

Medtronic Starts International Market Launch and U.S. Clinical Trial of Endurant Stent Graft

Continuing an Unprecedented Series of Innovations, Next-Generation Device Heralds a New Era in Endovascular Aortic Repair

MINNEAPOLIS – July 7, 2008 – Expanding the application of endovascular aortic repair around the world, Medtronic, Inc. (NYSE: MDT), today announced two major milestones: the international market launch of the Endurant Abdominal Stent Graft System and the first implants of this next-generation medical device in the U.S. clinical trial.

International Market Launch

The Endurant Stent Graft was CE (Conformité Européene) marked last week, and Medtronic will begin commercialization in mid-July. (CE mark is the European regulatory approval.) Outside the United States, the Endurant System expands the applicability of endovascular aortic repair (EVAR) to more patients with abdominal aortic aneurysms (AAAs), which are present in an estimated 1.2 million people and responsible for 15,000 deaths annually in the United States.

Building on more than a decade of industry-leading experience, the new device seeks to address those AAA patients whose aortas are highly angulated or whose aneurysms have short necks. Patients with these complex anatomies would previously have had no choice but watchful waiting or open surgical repair, in which the abdomen is opened and major organs temporarily moved in order to access the aorta. The Endurant Stent Graft System is an investigational device in the United States, where it is limited to investigational use only.

Prof. Hence Verhagen, chief of vascular surgery at the Erasmus Medical Center in Rotterdam, the Netherlands, led the European clinical trial of the Endurant Stent Graft System which supported the CE mark: “This next-generation device has performed exceptionally well in the treatment of abdominal aortic aneurysms. The Endurant System has the potential to expand the applicability of EVAR to more AAA patients who have been considered especially difficult to treat. I speak for my colleagues, too, by saying that physicians worldwide are eagerly awaiting the commercial release of this innovative new stent graft.”

U.S. Clinical Trial

The first implants of the Endurant Stent Graft System in the U.S. clinical trial took place during the last two weeks, with excellent periprocedural results. The initial implants at the Cleveland Clinic in Ohio were performed by Drs. Matthew Eagleton, Timur Sarac and Vikram Kashyap; those at Scott & White Memorial Hospital in Temple, Texas, were completed by a team led by Dr. C. J. Buckley.

Approved by the U.S. Food and Drug Administration in June under an investigational device exemption (IDE), the U.S. clinical trial of the Endurant Stent Graft System is designed to evaluate the device's safety and effectiveness in the endovascular treatment of abdominal aortic aneurysms. As the pivotal trial for the Endurant Stent Graft, it will be used to seek FDA approval of the device. The study will enroll 150 patients at up to 30 U.S. sites in the next 12–18 months. All patients who meet the single-arm study's inclusion criteria will receive an Endurant Stent Graft; their outcomes will be compared to those who received the Talent™ Abdominal Stent Graft as part of the pivotal study that led to that device's FDA approval.

“The Endurant Stent Graft System has shown great potential as a minimally-invasive treatment option for AAA patients with challenging anatomies,” said the U.S. clinical trial's principal investigator, Dr. Michel Makaroun, professor and chief of vascular surgery at the University of Pittsburgh School of Medicine in Pennsylvania. “Its innovative design features aim to address the clinical concerns of seal, conformity to tortuous anatomy and ease of deliverability for especially difficult endovascular interventions.”

Portfolio and Pipeline

These milestones follow FDA approvals received in April and June, respectively, of the Talent Abdominal and Thoracic Stent Grafts, which broaden Medtronic's industry-leading portfolio of aortic repair technology in the United States. Both devices offer an additional 20–25 percent of U.S. patients with aortic disease access to minimally-invasive endovascular treatment instead of open surgical repair.

“In collaboration with physicians worldwide, Medtronic has developed the richest product portfolio and the most robust product pipeline of aortic stent grafts in the industry,” said Tony Semedo, vice president and general manager of the Endovascular Innovations division at Medtronic. “From product development to clinical research, from technical support to medical education, our commitment to innovation through collaboration continues to deliver solutions to aortic disease that expand the indication for minimally-invasive endovascular repair and improve patient outcomes.”

In contrast to open surgery, EVAR involves a keyhole procedure in which a stent graft – a tube of woven polyester reinforced with a wire skeleton – is compressed on a delivery catheter, allowing it to be threaded through the femoral artery and expanded at the site of the aneurysm. Once in place, the stent graft creates a new path for blood flow, reducing pressure on the aneurysm and the risk of rupture. Left untreated, aortic aneurysms can burst, causing extensive internal bleeding that sometimes lead to death.

As the pioneer of endovascular therapy, Medtronic has been an innovator and leader in the aortic stent graft industry for more than a decade. Its long history includes more than 140,000 patients treated with stent grafts dating back to 1996. Through the company's CardioVascular business, Medtronic currently offers the broadest portfolio of aortic stent grafts in the industry. These include the Talent Abdominal and Thoracic Stent Graft Systems worldwide; the AneuRx AAAAdvantage® Abdominal Stent Graft System in the United States; and the Endurant Abdominal Stent Graft System and the Valiant® Thoracic Stent Graft System outside the United States.

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 Annual Report on Form 10-K for the year ended April 25, 2008. Actual results may differ materially from anticipated results.

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