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Discrete Fixation for Endovascular Aortic Grafting: Results of the Phase I Multicenter Trial of the Aptus™ Endovascular Repair System

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Objective: This phase I study evaluated the safety and feasibility of the Aptus™ Endovascular AAA Repair System to electively treat patients with abdominal aortic aneurysms. The system is characterized by a three-piece modular endograft and discrete fixation system enabled by a novel EndoStapling system. The unique features of the endograft include a main body with an unsupported mid-section and two radially supported limbs that physically lock to the main body. The fixation of the endograft is achieved with a helical staple (EndoStaple) measuring 4 mm (length) by 3 mm (diameter). The EndoStaple engages the full thickness of the aortic wall as it is implanted. The operator controls the number and position of EndoStaple implantations. The endograft delivery systems have an O.D. of either 16 or 18F. The endostapling system has a 16F O.D.

Methods: This was a prospective, single-arm, observational study. The two primary end points were absence of major device-related adverse events at 1 month (safety) and ability to successfully deploy all endograft components and EndoStaples (feasibility). Secondary end points include freedom from endoleaks, rupture, migration, device integrity, blood loss, procedure time, and other clinical parameters. Follow-up evaluations occur at 1, 6, and 12 months and annually. Inclusion criteria include a proximal neck length of 12mm and distal iliac fixation zone of 10mm.

Results: Twenty-one patients were treated between July 2006 and May 2007. All patients have completed 1 month of follow-up for evaluation of the primary end points of the study. Aneurysm diameter ranged from 46 to 85 mm, with a mean diameter of 57 mm. All endograft components were successfully deployed, including a total of 93 EndoStaples. The range of EndoStaples implanted was 2 to 10, with a median of 4 per patient. There were no type I, II, or IV endoleaks at 30 days. Device-related adverse events included two limb thromboses at 9 and 30 days. Adjunctive devices used were two proximal cuffs and one limb extension. There were no EndoStaple-related adverse events.

Conclusions: These results document the initial success of the first discrete fixation system for an endovascular device. These results support the continued clinical investigation of the Aptus™ Endovascular AAA Repair System. A phase II pivotal study is under way.