Boston Scientific

FDA Grants Boston Scientific Clearance to Expand PolarCath™ Peripheral Dilatation System Offering with New Balloon Length

Longer balloon gives physicians broader treatment options in peripheral artery disease

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NATICK, Mass., Jan. 29 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced it has received 510(k) clearance from the U.S. Food and Drug Administration to expand its PolarCath™ Peripheral Dilatation System offering to include a 100-millimeter (mm) balloon. The PolarCath System is used to restore blood flow and reduce the risk of amputation in patients with critical limb ischemia (severe blockages in the arteries below the knee), or femoropopliteal blockage, a result of peripheral artery disease.

Peripheral artery disease is a circulatory disorder that affects approximately 10 million people in the United States. It results from a build-up of plaque in one or more of the arteries of the legs. As the disease progresses, accumulation of plaque may significantly reduce blood flow through the arteries, resulting in pain and increasing disability. In severe cases, amputation may be the only treatment option. Angioplasty, bypass graft surgery and thrombolytic (anti-clotting) therapy have traditionally been used to prevent further disability and limb amputation.

"As demonstrated in the recent Below-The-Knee (BTK) CHILL trial, CryoPlasty Therapy with the PolarCath Peripheral Dilatation System is a less- invasive means of preventing amputation in patients with severe peripheral artery disease," said John Pedersen, President of Boston Scientific's Peripheral Interventions business. "The availability of this balloon length will enable interventionalists to address a wider range of these debilitating blockages, including longer lesions in the subfemoral arteries, more efficiently than with several shorter balloons."

The new, 100-mm balloon is available in both 0.014-inch and 0.035-inch diameters. The PolarCath System also offers balloon lengths of 20, 40, 60 and 80 mm.

CryoPlasty Therapy using Boston Scientific's PolarCath System is a novel form of balloon angioplasty that cools the inside of occluded arteries in the legs while opening the blockages. This technology uses nitrous oxide to fill an angioplasty balloon within a blocked artery, cooling the balloon's surface to -10 degrees C. As it is inflated, the cold surface of the balloon cools the vascular lesion, which may help prevent re-blockage of the artery. Typically completed in just a few hours, procedures using the PolarCath System may relieve significant pain and symptoms, allowing patients to participate in daily life activities they were not able to do with the debilitating effects of critical limb ischemia. For more information visit http://www.cryoplasty.com/.

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, 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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