Boston Scientific

Boston Scientific Announces Worldwide Launch Of Spyglass™ Direct Visualization System

Single-operator system allows unprecedented visual access to bile duct

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NATICK, Mass., May 17 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced worldwide commercial availability of its SpyGlass™ Direct Visualization System for single-operator duodenoscope assisted cholangiopancreatoscopy (SODAC), or visual examination of the bile ducts. SpyGlass is an innovative system that requires just one physician operator, providing unprecedented, direct visualization of all bile-duct quadrants. The SpyGlass System provides four-way steerability and dedicated irrigation channels in addition to a 1.2 mm working channel through which diagnostic and therapeutic devices can be used.

The SpyGlass Direct Visualization System will be demonstrated at booth #2401 at the Digestive Disease Week® (DDW) meeting, which runs from May 19 to 24 in Washington D.C.

Direct visualization of the biliary system (cholangioscopy) has been possible for more than 30 years and its benefits are well documented in numerous published studies. However, the technology has not been widely adopted due to the cost and limitations of available devices. Boston Scientific designed the SpyGlass System to help GI endoscopists overcome these hurdles and to make cholangioscopy feasible for a larger number of physicians. Direct visualization with the SpyGlass System potentially offers significant procedural and clinical advantages over conventional Endoscopic Retrograde Cholangiopancreatography (ERCP).

ERCP is used to diagnose and treat challenging conditions of the bile ducts and pancreas, such as removing gallstones, opening obstructed bile ducts and obtaining biopsies in suspected tumors. With conventional ERCP, physicians use an endoscope to view the entrance to the biliary tract while access to the ducts is gained with small catheters passed through the scope's working channel. Visualization is achieved by injecting contrast media and taking x-rays of the treatment area. However, the resulting flat, two-dimensional, black and white images often do not provide sufficient information to obtain a complete diagnosis. Estimates indicate that at least 30 percent of ERCPs performed using brush cytology or biopsy forceps for tissue acquisition result in the need for additional testing.

If ERCP is insufficient to make an adequate diagnosis, or therapeutic intervention requires direct visualization into the bile ducts, the physician may choose to perform cholangiopancreatoscopy. Historically, this procedure has required two endoscopists, one to operate the therapeutic duodenoscope (mother scope) and a second to steer the cholangioscope (baby scope) and to operate its working channel. Conventional cholangiopancreatoscopy has failed to gain widespread adoption as a solution because available systems are labor intensive, and include instrumentation that is commonly viewed as fragile and difficult to manipulate.

The SpyGlass System overcomes the shortcomings of both conventional ERCP and currently available peroral cholangiopancreatoscopy systems, enabling a single physician to potentially secure a definitive diagnosis and perform therapeutic intervention in one procedure. The SpyGlass System utilizes a miniature 6,000-pixel fiber-optic probe that attaches to a 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 the treatment area. The System attaches directly to a standard duodenoscope, eliminating the need for a second physician operator.

Studies Demonstrate Clinical Benefits of SpyGlass System

While cholangioscopes have improved in recent years, their shortcomings have limited use of these devices in many physician practices. A study evaluating the clinical utility and safety of the single-operator SpyGlass System for diagnostic and therapeutic endoscopic procedures in bile ducts was performed at the University of Colorado Health Sciences Center in Denver and the Beth Israel Deaconess Medical Center in Boston. Thirty-five patients underwent procedures with the SpyGlass System. Results were published in the May 2007 issue of Gastrointestinal Endoscopy, demonstrating that a single-operator system proved clinically feasible and provided adequate samples for histologic diagnosis and successfully guided stone therapy. The procedures were deemed safe and well tolerated.

In addition, a preclinical study described in the February 2007 issue of Gastrointestinal Endoscopy addressed one of the limitations hindering the use of cholangioscopes-standard two-way deflection as compared to the new four-way deflected steering with the SpyGlass System. The study evaluated access and biopsy in all simulated biliary-duct quadrants with the SpyGlass System as compared to a conventional two-way deflection system. Results showed that success rates for access in all quadrants were significantly higher with the SpyGlass System than with conventional systems. In addition, higher success rates were attained using the SpyGlass System to access biopsy targets and to perform simulated biopsies. The SpyGlass

System permitted access to 48 of 48 biopsy targets.

"These preliminary studies suggest that the direct visualization provided by the SpyGlass System may offer tremendous advantages that until now have not been possible with traditional ERCP systems," said Yang K. Chen, M.D., Division of Gastroenterology & Hepatology, University of Colorado at Denver and Health Sciences Center, and lead investigator of both studies. "In addition, the SpyGlass System eliminates a significant clinical staffing requirement, and provides the potential to improve the efficiency of the procedure."

"Given that nearly half a million ERCP procedures are performed in the U.S. each year, Boston Scientific is committed to developing a product that can overcome technical issues, and facilitate the widespread adoption of direct visualization technology," said Michael Phalen, President of Boston Scientific's Endoscopy division. "We worked closely with leading gastroenterologists to develop the SpyGlass System and provide an enhanced visual method to perform ERCP. We are delighted to formally make the SpyGlass System available to the GI community and help improve the quality of health care to patients."

Boston Scientific is also establishing a comprehensive patient registry to build further evidence of the clinical utility of the SpyGlass System.

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 (AGA) Institute, the American Society for Gastrointestinal Endoscopy and the Society for Surgery of the Alimentary Tract, DDW takes place May 19-24, 2007, at the Washington Convention Center, Washington, DC. 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 http://www.ddw.org/ .

About Boston Scientific Endoscopy

Boston Scientific Endoscopy offers a wide range of endoscopic solutions to diagnose and treat gastrointestinal diseases. We are committed to developing new technologies in collaboration with GI physicians to improve patient outcomes through greater procedural efficiency and less-invasive diagnostic and therapeutic options.

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 product development and commercialization, clinical trials, intellectual property, regulatory approvals, competitive offerings, 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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