Protocol Summary

Study Acronym/Protocol #: AAA 13-02

06 Dec 2017

NCT02528500

PROTOCOL SUMMARY

Study Title	Early Feasibility Assessment of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis in the Treatment of Type IV Thoracoabdominal Aortic Aneurysms Involving the Visceral Branch Vessels
Protocol Number	AAA 13-02
Sponsor	W. L. Gore & Associates, Inc. Medical Products Division Telephone: 800-437-8181
Study Design	This is a non-randomized, multicenter study designed to assess the initial feasibility of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device)
Study Objective	Assess the initial safety of the TAMBE Device implantation procedure in the treatment of Aortic Aneurysms Involving the Visceral Branch Vessels
Study Rationale	This study is designed to provide evidence to support the use of the TAMBE Device as an option for endovascular treatment of patients with Type IV Thoracoabdominal Aortic Aneurysms.
Study Endpoints	**Primary endpoint:** **Procedural Safety -** Absence of the following events through 30 days post-procedure: • Death • Stroke • Myocardial Infarction • Bowel Ischemia • Paraplegia • Respiratory Failure • Renal Failure • Procedural Blood Loss ≥1000 mL **Secondary endpoints:** **Technical Success -** All of the following: • Successful access to the necessary arterial sites • Successful deployment of all required TAMBE Device components and any required accessory components • Patency of all required TAMBE Device components and any required accessory components on completion angiography • Absence of surgical conversion within 24 hours of initiation of the procedure

	Device integrity - Absence of the following events through one year of follow-up: • Loss of functional patency in any branch component due to thrombus or mechanical failure of the branch components • Loss of functional patency in the main body component(s) due to thrombus or mechanical failure of the main body component(s) • Separation of the branch components from the main body component(s) • Separation of the main body component(s) from the accessory components (Distal Bifurcated Component and / or contralateral limb components) **Individual components of technical success** **Individual components of device integrity at one month, six months and one year follow-up** **Patency (Primary, Assisted Primary and Secondary)** **Absence of Type I and Type III endoleaks at one month follow-up**
Subject Population	Subjects with Thoracoabdominal Aortic Aneurysms Involving the Visceral Branch Vessels
Number of Subjects Treated	10
Number of Sites	Six in the United States
Expected Time to Complete Enrollment	18 Months
Schedule of Events	**Assessments at Pre-treatment:** • CT of chest, abdomen and pelvis • Physical exam • Creatinine measurement **Assessments at Treatment:** • Angiography **Assessments at Hospital Discharge:** • Physical exam • Creatinine measurement • Abdominal ultrasound (optional) **Assessments at Follow-up (One month, six months, and annually through 5 years):** • CT of chest, abdomen and pelvis (not required at hospital discharge) • Lumbar spine series X-ray (4 views) (annual follow-up only)* • Physical exam • Creatinine measurement • Abdominal ultrasound (optional) *As enrollment is closed for this study, for all subjects that have completed their one year follow-up prior to this protocol amendment being implemented, subjects will be

	expected to have radiograph assessments at their next annual follow-up exam (i.e. two year follow-up) and annually thereafter.
Anticipated Total Study Duration	7 years from initiation of enrollment