Medtronic News

First Patient Treated with Medtronic's Valiant(R) Thoracic Stent Graft in Aortic Dissection Trial

Minimally Invasive Procedure May Stabilize Bleeding and Improve Clinical Outcomes

MINNEAPOLIS, Aug 05, 2010 (BUSINESS WIRE) --

Marking a major milestone toward expanding the use and utility of minimally invasive endovascular procedures, Medtronic, Inc. (NYSE: MDT), today announced the enrollment of the first patient in the Medtronic Dissection Trial, which is evaluating the clinical performance of the Valiant Thoracic Stent Graft with the Captivia Delivery System for the treatment of acute, complicated Type B aortic dissection - a serious cardiovascular condition associated with high morbidity and mortality. The study is being conducted under an Investigational Device Exemption (IDE) in the United States.

Medtronic initiated its Dissection Trial in May 2010 and will enroll a total of 50 patients across 25 centers in the United States. Dr. Zvonimir Krajcer, M.D., co-director of the Peripheral Vascular Disease Service at St. Luke's Episcopal Hospital in Houston, treated the trial's first patient with Type B aortic dissection.

"Patients with acute, complicated Type B aortic dissection require immediate treatment, and the Valiant Captivia system holds great promise as a minimally invasive treatment for this challenging patient group," said Dr. Krajcer. "This trial will help to determine if the Valiant Captivia system is a safe and effective alternative to invasive surgery for these patients."

An aortic dissection is a potentially life-threatening condition in which there is bleeding into and along the wall of the aorta, which carries blood for the entire body. Aortic dissections are classified as Type A or Type B depending on where they occur. Type A aortic dissections begin in the ascending aorta, the segment closest to the heart, and require surgery to repair. Type B aortic dissections begin in the descending aorta, may extend into the abdomen and, if uncomplicated by rupture or malperfusion, can be treated with medication as a first-line intervention. Patients with acute, complicated Type B aortic dissections are reported to have a greater than 50% likelihood of dying from this disease and as such often require emergent treatment.

The exact cause of aortic dissection is unclear. Risk factors include atherosclerosis (hardening of the arteries) and hypertension (high blood pressure); however, the condition also can occur as the result of surgical complications, rare disorders (Marfan's syndrome, for example) or traumatic injury. Type B aortic dissections have historically been treated with medication or through invasive surgical techniques.

Stent grafts are tubular medical devices that endovascular interventionalists deliver through a catheter inserted in the patients' femoral arteries (a large artery that runs from the groin down the inner leg). Once deployed, the grafts conform to the wall of the aorta, the body's main artery, creating a new path for blood flow. Endovascular stent grafting is an effective way to treat some aortic conditions, such as aneurysms (a bulge in the wall of the aorta).

The Valiant Thoracic Stent Graft received the CE Mark in 2005 and is available in more than 90 countries outside the United States. Indicated for the treatment of a variety of thoracic aortic lesions, the device has been used to treat more than 15,000 patients worldwide. Both the Valiant Thoracic Stent Graft and the Captivia Delivery System are investigational in the United States, where their use is limited to clinical trials approved by the U.S. Food and Drug Administration.

Medtronic is committed to advancing the treatment of cardiovascular disease through collaboration with leading clinicians, researchers and scientists worldwide.

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.

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