Boston Scientific

FilterWire EZ™ Embolic Protection System Cleared By FDA For Carotid Artery Stenting

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(NYSE:BSX)

NATICK, Mass., Dec. 14 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced it has received clearance from the U.S. Food and Drug Administration (FDA) to market its FilterWire EZ™ Embolic Protection System for use in carotid artery stenting (CAS) procedures. The device was cleared by the FDA in August 2004 for use in coronary saphenous vein graft (SVG) interventions and is currently the market-leading embolic protection device for carotid artery stenting procedures outside the U.S.

The FilterWire EZ System is designed to efficiently capture plaque and other embolic material that may dislodge during stent implantation and prevent it from traveling into the microvasculature where it could pose an increased risk for stroke or heart attack. The device features simplified filter sizing -- one size can be placed in vessel diameters between 3.5 mm and 5.5 mm -- and is designed for easy preparation, delivery and retrieval. The safety and performance of the FilterWire EZ System was evaluated in the CABERNET Trial in conjunction with the recently approved NexStent® Carotid Stent and Monorail® Delivery System. With the new carotid indication, the FilterWire EZ Embolic Protection System can now be used in the U.S. to treat patients with carotid artery disease who are at high risk for surgery.

"We are pleased to now offer U.S. physicians the benefits of the FilterWire EZ System -- the world's leading embolic protection system -- in conjunction with the NexStent Carotid Stent to offer a less-invasive alternative to treating carotid artery disease and help reduce the devastating effects of stroke," said John Pedersen, President of Boston Scientific's Peripheral Interventions business. "With its second cleared indication, the FilterWire EZ System offers innovation and versatility to treat a variety of lesions and cases seen in every day practice."

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. Carotid artery disease occurs when plaque forms in these arteries, causing them 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 designed to be placed at the site of the blockage, where it expands and forces the walls of the arteries open, restoring the blood flow.

SVG disease occurs in patients who have previously had coronary artery bypass graft (CABG) surgery in which a vessel harvested from the patient's leg is surgically attached to the arteries of the heart. Blood is then redirected around the blocked artery, increasing blood flow to the heart. SVGs are more fragile and unpredictable than native coronary arteries, creating a challenging treatment situation and an increased need for embolic protection.

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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