Boston Scientific

Boston Scientific's SpyGlass® Direct Visualization System Achieves Global Utilization Milestones

System used in 25,000 patient procedures at 600 facilities worldwide since 2007

NATICK, Mass., May 4, 2011 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced several milestones in the adoption of its SpyGlass® Direct Visualization System since its worldwide launch in July 2007. The SpyGlass System guides visualization and accessory devices for diagnostic and therapeutic procedures in the pancreatico-biliary system, including the hepatic ducts. It was developed to overcome limitations of traditional cholangioscopes and ERCP (endoscopic retrograde cholangio-pancreotography) while reducing the need for exploratory surgery, potentially reducing cost and procedure time.

During nearly four years of clinical practice, the system has been:

- Installed in approximately 600 medical facilities worldwide
- Used globally in more than 25,000 patient procedures
- Supported by published clinical data in more than 60 abstracts and articles in peer-reviewed medical journals

The SpyGlass System features a miniature 6,000-pixel fiber optic probe attached to a camera that permits direct visualization of the pancreatico-biliary system. Using dedicated irrigation and working channels, physicians can sample diagnostic tissues within the bile duct using the disposable SpyBite® Biopsy Forceps and deliver therapeutic devices, such as electrohydraulic lithotripsy (EHL) or laser probes, to break up large stones.

"The SpyGlass System is an important element of the ERCP suite and critical to our leadership in therapeutic endoscopy solutions," said David Pierce, President of Boston Scientific's Endoscopy Division. "We are committed to pursuing further clinical evaluation, expanded indications and ongoing system development to deliver the most advanced treatment options for patients with biliary and pancreatic disease."

Conventional visualization technology limitations

Prior to the SpyGlass System's launch in 2007, ERCP and traditional cholangioscopes were used to examine patients requiring diagnosis or treatment within the pancreatico-biliary system. ERCP, a specialized endoscopic procedure performed with fluoroscopy, contrast injection and x-ray imaging, has conventional visualization capabilities limited to two-dimensional, black and white fluoroscopy x-ray images. This can make it difficult to obtain accurate diagnostic tissue samples and deliver effective treatment. Estimates indicate that approximately 70 percent of ERCPs performed using brush cytology result in the need for additional testing for a final diagnosis.

Similar to ERCP, traditional cholangioscopes, while offering clinical utility, failed to gain widespread adoption as the technology was generally fragile, difficult-to-use and required multiple operators. The SpyGlass System is designed to overcome many of these limitations by offering effective direct visualization of the pancreas and bile ducts with a robust single-operator system that allows use of both diagnostic and therapeutic devices.

International registry highlights benefits of real-time direct visualization

Boston Scientific also announced results of an international, multi-center registry of 297 patients who underwent cholangioscopy for stone therapy or investigation of suspected pathology with the SpyGlass System. Results showed targeted biopsies using the SpyGlass System with SpyBite Forceps provided specimens adequate for histology in 89 percent of cases. Results also demonstrated a 92 percent success rate in large stone management procedures. In 29 percent of stone management procedures, the system identified stones that had been missed during initial procedures using conventional ERCP, further validating the benefits of real-time, direct visualization for stone detection.

"The SpyGlass System has quickly become an important tool in my GI practice and an indispensable technology when performing ERCP procedures," said Douglas Pleskow, M.D., Beth Israel Deaconess Medical Center in Boston. "It provides excellent direct visual access to the bile ducts and pancreas, helping obtain an accurate diagnosis and deliver effective treatment options in one procedure."

Boston Scientific has completed compatibility testing of the SpyGlass System with the Lumenis® SlimLine GI™ Fiber 365 micron laser probe and the Northgate® EHL probe. Compatibility with these adjunct technologies allows the system to be used during ERCP for laser or EHL stone ablation procedures within the bile ducts, expanding the product's functional capabilities.

Lumenis and SlimLine GI are trademarks of Lumenis, Ltd.; Northgate is a trademark of Northgate Technologies, Inc.

For more information on the SpyGlass System, visit Boston Scientific's Endoscopy Channel at www.youtube.com/bostonscientificendo.

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.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and 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, statements regarding business initiatives, new product launches and launch cadence, regulatory approvals, clinical trials, registries and testing, product performance and importance to our market position, and competitive offerings. 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.

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