Medtronic News

Medtronic Receives FDA Approval for New Indication for Complete(R) SE Vascular Stent

Now Indicated for Treatment of Peripheral Disease in the Iliac Arteries, Self-Expanding (SE) Device Redefines Deployment Accuracy for Precise Placement

MINNEAPOLIS, Apr 21, 2010 (BUSINESS WIRE) --Broadening the scope of innovation for cardiovascular interventions beyond the heart, Medtronic, Inc. (NYSE: MDT), announced today that it has received approval from the U.S. Food and Drug Administration (FDA) for the Complete(R) SE Vascular Stent System to be used for the treatment of peripheral arterial disease (PAD) in the iliac arteries, major blood vessels within the pelvis that supply blood to the lower extremities.

"The Complete SE Vascular Stent System provides physicians with a new treatment option that offers significant benefits for patients with narrowed iliac arteries due to peripheral vascular disease," said Robert Molnar, M.D., of Michigan Vascular Research Center in Flint, Mich. "The system enables highly accurate stent placement in the iliacs, reducing the likelihood of stent 'jumping,' which we commonly see during deployment with the use of many self-expanding stent systems."

Dr. Molnar and William Gray, M.D., director of endovascular intervention at NewYork-Presbyterian Hospital/Columbia University Medical Center, led the study (as co-principal investigators) that contributed to this approval.

The Complete SE Vascular Stent System features several novel advances, including an innovative dual-deployment delivery system with a unique triaxial design. The new delivery system is made up of an inner shaft, a retractable sheath and a stabilizing sheath that reduces friction and allows the retractable sheath to move back freely. This decreases the amount of force required to deploy the stent, thereby making deployment easy and precise.

"FDA approval of the Complete SE Vascular Stent System for a peripheral indication marks a successful milestone in our PAD clinical research program," said Sean Salmon, vice president and general manager of Coronary and Peripheral, part of the CardioVascular business, at Medtronic. "Following our acquisition of Invatec, this approval augments Medtronic's offerings in a large and growing market where patients are significantly under-diagnosed and could benefit from expanded treatment options."

In other areas of Medtronic's PAD clinical research program, physicians are progressing with enrollment in two additional indication-specific trials, one investigating the use of the Complete SE stent for the treatment of superficial femoral artery stenoses, and the other studying the balloon-expandable Assurant Cobalt stent in treating iliac artery disease.

According to the Peripheral Arterial Disease Coalition, PAD of the lower extremities affects approximately eight million people in the United States, although many patients are unaware of their condition or the seriousness of it. PAD results in a two- to six-fold increase in cardiovascular mortality and a significantly increased risk of amputation, disability and diminished quality of life. It often signals atherosclerosis in the heart and the brain, the PAD Coalition reports.

Medtronic CardioVascular is committed to advancing the treatment of coronary, peripheral, aortic and structural heart 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.

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