Medtronic News

Medtronic Receives FDA Clearance for Riptide(TM) Aspiration System

New System Expands Neurovascular Product Portfolio for the Treatment of Acute Ischemic Stroke

DUBLIN - January 16, 2018 - Medtronic plc (NYSE:MDT) today announced that the company's Neurovascular business unit received U.S. Food and Drug Administration (FDA) clearance of the Riptide(TM) Aspiration System, adding a valuable tool to the Acute Ischemic Stroke (AIS) product portfolio.

The Riptide Aspiration System is designed to retrieve thrombus (or blood clot) through the Arc(TM) Catheter and restore blood flow in patients experiencing blockage of an artery in the brain, known as an ischemic stroke. The procedure involves inserting a catheter through an incision in the leg and up to the blocked artery allowing the physician to remove the blood clot.

The Riptide Aspiration System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral - M1 and M2 segments, basilar and vertebral arteries) within eight (8) hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

"While I primarily use the Solitaire(TM) Revascularization Device to treat patients with acute ischemic stroke, I utilize a direct aspiration approach as my first line treatment strategy in select circumstances such as basilar artery thromboembolism and in select anterior circulation cases," said Dr. Daniel Sahlein, interventional neuroradiologist, Goodman Campbell Brain and Spine, assistant professor of clinical neurology in the department of Neurological Surgery, Indianapolis University-Purdue University Indianapolis. "The Riptide Aspiration System will provide me with another proven Medtronic product to utilize when treating stroke patients."

The Riptide Aspiration System includes the Arc Catheter, RiptideAspiration Tubing, Riptide Aspiration Pump and RiptideCollection Canister with intermediate tubing. The Riptide Aspiration System is a foundational platform for future aspiration catheters, currently in development.

"Medtronic is committed to developing services and solutions that address healthcare needs by improving clinical and economic outcomes," said Stacey Pugh, vice president and general manager of Medtronic's Neurovascular business which is part of the Restorative Therapies Group. "We believe that the Riptide Aspiration System and SolitaireRevascularization Device provide our customers with a comprehensive suite of products to choose from. Medtronic is committed to being a complete solutions provider in the treatment of Acute Ischemic Stroke market."

According to the American Heart Association/American Stroke Association (AHA/ASA), stroke is the fifth leading cause of death in the U.S. and a leading cause of disability.1 In June 2015, the AHA/ASA published new stroke treatment guidelines that recommended the use of stent retriever technology - such as the Solitaire stent retriever device - in conjunction with IV rtPA/alteplase as a first-line treatment for eligible patients.2

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 84,000 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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Sources:

1. American Heart Association Media Alert: Stroke falls to No. 5 cause of death in the U.S. Available at: http://newsroom.heart.org/news/stroke-falls-to-no-5-cause-of-death-in-u-s. Accessed January 8, 2018.
2. 2015 American Heart Association/American Stroke Association Focused Update of the 2013 Guidelines for the Early Management of Patients With Acute Ischemic Stroke Regarding Endovascular Treatment. Available at: http://stroke.ahajournals.org/content/early/2015/06/26/STR.0000000000000074. Published June 29, 2015. Accessed January 8, 2018.

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