Medtronic News

Medtronic Expands Availability of Valiant(R) Captivia(R) Stent Graft in Major Global Markets

Implantable Medical Device for Endovascular Repair of Thoracic Aortic Aneurysms Also Being Studied for Minimally Invasive Treatment of Blunt Thoracic Aortic Injuries

MINNEAPOLIS--(BUSINESS WIRE)--May. 8, 2012-- Increasing patient access to endovascular repair of aortic aneurysms worldwide, Medtronic, Inc. (NYSE: MDT) is expanding availability of the Valiant® Captivia® Thoracic Stent Graft System in several countries, including China, Japan and the United States.

“The expanded offering of the Valiant Captivia Stent Graft in these major global markets epitomizes our commitment to globalization,” said Tony Semedo, general manager of the Endovascular Therapies business unit at Medtronic. “Now, more physicians across the globe than ever before will be able to offer their patients a minimally-invasive treatment option for life-threatening thoracic aortic aneurysms without the associated trauma of open surgery.”

The international market leader in its product category, the Valiant Captivia Stent Graft is approved by the U.S. Food and Drug Administration (FDA) for endovascular repair of aneurysms and penetrating ulcers of the descending thoracic aorta in patients with a non-aneurysmal aortic diameter in the range of 18–42 mm and non-aneurysmal aortic proximal and distal neck lengths ≥ 20 mm. The device’s approved indications in China and Japan are similar.

A thoracic aortic aneurysm (TAA) is a dangerous bulge in the body’s main artery near where it branches off the heart. The eventual outcome of an untreated thoracic aortic aneurysm is rupture, an emergency situation in which the artery bursts, causing extensive internal bleeding that usually leads to death.

Thoracic stent grafts are tubular medical devices that physicians deliver through a pre-loaded catheter that is inserted in the patients’ femoral arteries. Once deployed, the stent graft conforms to the wall of the aorta, the body’s main artery, creating a new path for blood flow.

The Valiant Captivia Stent Graft System updates earlier generation devices by featuring an eight-peak crown that effectively secures the deployed device inside the aorta. It is also more flexible and conformable through the elimination of the longitudinal connecting bar found in other stent grafts.

RESCUE

Medtronic also announced today the completion of enrollment in an investigational clinical study of the Valiant Captivia Stent Graft System as a minimally invasive treatment for blunt thoracic aortic injuries. Data from this FDA-approved clinical research study, called RESCUE, will be used to seek an expanded indication for the device to treat aortic transections. The study’s principal investigator is Dr. Rodney White, chief of vascular surgery at Harbor-UCLA Medical Center in Los Angeles.

A blunt thoracic aortic injury is an emergency medical condition in which the aorta is damaged due to traumatic force to the chest, usually the result of motor accidents, elevated falls or other high-impact injuries. It is the second leading cause of traumatic death after head injuries.

Fifty patients at 20 U.S. sites were enrolled in RESCUE to investigate the safety and effectiveness of stent grafts for the treatment of BTAI. Early results on the first 33 patients enrolled in the study were presented in late March at the 2012 Annual Scientific Meeting of the Society of Interventional Radiology. All-cause mortality at 30 days, the study’s primary endpoint, was 12 percent for this patient group.

“Traditionally, the mortality rates associated with surgical repair of blunt thoracic aortic injuries range from 15 to 20 percent,”

said Dr. Alan Matsumoto, professor and chair of the department of radiology and medical imaging at theUniversity of Virginia Health System in Charlottesville, Va., and presenter of the data. “With this frame of reference, the early data from RESCUE is very encouraging. We look forward to reporting the final results on all 50 patients in the study at a major upcoming scientific medical meeting.”

RESCUE is one of several clinical studies of the Valiant Thoracic Stent Graft. OtherMedtronic studies of this device include VALOR II and VIRTUE.

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.

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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