Medtronic News

Medtronic Reports Initial Implants of Novel Stent Graft for Aortic Aneurysms Involving Branch Vessel

FDA's Early Feasibility Pilot Program for New Medical Devices Encourages Clinical Studies of Innovative Technology to Occur First in U.S.

MINNEAPOLIS -- April 29, 2013 -- Vascular specialists at Carolinas HealthCare System in Charlotte, N.C., and the Cleveland Clinic in Ohio recently performed the initial implants of a novel stent graft system from Medtronic, Inc. (NYSE: MDT) as part of a U.S. Food and Drug Administration (FDA) initiative designed to encourage more early-stage clinical research on new medical devices in the United States. These implants were among the first to be performed under this FDA early feasibility pilot program, which includes a total of nine medical devices from different companies.

The first device of its kind to undergo clinical evaluation anywhere in the world, Medtronic's Valiant Mona LSA branch stent graft system is designed to enable the repair of thoracic aortic aneurysms encroaching on the left subclavian artery (LSA) with an entirely endovascular approach. Its initial usage earlier this month marks a major step forward in the company's efforts to develop standardized stent graft systems to treat aneurysms throughout the aorta when the involvement of a branch vessel requires the stent graft to allow perfusion of critical organs or tissue.

Investigators Envision Future

"A standardized stent graft system that addresses the anatomical variability in thoracic aortic aneurysms involving the LSA could make this repair technique even less invasive for a large number of patients," said the study's primary investigator, Dr. Eric Roselli, a cardiothoracic surgeon at the Cleveland Clinic. "This trial is a first step toward developing more disease-specific and patient-specific devices to treat a very complex disease problem."

Dr. Frank Arko, a vascular surgeon at Carolinas HealthCare System's Sanger Heart & Vascular Institute and the site's lead investigator, added: "This endovascular treatment for aortic aneurysms provides an important alternative to open-chest operations. By eliminating the need for invasive surgeries, we should be able to reduce certain complications and hopefully improve outcomes for patients facing a life-threatening illness."

Approved by the FDA under an investigational device exemption, the clinical study of Medtronic's Valiant Mona LSA branch stent graft system may enroll a total of seven patients at Carolinas HealthCare System and the Cleveland Clinic combined.

"This study will advance the development of future devices for the endovascular repair of aortic aneurysms that involve branch vessels," said Tony Semedo, president and general manager of Medtronic's Endovascular Therapies business. "It represents a gateway to stent grafts that could be used to treat aneurysmal disease across the aorta's thoracic arch and ascending segment."

The investigational device is based on the market-leading Valiant thoracic stent graft, which has been used to treat approximately 45,000 patients worldwide since 2005 when it received the CE (Conformité Européene) mark. It features modifications to the standard device, including a branch cuff that accommodates the LSA branch graft.

The LSA carries oxygenated blood to the posterior brain and left arm. Published reports show a higher rate of stroke and mortality associated with coverage of the LSA during endovascular repair of thoracic aortic aneurysms. As a result, the Society for Vascular Surgery suggests routine revascularization of the LSA in elective cases where achievement of an adequate seal zone for the stent graft requires coverage of the LSA.

Approximately 60,000 people in the United States are living with a thoracic aortic aneurysm, a dangerous bulge in the body's

main artery near where it originates from the heart that can rupture with catastrophic consequences if left untreated -- although only about half are ever diagnosed, due to lack of symptoms. In an estimated 40 percent of these patients, the aneurysm encroaches on the LSA, making an entirely endovascular repair more challenging.

A stent graft is a tubular medical device consisting of a metal frame, or stent, sewn onto a polyester fabric, or graft. It is delivered through a pre-loaded catheter inserted in the patient's femoral artery. Once deployed, the stent graft conforms to the wall of the aorta, creating a new path for blood flow that reduces pressure on the aneurysm and the risk of rupture.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

Drs. Arko and Roselli are both paid consultants and speakers for Medtronic. Dr. Roselli serves on an unrelated Medtronic advisory board.

ABOUT MEDTRONIC
Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, 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.

- end -

Contacts:
Joseph McGrath
Public Relations
+1-707-591-7367

Jeff Warren
Investor Relations
+1-763-505-2696

---

https://news.medtronic.com/2013-04-29-Medtronic-Reports-Initial-Implants-of-Novel-Stent-Graft-for-Aortic-Aneurysms-Involving-Branch-Vessel