Medtronic News

Medtronic's Solitaire(TM) Stent Retriever Device Receives Expanded Indication from the U.S. Food and Drug Administration for the Reduction of Stroke-Related Disability

FDA Allows Use of the Most Studied Stent Retriever with IV-tPA

DUBLIN - Nov. 16, 2016 - Medtronic plc (NYSE: MDT) today announced that the U.S. Food and Drug Administration (FDA) has cleared an expanded indication for the Solitaire(TM) stent retriever device. The FDA now allows the marketing of the Solitaire device as an initial therapy for acute ischemic strokes (AIS) for patients with a persistent, proximal anterior circulation, large vessel occlusion, and smaller core infarcts to reduce paralysis, speech difficulties and other stroke-related disabilities. The device should be used after patients have received intravenous tissue plasminogen activator (IV t-PA) and within six hours of symptom onset.

"This expanded indication for the Solitaire device demonstrates Medtronic's ongoing dedication to significantly improving the lives of stroke patients," said Stacey Pugh, vice president and general manager of the Neurovascular business, which is part of the Restorative Therapies Group at Medtronic. "As the only company with a device studied in all five of the global clinical trials responsible for changing the stroke treatment in the American Stroke Association guidelines1 (Early Management of Patients With Acute Ischemic Stroke Regarding Endovascular Treatment), we have seen firsthand how stroke patients benefit from this treatment option."

The FDA granted the expanded indication based upon a subset of data from the SOLITAIRE(TM) FR With the Intention For Thrombectomy as PRIMary Endovascular Treatment for Acute Ischemic Stroke trial (SWIFT PRIME)2. The data demonstrates that the addition of the Solitaire device to IV-tPA significantly decreased post-stroke disability and increased the number of patients who were functionally independent with mRS scores of 0-2 within 90 days after a stroke (62.7% vs. 36.8%).

Earlier this year, the Safety and Efficacy of Solitaire Stent Thrombectomy - Individual Patient Data Meta-analysis of Randomized Trials (SEER)3, a meta-analysis of SWIFT PRIME3, Endovascular Revascularization With Solitaire Device Versus Best Medical Therapy in Anterior Circulation Stroke Within 8 Hours (REVASCAT)4, EXtending the Time for Thrombolysis in Emergency Neurological Deficits - Intra-Arterial (EXTEND-IA)5 and Endovascular Treatment for Small Core and Proximal Occlusion Ischemic Stroke (ESCAPE)6, showed a strong significance in the numbers needed to treat (2.5) to reduce disability (i.e., for every 2.5 patients treated with the Solitaire device plus IV-tPA, 1 patient showed improved functional outcomes).

"Stroke is the fifth leading cause of death in the U.S. and the number one cause of severe disability," said Jeffrey L. Saver, MD, FAHA, FAAN, FANA, professor of Neurology, Geffen School of Medicine at the University of California, Los Angeles and director, UCLA Comprehensive Stroke Center. "The availability and access to a technology that reduces stroke disability is critically important because with such innovations, stroke patients and their families may experience less physical, emotional and financial burdens from their condition."

The Solitaire stent retriever device uses a micro-sized catheter to access arteries in the brain, helping to restore blood flow and remove large blood clots causing AIS.

Of the 795,000 AIS victims in the U.S., about 240,000 are eligible for treatment with stent retrievers. Despite this recommendation, currently only about 22,000 procedures are performed annually.7

Solitaire(TM) Revascularization Device

The Solitaire(TM) revascularization device restores blood flow and retrieves clots from occluded blood vessels in the brain for patients experiencing acute ischemic stroke (AIS) due to a large vessel occlusion.

Click the thumbnails 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 88,000 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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References:

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