

Covidien's HawkOne™ Directional Atherectomy System Receives FDA 510(K) Clearance for the Treatment of Peripheral Arterial Disease

The HawkOne™ System strengthens Covidien's directional atherectomy platform with a versatile solution for the treatment of peripheral arterial disease

DUBLIN, Ireland--(BUSINESS WIRE)--Nov. 4, 2014--

Covidien plc (NYSE: COV) today announced U.S. Food and Drug Administration 510(k) clearance for the HawkOne™ directional atherectomy system. The latest addition to Covidien's [directional atherectomy portfolio](#), the HawkOne™ system provides physicians with an enhanced cutting mechanism to more effectively treat the widest variety of plaque in patients with peripheral arterial disease (PAD).

PAD affects more than 202 million people worldwide¹ and more than 10 million people in the U.S.² 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.

"Covidien is committed to being the clear first choice for our physician and hospital partners by delivering new innovative technologies that help save and improve patient lives," said Brian Verrier, president, Peripheral Vascular, Covidien. "The FDA clearance of the HawkOne™ system enhances our leading peripheral vascular portfolio and further demonstrates Covidien's leadership in the atherectomy space."

Covidien's directional atherectomy portfolio includes the TurboHawk™ and SilverHawk™ 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.³

About Covidien

Covidien is a global health care leader that understands the challenges faced by providers and their patients and works to address them with innovative medical technology solutions and patient care products. Inspired by patients and caregivers, Covidien's team of dedicated professionals is privileged to help save and improve lives around the world. With more than 38,000 employees, Covidien operates in 150-plus countries and had 2013 revenue of \$10.2 billion. To learn more about our business visit www.covidien.com or connect with us on [Twitter](#).

1 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

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

3 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.

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<https://news.medtronic.com/2014-11-04-Covidien-HawkOne-TM-Directional-Atherectomy-System-Received-FDA-510-K-Clearance-for-the-Treatment-of-Peripheral-Arterial-Disease>