

Boston Scientific

## **FDA Clears Boston Scientific's SpyScope® Access and Delivery Catheter for Use in Endoscopic Procedures Throughout Pancreatico-Biliary System**

PRNewswire  
NATICK, Mass.  
(NYSE:BSX)

*SpyGlass® Direct Visualization System can now be used for diagnostic and therapeutic procedures for pancreatic disease*

NATICK, Mass., May 28 [/PRNewswire-FirstCall/](#) -- Boston Scientific Corporation (NYSE: BSX) today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its SpyScope® Access and Delivery Catheter for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system. The SpyScope Catheter is used in conjunction with the SpyGlass® Direct Visualization System. Previously available for use only in the bile and hepatic ducts, the SpyGlass System can now be used to guide visualization and accessory devices throughout the entire pancreatico-biliary system, enabling physicians to diagnose and treat pancreatic cancer or pre-cancerous tissues.

According to the American Cancer Society, in 2008 nearly 38,000 Americans were diagnosed with cancer of the pancreas -- the fourth-leading cause of cancer death in the U.S. Pancreatic cancer is a "silent" disease, with patients often not exhibiting symptoms until late in the disease process. As a result, the majority of patients with late-stage disease have a poor prognosis for survival.

"Early detection is critical to improving outcomes in patients with pancreatic cancer, but the 'silent' nature of the disease -- coupled with the inadequate diagnostic options of traditional x-ray or surgery -- have historically made this very difficult," said Douglas Pleskow, M.D., Beth Israel Deaconess Medical Center, Boston. "The SpyGlass System represents a tremendous advance in both the diagnosis and treatment process of pancreatic disease. With SpyGlass, I can navigate the ducts seamlessly, visualize the areas of interest and deliver treatment. In addition, I can use complementary technologies such as electrohydraulic lithotripsy (EHL) and lasers for stone ablation inside the biliary and hepatic ducts."

Until the introduction of the SpyGlass System, direct visualization of the pancreatico-biliary system was not widely performed, due to the significant limitations of traditional cholangioscopy systems. For many patients, exploratory surgery has been the only practical way to secure a diagnosis.

The SpyGlass Direct Visualization System is a single-operator system developed to overcome the limitations 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 EHL.

"Being able to diagnose pancreatic disease without the need for an invasive surgical procedure represents significant progress," said Michael Phalen, President, Boston Scientific Endoscopy. "With a more timely diagnosis, patients can begin treatment much earlier, resulting in the potential to dramatically improve outcomes. Physicians are already making the SpyGlass System an integral part of their practice, and they can now leverage this visualization technology across the entire pancreatico-biliary system to improve the quality of patient care. We are confident the SpyGlass System will be an important tool in the diagnosis and treatment of a broad range of diseases, most notably pancreatic cancer."

The upcoming Digestive Disease Week 2009 Conference will feature 14 abstracts on the clinical utility of the SpyGlass System in evaluating and treating pancreatic disease. The SpyGlass Direct Visualization System will be available for demonstration at Boston Scientific's booth #734.

The American Medical Association recently approved a new CPT® (Current Procedural Terminology) Code for cholangioscopy (43273), effective January 1, 2009, that can be used to describe cholangioscopy procedures using the SpyGlass System.

## 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.

CONTACT: Paul Donovan  
508-650-8541 (office)  
508-667-5165 (mobile)  
Media Relations  
Boston Scientific Corporation

Larry Neumann  
508-650-8696 (office)  
Investor Relations  
Boston Scientific Corporation

SOURCE: Boston Scientific Corporation

Web site: <http://www.bostonscientific.com/>

---

<https://stage.mediaroom.com/bostonscientific/spyscope-catheter-fda-clearance>