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**Aptus Endovascular AAA Repair System:
Initial US Clinical Experience at Georgetown University**

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Introduction: Endovascular aortic aneurysm repair (EVAR) is widely accepted as a superior to open aneurysm repair with respect to acute morbidity and mortality; however, requirements for annual imaging, revision, and occasionally rupture or conversion to open repair have restricted its use. The inability to faithfully reproduce the suture fixation of open grafts with endovascular techniques has generated a variety of approaches to endograft fixation, including radial force columnar rigidity, and a variety of proximal barbs and hooks. All current endograft technologies fail to approximate the fixation strength of sutured grafts, and all have been plagued by some degree of late migration and inability to treat unfavorable aortic neck morphology.

The Aptus endograft system is composed of 2 primary and independent catheter-based delivery systems: (1) an endograft delivery system and (2) a catheter-based endovascular stapling system. The Aptus stapling device delivers a helical metal screw that incorporates all layers of the vascular wall and generates a very high pullout force in all directions. The Aptus fixation paradigm introduces a set of capabilities to endovascular procedures that include: (1) bidirectional active fixation of a prosthesis to vascular tissue, (2) operator control of fixation location, strength, and geometry; and (3) the ability to deploy fixation at any time periprocedurally or as part of a secondary intervention. The staple also allows the operator to enhance graft apposition to the vascular wall in areas of mural irregularity where stent apposition is inadequate. The capabilities of an independent endovascular active fixation technology are amply demonstrated in the application of EVAR allowing for marked reduction in graft delivery catheter caliber to 16-F outer diameter, the

equivalent of a 14-F sheath, without sacrificing graft or stent caliber.

The eventual goal of EVAR to surpass open repair is dependent on its ability to improve long-term complication and durability and its ability to treat the wide variety of aortoiliac morphologies seen in aneurysmal pathology. The Aptus endograft system represents the first technology that allows the surgeon to regain the ability to effectively suture the graft in place and duplicate the surgical principles of sutured grafts that serve as the foundation of all vascular reconstructive procedures.

Background: The Aptus Endovascular AAA Repair System is the first to implement a discreet, active fixation methodology. The graft utilizes a polyester bifurcated main body with a proximal nitinol stent. The limbs of the main body has distal nitinol stents that allow modular limb deployment of 2 docking limbs. The remainder of the body and limbs of the main body are unsupported polyester fabric, allowing tension-free orientation of the proximal anastomosis, both acutely and chronically. The 2 modular graft limbs are thus “locked” in place, creating a functional unibody graft in situ. Preclinical bench and animal testing over a period of 4 years and 2 cases performed outside the US in 2005 precede the initiation of a FDA Phase I US trial. The first US case was performed at Georgetown University Hospital (GUH) in July of 2006. We present initial results of 4 cases performed at GUH.

Methods: The Aptus Endovascular AAA Repair System is implanted with a low profile (14F sheath equivalent delivery catheter. The main body is a bifurcated proximal endograft that is secured to the proximal aortic neck with helical metal screws

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(EndoStaples) and completed with bilateral lumen ex-tensions that physically lock with the main body increasing limb distraction forces many fold over the forces that prevent distraction with radial force only. EndoStaples are delivered via a hand-held staple applicator and a steerable guiding catheter that is identical in diameter to the main body delivery catheter. All patients were treated for abdominal aortic aneurysm with the Aptus Endovascular AAA Repair System. Four subjects met the inclusion/exclusion criteria of the protocol (STAPLE-1) and consented to inclusion in the protocol after informed consent. The protocol and all informed consent documents were reviewed and approved by the Georgetown University IRB. All aneurysm characteristics were documented using contrast enhanced CT scans with 3-D reconstructions. A core lab is employed to document all initial anatomical measurements and to characterize and document the results of the endograft placement.

Results: The first clinical case in the US was performed in July of 2006. A total of 4 cases have been performed at GUH through December 2006. Procedural success was achieved in all subjects (n=4). All devices were successfully implanted and secured with the EndoStaple system. The number of EndoStaples deployed ranged from 4 to 10 per patient, depending on anatomical requirements. A total of 26 staples were implanted. There were no instances where a staple failed to engage the aortic wall or embolized. All staples were deployed in the desired location and there were no instances where staples were desired but could not be applied. Ancillary devices were utilized in two cases. The first used a proximal aortic cuff (Excluder) for a perceived type I endoleak and the second was an iliac extender (Zenith) for distal limb extension in tortuous anatomy. No endoleaks or limb stenoses were identified in postoperative imaging. No endograft device complications occurred perioperatively or through the most recent

follow-up period (30 days).

The ability to successfully delivery and deploy multiple EndoStaples from a contralateral femoral access site during an endovascular AAA repair procedure was demonstrated. All 4 patients completed 30-day follow-up with computed tomography and abdominal radiography. All patients demonstrated good device position with no migration, endoleaks, or other graft-related problems noted at the 30-day follow-up.

Conclusion: The Aptus Endovascular AAA Repair System was used to successfully treat abdominal aortic aneurysms in this initial series of 4 patients at GUH. Each patient tolerated the procedure well, and there were no device related complications noted in the recovery period.