Starnes' Physician-Sponsored IDE Study Gains FDA Approval to Add More AAA Devices & Introduce Planning Tool

Leading Vascular Surgeon Expands IDE Study That Could Significantly Reduce the Number of AAA Patients Requiring Open Surgery

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BELLEVUE, Wash.--Benjamin W. Starnes, MD, Chief of Vascular Surgery at Harborview Medical Center and one of the world's foremost authorities in the treatment of abdominal aortic aneurysms (AAA) today announced that he has received FDA approval to expand his physician-sponsored IDE study, administered in conjunction with Harborview. The study is designed to assess a new technology that could significantly reduce the need for invasive open surgery in patients with aneurysms that are too close to branch arteries that supply blood to vital organs. The approval allows Dr. Starnes to introduce a new software-planning tool and to expand the number of AAA endografts from one up to five. There are currently six manufacturers of commercially available AAA endografts in the United States. To date, Dr. Starnes has enrolled and successfully treated over 70 patients with AAA disease in the study, which is approved to enroll 150 patients.

Over the past 15 years, Endovascular Aneurysm Repair (EVAR) has gradually replaced open surgery as a minimally invasive treatment option for the majority of patients with this disease. "Unfortunately about 40% of these aneurysmal patients have aneurysms that are either too close to branch arteries that supply blood to vital organs or the aorta itself is highly angulated," said Dr. Starnes. "When this happens, it is difficult to place an endograft in the aorta and achieve a secure seal of the graft to the artery wall. As a result, the patient can experience a leak along the outside of the graft which causes the aneurysm to continue to grow. For these patients, EVAR is not an option and we have to treat them with open surgery.

"Our goal is to simplify the process for managing these branch arteries and achieve a reliably sealed, securely anchored endograft at low cost," he continued. "By creating openings (or fenestrations) in a standard 'off-the-shelf' endograft to correspond with the locations of branch arteries that feed the kidneys and other abdominal organs, we can treat patients using EVAR rather than subjecting them to open surgery. This approach—called 'Fenestrated' EVAR (or FEVAR) will allow physicians to protect the branch arteries by anchoring the graft securely in healthy tissue while preserving blood flow to vital organs."

Physicians have long appreciated the benefits of FEVAR, but have shied away from broad use in its current form because it is difficult to implement. Expensive equipment is required to make measurements that must be extremely precise. In addition, the physician must possess a high degree of skill and patience to carry out both the up-front planning and the procedure.

“In our study, we are introducing an algorithm that I call Patient Match Technology, which will dramatically simplify the FEVAR procedure,” said Dr. Starnes. “The algorithm digitizes a patient’s CT scan and uses a 3D printer to create an exact replica of each patient’s aortic anatomy. From this template, we can customize an ‘off-the-shelf’ endograft to precisely match each patient’s anatomy. This algorithm is currently being refined and automated by an early stage privately held company founded by Starnes called Aortica™ Corp.” Dr. Starnes hopes to incorporate the Aortica™ software into his study later this year or early 2016.

“With FDA’s approval of this supplement to the IDE, we can begin to demonstrate the broad applicability of the Patient Match Technology across the vast majority of endografts available on the market today,” stated Dr. Starnes. “Down the road, we hope the addition of the Aortica’s automated version—called the REFLECTION™ System—will yield both a technology and an approach that will eliminate the hours of planning, heavy expense, and the general “headache” currently experienced by physicians and institutions interested in treating these patients less invasively.”

About Abdominal Aortic Aneurysm (AAA) Disease

Each year between 150,000 and 180,000 people in the United States are diagnosed with abdominal aortic aneurysms (AAA). An aneurysm is a large bulge in the aorta (the largest artery in the human body). It can gradually expand over time—without any symptoms—until it bursts, causing massive internal bleeding that results in death if not treated at a specialized center immediately. For years major open surgery was the only treatment option, which is risky due to its complicated nature and because it carries a 3.0% mortality rate within 30 days of surgery.

About Endovascular Aneurysm Repair (EVAR)

In the 1990’s, a new technique for controlling aneurysms was developed using a graft inserted through the femoral arteries. This technique is called **e**ndo**v**ascular **a**neurysm **r**epair (EVAR). EVAR is significantly less invasive than open surgery and is associated with a mortality rate six times lower. Patients recover faster, leave the hospital sooner, and return to activities of normal daily life more quickly. Consequently, EVAR has become the gold standard for treatment of AAA disease.

About Aortica Corporation

Aortica Corporation was founded to design, manufacture, and market tools for treatment of patients with AAA disease who have aortic anatomy that limits their treatment options. While EVAR has become a highly desirable option for treatment of AAA disease, approximately 40% of patients are not candidates for EVAR because their aortic anatomy is structured in a manner that does not allow an endograft to be anchored properly. These patients face either open surgery or may be treated sub-optimally with standard EVAR. Aortica is advancing the science of personalized medicine by developing a “patient-specific” solution to this problem that combines a patient’s CT scans with its proprietary software and 3-D printing to personalize a standard endograft to fit precisely and anchor securely within each patient’s unique anatomy.

For further information visit the company’s website at www.aorticacorp.com

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