

Boston Scientific

## **Boston Scientific's SpyGlass® Direct Visualization System Featured in Broad Range of Clinical Studies at Upcoming Digestive Disease Week®**

PRNewswire  
NATICK, Mass.  
(NYSE:BSX)

*Studies to be presented on safety and efficacy of SpyGlass System for diagnostic and therapeutic procedures throughout pancreatico-biliary system*

NATICK, Mass., May 28 [PRNewswire-FirstCall/](#) -- Boston Scientific Corporation (NYSE: BSX) today announced that 14 abstracts and additional clinical data analyses involving the SpyGlass® Direct Visualization System will be presented at Digestive Disease Week® (DDW), which runs from May 30 to June 4 in Chicago.

"The impressive number of presentations on the SpyGlass System underscores the potential of this technology as a vital new tool in endoscopic procedures for diagnosing and treating pancreatic and biliary disease," said Michael P. Phalen, President, Boston Scientific Endoscopy. "Boston Scientific is dedicated to developing technologies and expanding indications that enhance the quality of life for patients, as demonstrated by our new pancreatic indication for the SpyGlass System, as well as the broad range of endoscopic innovations showcased at DDW."

Previously available for use only in the bile and hepatic ducts, Boston Scientific recently received clearance from the Food and Drug Administration to market its SpyScope® Access and Delivery Catheter for diagnostic and therapeutic applications during endoscopic procedures in the entire pancreatico-biliary system, including the pancreatic ducts. The SpyScope Catheter is used in conjunction with the SpyGlass Direct Visualization System. The system is intended to guide visualization and accessory devices throughout the pancreatico-biliary system, enabling physicians to diagnose and treat pancreatic cancer or pre-cancerous tissues.

The SpyGlass System is a single-operator system developed to overcome the challenges of traditional cholangioscopy systems and reduce the need for exploratory surgery. The SpyGlass System is designed to enable physicians to directly visualize the target site, obtain a diagnostic tissue sample with the disposable SpyBite® Biopsy Forceps, and deliver therapies such as laser and electrohydraulic lithotripsy (EHL).

### **Schedule of Key Podium and Poster Presentations (partial listing, all times are Central Time):**

All posters are available from 8:00 a.m. - 5:00 p.m. in South Hall of McCormick Place.

#### Sunday, May 31

- ***Holmium-YAG Laser Lithotripsy in the Treatment of Difficult Biliary Stones Utilizing SpyGlass: a Multi-Center Experience (Poster Presentation)***

This multi-center cumulative study reports on the use of Holmium-YAG laser lithotripsy with SpyGlass cholangioscopy in the management of difficult intraductal biliary stones. Five to ten percent of biliary stones are not amenable to standard endoscopic extraction

techniques and while electrohydraulic and laser lithotripsy have been shown to be effective, they have been used sparingly. The study reports that the SpyGlass System now permits for routine use of these technologies. Lead author of the study is Sandeep Patel, M.D.

Tuesday, June 2

- ***It Looks Like Cholangiocarcinoma -- But is it? Using SpyGlass for Diagnosis of Cholangiocarcinoma in Patients with Primary Sclerosing Cholangitis (Podium Presentation)***

This study is designed to evaluate the characteristics of bile duct lesions in patients with primary sclerosing cholangitis (PSC) using the SpyGlass System and compare them to the characteristics of cholangiocarcinoma (CC) found in the literature with the cholangioscopic findings in combination with histologic, cytologic follow-up results. Patients with PSC are at increased risk of developing CC but the absence of symptoms and the lack of reliable diagnostic instruments for early detection of tumors contribute to the poor prognosis in patients. Direct visualization of the biliary system is not yet a standard tool for excluding malignancy in bile duct stenoses, but certain cholangioscopic characteristics of CC have been described. This podium presentation will be given by Alexander Dechene, M.D., Gastroenterology and Hepatology, University Hospital Essen, Essen, Germany, at 8:42-8:54 a.m. in Room S100 of McCormick Place.

- ***Assessment of SpyGlass for Cholangioscopy and Pancreatography in 102 Consecutive Patients (Poster Presentation)***

This study describes the performance, safety and utility of the SpyGlass System for peroral cholangioscopy and pancreatoscopy in patients at Beth Israel Deaconess Medical Center in Boston. Peroral cholangioscopy and pancreatoscopy allow direct visualization of the bile and pancreatic ducts while being able to take site-directed biopsies and perform electrohydraulic lithotripsy. Lead authors of the study are Ram Chuttani, M.D., and Douglas K. Pleskow, M.D.

- ***POC Using a Disposable Steerable Single Operator Catheter for Biliary Stone Therapy and Assessment of Indeterminate Strictures - a Multi-Center Experience Using SpyGlass (Poster Presentation)***

A poster presentation reports the results of a prospective 297-patient, 15-center registry that studied the utility and performance of the SpyGlass System for peroral cholangioscopy (POC). The international study was led by Yang K. Chen, M.D.

The SpyGlass Direct Visualization System will be available for demonstration at Boston Scientific's booth #734. The Company will also offer hands-on demonstration sessions in its Simulated Clinical Endoscopy Suites and at its booth stations for the

following products: WallFlex® Biliary, Esophageal and Enteral Stents, Polyflex® Esophageal Stents, Radial Jaw® 4 Biopsy Forceps, Resolution® Clip, CRE™ Balloon Dilators, the RX Biliary System™ and the EndoVive® Enteral Feeding initial placement and replacement devices. For more information on Boston Scientific's presence at DDW, visit [www.bostonscientific.com/ddw2009](http://www.bostonscientific.com/ddw2009).

To date there have been more than 50 clinical studies published or presented on the SpyGlass System.

### **About Digestive Disease Week®**

DDW is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases, the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy and the Society for Surgery of the Alimentary Tract, DDW takes place May 30 - June 4, 2009, at the McCormick Place, Chicago, IL. The meeting showcases approximately 5,000 abstracts and hundreds of lectures on the latest advances in gastrointestinal research, medicine and technology. For more information, visit [www.ddw.org](http://www.ddw.org).

### **About Boston Scientific**

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: [www.bostonscientific.com](http://www.bostonscientific.com).

### **About Boston Scientific Endoscopy**

Boston Scientific Endoscopy develops innovative technology for less invasive, more efficient gastrointestinal procedures.

### **Cautionary Statement Regarding Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things our product performance, regulatory approval of our products, competitive offerings, our growth strategy, and our market position. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; intellectual property; litigation; financial market conditions; and, future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A - Risk Factors in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A - Risk Factors in Quarterly Reports on Form 10-Q we have filed or will file thereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions, or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

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