# Boston Scientific's Endoscopy Products Featured in Clinical Studies at DDW 2010

NATICK, Mass., April 30 <u>PRNewswire-FirstCall</u>/ -- Boston Scientific Corporation (NYSE: BSX) today announced that multiple clinical abstracts examining the diagnostic and therapeutic utility of its SpyGlass<sup>®</sup> Direct Visualization System, Radial Jaw<sup>®</sup> 4 Biopsy Forceps and WallFlex<sup>®</sup> Duodenal Stent will be presented at Digestive Disease Week<sup>®</sup> (DDW<sup>®</sup>), May 1 – 5 in New Orleans.

"The large number of studies at DDW evaluating Boston Scientific technologies highlights our commitment to advancing the field of endoscopy for diseases throughout the GI tract," said Michael Phalen, Senior Vice President, and President of Boston Scientific's Endoscopy Division. "Boston Scientific is committed to developing new innovations that help physicians improve the quality of life for patients worldwide."

# Schedule of Key Presentations (All times are Central Time):

All posters are available from 8:00 a.m. - 5:00 p.m. in Hall F of the Ernest N. Morial Convention Center.

# Sunday, May 2

• Holmium Laser Lithotripsy Under Direct Cholangioscopic Guidance in Complicated Stone Cases: Long Term Experience (Poster Presentation featuring SpyGlass System)

This study, led by Bryan G. Sauer, M.D., found that laser lithotripsy using the Holmium laser under cholangioscopic guidance is safe and effective for treating complex biliary stones.

Does Contrast Affect Cholangioscope Image Quality? (Poster Presentation featuring SpyGlass System)

This multi-center study, led by Jeffrey T. Laczek, M.D., suggested that cholangioscope image quality is not different when immersed in normal saline, contrast or a mixture of normal saline and contrast, and that endoscopists should use intraductal contrast prior to cholangioscopy if needed for lesion localization.

SpyGlass Peroral Cholangioscopy System for Visual Differentiation and Optically Guided Tissue Sample Biopsy
of Biliary Strictures: A Single-Center Preliminary Observational Study (Poster Presentation featuring SpyGlass
System)

This study, led by Dimitrios Xinopoulo, M.D., found that the SpyGlass System is a useful diagnostic tool when dealing with radiologically evident biliary strictures, and that tissue sampling under visual control is technically feasible and clinically safe.

• Cholangioscopic Characterization of Dominant Biliary Strictures in Patients With Primary Sclerosing Cholangitis (PSC) May Not Be Indicative of Malignancy (Poster Presentation featuring SpyGlass System)

This study, led by Kalpesh K. Patel, M.D., demonstrated that dominant biliary strictures in PSC patients can be successfully visualized with the SpyGlass System, and adequate tissue can be acquired for biopsy sampling.

• A Novel Biopsy Protocol for Assessment of Neosquamous Epithelium After Radiofrequency Ablation of Barrett's Esophagus With High Grade Dysplasia (Poster Presentation featuring Radial Jaw 4)

This study, led by Srinadh Komanduri, M.D., found that tissue acquisition with jumbo biopsy forceps facilitates assessment for buried glands after radiofrequency ablation.

• Randomized Controlled Trial of Two Types of Biopsy Forceps for Polypectomy of Small Sessile Colorectal Polyps (Poster Presentation featuring Radial Jaw 4)

This study, led by Peter V. Draganov, M.D., demonstrated that Radial Jaw 4 Forceps are more effective for complete eradication of small sessile colorectal polyps than Radial Jaw 3 forceps.

## Monday, May 3

• The Utility of New Jumbo Biopsy Forceps for Tissue Acquisition of Gastric Subepithelial Masses (Oral Poster Presentation featuring Radial Jaw 4)

This study, led by Srinadh Komanduri, M.D., demonstrated the efficacy and safety of jumbo biopsy forceps in obtaining diagnostic tissue in gastric subepithelial masses, resulting in cost savings by reducing unnecessary referrals for endoscopic ultrasound and endoscopic surveillance. Dr. Komanduri will present results of the study from 9:06 - 9:18 a.m.

## Tuesday, May 4

 Endoscopic Stenting Versus Surgical Gastrojejunostomy for Management of Malignant Gastric Outlet Obstruction: Comparison of Clinical Outcomes and Hospital Costs (Podium Presentation featuring WallFlex<sup>®</sup> Duodenal Stent)

This study, led by Shyam Varadarajulu, M.D., found that endoscopic stenting is associated with lower costs and shorter hospital stays than surgical gastrojejunostomy, which is considered the current gold standard for the relief of malignant gastric outlet obstruction. Dr. Varadarajulu will present results of the study from 4:36 - 4:48 p.m. The Company plans to issue a press release at that time.

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<sup>®</sup> Biopsy Forceps, and deliver therapies such as laser and electrohydraulic lithotripsy. The SpyGlass System can be used to guide visualization and accessory devices throughout the pancreatico-biliary system. Accessory devices can be used to diagnose and treat diseases such as cholangiocarcinoma, pancreatic cancer or pre-cancerous tissues. To date there have been more than 50 clinical studies published or presented on the SpyGlass System, and more than 15,000 cases have been performed with the device in the U.S. and Europe.

Radial Jaw 4 Biopsy Forceps are designed to enable collection of large, high-quality tissue specimens without the need to use large channel therapeutic endoscopes. Acquiring tissue for diagnosis is the most frequently performed procedure by gastroenterologists, with approximately 7.15 million biopsy procedures performed in the U.S. in 2008(1).

The WallFlex® Duodenal Stent is a large diameter, radiopaque, flexible self-expanding metal stent designed to help maintain luminal patency in patients with gastroduodenal obstructions. This stent has atraumatic looped ends and incorporates a flared design intended to reduce the risk of migration. The low profile, reconstrainable delivery system features a tapered tip to support access and radiopaque markers to aid in placement accuracy.

The SpyGlass Direct Visualization System, Radial Jaw 4 Biopsy Forceps and WallFlex Duodenal Stent will be available for demonstration at Boston Scientific's booth (#935) at DDW. The Company will also offer hands-on demonstration sessions in its

Simulated Clinical Endoscopy Suites and at its booth.

## **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 Institute, the American Society for Gastrointestinal Endoscopy and the Society for Surgery of the Alimentary Tract, DDW takes place May 1 – 5, at the Ernest N. Morial Convention Center, New Orleans. The meeting showcases approximately 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. For more information, visit <a href="https://www.ddw.org">www.ddw.org</a>.

## **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: <a href="https://www.bostonscientific.com">www.bostonscientific.com</a>.

## **About Boston Scientific Endoscopy**

Boston Scientific Endoscopy develops innovative technologies 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 hereafter. 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.

(1) 2008 Medicare Outpatient Prospective Payment Files OPPS(OP), 2008 Physician/Suppliers Procedure Summary Master Files (PSPSF), and BSC proprietary Estimate Data.

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