

# Aortica Corporation Announces First-in-Man Uses of AortaFit™ System

## *Successful Initial IDE Cases Using Endografts from Two Different Manufacturers*

**FEBRUARY 11, 2016--BELLEVUE, WA**—Aortica Corporation today announced the successful completion of the first two cases using their AortaFit™ system to support simplified fenestrated endovascular aneurysm repair (FEVAR). Two procedures were performed by Dr. Benjamin Starnes, Chief of Vascular Surgery at the University of Washington (UW), as part of his physician-sponsored IDE study. The AortaFit™ System is an investigational surgical planning tool comprised of Aortica's Fenestration Alignment Software and a patient-specific 3D printed fenestration template. In both cases, the presence of branch arteries near the aneurysms and angulated patient anatomy limited the available treatment options. Using only a CT scan the Aortica software analyzed each patient's native aorta, and determined how each endograft would influence the vessel geometry once it was implanted. Using this information, the software precisely determined the appropriate locations of fenestrations (or holes in the graft) to align with the branch arteries. A 3D printer then generated patient-specific AortaFit™ templates that Dr. Starnes used in the operating room to guide his modification of each graft. Standard "off-the-shelf" Medtronic and Bolton Medical endografts were used in these first two cases. By accounting for the branch arteries, the grafts provided a more secure fixation and seal while still allowing for blood to continue to flow to vital organs fed by the branch arteries.

"These two cases represent a first step toward making fenestrated EVAR a simple procedure that is available to many more physicians and patients," stated Dr. Starnes. "The Aortica software made case planning so much easier and the AortaFit™ template shortened the time for graft modification in the OR. Our first case was a 74-year old male with a 6cm juxtarenal aneurysm. The arteries that supplied his kidneys were only 7mm from the beginning of the aneurysm, meaning there was not adequate space to anchor a standard endograft," continued Dr. Starnes. "Using the AortaFit™ System, we generated a 3 fenestration template that precisely matched the anatomical requirements of our patient. I was able to very quickly and easily modify a standard Medtronic Endurant II endograft. The alignment of the fenestrations was perfect; the graft was easily placed and we increased the effective seal zone from 7mm to 39.2mm. The entire procedure took 1 hour and 53 minutes."

"The second case was also a 74-year old male who underwent open surgical repair 6 years earlier," Dr. Starnes continued. "Unfortunately his disease continued to progress. The aneurysm had grown to 6cm, and was now located just 2mm from arteries branching out to the kidneys. Again the AortaFit™ System was used to quickly determine the location of 3 fenestrations and to guide modification of a standard Bolton Medical endograft, enabling the patient to be treated endovascularly while increasing the effective seal zone from 2mm to 35.3mm."

“These first-in-man cases are significant milestones for Aortica,” said Tom Douthitt, Aortica CEO. “FEVAR offers so many advantages for a dramatically underserved patient population. Unfortunately, the current endovascular treatment options for juxtarenal aneurysms: Chimneys, commercially available FEVAR, and short neck grafts all suffer from clinical limitations, complexity, and long procedure times. Consequently, none of these approaches enjoy widespread adoption,” continued Douthitt. “Our team has patterned the Fenestration Alignment Software after the manual method used by Dr. Starnes in an effort to automate and simplify FEVAR and provide a tool that many more physicians might use. To see the AortaFit™ System used successfully in these initial cases using standard endografts from two different manufacturers is tremendously satisfying. The study is approved to use grafts from multiple graft manufacturers in the US, and we look forward to continuing our clinical evaluation in Dr. Starnes’ study.”

### **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 endovascular aneurysm repair (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](http://www.aorticacorp.com)

## **Contacts**

Aortica Corporation

Stacy Douthitt, 425-209-0023

[stacydouthitt@aorticacorp.com](mailto:stacydouthitt@aorticacorp.com)