Medtronic News

Medtronic Receives FDA Approval on Expanded Indication for Pipeline Flex Embolization Device

Approval Based on Clinical Data from the PREMIER Trial - New Indication Provides Options for Patients with Small or Medium, Wide-Necked Brain Aneurysms

DUBLIN - February 7, 2019 - Medtronic plc (NYSE:MDT) announced today that it has received U.S. Food and Drug Administration (FDA) approval on an expanded indication for its Pipeline(TM) Flex embolization device.1Previously indicated for the endovascular treatment of adults with large or giant wide-necked intracranial aneurysms (IAs) in the internal carotid artery from the petrous to the superior hypophyseal segments, the new indication opens options for patients with small or medium, wide-necked brain aneurysms in the territory from the petrous to the terminus of the internal carotid artery.

An estimated 500,000 people throughout the world die each year due to ruptured brain aneurysms, with half the victims younger than 50 years of age.2

Approval was based on clinical data from the Prospective Study on Embolization of Intracranial aneurysms with the Pipeline(TM) Device (PREMIER) trial, which expands understanding of the safety and efficacy for this device for a broader patient population. A total of 141 subjects with a mean aneurysm size of 5.0±1.92 mm were analyzed. Data showed one-year occlusion rates of 76.7 percent with the use of 1.1 device per subject on average and a 2.2 percent occurrence of major stroke or neurological death.3

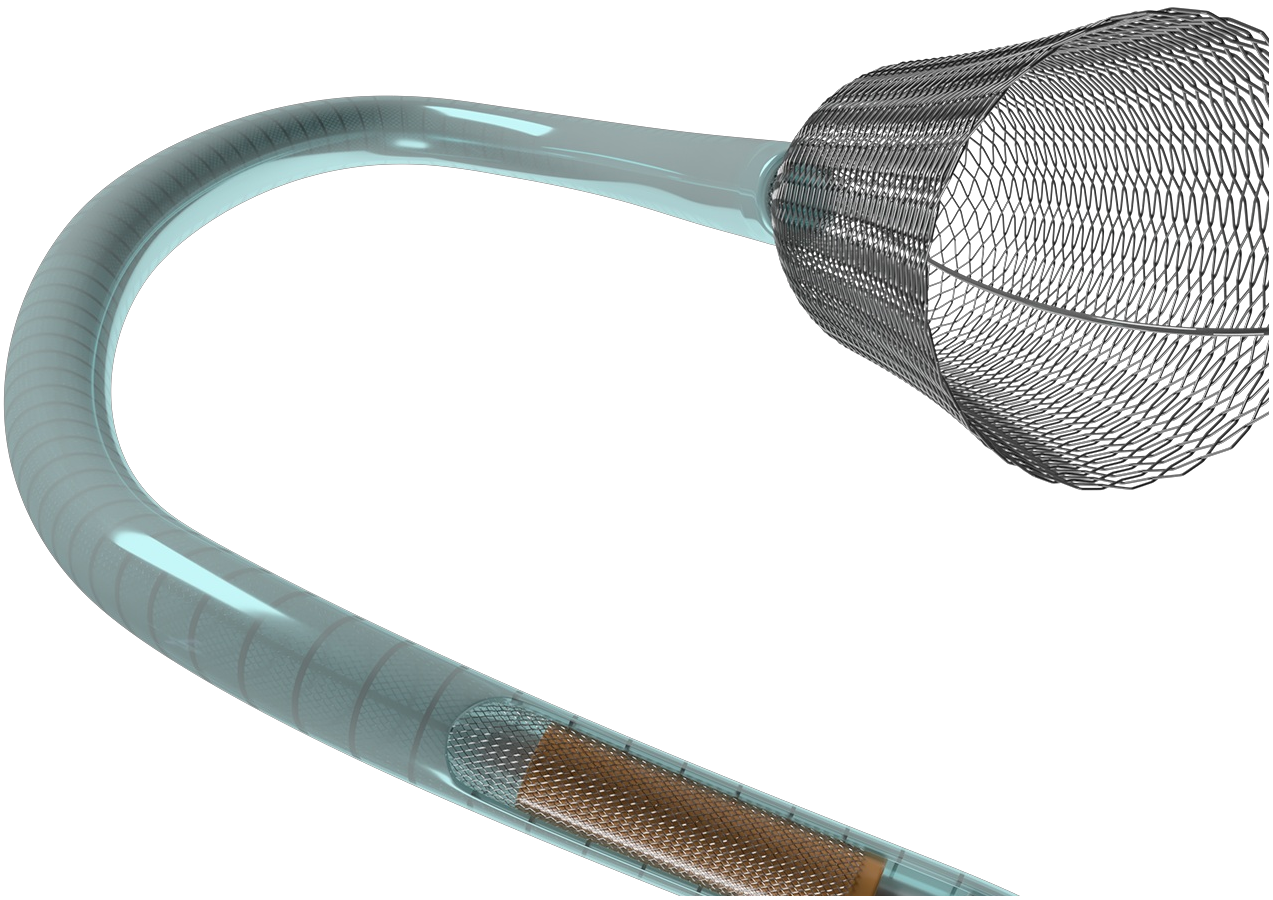
"PREMIER is another landmark study with Pipeline and moves the bar on the safe treatment of wide-necked brain aneurysms," said Dr. Ricardo Hanel, neurosurgeon, director of Stroke and Cerebrovascular Center at Baptist Health in Jacksonville, Fla., and principal investigator for the PREMIER trial. "This data changes the way we, as physicians, think about using Pipeline Flex to treat our patients."

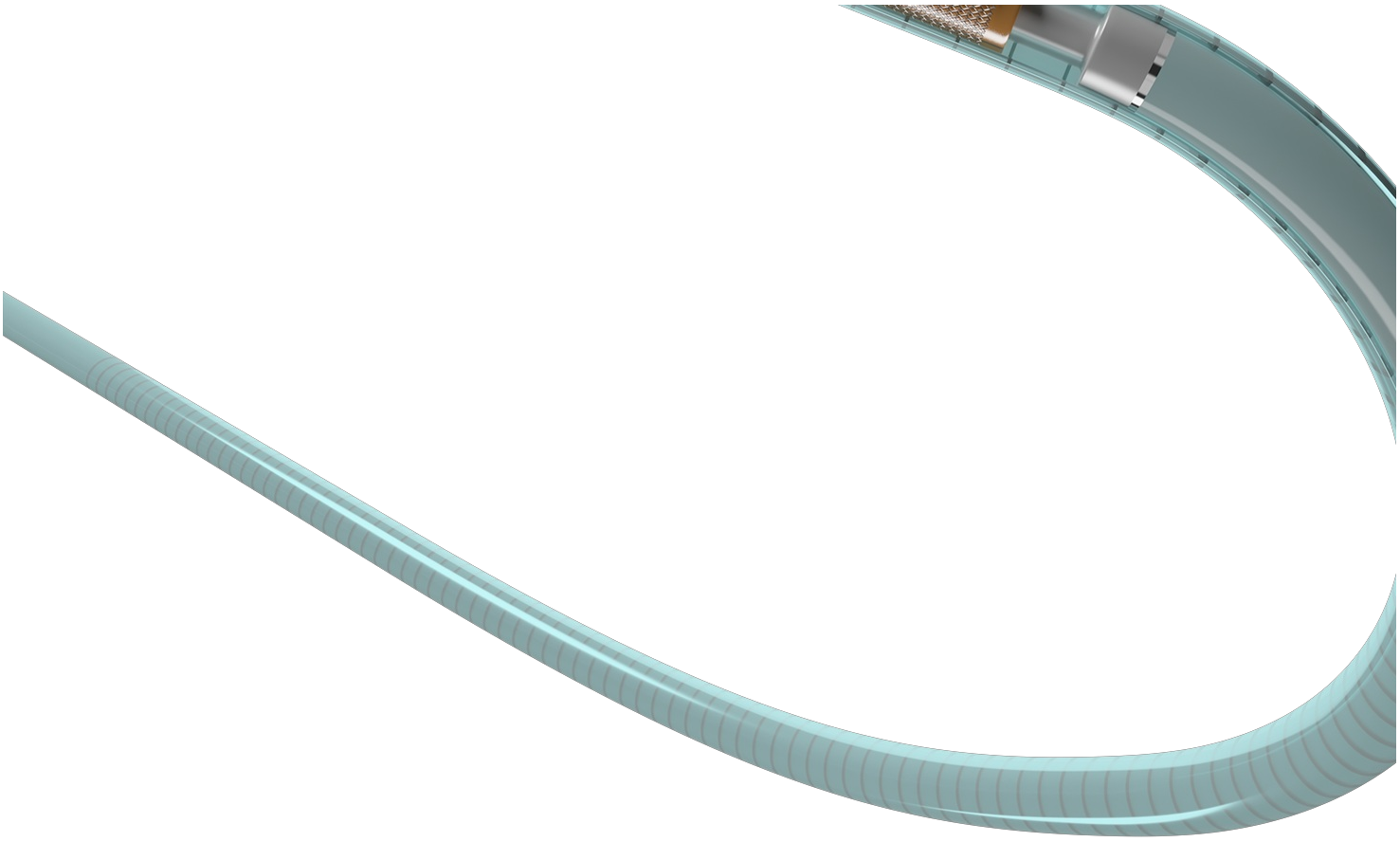
Designed to divert blood flow away from an aneurysm, the Pipeline Flex embolization device features a braided cylindrical mesh tube that is implanted across the base or neck of the aneurysm. The device cuts off blood flow to the aneurysm, reconstructing the diseased section of the parent vessel. This is the second Investigational Device Exemption (IDE) study for this implant which gained FDA approval after completing the 'Pipeline for Uncoilable or Failed aneurysms' (PUFs) trial, a 5-year study for large and giant wide-necked aneurysms of the intracranial internal carotid artery (ICA) where efficacy rates were reported at 70.8 percent at 1 year that progressed to 95 percent in subjects with angiographic follow up at the 5 year time period. In the PUFs study the overall occurrence of major stroke or neurological death was 5.6 percent4. There were no documented cases of aneurysm recurrence in patients treated with the implant.

"Working hand-in-hand with physicians to develop new technology and clinical data is at the core of our mission. The PREMIER study not only demonstrated excellent safety and efficacy outcomes but also delivered on our commitment to broadening access to innovative therapies for new groups of patients requiring aneurysm treatment," said Stacey Pugh, vice president and general manager of the Neurovascular business, which is part of the Restorative Therapies Group at Medtronic.

In the United States, the Pipeline Flex device is intended for use for the endovascular treatment of complex wide-necked intracranial aneurysms located in the ICA, attached to parent vessels measuring between 2.0 and 5.0 mm in diameter.

Flow diversion has been used to treat patients in the United States since 2011. This product is part of the Neurovascular portfolio in Medtronic's Restorative Therapies Group.





Medtronic Neurovascular's Pipeline(TM) Flex embolization device received FDA approval of an indication expansion for patients with small or medium, wide-necked brain aneurysms. Click the thumbnail above for a larger image.

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 86,000 people worldwide, serving physicians, hospitals, and patients in more than 150 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. PMA- P100018-S015
2. Brain Aneurysm Statistics and Facts. (2019, January 16). https://www.bafound.org/about-brain-aneurysms/brain-aneurysm-basics/brain-aneurysm-statistics-and-facts/
3. PREMIER Clinical Study Report Medtronic FD3563, mITT Population, Rev B. 12-SEP-2018
4. Becske T. et al., Long-Term Clinical and Angiographic Outcomes Following Pipeline Embolization Device Treatment of Complex Internal Carotid Artery Aneurysms: Five-Year Results of the Pipeline for Uncoilable or Failed Aneurysms Trial., (JNS) Neurosurgery Published online Jan 9, 2017

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