Medtronic News

Medtronic Receives CE Mark Approval for the Valiant Navion(TM) Thoracic Stent Graft System

Lower-Profile Thoracic Endovascular Aortic Repair (TEVAR) Device Broadens Treatable Patient Population with Thoracic Aortic Disease

DUBLIN - November 13, 2018 - Medtronic plc (NYSEMDT) today announced it has received CE Mark approval for the Valiant Navion(TM) thoracic stent graft system for the minimally invasive repair of all lesions of the descending thoracic aorta, including thoracic aortic aneurysms (TAA), blunt traumatic aortic injuries (BTAI), penetrating atherosclerotic ulcers (PAU), intramural hematomas (IMH), and type B aortic dissections (TBAD). This news also follows the recent U.S. FDA approval of the Valiant Navion system.

"In clinical practice we often see patients with a wide range of thoracic aortic anatomies. For example, TEVAR in females doubles the risk of needing an adjunctive iliac access procedure1, which can potentially add risk, time, and cost to the procedure," said Professor Fabio Verzini, M.D., Ph.D., associate professor of Vascular Surgery, University of Turin, Italy and European principal investigator for the Valiant Navion IDE study. "The approval of Valiant Navion gives us the ability to broaden the treatable patient population with thoracic aortic disease, including more female patients and those who were previously considered ineligible for TEVAR with a percutaneous approach."

The Valiant Navion system is a lower-profile evolution of the market-leading Valiant(TM) Captivia(TM) thoracic stent graft system, which has treated more than 100,000 patients globally. Valiant Navion is built on the design philosophy of the Valiant Captivia system for improved performance and increased patient applicability. The system also features the CoveredSeal (proximal covered) and FreeFlo (proximal bare metal) stent configurations - both with tip-capture accuracy, providing physicians with two graft options to treat varying patient anatomies and pathologies.

Approval was based on 30-day primary endpoint analysis of 87 subjects consecutively enrolled in the international, multicenter, prospective investigational device exemption (IDE) study analyzing the safety and efficacy of Valiant Navion in subjects with TAA and PAU. The results demonstrated efficacy in both FreeFlo and CoveredSeal configurations, with no instances of access or deployment failures at implant in the full study cohort. Through 30 days, data showed low rates of peri-operative mortality at 2.3 percent and secondary procedures at 2.3 percent. The rate of Type Ia endoleaks was 1.2 percent at one-month imaging follow-up.

"In just a few short weeks, we have achieved significant momentum with Valiant Navion - obtaining both FDA and CE Mark approvals," said John Farquhar, vice president and general manager of the Aortic business, which is part of the Cardiac and Vascular Group at Medtronic. "We're proud to introduce the Valiant Navion system in Europe and believe in its potential to expand treatment options for physicians and patients with thoracic aortic disease."

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 86,000 people worldwide, serving physicians, hospitals and patients in more than 150 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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1 Deery SE et al. Female sex independently predicts mortality after thoracic endovascular aortic repair for intact descending thoracic aortic aneurysms. J Vasc Surg. 2017 Jul;66(1):2-8. doi: 10.1016/j.jvs.2016.12.103.

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