

Covidien Announces Start of Enrollment in Two Neurovascular Clinical Trials

DUBLIN, Ireland--(BUSINESS WIRE)--Sep. 15, 2014-- [Covidien plc](#) announced today the start of enrollment in two clinical trials designed to further underscore the safety and effectiveness of the company's advanced neurovascular solutions.

[Baptist Medical Center](#) in Jacksonville, Florida, treated the first patient enrolled in the PREMIER Prospective study, an international Investigational Device Exemption (IDE) clinical study to evaluate the [Pipeline™ embolization device](#) in smaller unruptured intracranial aneurysms. Separately, [Baptist Health Lexington](#) in Kentucky, enrolled the first patient in the STRATIS Registry for Endovascular Stroke Devices, which will evaluate the use of all Covidien market-released stroke devices.

The PREMIER study will enroll up to 141 patients in 20 global sites and is designed to assess the safety and effectiveness of the Pipeline device in the treatment of unruptured, small and medium wide-necked intracranial aneurysms (IAs).

"We are excited to be the first hospital to enroll a patient in this important study. There is a need for an effective and sustained treatment option for patients with wide neck small or medium intracranial aneurysms," said Ricardo Hanel, M.D., Ph.D., neurovascular surgeon with Lysterly Neurosurgery at Baptist Medical Center. "Redirecting blood flow away from the aneurysm with the Pipeline device has been shown to reduce aneurysm recurrence and the need for retreatment in large and giant internal carotid artery (ICA) aneurysms. This study will provide valuable clinical evidence in a new population of aneurysms."

The STRATIS Registry, a prospective, multi-center, non-randomized, observational registry designed to evaluate the use of Covidien endovascular stroke devices in patients diagnosed with an acute ischemic stroke. Covidien's current endovascular stroke device in the U.S. is the [Solitaire™ 2 revascularization device](#).

"The STRATIS Registry will assess mechanical thrombectomy (MT) as a treatment option in patients who can't get access to or are not eligible for IV-tPA - a medication that dissolves blood clots," said Curtis Given, M.D., co-director of neurointerventional services at Baptist Health Lexington. "It is very important to provide registry data to not only demonstrate the safety of a MT procedure on these patients, but also to track the outcomes, so we can compare the results to historical IV-tPA data. In some states, insurance carriers are refusing to reimburse MT procedures, so it's vital that we collect the data to show not only safety, but efficacy, in order to ensure that we can continue to provide care to these patients that would otherwise not be offered any treatment for their stroke."

As many as 60 U.S. sites are expected to participate in the STRATIS Registry, which will enroll up to 1,000 patients to collect clinical outcomes for interventional stroke patients in a real world setting.

"Covidien continues to design outcomes-based clinical studies to confirm the real world safety and effectiveness of its advanced neurovascular technologies and explore new applications where there is a significant unmet medical need for additional treatment options," said Stacey Pugh, vice president Medical Affairs, Neurovascular, Covidien. "The PREMIER study underscores Covidien's ongoing commitment to improve outcomes, and expand the use of flow diversion technology as a primary treatment for IA patients. We are confident that the STRATIS Registry will generate real world evidence on patients treated with MT and will help improve systems of care, resulting in better patient care and clinical outcomes."

According to the [World Stroke Organization](#), nearly six million people worldwide die from stroke each year.

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](#).

Source: Covidien

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