications**
- ▶ **Don't start their bowel prep in time**
- ▶ **Forget to arrange for a ride to and from the procedure**

Not properly engaging or managing a patient could mean a last-minute cancellation or poor preparation, potentially leading to an incomplete or unsuccessful colonoscopy, which could lead to a patient having to schedule another procedure. A 2012 study

conducted at Washington University found that 33% of missed lesions during colonoscopy are due to inadequate bowel preparation.³ These scenarios may negatively impact operations and costs, but also may not make for an overall positive patient experience.

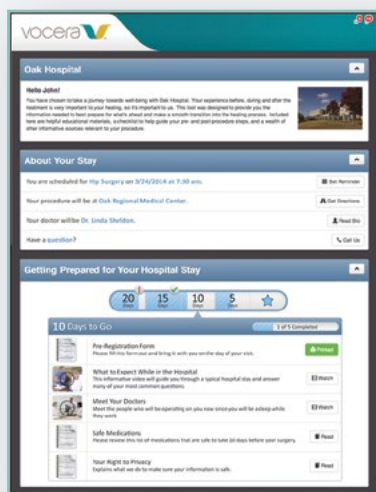
Over time, healthcare providers have come to realize that it is no longer solely about what happens during the procedure. If healthcare providers focus on the overall patient experience, they may find immediate improvements in terms of operational efficiencies and cost savings, as well as opportunities to create long-lasting patient relationships.

1) Data calculated by BSC project team.

2) Source: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ASC-Quality-Reporting/>

3) Poor colonoscopy prep hides pre-cancerous polyps, March 26, 2012, Jim Dryden, Washington University in St. Louis

A NEW APPROACH TO ENHANCING PRE-ARRIVAL PROCEDURE PREP



Vocera HIPPA-secure web portal

Limited availability in 2017. For U.S. customers only.

Boston Scientific recently introduced the Patient Navigator powered by Vocera® to help ambulatory surgical centers (ASCs) better manage pre-arrival procedure preparation with patients. Using their HIPPA-secure web portal, healthcare providers can communicate and interact with patients prior to a scheduled procedure.

Different from other systems that simply automate reminder phone calls or text messages, the Patient Navigator powered by Vocera provides patients with a 24/7 portal for instructions specific to their medical needs, along with in-depth educational videos and other day-of-visit information. In addition, a patient can read about the ASC's clinical and administrative personnel, allowing them to get to know the staff ahead of time.

Staff members are able to see if patients are utilizing the portal information, allowing them to determine if additional patient outreach and support are needed. The Patient Navigator is designed to improve operational efficiencies, reduce costs, and create a more satisfying experience for the patient.

EndoSuite Update:

New Section on Hemostasis Added

Visit EndoSuite.com

As part of its ongoing commitment to training and education, Boston Scientific has launched a new disease management area on EndoSuite.com focused on hemostasis and managing gastrointestinal (GI) bleeds.

"If you ask any gastroenterologist, GI bleeding is the number-one emergency that we deal with on a daily basis. Successfully managing GI bleeding endoscopically is the number-one lifesaving intervention that we have to offer within GI endoscopy," explained Dr. Tyler Berzin, Beth Israel Deaconess Medical Center, Boston, Massachusetts.

In today's fast-paced environment, **78% of physicians surveyed say they value having 24/7 access** to educational videos.*

Access to important educational information at the point of care, is extremely valuable. The new section within EndoSuite.com will focus on various causes and treatment options for GI bleeding, including didactic lectures from Dr. David Carr-Locke, Beth Israel Medical Center, New York, N.Y., and Dr. Tyler Berzin, among others.

Launched in 2016, EndoSuite.com provides access to over 70 physician-led educational videos from virtually any laptop or mobile device. In its first year, over 30,000 visitors came to EndoSuite.com to learn from experts in GI disease management through lectures

and panel discussions, case reports and procedural techniques, clinical research updates, and device training videos. Physicians may also register for upcoming webcasts and to receive updates on our in-person and virtual education programs.

Content is continually being updated. In addition to hemostasis, other areas of focus include:

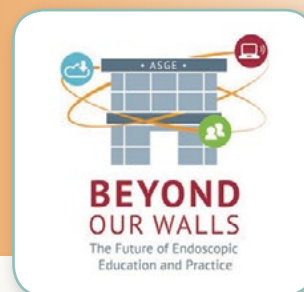
- Procedural and Device Tutorials
- Access and Cannulation
- Diagnostic and Therapeutic Endoscopic Ultrasound
- Stricture Management
- Cholangioscopy
- Stone Management
- Tissue Resection/Endoscopic Mucosal Resection

*Taking the Pulse® U.S. v11.0 Online/phone survey of 2,041 U.S. practicing physicians including gastroenterologists.
- Manhattan Research - Google Physician Channel Adoption Study; Among those watching professional video online, n=285.
- BroadcastMed survey among HCP members, n=315, August 2016.



Donation Supports the Future of Endoscopic Education

Boston Scientific Endoscopy has been a proud corporate partner of the ASGE Foundation for over a decade and was a major sponsor, providing a \$1 million grant to help build the ASGE's state-of-the-art Institute for Training and Technology (IT&T) in Downers Grove, Illinois, that opened its doors in 2013.



Today, Boston Scientific is continuing its long-standing support with another \$1 million pledge as the first sponsor of the ASGE's current fundraising campaign, **Beyond our Walls: The Future of Endoscopic**

Education and Practice. The campaign seeks to build on the success of the IT&T by **delivering clinical education** anywhere through the expansion of online learning programs, providing practical solutions for practice operations to help meet the business challenges of today's healthcare environment, and **focusing on**

innovation and technology by teaching new techniques, technologies and treatments that can improve quality, efficiency and effectiveness.

ASGE President Kenneth R. McQuaid, MD, FASGE thanked Boston Scientific for its support of the campaign and commitment to the field of endoscopy, saying:

"We are incredibly grateful to Boston Scientific for this very generous donation. It is such a gratifying demonstration of the value placed on high-quality, cutting-edge education, and training, and practice-improvement resources for the GI community."

Global Perspectives on User Experience of Acquire™ Endoscopic Ultrasound Fine Needle Biopsy Device

▶ Learn more about the Acquire Needle.

The Acquire Endoscopic Ultrasound (EUS) Fine Needle Biopsy (FNB) Device may allow physicians to procure larger tissue specimens in a more efficient manner, even in cases where fine needle aspiration (FNA) may not have been successful before. The Franseen needle tip design of the Acquire EUS-FNB Device is an optimized, proven solution to procure larger tissue specimens for histological analysis based on 50 years of clinical use in interventional radiology. The three points are designed to provide stability at puncture, while the fully formed heels are designed to maximize tissue capture and minimize fragmentation, which may result in improved diagnostic yield and specimen adequacy to support oncology research. This is a global perspective on early use of the Acquire EUS FNB Device.*



Percentage that provided diagnostic pathology from tissue biopsies



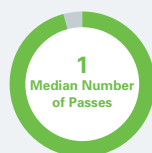
Median Number of Passes

Dr. Bertrand Napoleon et al. of the Ramsay Générale de Santé, Jean Mermoz Private Hôpital in Lyon, France¹, aimed to evaluate the diagnostic yield in solid pancreatic and non-pancreatic lesions of the Acquire 22-gauge EUS FNB Device. In this physician-user experience, 22 consecutive patients with 25 solid lesions underwent EUS-FNB carried out by five operators. One needle pass was performed consisting of 10 to-and-fro movements with a fanning technique after the stylet removal and without suction. If no tissue core was observed by the operator in expressing the specimen into a preservative solution, a second pass was performed either with suction or without and with only five to-and-fro movements in case of a bloody sample without, a tissue core. The final diagnosis was based on surgical pathology, and/or clinical follow-up, or unequivocal histopathology in the FNB specimen. The FNB biopsies provided diagnostic pathology in 24 out of the 25 lesions (96%). Only one needle pass was performed in all lesions but one, which required two passes. No complications were reported. This experience showed that the Acquire EUS FNB Device reduced the required number of passes to only one pass for almost all patients who participated in this experience.

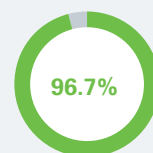
Results were reproducible among all the operators. FNB with the Acquire needle was technically easy and allowed adequate specimens without the need of an on-site pathologist in this experience.

EUS-guided biopsy using a Franseen needle design: An initial assessment Ji Young, Bang M.D., M.P.H., Shantel Hebert-Magee, M.D., Muhammad K. Hasan M.D., Udayakumar Navaneethan M.D., Robert Hawes M.D., Shyam Varadarajulu, M.D. of the Center for Interventional Endoscopy, Florida Hospital, Orlando, Florida² recently

evaluated the Acquire 22-gauge EUS FNB Device and its performance in EUS-guided tissue acquisition. Lesions were sampled either using only the Acquire needle or after failed diagnostic FNA. After rapid on-site evaluation (ROSE), two dedicated passes were performed for histological assessment using the cell block technique. Thirty patients underwent EUS-FNB of pancreatic or other masses over a three-month period. Twenty-four lesions were sampled using only the Franseen needle, and six after failed diagnostic FNA. Diagnostic adequacy for ROSE was 96.6%, and a histological diagnosis was established in 96.7% of patients. The rate of technical success was 96.7%. Preliminary data from this study suggest that the Franseen needle yields diagnostic material for ROSE and histology in greater than 95% of patients.



96.6% Achieved Diagnostic Adequacy at ROSE



Overall Diagnostic Accuracy for Histology

* Data on file; Acquire™ Product Brochure; 1 Bang, J. Y., Hebert-Magee, S., Hasan, M. K., Navaneethan, U., Hawes, R. and Varadarajulu, S. (2016), Endoscopic ultrasonography-guided biopsy using a Franseen needle design: Initial assessment. *Digestive Endoscopy*. doi:10.1111/den.12769.

1) MV Alvarez-Sánchez, I Lemaistre, B Pujol, R Gincoul, F Fumec, C Lefort, B Napoléon. PILOT EXPERIENCE WITH A NOVEL ENDOSCOPIC ULTRASOUND FINE NEEDLE BIOPSY (EUS-FNB) DEVICE. EUS2016, 20th International Symposium on Endoscopic Ultrasonography. Sep 25 2016.

2) Bang, Ji Young, Shantel Hebert-Magee, Muhammad K. Hasan, Udayakumar Navaneethan, Robert Hawes, and Shyam Varadarajulu. "Endoscopic Ultrasonography-guided Biopsy Using a Franseen Needle Design: Initial Assessment." *Digestive Endoscopy*. N.p., 20 Dec. 2016. Web. 06 Apr. 2017.

Management of Intrahepatic Lithiasis Leading to Recurrent Pyogenic Cholangitis and Liver Abscess



CASE PRESENTED BY:
TEODOR C. PITEA, M.D.
(Left)
RASHMI KUMAR, M.D.
Banner University
Medical Center
Phoenix, Arizona, USA

[View an EHL case in the Video Case Atlas on EndoSuite.com.](#)

PATIENT HISTORY

A 26-year-old female with a past medical history of cholelithiasis and choledocholithiasis, status post-open common bile duct exploration, and T-tube drainage four years ago, presented back to the hospital with acute cholangitis-related symptoms. A CT of the abdomen and pelvis showed a large, partially necrotic-appearing mass (91mm x 52mm) involving most of the superior aspect of the right lobe of the liver (**Figure 1**). The mass was suspicious for neoplasia versus a hepatic abscess. Four days later, an MRI of the abdomen was performed with MRCP showing severe biliary ductal dilation (20mm common bile duct, 17mm left hepatic duct) with intrahepatic stones measuring up to 19mm. There was a slight decrease in the large right hepatic lobe lesion (68mm x 50mm), which was felt to be related to the resolving infection/abscess. An urgent ERCP was performed for cholangitis which showed filling defects in the common bile duct (CBD), left hepatic duct (LHD) and right hepatic duct (RHD). The biliary tree was swept with an 18mm balloon and plastic stents were placed in both left and right hepatic ducts. The patient returned with acute cholangitis two months later, and a repeat CT scan of the abdomen showed both stents had migrated spontaneously. The liver abscess now measured 37mm x 32mm. Again, she was noted to have numerous stones in the right intrahepatic biliary system. An ERCP was performed urgently for management of acute cholangitis and plastic stents were placed again in the right and left hepatic ducts. Plans were made for a repeat ERCP using the SpyGlass™ DS System and electrohydraulic lithotripsy (EHL) for management.

PROCEDURE

The bile duct was deeply cannulated with a 15-18mm Extractor™ Pro RX Retrieval Balloon Catheter and guidewire. Contrast was injected. The main bile duct contained filling defects thought to be stones and sludge. The biliary tree was swept with the 18mm balloon and

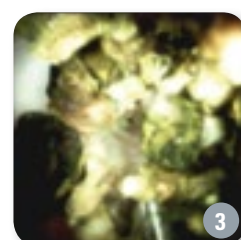
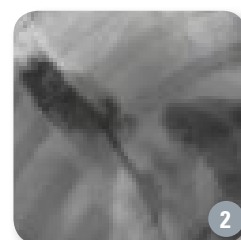
the CBD was cleared. The SpyScope™ DS Catheter was introduced and advanced to the right intrahepatic duct. Multiple stones were visualized and were completely occluding the system. EHL was performed for a total procedure duration of 3 hours 30 minutes, exclusively targeting the right intrahepatic system (**Figures 2 and 3**). Sludge and stones were removed utilizing the 15-18mm Extractor Pro RX Retrieval Balloon Catheter. Double-pigtail Advanix™ Biliary Plastic Stents were placed in the left and right hepatic systems and the common bile duct, and plans were made for repeat treatment targeting the left intrahepatic stones. Five weeks later, the patient returned for a final session of intrahepatic EHL targeting the left hepatic system (**Figure 4**). All visible residual stones were targeted and removed with a total procedure time of 1 hour 30 minutes.

OUTCOME

The patient tolerated the procedures well. The liver abscess completely resolved and her liver biochemistry normalized. The patient did not experience a recurrence of cholangitis over the last three months.

CONCLUSION

The mortality rate for acute cholangitis remains high (20-30%) despite advances in treatment. This patient had intrahepatic lithiasis and recurrent cholangitis, therefore, without the SpyGlass DS System to allow for EHL, her prognosis would have been grim. Management of intra- and extrahepatic duct stones can be challenging, and the SpyGlass DS System allows for the direct visualization of the stones in intrahepatic ducts and helps direct fragmentation using EHL. This endoscopic procedure not only improved the clinical outcome by preventing further episodes of cholangitis, it also avoided the need for surgical exploration and associated complications of what the patient experienced four years ago.



[View an EHL case in the Video Case Atlas on EndoSuite.com.](#)

Using Cholangioscopy as a New Standard for Diagnosing and Staging Main Duct Cholangiocarcinomas

➤ View an EHL case in the Video Case Atlas on EndoSuite.com.



PATIENT HISTORY

The patient, a 49-year-old male, was admitted to the hospital with jaundice, dark urine and epigastric abdominal pain that had been worsening over the previous three weeks. The patient had no significant past medical history. Upon admission, he rated his epigastric pain as 3/10, which mildly worsened when he ate, and nothing helped relieve his pain. He saw his family practitioner, who drew labs and found that his bilirubin levels were elevated to 12.6. The patient's transaminases and alkaline phosphatase levels were elevated as well.

PROCEDURE

On initial admission, a CT scan of the abdomen and pelvis was performed. The results of the CT scan demonstrated a moderate dilation of the intrahepatic biliary ducts of the liver and a distended common bile duct to 14mm. The gallbladder was also moderately distended but with no definite gallbladder wall thickening. The transition point of the dilated common bile duct was located in the head of the pancreas. No gallbladder, biliary or pancreatic masses were observed. Cholangitis was not excluded. The recommendation was to consider ERCP for further evaluation.

A right upper quadrant ultrasound was also performed, which showed a distended gallbladder with layering sludge within the gallbladder. A small, hyperechoic area (5mm in size) within the gallbladder was also seen, possibly representing a small polyp. Biliary ductal dilation of the intrahepatic and extrahepatic bile ducts was also observed. The distal common duct was obscured by overlying bowel gas and no definite mass was identified in the pancreas.

The patient was then taken for an ERCP, the results of which demonstrated a normal papilla and dilated intrahepatic ducts. There was a tight, 'apple-core-type' stricture at the distal 1/3 of the common bile duct. A sphincterotomy was performed as well as brushings of the stricture for cytology, and a plastic biliary stent was placed (**Figure 1**). Cytology from common bile duct brushings (smears and cytospins) were negative for malignant cells. Benign groups of ductal epithelial cells were seen mixed with rare atypical groups and favor reactive tissue.

The advanced interventional endoscopy service was consulted. We checked the CA 19-9, which was elevated to 42, and liver enzymes were elevated as well. At this point, there was an option of conducting an initial evaluation with endoscopic ultrasound or cholangioscopy. Cholangioscopy using direct visualization and histologic tissue acquisition was chosen after a review of the ERCP images revealed that the stricture had a malignant appearance, which was more likely intrinsic (cholangiocarcinoma) rather than extrinsic (pancreatic carcinoma).

An ERCP with cholangioscopy using the SpyGlass™ DS System was performed. The plastic stent was removed, and the initial cholangiogram once again showed a stricture that appeared to be malignant.

Our initial cholangiogram revealed a lesion located 3-5 mm below the cystic duct take off. The sphincterotomy was extended and the SpyScope™ was prepped and carefully inserted into the bile duct for direct visualization.

(Continued on next page)



CASE PRESENTED BY:

NEIL R. SHARMA, M.D.

Director of Advanced Interventional Endoscopy & Endoscopic Oncology
Medical Director of GI Oncology Program
President Parkview Cancer Institute
Volunteer Assistant Professor of Medicine,
Indiana University, Indianapolis, Indiana, USA



KEVIN LOWE, M.D.

Director of Surgical Oncology Parkview Health
Chairman of Data Quality & Metrics Division
Parkview Cancer Institute
Indianapolis, Indiana, USA

ERCP WITH CHOLANGIOSCOPY

The cholangioscopy examination using the SpyGlass™ DS System started at the bifurcation. The left and right main hepatic ducts as well as the common hepatic duct appeared normal. There was a mass lesion with atypical villiform growth and increased vascularity seen in the proximal-to-mid CBD. This growth occupied 50-100% of the lumen and had the classic appearance of cholangiocarcinoma (**Figures 2 and 3**). The lesion extended from 3mm below the cystic duct takeoff and through the mid CBD and ended 4-5mm above the ampullary insertion.

Targeted biopsies were performed of the biliary stricture using SpyBite™ Biopsy Forceps (**Figures 4 and 5**) and the frozen section was done. Additional biopsies were taken and sent for immunohistochemical staining. Intraoperative Pathology from the frozen section was evaluated by pathology and showed carcinoma. The final pathology was cholangiocarcinoma (**Figure 6**).

A WallFlex™ Biliary RX Fully Covered Stent (10mm x 60mm) was placed in the bile duct to relieve the biliary obstruction.

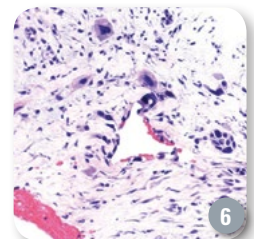
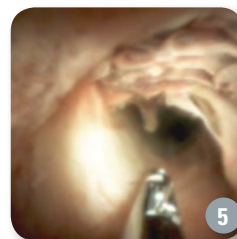
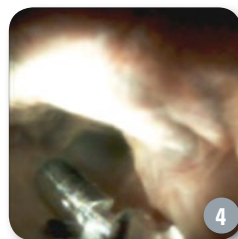
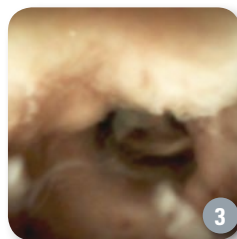
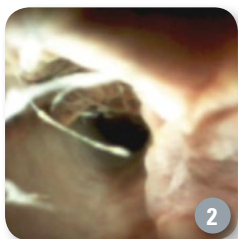
OUTCOME

The patient underwent an EUS and a PET scan to complete the staging. The EUS showed that the lesion was a T1 lesion with a single 4mm regional lymph node that appeared to be benign. The PET scan showed a focal hypermetabolic lesion in the distal CBD which caused mild-caliber narrowing of the biliary stent. There was no evidence of abdominal or pelvic metastatic disease.

The patient was presented at multidisciplinary review at the tumor board. There was consensus that the final clinical staging was T1N0M0 cholangiocarcinoma. The patient's cholangioscopy, pathology and ERCP films were reviewed by surgical oncology, and planning was made for an attempt at curative surgery. The mass, which was located in the mid-CBD, was well defined by cholangioscopy. The patient was set up for a Whipple procedure with surgical oncology, with planned removal of the fully covered stent at the time of surgery.

KEY TAKEAWAYS

- 1) **Brush cytology had a low sensitivity for diagnosis of cholangiocarcinoma in the setting of a biliary stricture.**
- 2) **The SpyGlass DS System should be the gold standard for tissue acquisition and considered as a standard of care for the staging of main duct cholangiocarcinomas (those involving left main, right main, common hepatic duct, or common bile duct).**
- 3) **The SpyGlass DS System allowed for the precise determination of intraductal margins, which enabled more accurate assessment of cholangiocarcinoma for preoperative planning. This should be documented in the operative note, and can be used by surgical oncologists to determine the ability and type of resection.**
- 4) **The use of the SpyGlass DS System can change management when used in the preoperative multi-disciplinary approach to cancer. The use of the SpyGlass DS System may be able to stratify patients to appropriate surgical management and potentially avoid it when not necessary.**



Using Cholangioscopy to Diagnose an Inflammatory Stricture



▶ Learn more about cholangioscopy.

CASE PRESENTED BY:

PROF. MASSIMILIANO MUTIGNANI, M.D.

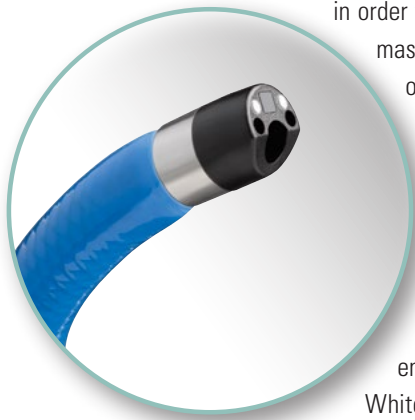
Niguarda Hospital
Milan, ITALY

PATIENT HISTORY

In May 2015, a 65-year-old male was admitted to the emergency unit of the hospital for onset of jaundice and fever, without abdominal pain, that had started the week prior. His medical history included chronic HBV-related hepatitis and benign prostatic hypertrophy. He had no previous history of gallstones or choledocholithiasis. The blood tests showed moderate leukocytosis, and hyperbilirubinemia and cholestasis levels were increased. A CT scan of the abdomen showed stenosis of the hepatic duct and a hilum mass-forming (**Figure 1**). ANA, AMA, ANCA, LKM and pANCA were negative. IgG4 was normal.

PROCEDURE

A percutaneous transhepatic biliary drainage procedure was performed in another hospital and a brushing was conducted (**Figure 2**). Cytology results were negative for neoplasia. In June 2015, the patient underwent a laparotomy in order to remove the mass. A cholecystectomy was performed but the excision of the mass was not possible due to the involvement of the hepatic artery, thus a biopsy of the mass and hilar nodes was performed. The histology results were again negative for neoplasia.



An additional CT scan was performed in September 2015, and showed the growth of the hilar mass and confirmed the infiltration of the hepatic artery. An ERCP was then performed at another hospital, during which two plastic stents were placed and a second brushing was performed, but results were found to be inconclusive. Two weeks later, another ERCP was performed at the endoscopy unit of our hospital using the SpyGlass™ DS System (**Figures 3 and 4**).

White, irregular and hard-consistency tissue was found on the stenosis of the left hepatic duct and biopsies were performed using SpyBite™ Biopsy Forceps. Histological findings were suggestive of chronic inflammation with the presence of many granulocytes.

By November 2015, the patient's cholestasis levels had increased and a new CT scan was performed, showing that the stents were becoming occluded. An ERCP confirmed the presence of sludge and stones inside the stents. New biopsies were then performed (**Figures 5a and 5b**), and confirmed chronic inflammation with granulation aspects.

In February 2016, the patient presented with hemobilia. An arteriography was performed and showed a pseudoaneurysm in a branch of the hepatic artery. A minimally invasive embolization procedure was then performed using 2-6mm coils.

In April 2016, the patient was admitted to the endoscopic unit due to onset of jaundice and fever. Fluoroscopy was performed during the ERCP and showed recurrence of the hilar stenosis with the same morphological characteristics (**Figure 6**). Pneumatic dilation was then performed at the site of the stricture (**Figure 7**) and fully covered metal stents were placed for drainage. The jaundice and fever improved.

In this case, cytology was important in order to exclude neoplastic disease, but brushing is often inconclusive. Therefore, targeted biopsies were performed using the SpyGlass DS System, which has been shown to approximately double biopsy sensitivity compared to brush cytology¹. Practicing biopsies in the hilum with normal biopsy forceps is a very risky procedure and should only be performed by experienced endoscopists.

(Continued on next page)

OUTCOME

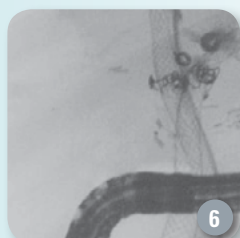
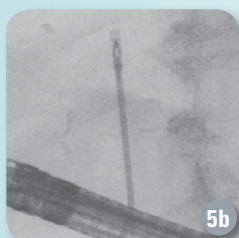
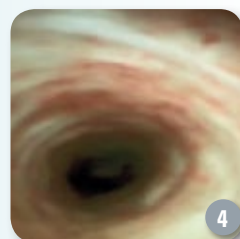
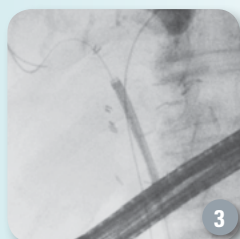
To date, the patient is still in good clinical condition, and has no fever or jaundice. An ERCP was scheduled after six months to replace/remove the metal stents. In the interim, we recommended that the patient have blood tests (particularly cholestasis tests) every two months.

The patient started an evaluation for liver transplantation, but prostatic cancer with bone metastases was found.

CONCLUSION

In this case, diagnosis of an inflammatory stricture was confirmed after several cytological exams, biopsies, and endoscopic procedures. The course of this type of stricture is often indolent and relapsing, thus follow-up performed by blood tests and imaging is very important. The experience and technical skills of the endoscopist are crucial, but the availability of devices is equally important to enable a wide variety of therapeutic options. In this case, the use of the SpyGlass™ DS System with SpyBite™ Biopsy Forceps helped to perform biopsies and confirm the diagnosis.

Correct placement of stents during an ERCP may also help avoid complications that may be associated with higher rates of morbidity and mortality, such as cholangitis, which has the potential to prolong a hospital stay and increase costs.



References:

- 1) Yang Chen, MD, et al, GIE, Vol. 74, 2011
Images provided courtesy of Prof. Mutignani

Utilizing 'Twist & Clip' Technique during Post EMR Defect Closure

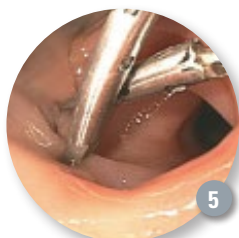
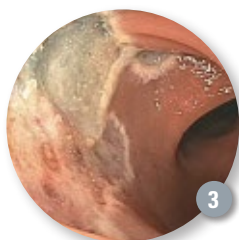
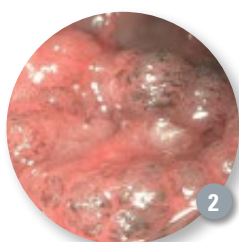
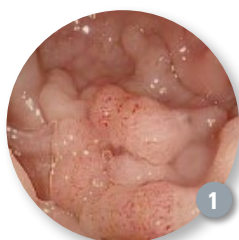
➤ Visit the new hemostasis page on EndoSuite.com.



CASE PRESENTED BY:

J. DAVID HORWHAT, M.D., FASGE, FACP

Regional Gastroenterology
Lancaster, Pennsylvania, USA



PATIENT HISTORY

Upon initial screening colonoscopy, a 51-year-old female was found to have a 2.9 cm laterally spreading polyp in the rectum (**Figures 1 and 2**). The polyp was Paris class IIa and Is with Kudo pit patterns IIIL and IV, and was felt to be amenable to endoscopic mucosal resection (EMR).

PROCEDURE

The polyp was successfully removed via piecemeal EMR (**Figure 3**). The decision was made to close the defect using hemoclips. The Resolution 360 Clip was chosen for its ability to facilitate a "twist and clip" technique. The clip was positioned at the left margin of the resection site grasping the edges of the defect, was partially closed and then rotated 90 degrees before fully closing and deploying (**Figure 4**).

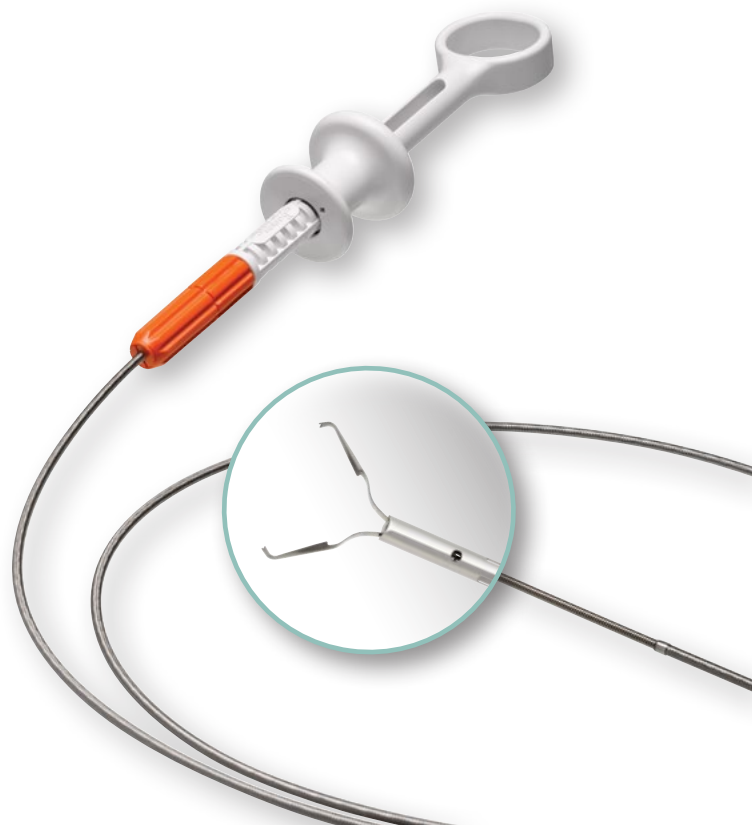
A second clip was used along the right side of the defect (**Figure 5**). Given the location of the resection site in the rectum where even low intraluminal pressure will distend the bowel wall, a third clip was placed in the middle to ensure a more secure closure along the entire border.

POST-PROCEDURE

The patient tolerated the procedure well with no complications. The objective post-resection was to close the defect of the EMR site with endoscopic clips. This was successfully accomplished with the use of three clips.

DISCUSSION

I envision using the Resolution 360 Clip with the "twist and clip" technique to close my resection sites during EMR. The unique design that allows physician-controlled and one-to-one rotation response elevates this clip as my hemoclip of choice.



Using a High-Performance Guidewire to Facilitate Access Through a Difficult Hilar Stricture



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

CASE PRESENTED BY:

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PATIENT HISTORY

A 52-year-old man with a history of primary sclerosing cholangitis had previously undergone an orthotopic liver transplant in 2007, and had been successfully treated between 2009 and 2010 for an anastomotic stenosis by placing plastic stents. One year post-stent removal, the patient had a near-normal MR-cholangiogram. Then, four years later, in 2015, the patient developed recurrent cholestasis progressively followed by severe jaundice and pruritus.

PROCEDURE

An MRI and liver biopsy showed evidence of recurrent PSC on the site of the liver transplant, with a dominant hilar stricture and mildly dilated intrahepatic ducts. Brush cytology during an ERCP found no atypical cells. A second transplant was necessary, but before being registered on the liver transplant waiting list, biliary drainage needed to be attempted to improve the patient's nutritional status and control the pruritus. A second ERCP was performed, showing an extremely tight and tortuous dominant hilar stricture from recurrent PSC on a liver transplant (**Figure 1**), which only allowed for the insertion of an 8.5Fr plastic stent in segment IV. Segment IV was the only part of the liver that could be stented after the first ERCP (**Figures 2 and 3**). This partial drainage was not complicated, but bilirubinemia decreased by less than 30% within one month of the ERCP, the pruritus was not completely relieved, and nutritional status did not improve significantly.

Therefore, an additional ERCP was subsequently performed in order to try to improve the biliary drainage. After spending nearly one hour trying to gain access using various wires, a NovaGold™ High Performance Guidewire was finally used and successfully found a path to the right posterior duct. The wire helped facilitate the passage of a hydrostatic dilator and the insertion of a 10Fr, 15cm long plastic stent, which caused a relatively rapid decrease in bilirubin. After unsuccessful attempts with other wires, the NovaGold High Performance Guidewire enabled passage into the right liver lobe, with subsequent stenting and rapid jaundice resolution (**Figure 4**).

OUTCOME

The patient now has a non-icteric, moderate cholestasis and is completely relieved of his pruritus. He is still waiting for a new liver transplant and is in generally good condition.

CONCLUSION

The NovaGold High Performance Guidewire enabled wire-guided pathfinding during ERCP, as demonstrated by this case in which previous attempts were unsuccessful.



Endoscopic Ultrasound Fine Needle Biopsy Device May Lead to Rapid Diagnosis

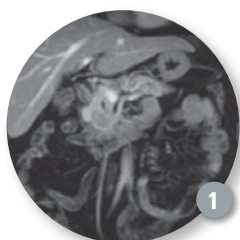
▶ Learn more about the Acquire Needle.



CASE PRESENTED BY:

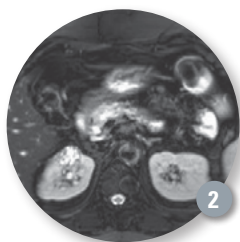
DEMETRIOS TZIMAS, M.D.

Assistant Professor, Dept of Medicine
Stony Brook School of Medicine
Stony Brook, NY, USA



PATIENT HISTORY

A 55-year-old woman with coronary artery disease (CAD) and five drug-eluting stents (DES) was admitted to our hospital with acute pancreatitis. She had a previous cholecystectomy, did not drink alcohol or start any new medications, and her liver function tests and triglycerides were all normal on admission. On cross-sectional imaging with computed tomography (CT) scan, she had inflammation in the head of the pancreas without local complications, but there was concern for a renal cell carcinoma (RCC). To ensure there was no lesion in the pancreas as a cause of her acute pancreatitis, follow-up imaging as an outpatient, utilizing magnetic resonance imaging (MRI), demonstrated a 2.4 cm mass in the head of the pancreas with upstream pancreatic ductal (PD) dilation to 5 mm and common bile duct (CBD) dilation to 1.2 cm (**Figure 1**) in addition to the RCC (**Figure 2**). Although considered surgically resectable, as the patient had imaging characteristics concerning for two primary malignancies, a needle biopsy was needed to ensure that the patient did not have metastatic RCC as a cause of both lesions. An endoscopic ultrasound (EUS) performed at that time confirmed a pancreatic head mass (**Figure 3**), but using a 22 gauge core biopsy needle did not yield a positive diagnosis and the patient was admitted post-procedure with acute pancreatitis. As the patient was a high-risk surgical candidate, and a combined pancreaticoduodenectomy with partial nephrectomy was likely indicated, another EUS was planned, this time using the Acquire™ Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device.



PROCEDURE

Linear EUS was scheduled a few weeks after the pancreatitis with rapid on-site evaluation (ROSE). Diagnostic accuracy for this patient, who already had a delay in diagnosis, and the high-risk nature of the patient's CAD and 5 DESs, with a previous post-EUS adverse event, required a needle that was both safe and accurate, and would not lead to a prolonged procedure or excessive needle passes. In order to reduce the risk of pancreatitis, a 25 gauge needle was chosen, along with intraprocedural rectal indomethacin. The linear EUS was performed at 7.5 MHz with Doppler imaging. A 2.4 cm hypoechoic mass was identified in the head of the pancreas, with associated upstream dilation of the CBD and PD. Fine needle biopsy was performed using a 25 gauge Acquire needle (**Figure 4**). Color Doppler imaging was utilized to confirm a lack of significant vascular structures within the needle path. Four passes were made using a transduodenal approach using the wet-suction technique. There was no significant bleeding at the end of the procedure.

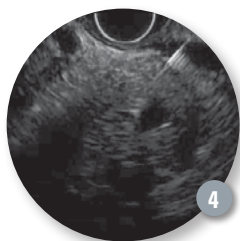


POST-PROCEDURE

The patient tolerated the procedure well and we confirmed that the patient had two primary malignancies, not metastatic RCC. The patient went for an uneventful combined pancreaticoduodenectomy and partial nephrectomy with our Surgical Oncology and Urology services.

CONCLUSION

This case helps demonstrate that a 25 gauge Acquire FNB may help lead to a rapid diagnosis even when previous core biopsies using larger gauge needles were negative.



Sales Donation Programs Are Making a Difference

IN SUPPORT OF PANCREATIC CANCER RESEARCH



In support of Pancreatic Cancer Awareness Month (November 2016), Boston Scientific donated one percent of November sales from products used to diagnose

and treat conditions caused by pancreatic cancer, including the WallFlex™ Biliary RX Stent, Acquire™ Endoscopic Ultrasound Fine Needle Biopsy Device, and SpyScope™ DS. The money was donated to The Lustgarten Foundation, the National Pancreas Foundation, and the Pancreatic Cancer Action Network.

“We are so grateful for your gift. Having Boston Scientific supporting our efforts allows us to continue to pursue better outcomes and treatment for pancreatic cancer patients. Thank you for identifying the need and seeing yourselves as a part of the solution.”

— **Alexandra Weiss**, Strategic Partnerships Manager, Pancreatic Cancer Action Network

- Since 2015, Boston Scientific's sales donation programs have contributed more than \$300,000 to five health organizations in support of colon cancer, pancreatic cancer and lung cancer awareness and prevention.

IN SUPPORT OF COLON CANCER PREVENTION



In support of Colon Cancer Awareness Month (March 2017), Boston Scientific donated one percent of sales from colonic stent, clip, snare and biopsy forceps made during March to the Colon Cancer Alliance (CCA). This money helps fund the Colon Cancer Alliance's Blue Hope Financial Assistance Program that provides qualifying individuals with access to lower-cost screenings.

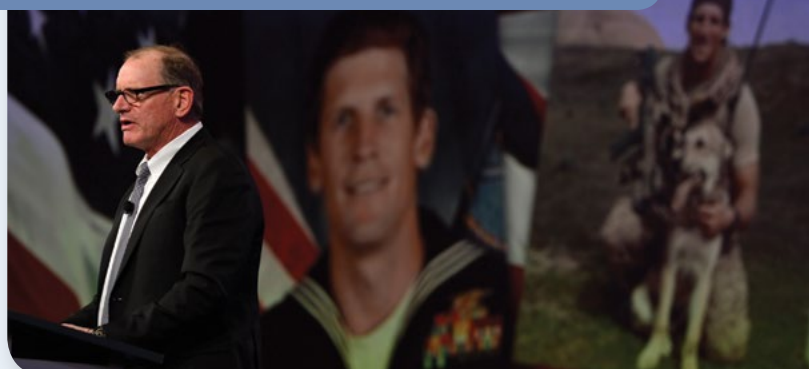
As a result of the Blue Hope Financial Assistance program, as of February 2017, 602 patients from across the U.S. have been referred to Colonoscopy Assist to receive screening assistance.

“At the Colon Cancer Alliance, we believe colon cancer is a senseless killer that must be stopped. Every year there are over 130,000 new cases of colon cancer and almost 50,000 deaths, many of which could have been prevented through screenings and early detection. Boston Scientific has been a great partner in furthering our prevention pillar in providing colorectal screenings to people in need. It is through partnerships like these that we can largely end this disease in our lifetime. We sincerely thank Boston Scientific for their continued commitment to cancer prevention.”

— **Patrice Brown**, Senior Director, Program Development, Colon Cancer Alliance

Boston Scientific Donates \$50,000 to the Navy SEAL Foundation

During a recent sales meeting in Phoenix, Arizona, Boston Scientific hosted an event to honor service members and present a \$50,000 donation to the Navy SEAL Foundation, a non-profit focused on the preservation of the Naval Special Warfare force and its families.

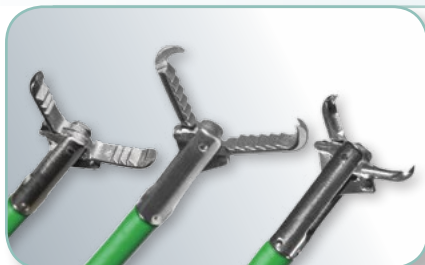


Charles Humphrey Keating III spoke on behalf of the Navy SEAL Foundation and recognized his son, Special Warfare Operator Chief (SEAL) Charles Humphrey Keating IV, who was killed in active duty in 2016.

“For the second year in a row at our national sales meeting, we incorporated a way of giving back to the community. Once again, we had the honor of giving thanks to the men and women who serve our country, as well as their families,” said **Mike Jones**, vice president of sales for Boston Scientific's Endoscopy business.

News and New Devices

- The **RescueNet™ Retrieval Device** is designed for visibility, control and strength. OmniLoop™ technology is designed to provide control by enabling smooth flat-loop deployment and retraction, minimizing scope repositioning. Ultra-strong ProMesh™ netting is designed to minimize tearing, fraying or shearing.



- The **Rescue Retrieval Forceps** portfolio provides a comprehensive offering of rat tooth, alligator and combination forceps suitable for retrieving a variety of foreign objects.

- Boston Scientific now offers **GI Specialized Pathology Services**. While the vast majority of commercial and hospital laboratories provide services for specialties, such as dermatology and urology along with gastrointestinal (GI), Boston Scientific provides a subspecialty model dedicated solely to the practice of GI pathology.

The lab employs GI-subspecialty trained and experienced pathologists and histotechnicians who are particularly skilled in preparing biopsies for viewing. For instance, colonic polyps must be appropriately oriented if the pathologist is to deliver a definitive diagnosis. "Throughout my career I have seen instances where colon polyps are not properly oriented and the margins cannot be identified. If the polyp is malignant but the pathologist cannot deliver a definitive diagnosis, the patient may be subject to an unnecessary segmental resection or even colectomy," explained Jeremy S. Miller, M.D., director of pathology services at Boston Scientific.

In November 2016, Boston Scientific acquired EndoChoice, a GI company that provides devices, diagnostics, infection control and imaging for specialists treating a wide range of gastrointestinal conditions.

Available for U.S. customers only.

For product information visit www.bostonscientific.eu

For educational videos visit www.endsuite.com

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.

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.

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Results from case studies are not predictive of results in other cases. Results in other cases may vary.

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

CAUTION: 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 labelling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France.

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