FDA Approves Aortica Corporation to Supply AortaFit™ System for Starnes' Physician-Sponsored IDE Study

Fenestration Alignment Software & Patient-Specific 3D Printed Template Could Simplify Treatment of Complex AAA Disease / Provide Personalized Vascular Therapy

January 26, 2016

BELLEVUE, Wash.—Aortica Corporation today announced that FDA has approved a supplement to an ongoing Physician Sponsored IDE study sponsored by Dr. Benjamin Starnes – Chief of Vascular Surgery at the University of Washington (UW). The supplement names Aortica as the supplier of both a Fenestration Alignment Software and a patient-specific 3-D printed fenestration template. Together the software and the template comprise the investigational AortaFit™ System, which is designed to improve treatment options for patients with juxtarenal Abdominal Aortic Aneurysms (AAA). Dr. Starnes, one of the world's foremost authorities in the treatment of AAA, hopes that both the software and the 3D printed template could significantly reduce the need for invasive open surgery in patients suffering from aneurysms that are too close to branch arteries that supply blood to vital organs. To date, Dr. Starnes has enrolled and successfully treated over 80 AAA patients in the study, which is approved to enroll 150 patients.

"This is an exciting step for both the UW study and for Aortica" stated Tom Douthitt, Aortica CEO. "Dr. Starnes and only a very few others around the world have been treating these patients with challenging anatomy using 'manual' techniques that require expensive equipment, a high degree of skill, and hours of planning. The combination of challenging anatomy along with the complexity of managing these patients endovascularly results in the patient typically being sent to surgery, which results in higher mortality rates, longer hospital stays and greater costs." He adds, "We hope that Dr. Starnes' study demonstrates that the AortaFit™ System will greatly simplify the process for managing these patients using less invasive and highly desirable Endovascular Aneurysm Repair (EVAR) rather than open surgery."

"Accurately planning these cases using current manual techniques is challenging, time consuming and fraught with error for less experienced surgeons" stated Dr. Starnes. "Consequently, surgeons tend to shy away from Fenestrated EVAR (or FEVAR) because they can't accurately predict how the endograft will alter the existing anatomy. The team at Aortica has replicated and automated the manual technique I have used successfully in nearly 200 fenestrated cases. The AortaFit™ System removes the time, the expense, and the headache of planning fenestrated EVAR, and really simplifies what has historically been a very complex process."

The Fenestration Alignment Software utilizes a multi-factorial assessment to determine the precise location and size of branch arteries and designs a template with holes (or fenestrations) corresponding to the unique location of a given patient's branch arteries. Next, a 3D printer generates a template of the diseased section of the patient's aorta, which is then used by surgeons to create fenestrations in the endograft. The modified endograft will perfectly match the patient's anatomy and significantly increase the available endograft seal zone. As a result, blood flow is preserved to vital organs, and the patient avoids open surgery.

"With FDA's approval of this IDE supplement, we hope the study will yield two broad outcomes: first to provide vascular surgeons the tools to facilitate the provision of Personalized Vascular Therapy, consistent with the national Precision Medicine Initiative; and second is the simplification of FEVAR." explained Dr. Starnes.

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 without blocking blood flow to vital organs. These patients face either open surgery or may be treated sub-optimally with standard EVAR. Aortica is dedicated to simplifying Fenestrated EVAR (FEVAR), and advancing the science of Personalized Vascular Therapy.

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

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