Medtronic News

Medtronic Announces CE Mark for New Lower Profile HawkOne 6F Directional Atherectomy System

Expands Treatment Options for Patients in Europe with Peripheral Artery Disease Both Above and Below the Knee

DUBLIN - Jan. 24, 2017 - Medtronic plc (NYSE: MDT) today announced CE (*Conformité Européene*) Mark approval for the HawkOne(TM) directional atherectomy system in a lower profile size for treating patients with peripheral artery disease (PAD). The new HawkOne 6 French (6F) provides an effective and easy-to-use treatment option for patients with PAD both above and below the knee with a single device. The HawkOne system is designed to remove plaque from the vessel wall and restore blood flow.

PAD is a serious, chronic condition that affects more than 200 million people worldwide.1 In PAD, arteries in the legs become narrowed or blocked by plaque. This narrowing of the blood vessel reduces blood flow to the leg, which can result in severe pain and limit physical mobility. Blocked arteries below the knee are more likely to be calcified, linked to lower treatment success,2 and may also develop into critical limb ischemia (CLI), which can result in non-healing leg ulcers and increased risk of amputation.3, 4

"Directional atherectomy is an established treatment modality for patients with complex PAD to restore patency, maximize luminal gain and preserve future treatment options," said Professor Thomas Zeller, M.D., head, Department of Angiology at Universitäts-Herzzentrum Freiburg, Bad Krozingen, Germany. "The new smaller HawkOne 6F size is an advanced option to treat patients with multi-level PAD, addressing lesions of various length, morphology, and location, particularly those below the knee."

The HawkOne system also enables physicians to treat severe calcified lesions more efficiently with no increase in cut depth. The system can treat calcified lesions up to two times more effectively than the TurboHawk(TM)device.5 The HawkOne system has a preloaded flush tool, which improves cleaning time by up to 55 percent when compared to the TurboHawk high efficiency cutter.6 The 6F size is designed to simplify device selection and provide easy set-up with no capital equipment.

"We are excited to announce CE Mark approval for HawkOne 6F shortly after receiving FDA clearance for the system in October," said Mark Pacyna, vice president and general manager of the Peripheral business, which is part of the Aortic & Peripheral Vascular division at Medtronic. "The HawkOne 6F system provides physicians with an effective and efficient treatment option for treating PAD above and below the knee and reinforces our commitment to expand access to therapy innovations that protect limbs and enhance lives."

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 Directional Atherectomy

The new 6F HawkOne expands Medtronic's directional atherectomy portfolio, which also includes the TurboHawk and SilverHawk(TM) systems and is backed by more than 15 peer-reviewed studies.7 These include DEFINITIVE LE, the largest independently-adjudicated study of an atherectomy procedure ever conducted, and DEFINITIVE AR, a pilot study, and the first randomized look into the effects of preparing a vessel with directional atherectomy followed by treatment with a drug-coated balloon (DCB).

Results from DEFINITIVE LE demonstrated 95 percent limb salvage in patients with critical limb ischemia (CLI) and 78 percent overall patency in claudicant patients 12 months post treatment.8 A subset analysis of DEFINITIVE LE in claudicant patients with infrapopliteal disease observed 12-month patency rates of approximately 90 percent.9 Both DEFINITIVE LE and DEFINITIVE AR showed low dissection and provisional stent rates when patients were treated with directional atherectomy.9

Furthermore, directional atherectomy can also be used as an adjunctive treatment prior to using the Medtronic IN.PACT® Admiral® drug-coated balloon.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 88,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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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1 Fowkes, F. G., et al. (2013). Lancet 382(9901): 1329-1340.

2 Roberts, D., et al. (2014). Catheter Cardiovasc Interv 84(2): 236-244.

3 Dua, A. and C. J. Lee. (2016). Tech Vasc Interv Radiol 19(2): 91-95.

4 Liistro, F., et al. (2013). Circulation 128(6): 615-621.

5 Medtronic data on file.

6 Medtronic data on file.

7 Medtronic data on file.

8 McKinsey, J. F., et al. (2014). JACC Cardiovasc Interv 7(8): 923-933.

9 Zeller, T. (2014). DEFINITIVE AR, VIVA 14.

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