Boston Scientific

Study Shows That SpyGlass™ Direct Visualization System May Alter ERCP Diagnosis and Treatment Strategy

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NATICK, Mass. and LOS ANGELES, May 22 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced favorable results from an investigator initiated first human use experience and bench simulation study of its SpyGlass™ Direct Visualization System for single-operator duodenoscope assisted cholangiopancreatoscopy (SODAC). The results were presented at the Digestive Disease Week® (DDW®) meeting in Los Angeles. Highlighting these and other new information about the SpyGlass System at DDW, researchers reported that direct visualization with SpyGlass altered their diagnosis or treatment strategy with most patients who had been previously examined with ERCP (Endoscopic Retrograde Cholangio-Pancreotography).

ERCP is a specialized endoscopic procedure that is performed with fluoroscopy and contrast injection to examine and treat conditions of the bile ducts and pancreas, such as removing gallstones, opening obstructed bile ducts, and obtaining biopsies in suspected tumors. Conventional ERCP is hindered by the flat, two-dimensional, black and white image rendered by fluoroscopy, which can make it difficult to determine where to obtain tissue samples and potentially lead to an inaccurate or inconclusive clinical diagnosis. As a result, gastrointestinal endoscopists may need to conduct additional testing or even repeat the entire ERCP procedure. Data shows that up to 30 percent of diagnostic ERCPs are inconclusive, potentially creating the need for additional testing.

"Direct visualization significantly improves the chances of accurately diagnosing and treating a patient in one procedure, thus achieving the full potential of ERCP," said lead investigator Yang K. Chen, M.D., Division of Gastroenterology & Hepatology, University of Colorado at Denver and Health Sciences Center. "Bench simulation and animal testing showed that the SpyGlass System was effective for access, direct visualization and biopsy in all bile duct quadrants. In addition, SpyGlass can be performed by a single operator, unlike conventional systems which require two operators."

To overcome the imaging limitations of conventional ERCP, the SpyGlass System utilizes a miniature 6,000-pixel fiber optic SpyGlass probe that attaches to the camera head. The probe is inserted through a single-use access and delivery catheter that can be steered in four directions to access and inspect all four quadrants of the treatment area. The SpyGlass System attaches directly to a standard duodenal scope.

According to investigator and DDW co-presenter Douglas Pleskow, M.D., Co-Director, Endoscopy and Director of the Colon Cancer Center, Beth Israel Deaconess Medical Center, Boston, Massachusetts, "We used the SpyGlass System to examine and treat 22 patients. The group included patients with suspected malignancy, bile duct strictures, retained bile duct stones that had failed conventional ERCP treatment, and cystic lesions of the bile duct. The use of SpyGlass altered the initial ERCP impression and ultimately changed patient treatment strategy in most patients. SpyGlass examination with or without biopsy was accomplished without technical difficulty in 20 of the 22 cases. Additionally, SpyGlass findings changed patient management in 19 of the 22 cases."

"These studies indicate that the SpyGlass Direct Visualization System has the potential to redefine how ERCP is performed and to potentially help physicians obtain a more accurate diagnosis quickly," said Steve Moreci, Boston Scientific Senior Vice President and Group President, Endosurgery. "Gastroenterologists collaborated with Boston Scientific to successfully integrate a single-operator visualization technology with access and therapeutic devices. We will continue to refine SpyGlass System technology and support its initial deployment at selected, leading medical centers. We look forward to formally making the system more broadly available to the GI community sometime next year."

An estimated 445,000 ERCP procedures are performed in the United States each year. Although ERCP was initially a diagnostic procedure, the vast majority of cases now include therapeutic intervention performed with endoscopic accessory devices such as biopsy forceps, stone retrieval baskets and probes that administer electrohydraulic lithotripsy to break up biliary stones. The SpyGlass System will allow a single physician to perform both diagnostic and therapeutic procedures under direct vision.

About the SpyGlass™ Direct Visualization System

The SpyGlass Direct Visualization System is designed to provide direct visualization into the biliary ducts to identify stones and strictures. The SpyGlass System consists of capital equipment, including a monitor, light source, camera and mobility cart; the single-use SpyScope Access and Delivery Catheter; the miniature 6,000-pixel SpyGlass Direct Visualization Probe; and system accessory devices designed to acquire tissue samples and remove stones. The SpyGlass System is designed to be controlled by a single operator.

About Digestive Disease Week®

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, the American Society for Gastrointestinal Endoscopy, and the Society for Surgery of the Alimentary Tract, DDW takes place May 20 - 25, 2006, in Los Angeles. The meeting showcases approximately 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. Boston Scientific is exhibiting at booth #1227 at the conference.

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: http://www.bostonscientific.com/.

This press release contains forward-looking statements. Boston Scientific wishes to caution the reader of this press release that actual results may differ from those discussed in the forward-looking statements and may be adversely affected by, among other things, risks associated with new product development and commercialization, clinical trials, intellectual property, regulatory approvals, competitive offerings, integration of acquired companies, Boston Scientific's overall business strategy, and other factors described in Boston Scientific's filings with the Securities and Exchange Commission.

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