

Medtronic Initiates U.S. Launch of HawkOne(tm) Directional Atherectomy System for Treatment of Peripheral Arterial Disease

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Third-Generation System Treats All Plaque Morphologies Including Severe Calcium, While Streamlining Procedural Efficiency

DUBLIN -- April 9, 2015 -- Medtronic plc (NYSE: MDT) enhances its leading directional atherectomy portfolio with the U.S. launch of the HawkOne(TM) directional atherectomy system. The HawkOne system provides physicians with a solution to treat all plaque morphologies in patients with peripheral arterial disease, including patients who have plaque blockages that have become severely calcified.

Calcium is a prevalent, real-world treatment challenge that is widely seen across many chronic conditions and is often linked to lower procedural success and suboptimal outcomes. The HawkOne system enables operators to treat severe calcium more efficiently, and the technology design improves lesion engagement. In benchtop testing, the system was able to treat calcified lesions up to two times more effectively than the TurboHawk(TM) device.

"I use directional atherectomy in my practice because of its ability to achieve luminal gain and restore patency," said Dr. Mark Fugate, M.D., University Surgical Associates, Chattanooga, Tenn., who performed the first case in the U.S. with the HawkOne system. "The HawkOne system's improved crossability and efficient calcium cutting will further enable our ability to effectively and efficiently treat practically any patient with PAD."

The HawkOne system's unique design also streamlines procedural efficiency, with improved crossing and cleaning capabilities. Its lower crossing profile improves sheath deliverability and allows physicians to cross challenging lesions more predictably. The HawkOne system has been enhanced with a preloaded cleaning tool, which improves cleaning time by up to 55 percent when compared to the TurboHawk(TM) High Efficiency Cutter.

"In the cath lab, we are always looking for new technologies that effectively treat the disease, while improving efficiency in the lab," said Dr. Louis Lopez, M.D., St. Joseph Hospital, Fort Wayne, Ind. "I was very impressed with the significant improvements of the device's crossing and cleaning capabilities."

Medtronic's directional atherectomy portfolio also includes the TurboHawk and SilverHawk(TM) systems and is backed by more than 15 peer-reviewed studies. Recent published data from the [DEFINITIVE LE study](#) in *the Journal of American College of Cardiology, Cardiovascular Interventions* demonstrated 95 percent limb salvage in patients with critical limb ischemia (CLI) and 78 percent overall patency (the ability for the treated artery to remain open) in claudicant patients at 12 months following treatment with directional atherectomy.¹

"Based on physician feedback and collaboration, we have developed a technology that enables physicians to treat lower extremity PAD more efficiently and effectively," said Brian Verrier, Vice President and General Manager, Peripheral Vascular, Medtronic. "The HawkOne system enhances our directional atherectomy platforms and reinforces our commitment to therapy innovation by providing physicians and patients with new treatment solutions that protect limbs and enhance lives."

In collaboration with leading clinicians, researchers and scientists, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular diseases and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers worldwide.

About Peripheral Arterial Disease

Peripheral arterial disease (PAD) affects more than 202 million people worldwide² and more than 10 million people in the U.S.³ It occurs when arteries in the legs become narrowed or blocked by plaque, and it can cause severe pain, limited physical mobility and non-healing leg ulcers. PAD can also lead to serious health consequences such as amputation, cardiovascular disease and death.

ABOUT MEDTRONIC

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, 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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¹ McKinsey J, Zeller T, Rocha-Singh K, Jaff M, Garcia L, DEFINITIVE LE Investigators. Lower Extremity Revascularization Using Directional Atherectomy: 12-Month Prospective Results of the DEFINITIVE LE Study. *JACC: Cardiovascular Interventions* 2014; 7(8):923-33.

² Fowkes, F G et al. Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. *The Lancet*. 19 October 2013 (Vol. 382, Issue 9901, Pages 1329-1340) doi: 10.1016/S0140-6736(13)61249-0

³ Peripheral Artery Disease. The Society for Cardiovascular Angiography and Interventions. <http://www.scai.org/SecondsCount/Disease/PeripheralArteryDiseasePAD.aspx>

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