

Boston Scientific Announces FDA Approval of NexStent® Carotid Artery Stenting System Company to acquire EndoTex

PRNewswire-FirstCall
Natick, Mass.
(NYSE:BSX)

Natick, Mass., Nov. 3 [PRNewswire-FirstCall](#)/ -- Boston Scientific Corporation (NYSE: BSX) today announced that the U.S. Food and Drug Administration (FDA) has approved the NexStent® Carotid Stent and Monorail Delivery System for use in patients with carotid artery disease who are at high risk for surgery. The NexStent Carotid Stent is manufactured by EndoTex Interventional Systems, Inc. and has been distributed exclusively by Boston Scientific outside the U.S. since receiving European CE Mark in 2005. The Company said it will acquire EndoTex within 90 days under the terms of the companies' existing agreements. The Company said its FilterWire EZ™ Embolic Protection System, which was studied together with the NexStent Carotid Stent in the CABERNET clinical trial, is still pending 510(k) clearance by the FDA.

"This is an innovative stenting system that interventionalists in the U.S. have been waiting for," said Subbarao Myla, M.D., Co-Principal Investigator of the CABERNET Trial, of Hoag Memorial Hospital in Newport Beach, CA. "Study results demonstrate excellent outcomes at one month -- when there is the greatest risk of procedure-related stroke -- through one year in patients with a wide range of lesions and vessel anatomy."

The NexStent Carotid Stent is a laser-cut, nitinol stent with a rolled sheet design that enables one stent size to adapt to multiple diameters in tapered or non-tapered vessel configurations. Its self-sizing feature is designed to provide adaptability when treating lesions in the carotid arteries, and its closed-cell configuration is designed to increase lesion coverage and provide a smooth inner lumen to help facilitate delivery and retrieval of ancillary devices. The NexStent Carotid Stent provides an effective, low profile option for physicians who want a high degree of flexibility and plaque stabilization.

"Approval of this novel system was based upon the favorable results of the CABERNET trial," said Joseph Tartaglia, President and CEO of EndoTex Interventional Systems. "We are happy to provide patients with this effective therapy through our alliance with Boston Scientific."

"Boston Scientific has a long history of providing the science and technology physicians need to address a variety of clinical situations," said John Pedersen, President of Boston Scientific's Peripheral Interventions business. "By introducing this innovative and proven system to physicians in the United States, we're providing another treatment option for patients with carotid artery disease who are at high-risk for surgery."

Boston Scientific offers a full complement of accessories for use with this stenting system, including the Sterling™ Monorail® PTA Balloon Dilation Catheter, Thruway™ Peripheral Guide Wire, Amplatz Super Stiff™ Guide Wire, the Mach 1® Peripheral Guide Catheter, and Imager™ II Angiographic Catheter. As part of its commitment to fostering the advancement of interventional procedures for the treatment of vascular disease, Boston Scientific also offers comprehensive training, educational and support services to enhance procedural skills.

The carotid arteries are located on either side of the neck and are the main conduit through which blood flows from the heart to the brain. Plaque formation in these arteries can cause the arteries to harden and narrow, impeding blood flow and increasing the risk of stroke in affected patients. Until recently, the only option for opening the vessels was to perform carotid endarterectomy, a surgical procedure involving a vertical incision in the neck and artery and removal of the plaque from the vessel walls. Carotid artery stenting is a less-invasive procedure in which a stent-bearing catheter is guided to the affected area of the carotid arteries. The stent is placed at the site of the blockage, where it expands and forces the walls of the arteries open, restoring the blood flow.

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/>.

About EndoTex Interventional Systems

EndoTex Interventional Systems, Inc. is a private company located in Cupertino, CA that develops and manufactures less-invasive medical devices for use in the vascular system. For more information, please visit: <http://www.endotex.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.

CONTACT:
Dan Brennan
508-650-8538 (office)
617-459-2703 (mobile)
Investor Relations
Boston Scientific Corporation

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

Paul Edwards
408-517-2800
EndoTex Interventional Systems

SOURCE: Boston Scientific Corporation

CONTACT: Dan Brennan, Investor Relations, +1-508-650-8538, mobile:
+1-617-459-2703, or Paul Donovan, Media Relations, +1-508-650-8541, mobile:
+1-508-667-5165, both of Boston Scientific Corporation; or Paul Edwards of
EndoTex Interventional Systems, +1-408-517-2800

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

<https://news.bostonscientific.com/fda-approval-nexstent-carotid-artery-stenting-system>