

Boston Scientific SpyGlass® Direct Visualization System Demonstrates High Procedural Success Rate in Published Study

Multi-center study published in *Gastrointestinal Endoscopy* is largest ever reported on peroral cholangioscopy

NATICK, Mass., Nov. 2, 2011 [/PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) welcomes study results published in the October issue of *Gastrointestinal Endoscopy* showing an overall procedural success rate of 89 percent for the SpyGlass® Direct Visualization System, a single-operator cholangioscopy (SOC) device. The Boston Scientific-sponsored study followed nearly 300 patients at 15 centers in the U.S. and Europe and is the largest ever to report on peroral cholangioscopy (POC), a procedure that provides imaging and examination of the bile ducts.

Direct visualization of the bile ducts by POC can be valuable in diagnosing biliary abnormalities, obtaining biopsy specimens and guiding stone therapy. Although POC was first introduced four decades ago, adoption was slowed in part by technological limitations of the cholangioscope. The Boston Scientific SpyGlass System was designed to overcome those limitations, allowing physicians to directly visualize the pancreatobiliary system through a robust, single-operator system permitting use of diagnostic and therapeutic devices while providing color images from a 6,000-pixel fiber optic camera.

Data from the published study show the SpyGlass System technology can be safely used for both diagnostic and therapeutic procedures of the bile duct. In nearly two-thirds of diagnostic cases, procedure results prompted clinicians to make informed changes in disease management. In addition to an 89 percent overall procedural success rate, the study revealed:

- 64 percent of diagnostic procedures resulted in altered patient management
- 88 percent of collected biopsies were adequate for histology
- 66 percent accuracy in identifying a malignancy
- 92 percent procedural success for stone management
- 71 percent of patients achieved complete stone clearance in one session

The study authors conclude that evaluation of bile duct disease and biliary stone therapy can be safely performed with a high success rate by using the SpyGlass System.

"Study results reinforce what I have experienced in my own GI practice," said study author Douglas Pleskow, M.D., Beth Israel Deaconess Medical Center in Boston. "The SpyGlass System is a versatile and beneficial technology for a variety of diagnostic and therapeutic needs in endoscopic procedures. Having direct visual access to the bile ducts and pancreas allows physicians to deliver effective treatment in one procedure, thus improving patient care and potentially reducing costs."

"Findings from this clinical study continue to support previously published data and validate the safety and efficacy of the SpyGlass System as a leading diagnostic and therapeutic endoscopy solution," said David Pierce, President of Boston Scientific's Endoscopy Division. "We are committed to continuously developing innovative treatment options for patients with biliary and pancreatic disease that improve outcomes and advance the standard of care."

Launched worldwide in 2007, the SpyGlass System has been used in approximately 25,000 patient procedures at more than 700 facilities. For more information, 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.

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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 the performance of the Spyglass System and our product development plans. 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.

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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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