Medtronic Garners FDA Approval for Stent Graft System

Medtronic Inc.

Global Market-Leader in Medical Technology for Endovascular Aortic Repair Also Receives 510(k) Clearance for Sentrant Introducer Sheath

Medtronic, Inc. (NYSE: MDT) is expanding its market-leading portfolio of products for endovascular aortic repair in the United States with two new medical devices: the company recently received approval from the U.S. Food and Drug Administration (FDA) for the Endurant II Aorto-Uni-Iliac (AUI) Stent Graft System and the FDA's 510(k) clearance for the Sentrant Introducer Sheath; both devices will be on exhibit at the Medtronic booth during the Society for Vascular Surgery's "Vascular Annual Meeting," which runs May 30–June 2 in San Francisco.

Endurant II AUI Stent Graft System

The Endurant II AUI Stent Graft System is the only FDA-approved AUI device in the United States indicated for the primary endovascular treatment of infrarenal abdominal aortic or aorto-iliac aneurysms in patients whose anatomy does not allow for the use of a bifurcated device. Both the bifurcated and AUI configurations of the Endurant Stent Graft System provide a new pathway for blood flow through the iliac arteries in abdominal aortic aneurysms, thereby reducing risk of aneurysm rupture.

Whereas use of the bifurcated device requires access to both iliac arteries, the AUI device requires access to only one iliac artery. In published studies of endovascular abdominal aortic aneurysm (AAA) repair, current global usage of AUI stent graft configurations averages 5 percent (range 0–26%) for intact AAA and 39 percent (range 0–91%) for ruptured AAA.[i,ii]

"The new Endurant II Aorto-Uni-Iliac Stent Graft extends the proven performance of the Endurant System to patients with difficult access," said Dr. Michel Makaroun, chief of vascular surgery at the University of Pittsburgh Medical Center and co-director of the UPMC Heart and Vascular Institute. "By maintaining the deliverability, conformability and deployment accuracy of the bifurcated Endurant device, the AUI configuration offers aneurysm patients with challenging outflow anatomies a better option for a successful endovascular aortic repair."

As with the bifurcated Endurant II Stent Graft, distinguishing features of the Endurant II AUI Stent Graft include a low delivery profile, tip capture for easy and accurate deployment and compatibility with contralateral iliac limbs and aortic extensions for ultimate patient applicability.

Sentrant Introducer Sheath

The Sentrant Introducer Sheath complements Medtronic's market-leading portfolio of stent grafts for endovascular aortic repair. It is specially designed for use with the

Endurant II AAA and Valiant Captivia Stent Graft Systems and is also compatible with competitive systems. The Sentrant Introducer Sheath is inserted at the access site in the patient's femoral artery and advanced upwards into the iliac arteries to facilitate the implant procedure and enable smooth passage of the stent graft delivery system en route to the treatment site in the aorta.

The Sentrant Introducer Sheath can accommodate a wide range of anatomies, with diameters of 12–26 French and shaft lengths of 28cm. Other distinguishing features of the accessory device include optimal seal for superior hemostasis, reinforced coil for kink resistance, hydrophilic coating and flexibility for easy tracking through tortuous and calcified iliacs and a dilator locking mechanism for secure positioning.

The Sentrant Introducer Sheath received the CE (Conformité Européenne) mark in April 2013. Its FDA clearance expands the accessory device's availability to endovascular specialists in the United States.

In collaboration with leading clinicians, researchers and scientists, 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 worldwide.

[i]. Ricotta , J.J. 2nd, Malgor, R.D., Oderich, G.S. (2009) Endovascular abdominal aortic aneurysm repair: part I. Ann Vasc Surg, 23(6), 799-812.
[ii]. Ricotta , J.J. 2nd, Malgor, R.D., Oderich, G.S. (2010). Ruptured endovascular abdominal aortic aneurysm repair: part II. Ann Vasc Surg, 24(2), 269-77.

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