Aortica™ Corp. Reports Successful Results of First 30 Fenestrated EVAR Patients Using Automated Case Planning Software

Dr. Benjamin Starnes presents results from PS-IDE Study at Western Vascular Society

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BELLEVUE, Wash. Aortica Corp. today announced that Dr. Benjamin Starnes, Chief of Vascular Surgery at the University of Washington (UW), has reported successful results for the first 30 patients undergoing Fenestrated Endovascular Aneurysm Repair (FEVAR) planned and performed using Aortica's AORTAFIT™ automated case planning software. The cases are part of Dr. Starnes' FDA approved physician-sponsored investigational device exemption (IDE) study, administered in conjunction with Harborview Medical Center. EVAR is the gold standard for treatment of Abdominal Aortic Aneurysms (AAA), while "FEVAR" is a highly effective treatment for more complex AAA cases. The complexity arises when branch arteries are too close to the origin of the aneurysm and complicate or preclude safely deploying a standard endograft. In a FEVAR procedure, holes (or fenestrations) are carefully created on the endograft to line up with branch arteries that supply blood to vital organs. Unfortunately, given the technology available today, both the planning of where to place the fenestrations and the delivery of the fenestrated endograft are highly complex and time-consuming, significantly limiting adoption. Dr. Starnes' IDE study is evaluating technologies and methods to dramatically simplify both the case planning and the delivery of FEVAR endografts. Since 2016, Aortica's AortaFit™ planning software has been a key part of Dr. Starnes' study. Results from these first 30 patients using Aortica's AortaFit automated case planning software were presented at the Western Vascular Society meeting.

"I have now used Aortica's AortaFit™ automated case planning software successfully in 30 patients overall, using standard endografts from three of the major manufacturers—Bolton, Cook and Medtronic," stated Dr. Starnes. "The software digitizes a patient's CT scan and utilizes an algorithm to account for the effect of the implant on the geometry of the anatomy to create an exact replica of each patient's aortic anatomy as it would look with the introduction of the implant. The entire process takes just a few minutes to create an accurate multi-vessel fenestrated graft plan. This compares to the hours it takes to plan cases using manual planning and today's existing technology. Because the graft plan is so precise, the software also simplifies the process of aligning and placing the endograft in the patient," Dr. Starnes continued. "The results in these first 30 patients are highly favorable with low morbidity and mortality. Graft implantation was successful in 100% of patients (30/30), with 97% of branch arteries preserved at index (84/87). The three branch arteries not cannulated were due to complications not related to the graft plan. There have been no type 1a or type 3 endoleaks through 30 days. Two deaths were reported, but both were unrelated to AAA disease."

Dr. William Quinones-Baldrich, professor of surgery at UCLA commenting on the results stated, "This is the future. Everyone at this conference [WVS] should remember you saw this here today."

“We appreciate being part of Dr. Starnes’ efforts to simplify the procedure and incorporate new technology that will significantly improve the treatment options for juxtarenal AAA patients,” stated Tom Douthitt, CEO of Aortica. “As we gain more experience with the automated approach using Aortica’s AortaFit™ System, the next step will be collaboration with an endograft manufacturer, moving beyond ‘physician modification’ of endografts used in this study, to a more elegant, simplified and rapid ‘direct manufacture’ of a FEVAR graft in the commercial setting. I believe FEVAR will then become the preferred method of treatment for the vast majority of juxtarenal AAA patients and perhaps any AAA patients with disease in the infrarenal neck.”

About Abdominal Aortic Aneurysm (AAA) Disease, EVAR & FEVAR

In 2016, approximately 515,000 people worldwide are diagnosed with abdominal aortic aneurysms (AAA), and 185,000 of these required some form of repair. 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. EVAR is a significantly less invasive option to 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. Unfortunately, 40% of patients requiring repair (82,000) have aortic anatomy structured in a manner that does not allow an endograft to be deployed safely without blocking blood flow to vital organs. FEVAR is the preferred treatment option for these patients. FEVAR involves placing reinforced, radiopaque holes (or fenestrations) in the endograft that align with branch arteries. This allows the physician to place the graft higher up in the aortic anatomy allowing for reliable anchoring and secure seal, while preserving blood flow to vital organs. Today only 6% of candidate patients actually receive FEVAR today due to the complexity of current FEVAR technology. Simplification of the procedure will result in significantly more patients becoming candidates for FEVAR therapy.

About Aortica Corporation

Aortica Corporation was founded to design, manufacture, and market tools for treatment of patients with juxtarenal AAA disease. Aortica is dedicated to simplifying Fenestrated EVAR (FEVAR), and advancing the science of Personalized Vascular Therapy.

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

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