

Boston Scientific Receives Two FDA Approvals on Cutting Balloon™ Product Line

(March 15, 2005) -- Boston Scientific Corporation (NYSE: BSX) today announced that the U.S. Food and Drug Administration (FDA) has approved the Company's Quincy Distribution Center as a sterilization site for its Cutting Balloon™ microsurgical dilatation device product line. The Quincy facility will use electron-beam ("e-beam") technology to sterilize the Cutting Balloon device. The Company also announced that its Letterkenny, Ireland facility has received FDA approval to manufacture two versions of the Company's Cutting Balloon product line for distribution in the United States market. Both approvals came in the form of pre-market approval supplements and followed quality systems inspections at Boston Scientific facilities in California, Quincy and Letterkenny, in which the Company received no adverse observations from the FDA.

"These FDA approvals will enable us to deliver the Cutting Balloon technology to more clinicians more efficiently," said Paul LaViolette, Boston Scientific Chief Operating Officer. "In-house sterilization of the Cutting Balloon product line in Quincy, combined with expanded manufacturing in Letterkenny, will allow us to increase production, improve operational efficiency and decrease the time it takes to get our products from the manufacturing floor to the customer and ultimately, the patient. We are particularly gratified that our facilities received no observations from the FDA following extensive quality systems inspections."

The Letterkenny facility received FDA approval to manufacture the Cutting Balloon Ultra²™ device and the 2cm Peripheral Cutting Balloon™ device for distribution in the U.S. market. The Letterkenny facility has previously manufactured both products for distribution outside the U.S. The Cutting Balloon Ultra² device represents the current generation of the Company's Cutting Balloon™ product for the treatment of coronary artery disease. It has a novel mechanism that safely dilates coronary lesions at lower pressures. The Cutting Balloon Ultra² features tiny, longitudinally mounted atherotomes (microsurgical blades) that relieve stress in the artery as the balloon inflates, reducing resistance of a lesion to expansion. The device's proprietary fold mechanism shields the blades and protects the vessel wall as the catheter is passed to and from the treatment site.

The Peripheral Cutting Balloon device uses the same mechanism of action as the Cutting Balloon Ultra² yet in a larger size (2 cm length and diameters up to 8 mm). The Peripheral Cutting Balloon will be used to treat the synthetic grafts of 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.

The Company also plans to use the Quincy Distribution Center to sterilize other devices in the Boston Scientific product portfolio in the future.

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, the regulatory approval process, operational improvements, competitive offerings and other factors described in the Company's filings with the Securities and Exchange Commission.

<https://news.bostonscientific.com/news-releases?item=58723>