Boston Scientific Announces FDA Approval of RenegadeÃ,® HI-FLOâ„¢ FathomÃ,® Pre-Loaded System

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NATICK, Mass., Jan. 31, 2011 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX [1]) today announced that the U.S. Food and Drug Administration (FDA) has approved its Renegade® HI-FLO™ Fathom® Pre-Loaded System for selective access and delivery of diagnostic, embolic and therapeutic materials into the peripheral vasculature. The system will primarily be used by interventional radiologists for minimally invasive procedures to treat uterine fibroids and liver cancer. The Company said it plans to launch the product immediately in the United States.

The Renegade HI-FLO Fathom Pre-Loaded System combines the turn-for-turn torque response, flexibility and high visibility of the Fathom-16 Steerable Guidewire with the clinically proven performance of the Renegade HI-FLO Microcatheter, pre-loaded in a single convenient platform. The system will be available in eight configurations to suit a broad range of peripheral embolization procedures.

"The excellent deliverability, torque transmission and flow capacity of the Renegade HI-FLO Fathom Pre-Loaded System provides physicians with the performance they need to efficiently access tortuous vessels across many types of interventional oncology procedures," said Jeff Geschwind, M.D., Professor of Radiology, Surgery and Oncology, and Director of Vascular and Interventional Radiology at the Johns Hopkins University School of Medicine. "Having the Fathom-16 Guidewire pre-loaded in the Renegade HI-FLO Microcatheter will reduce my procedural preparation time and the number of devices that my staff must manage."

The Renegade HI-FLO Fathom Pre-Loaded System complements Boston Scientific's extensive portfolio of minimally invasive access and embolization products to provide physicians with a range of diagnostic and treatment options for uterine fibroids, liver cancer and other conditions requirin
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