Boston Scientific

Boston Scientific Announces FDA Clearance for Peripheral Cutting Balloon Microsurgical Dilatation Device

(August 25, 2004) -- Boston Scientific Corporation (NYSE: BSX) today announced that it has received clearance from the U.S. Food and Drug Administration (FDA) to market its Peripheral Cutting Balloon microsurgical dilatation device in the United States. The Company will launch the device immediately.

The Peripheral Cutting Balloon device features tiny, longitudinally mounted atherotomes (microsurgical blades) on the surface of an angioplasty balloon and will be used to treat patients who are currently undergoing hemodialysis for End Stage Renal Disease (ESRD). A form of kidney disease, ESRD occurs when both kidneys are impaired or functioning at less than 10 percent of their normal rate.

Reliable access to the bloodstream three or more times a week is required to perform hemodialysis. This access must be created either through a direct connection to an artery (arteriovenous fistula) or via a graft, which involves connecting a soft, synthetic tube from the end of an artery to the end of a vein. The Peripheral Cutting Balloon device has been cleared by the FDA to treat patients with the second type of access point: the graft. A graft is typically used when patients have small or weak veins. Because of the need for repeated needle sticks during hemodialysis treatments, these access points are prone to stenosis (blockage of a vessel) that leads to decreased blood flow. In order to treat such stenosis, clinicians have traditionally used percutaneous transluminal angioplasty (PTA). However, in many cases the high inflation pressure associated with PTA can put unwanted pressure on the vessel wall. The Peripheral Cutting Balloon device provides an innovative option to conventional angioplasty because it reduces this type of trauma on the vessel. As the balloon is expanded, the atherotomes score the lesion with precise incisions, allowing the balloon to dilate the vessel with less pressure.

The stubborn make-up of these blockages may also pose a challenge called elastic recoil. The Peripheral Cutting Balloon device scores the lesion, disrupting the fibrotic continuity of the lesion.

The Peripheral Cutting Balloon device's availability comes amid a growing prevalence of ESRD, which affects more than 500,000 people worldwide every year, nearly 400,000 of them in the U.S.

"This device will undoubtedly have an important role in interventional medicine, particularly for the treatment of recalcitrant stenoses which are unyielding to conventional angioplasty," said Thomas Vesely, M.D., of the Washington University School of Medicine in St. Louis. "Because the device scores the lesion with precise incisions, it may also prevent elastic recoil in these stubborn lesions. There also appears to be a pain benefit associated with the device, as well as a six-month long-term benefit to patients with thrombosed dialysis grafts."

"The introduction of the Peripheral Cutting Balloon device shows Boston Scientific's continuing commitment to developing advanced technology for peripheral intervention," said Paul LaViolette, Boston Scientific Senior Vice President and Group President, Cardiovascular. "Physicians now have a new, highly effective tool for treating the complications that can result from hemodialysis access grafts."

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: www.bostonscientific.com.

This press release contains forward-looking statements. The Company 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 litigation, clinical trials, the regulatory approval process, reimbursement policies, commercialization of new technologies, intellectual property, and other factors described in the Company's filings with the Securities and Exchange Commission.

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