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The Feasibility of Aptus Endovascular System for Treatment of AAA: Early Results of a Phase I Investigation.

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PURPOSE: To assess the feasibility of Aptus stent graft system for treatment of infrarenal abdominal aortic aneurysms (AAA).

MATERIALS AND METHODS: The first successful human implant of the Aptus Endovascular AAA Repair System was performed in Venezuela over a year ago. The FDA has approved the STAPLE-1 feasibility trial of the Aptus endovascular AAA repair system (Aptus Endosystems, Sunnyvale, CA) in May, 2006. The Aptus stentgraft is unique in that it consists of a main body endograft that is secured to the proximal neck with specially designed EndoStaples, and modular bilateral lumen extensions that interlock with the main body. The deployment system for the main body of the modular bifurcated stentgraft includes multiple controlled stages that facilitate placement of Endostaples at the infrarenal aortic neck. The EndoStaples are delivered via a steerable guiding delivery catheter that is placed through the contralateral gate of the modular bifurcated stentgraft. As part of the Phase I feasibility study, the Aptus Endovascular AAA Repair System is designed to treat infrarenal AAA neck diameters of 21-26 mm, and neck length of 12 mm. All AAA measurements are documented using contrast enhanced CT scans with 3-D reconstructions by the study core lab (M2S, Lebanon, NH).

RESULTS: To date, 100% procedural success has been achieved in all patients with the Aptus Endovascular AAA Repair System. In all cases, the EndoStaple system was successfully inserted from the contralateral femoral access site and 2-6 staples implanted at the infrarenal aortic neck. We will present up to date single center outcomes of the STAPLE-1 investigation evaluating the feasibility of Aptus endovascular AAA repair system.

CONCLUSION: Early results of a single center experience indicate that Aptus endovascular system with infrarenal active fixation via Endostaples can be used successfully to treat AAA. Data from the multi-center US feasibility STAPLE-1 trial is currently underway.