Medtronic's Pipeline(TM) Flex Embolization Device Receives FDA Approval

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Minimally-Invasive Flow Diversion Device for Unruptured Brain Aneurysms Designed for More Exact and Controlled Placement[1]

DUBLIN - February 5, 2015 - Medtronic plc (NYSE:MDT), a global leader in medical technology, services and solutions, announced today that it has received U.S. Food and Drug Administration (FDA) approval for its Pipeline(TM) Flex embolization device. Available through a limited U.S. launch in the coming weeks, Medtronic's latest-generation flow diversion device represents an unrivaled advancement in large and giant brain aneurysm treatment.

"Flow diversion has been a major breakthrough therapy for large or giant wide-necked brain aneurysms that are complex and have considerably higher risk of rupture and higher rates of complication with conventional treatment," said Dr. Ricardo Hanel, Neurosurgeon, Director of stroke and Cerebrovascular Center at Baptist Health in Jacksonville, Florida. "With thousands of patients successfully treated with Pipeline Embolization Device, the Pipeline Flex's innovative delivery system will result in further advancing endovascular treatment and care."

Designed to divert blood flow away from an aneurysm, the Pipeline Flex embolization device features a braided cylindrical mesh tube that is implanted across the base or neck of the aneurysm. The device cuts off blood flow to the aneurysm, reconstructing the diseased section of the parent vessel.

"The Pipeline Flex embolization device is the next advancement in flow diversion, combining our clinically-proven braid design[2] with a new delivery system designed to offer improved accuracy and control when performing these advanced procedures inside the brain," said Brett Wall, president, Neurovascular, Medtronic. "We are excited to bring new value to our medical community and patients."

In the United States, the Pipeline Flex device is intended for use for the endovascular treatment of complex intracranial aneurysms that are not amenable to treatment with surgical clipping and are attached to parent vessels measuring between 2.5 and 5.0 mm in diameter. An estimated 500,000 people throughout the world die each year caused due to ruptured brain aneurysms, and half the victims are younger than 50 years of age.[3]

The first-generation Pipeline(TM) embolization device has been used to treat patients in the United States since it was approved by the FDA in 2011. This product is part of the Neurovascular portfolio in Medtronic's Restorative Therapies Group.

Multimedia Release

A multimedia version of this release, with downloadable graphics can be found at: http://bit.ly/1ubZktx

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] Covidien Internal Report: Report on File
[2] Becske T, Kallmes DF, Saatci I, et al. Pipeline for Uncoilable or Failed Aneurysms: Results from a Multicenter Clinical Trial. Radiology. Published online before print February 15, 2013, doi: 10.1148/radiol.13120099
[3] The Brain Aneurysm Foundation: http://www.bafound.org/Statistics_and_Facts

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