Assessment of the GORE® EXCLUDER® Conformable AAA Endoprosthesis in the Treatment of Abdominal Aortic Aneurysms

Protocol number: AAA 13-03

07September2022
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W. L. Gore & Associates, Inc.
Medical Products Division

PROTOCOL SUMMARY

Study Title	Assessment of the GORE® EXCLUDER® Conformable AAA Endoprosthesis (CEXC Device) in the Treatment of Abdominal Aortic Aneurysms
Protocol Number	AAA 13-03
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IDE or PMA Number	IDE # G150057
Sponsor	W. L. Gore & Associates, Inc. [redacted] Telephone: 800-437-8181 [redacted]
Study Design	Prospective, nonrandomized, multicenter, study with two parallel substudies: Short Neck Substudy: Subjects with abdominal aortic aneurysms having aortic neck angulation ≤ 60˚ and infrarenal aortic neck length ≥ 10 mm High Neck Angulation Substudy: Subjects with abdominal aortic aneurysms having aortic neck angulation > 60 ˚and ≤ 90˚ and infrarenal aortic neck length ≥ 10 mm
Study Objective	Assess the safety and effectiveness of the CEXC Device for the treatment of infrarenal AAA
Primary Safety Endpoint (Both Substudies)	• Composite of any of the following events through 30 days post-treatment: • Death • Stroke • Myocardial Infarction • Bowel Ischemia • Paraplegia • Respiratory Failure • Renal Failure • Blood Loss > 1000 mL • Thromboembolic Events (including limb occlusion and distal embolic events)

Primary Safety Endpoint Hypothesis (Both Substudies)	Percentage of subjects free from safety events as adjudicated by the Clinical Events Committee (CEC) at 30 days will be > 79%
Primary Effectiveness Endpoint (Both Substudies)	Treatment success, defined as technical success (defined as successful access and deployment of all required CEXC Device components) and freedom from the following events: • Type I endoleak • Type III endoleak • Migration (10 mm or more) • AAA enlargement ≥ 5 mm with or without intervention • AAA rupture • Conversion to open repair
Primary Effectiveness Endpoint Hypothesis (Both Substudies)	The percentage of subjects with treatment success at one year will be > 80%
Subject Population	Subjects with infrarenal abdominal aortic aneurysm (AAA)
Number of Subjects	Initial Cohort: A total of 175 subjects: 80 Short Neck Substudy, 95 High Neck Angulation Substudy Continued Enrollment Cohort (optional): Up to 15 High Neck Angulation Subjects.
Number of Sites	A maximum of 56 sites located in the U.S. The Sponsor shall maintain an updated list of principal investigators, investigational sites, and institutions. This list shall be kept separately from this Protocol.
Expected Time to Complete Enrollment	Subject accrual – 2 years Follow-up – 5 years from last subject enrollment Total investigation duration – 10 years (including site initiation and closing period)
Expected Time of each Study Subject to Complete the Study	Total of 60 months for each subject to complete the study
Pre-Treatment Evaluation	• Physical exam / medical history within 30 days of procedure • Serum creatinine concentration • Contrast enhanced spiral CT of the abdomen and pelvis ≤ 90 days from procedure
Follow-Up Evaluations	Follow-up conducted at one, six, and twelve months post-treatment and annually thereafter for five years to consist of: • Physical examination • Contrast enhanced CT scan • Non-contrast CT scan (1 month only)

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Significant Inclusion Criteria	AAA meeting any of the following criteria: • Maximum diameter ≥ 50 mm • Rapid growth (> 5 mm in a 6 month period) • Non-ruptured AAA presenting with clinical symptoms • Adequate anatomy to receive the CEXC Device, including: • Adequate iliac / femoral access • Infrarenal aortic neck diameter 16-32 mm • Infrarenal aortic neck length ≥ 10 mm • Aortic neck angle ≤ 90˚ • Distal iliac artery seal zone ≥ 10 mm • Iliac artery diameter 8-25 mm • An Informed Consent Form (ICF) signed by subject • Male or infertile female* • Able to comply with Protocol requirements including following-up • Life expectancy > 2 years • Age ≥ 21 years • * Infertile female – condition which prevents pregnancy, e.g., hysterectomy, tubal ligation or post-menopausal for greater than 1 year • Subjects will be allocated to the appropriate substudy based on the aortic neck angle measurement recorded during screening.
Significant Exclusion Criteria	• Mycotic or ruptured aneurysm • Known concomitant thoracic aortic aneurysm which requires surgical intervention • Renal insufficiency defined as creatinine > 2.5 mg / dL or patient undergoing dialysis • New York Heart Association (NYHA) class IV • Aneurysmal, dissected, heavily calcified, or heavily thrombosed landing zone(s) • Severely tortuous or stenotic iliac and / or femoral arteries • Patient has body habitus or other medical condition which prevents adequate delineation of the aorta • Participating in another investigational device or drug study within 1 year of treatment

	• Systemic infection which may increase the risk of endovascular graft infection • Known degenerative connective tissue disease, e.g., Marfan or Ehler-Danlos Syndrome • Planned concomitant surgical procedure or major surgery within 30 days of treatment date • Known history of drug abuse • Known sensitivities or allergies to the device materials
Total Expected Duration of the Study	Total investigation duration – 10 years (including site initiation and closing period)
Schedule of Events- **All Enrolled Subjects**	Screening Pre-Treatment Treatment Discharge Follow-up (30 day, 6 and 12 month and annually through 5 years).
Data Monitoring Committees	Clinical Events Committee (CEC) Data Safety Monitoring Board (DSMB)
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