Medtronic News

First Patient Treated with Valiant(R) Thoracic Stent Graft in Medtronic's "RESCUE" Clinical Study

Minimally-Invasive Procedure May Stabilize Aortic Bleeding When Surgery Is Not an Option

MINNEAPOLIS, May 19, 2010 (BUSINESS WIRE) --Further demonstrating its commitment to proving the benefits of minimally-invasive procedures, Medtronic, Inc. (NYSE: MDT), today announced that the first patient has been treated with the company's Valiant(R) Thoracic Stent Graft with the Captivia Delivery System in Medtronic's RESCUE Clinical Study.

The RESCUE (Evaluation of the Clinical PeRformanceE of the Valiant Thoracic Stent Graft with the Captivia Delivery System for the EndovaSCUlar TrEatment of Blunt Thoracic Aortic Injuries) clinical trial will evaluate the safety and effectiveness of the Valiant Captivia system in the treatment of patients with blunt thoracic aortic injury, a condition that has historically been treated through invasive surgical techniques.

Stent grafts are tubular medical devices that vascular surgeons deliver through a catheter inserted in their patients' femoral arteries. Once deployed, the grafts conform to the wall of the aorta, the body's main artery, creating a new path for blood flow.

Blunt thoracic aortic injury (BTAI) is an urgent medical condition in which the aorta is perforated due to traumatic force to the chest, a common result of motor vehicle accidents, high falls and other high-impact injuries. Last year there were more than 33,000 motor vehicle accidents resulting in fatalities in the United States alone; more than 15 percent of these fatalities involved injury to the aorta. In total, more than 8,000 people suffer a BTAI in the United States each year.

A conventional and standard method of treatment to repair the aorta and to stabilize blood flow is open surgical repair; however, since 90 percent of trauma patients with injury to the aorta also suffer from other life-threatening injuries, open surgical repair for BTAI is not always possible or optimal.

Medtronic initiated the RESCUE clinical trial in March 2010 and expects to enroll a total of 50 patients at up to 25 sites in the United States. Dr. Anthony Murphy, a vascular surgeon at the Suncoast Medical Clinic, and Dr. Joshua Rovin, a cardiothoracic surgeon with Cardiac Surgical Associates, both in St. Petersburg, Fla., collaborated on the first Valiant Captivia implant in RESCUE. Drs. Murphy and Rovin successfully treated a 21-year-old patient who suffered BTAI in a motor vehicle accident.

"Many patients with BTAI never make it to the emergency room," said Dr. Rovin, "Those who do typically arrive with tears of the aortic wall and internal bleeding that require surgery to repair. But for some patients, due to other circumstances of their injury, surgery is too risky to attempt."

Dr. Murphy added, "This trial will help to determine if Valiant Captivia is effective for patients with BTAI. If the technology works in demanding clinical situations such as total aortic transection, it may have positive implications for the treatment of other aortic injuries."

The Valiant Captivia system is indicated for the treatment of a variety of thoracic aortic lesions and has been used to treat more than 15,000 patients worldwide. Both the Valiant Thoracic Stent Graft and 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 CardioVascular is committed to advancing the treatment of coronary, peripheral, aortic and structural heart 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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