Medtronic News

Medtronic Completes Enrollment in Clinical Study of Complete SE(R) (Self-Expanding) Vascular Stent

Milestone Shows Progress on Indication-Specific Trials for Treating Peripheral Arterial Disease

MINNEAPOLIS, Aug 06, 2010 (BUSINESS WIRE) --

With an expanded focus on addressing peripheral arterial disease (PAD), Medtronic, Inc. (NYSE: MDT), today announced that it has completed enrollment in a clinical trial of the company's Complete SE (self-expanding) vascular stent for the treatment of atherosclerosis in the superficial femoral artery (SFA), including the proximal popliteal artery (PPA), which runs under the skin of the thigh.

Approved by the FDA under an investigational device exemption (IDE), the Complete SE SFA study is a prospective, multicenter, single-arm trial to evaluate the safety and efficacy of the Complete SE vascular stent system in the treatment of *de novo* and/or restenotic lesions or occlusions in the SFA/PPA. The study enrolled 196 patients with symptomatic, ischemic PAD. The primary endpoints are major adverse events (MAEs) and patency of the stent at 12 months.

PAD of the lower extremities, including the SFA, affects approximately 8 million people in the United States each year, although many patients are unaware of their condition or its consequences. PAD patients have a two- to six-fold increase in cardiovascular mortality and a significantly increased risk of amputation, disability and diminished quality of life.

"Many people are unable to recognize the symptoms of PAD, and the condition is often undiagnosed by healthcare professionals," said Dr. John Laird, M.D., medical director of the Vascular Center at the University of California (UC), Davis, who served as the study's U.S. principal investigator. "With this trial, Medtronic is partnering with physicians around the world to expand clinical knowledge about a potentially serious health condition while at the same time generating data in support of the safety and efficacy of its Complete SE stent in the treatment of PAD."

Medtronic is committed to advancing the treatment of cardiovascular disease through collaboration with leading clinicians, researchers and scientists worldwide.

About Medtronic
Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

SOURCE: Medtronic, Inc.

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