Medtronic News

Medtronic Endurant(TM) II/IIs Stent Graft System Receives FDA Approval to Treat Short Neck Anatomies When Used with Heli-FX(TM) EndoAnchor(TM) System

New Indication Expands Treatment Options for AAA Patients with Hostile Neck Anatomy

DUBLIN - October 9, 2017 - Medtronic plc (NYSE: MDT) today announced that it has received U.S. Food and Drug Administration (FDA) approval for the Endurant(TM) II/IIs stent graft system to treat abdominal aortic aneurysm (AAA) patients with neck lengths down to 4mm and <=60° infra-renal angulation when used in combination with the Heli-FX(TM) EndoAnchor(TM) system. The expanded indication enables the Endurant II/IIs stent graft to be used in conjunction with the Heli-FX EndoAnchor system to treat a wider range of patients with short, hostile aortic neck anatomies, independent of renal stenting.

Until now, some patients with short infra-renal necks (<10mm) were considered ineligible for endovascular aneurysm repair (EVAR), leaving them with limited treatment options. Up to 30 to 40 percent of patients with AAA disease are considered unsuitable candidates for conventional EVAR.1 According to estimates from physicians across Europe and the United States, more than one-third of these patients have AAA proximal neck anatomies <= 10mm.2

"Due to the complex and hostile proximal aortic neck anatomy, this patient population remains a challenge to treat," said William Jordan, Jr., M.D., professor of surgery and chief, Division of Vascular Surgery and Endovascular Therapy at Emory University School of Medicine and co-principal investigator of the ANCHOR registry. "With minimal time added to the procedure, EndoAnchor fixation has been proven to enhance outcomes and durability, establishing a new treatment approach that addresses this critical patient need."

The FDA approval is supported by a short neck cohort of the ANCHOR registry, a global multi-center, multi-arm, prospective, post-market registry evaluating the real-world applicability of the Heli-FX EndoAnchor system. Led by co-principal investigators Dr. Jordan and Jean-Paul de Vries, M.D., chief of Vascular Surgery at St. Antonious Hospital in Nieuwegein, the Netherlands, outcomes from a sub-analysis of 70 patients with proximal AAA neck lengths <10mm down to 4mm who were treated with Endurant and Heli-FX demonstrated a technical success rate of 88.6 percent, based on delivery and deployment of the stent graft and each EndoAnchor implant used, and a 97.1 percent procedural success rate (investigator-assessed), with a rate of 1.9 percent proximal type Ia endoleaks at one year. Additionally, there was only one type Ia endoleak that resulted in a secondary procedure through one year.

At one year there were no AAA expansions or instances of main body migration and through one year, no instances of AAA ruptures. There was minimal EndoAnchor implant time added to the overall procedure, with an average of 17 minutes.

"The acquisition of Aptus Endosystems in 2015 demonstrated our deep-rooted commitment to investing in solutions that treat complex aortic disease, and this new indication expansion for the Endurant II/IIs stent graft system is a significant milestone that underscores our promise to improve patient outcomes in partnership with the clinician community," said Daveen Chopra, vice president and general manager of the Aortic business, which is part of the Aortic & Peripheral Vascular division at Medtronic. "With the use of the Heli-FX Endoanchor system, physicians can now provide durable seal and fixation with a proven stent graft technology to expand care to patients with hostile neck anatomies."

About the Endurant(TM) II/IIs Stent Graft System

The Endurant II/IIs stent graft system is based on the leading Medtronic Endurant stent graft system, which is selected for nearly one of every two endovascular AAA repairs globally resulting in nearly 300,000 successful implants. The original Endurant system received the CE (*Conformité Européenne*) Mark in June 2008 and approval from the FDA in December 2010. The Endurant II/IIs stent system is approved in the U.S. for neck lengths >=10 mm and <=60° infra-renal angulation. With the new indication expansion, Endurant with Heli-FX EndoAnchor system has been approved by the FDA for use in patients with shorter neck lengths (less than 10mm down to 4mm).

Additionally, in December 2016, Medtronic received CE Mark for the Endurant(TM) II/IIs stent graft system to treat abdominal aortic aneurysm (AAA) patients using a ChEVAR procedure.

About the Heli-FX and Heli-FX(TM) Thoracic EndoAnchor Systems

The Medtronic Heli-FX and Heli-FX Thoracic EndoAnchor systems feature an endovascular-deployed anchor designed to attach a variety of aortic endografts to the native vessel wall. This off-the-shelf, customized solution minimizes the need for complicated procedures for the select subset of patients who would benefit from supplementary fixation including patients with challenging anatomies, risk factors for a secondary intervention, existing seal complications, as well as in situations where a physician may intraoperatively determine the need for additional security.

The Heli-FX system is cleared by the FDA for distribution in the U.S. and has been granted CE Mark for distribution in the European Union. Both products are also commercialized in other countries worldwide. The Heli-FX EndoAnchor system can be used with a wide variety of commercially available stent grafts, including the Medtronic Endurant and Valiant(TM) stent graft systems.

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. The company strives to offer products and services of the highest quality that deliver clinical and economic value to healthcare consumers and providers around the world.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 84,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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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1Skelly, Christopher L., and Ross Milner. Difficult Decisions in Vascular Surgery: an Evidence-Based Approach. Springer, 2017.

2Medtronic data on file.

Contacts:
Krystin Hayward Leong
Public Relations
+1-508-261-6512

Ryan Weispfenning
Investor Relations
+1-763-505-4626

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