Medtronic News

Medtronic Launches Lower-Extremity Indication for Complete 'SE' Vascular Stent Internationally

Self-Expanding Peripheral Device Gets CE Mark for Superficial Femoral and Proximal Popliteal Arteries

MINNEAPOLIS -- Jan. 24, 2013 -- Expanding its role in the treatment of peripheral artery disease, Medtronic, Inc. (NYSE: MDT) today announced the CE *(Conformité Européene)* mark and international launch of its Complete SE (self-expanding) vascular stent for use in the lower extremities -- specifically, the superficial femoral arteries (SFA) and proximal popliteal arteries (PPA), which supply blood to the legs.

In the United States, the Complete SE stent is approved by the U.S. Food and Drug Administration (FDA) only for use in the iliac arteries, which supply blood to the pelvis and legs. Its use in lower-extremity arteries in the United States is under review by the FDA. Previously CE marked only for use in the iliac arteries, the Complete SE stent can now be used internationally in the lower extremities as well.

The new indication was obtained after clinical data from the Complete SE SFA study -- an independently adjudicated single-arm, multicenter trial that enrolled 196 patients at 28 sites in the United States and Europe -- showed a low clinically-driven target lesion revascularization (i.e. repeat procedure) rate of 8.4 percent at 12 months. Additionally, and unique among similar studies utilizing bare-metal stents in this vessel bed, there were no (0.0 percent) stent fractures at 12 months in the study.

These outcomes were achieved despite the challenging nature of the patient population represented:

- 45 percent of the patients had diabetes.
- 50 percent of the lesions were located in the distal segment of the superficial femoral /proximal popliteal artery.
- 56 percent of the lesions were defined as highly calcified.
- 67 percent of patients had a Rutherford Category rating of three or higher.

The Complete SE SFA study showed statistically significant improvements in multiple measures of clinical and functional effectiveness:

- More than 80 percent of study subjects had achieved a Rutherford Category value of 0 or 1, the favorable end of the 0-6 scale, at 30 days, and that benefit persisted through six months and one year of follow-up.
- Treatment with the Complete SE stent also resulted in highly significant positive shifts in mean ankle brachial index (ABI) or toe brachial index (TBI) scores at six and 12 months, with 65 percent of study subjects improving by at least 0.15 percent over the follow-up period.
- On Walking Assessment measures, impairment improved by 37 percent, distance by 33 percent, speed by 22 percent and stair climbing by 23 percent.

"The Complete SE stent not only delivers compelling clinical results, but its unique features and delivery system offer an ease-of-use unparalleled with other devices designed to treat lower-extremity lesions," said Prof. Dierk Scheinert, chairman of the Center for Vascular Medicine at Part Hospital in Leipzig, Germany.

With risk factors including smoking, diabetes, obesity, high blood pressure, high cholesterol, age (50 or older) and familial history, peripheral artery disease narrows the vessels that supply blood to the body, especially the limbs. Typically characterized by an excessive buildup of plaque in these vessels, the condition can progress without treatment to critical limb ischemia, which often leads to amputation and premature death.

A variety of treatments are used to restore normal blood flow in patients with peripheral artery disease. Stents are metallic scaffolds used to improve blood flow by expanding the interior diameter of narrowed arteries. They are implanted in a minimally invasive procedure that uses catheters to access the arterial segment requiring treatment.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative

medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

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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