Evaluation of the GORE® TAG® Thoracic Branch Endoprosthesis (TBE Device) in the Treatment of Lesions of the Aortic Arch and Descending Thoracic Aorta

Protocol Number: SSB 11-02

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

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NCT # 02777528

PROTOCOL SUMMARY

Subjects enrolled on the SSB 11-02 Protocol prior to a site's IRB approval of Revision 4 should be followed under Revision 3 of the Protocol located in Appendix E (US only).

Study Summary

Study Title	Evaluation of the GORE® TAG® Thoracic Branch Endoprosthesis (TBE Device) in the Treatment of Lesions of the Aortic Arch and Descending Thoracic Aorta
Protocol Number	SSB 11-02
Revision	10
IDE or PMA Number	G130120
Sponsor	W. L. Gore & Associates, Inc. [redacted]
Sponsor (Japan)	W. L. Gore & Associates G.K. Medical Products Division [redacted]

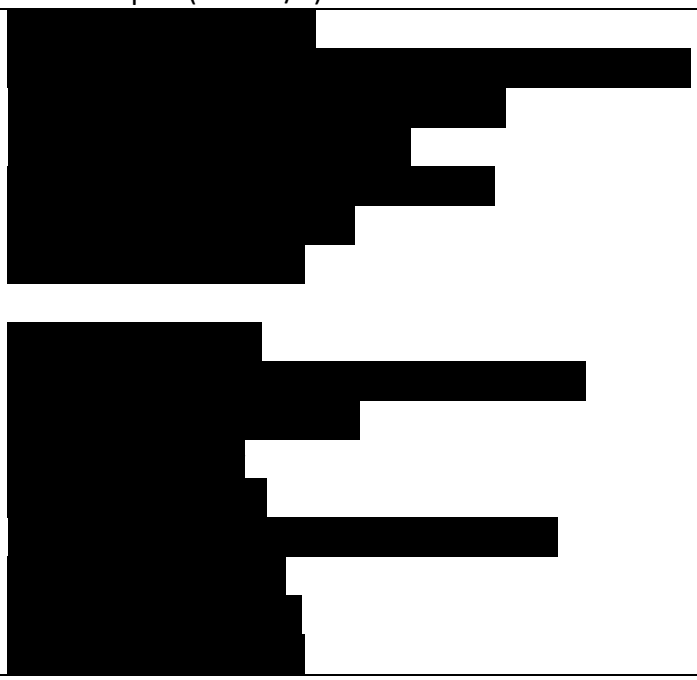
Study Design	Prospective, non-randomized, multicenter study with four independent arms consisting of a total of seven cohorts:
	• Zone 2 – Aneurysm, hypothesis-driven analysis
	• Zone 2 – Non-aneurysm aortic lesions which are anatomically suitable for treatment with the TBE Device, descriptive analysis
	  o Dissection cohort
	  o Traumatic Transection cohort
	  o Other isolated lesion types
	• Zone 0/1 – Aneurysm, hypothesis-driven analysis
	• Zone 0/1 – Non-aneurysm aortic lesions which are anatomically suitable for treatment with the TBE Device, descriptive analysis
	  o Dissection cohort
	  o Other isolated lesion types

Study Objective	Determine whether the GORE® TAG® Thoracic Branch Endoprosthesis is safe and effective in treating lesions of the aortic arch and descending thoracic aorta

Study Endpoint(s)	Primary Endpoint- Zone 2 Subjects (Aneurysm Cohort)
	Composite of the following events from the time of enrollment through one year:
	• Device Technical Success
	• Absence of the following:
	  o Aortic rupture;
	  o Lesion-related mortality;

	○ Disabling stroke; ○ Permanent paraplegia; ○ Permanent paraparesis; ○ New onset renal failure requiring permanent dialysis; ○ Additional unanticipated post-procedural surgical or interventional procedure related to the device, procedure, or withdrawal of the delivery system. Primary Endpoint- Zone 0/1 Subjects (Aneurysm Cohort) Composite of the following events from time of enrollment through one month following endovascular procedure: • Initiation of the index endovascular procedure following the debranching procedure • Device Technical Success for the index endovascular procedure • Absence of the following: ○ Aortic rupture; ○ Lesion-related mortality; ○ Disabling stroke; ○ Permanent paraplegia; ○ Permanent paraparesis; ○ New onset renal failure requiring permanent dialysis; ○ Additional unanticipated post-procedural surgical or interventional procedure related to the device, procedure, or withdrawal of the delivery system.
Subject Population	Subjects with thoracic aortic lesions which require coverage of the left subclavian artery, left common carotid artery and/or the brachiocephalic trunk/innominate artery for effective treatment.
Number of Subjects	Total Enrollment of 175-465 Subjects across four independent arms with a total of seven cohorts as follows: • Zone 2 – Aortic Aneurysm; A maximum of 115 Subjects ○ Primary Enrollment (n=85 Subjects) ○ Continued Access Enrollment (maximum 30 Subjects) • Zone 2 – Non-aneurysm aortic lesions; A maximum of 200 Subjects in all cohorts combined. ○ Dissection cohort (minimum 20 Subjects) ○ Traumatic Transection cohort (minimum 10 Subjects) ○ Other isolated lesion types

	• Zone 0/1 – Aortic Aneurysm; 50 Subjects
	• Zone 0/1 – Non-aneurysm aortic lesions; A maximum of 100 Subjects in all cohorts combined.
	  ○ Dissection cohort (minimum 10 Subjects)
	  ○ Other isolated lesion types

Number of Sites	Up to 40 sites in the U.S. (Zone 2 and Zone 0/1) and up to 5 sites in Japan (Zone 0/1).
Coordination PI	
Expected Time to Complete Enrollment	• Zone 2 - Aortic Aneurysm Subject accrual: 18-24 months • Zone 0/1 - Aortic Aneurysm Subject accrual: 48-60 months • Follow-up – Five years from treatment date Total study duration –Ten years
Schedule of Events Zone 2 Cohorts	Screening Evaluation: *(Within 30 days prior to enrollment unless otherwise noted)* • Physical examination, medical history • Modified Rankin Scale • Spinal Cord Ischemia Scale • NIH Stroke Scale • Spiral Computed Tomographic Angiography (CTA) of the chest, abdomen, and pelvis (contrast only) within 90 days prior to enrollment • Serum creatinine concentration Procedure: • Endovascular repair with the TBE Device with distal extension using the Conformable GORE® TAG® Thoracic Endoprosthesis as needed • Post deployment angiogram

	Post Procedure: *(Performed prior to discharge unless otherwise noted)* • Physical examination • Modified Rankin Scale • Spinal Cord Ischemia Scale • NIH Stroke Scale • In addition, NIH Stroke Scale should be performed for any Subject suspected of having a stroke event that undergoes the treating site's stroke Protocol during the study interval from the initiation of index endovascular procedure until discharge, and should be performed as soon as possible after learning of the event Follow-Up Evaluations: Intervals: 1, 6, 12, 24, 36, 48, and 60 months post-treatment • Physical examination • Modified Rankin Scale (also completed at 3 months for Subjects suspected of experiencing a stroke event through 30 days) • Spinal Cord Ischemia Scale • Spiral CTA of the chest (contrast) • NIH Stroke Scale (one month only) • Dissection Subjects only: Spiral CTA of the chest, abdomen, and pelvis (contrast) • Spiral CT of the chest (non-contrast - one month only, or if endoleak suspected) • Dissection Subjects only: Spiral CTA of the chest, abdomen, and pelvis (non-contrast - one month only, or if endoleak suspected)
Schedule of Events Zone 0/1 Cohorts	Screening Evaluation: *(Within 30 days prior to enrollment unless otherwise noted)* • Physical examination, medical history • Modified Rankin Scale • Spinal Cord Ischemia Scale • NIH Stroke Scale • Serum creatinine concentration • Spiral Computed Tomographic Angiography (CTA) of the chest, abdomen, and pelvis (contrast only) within 90 days prior to the Phase 2 procedure • Radiological Evaluation of the Head/Neck within 90 days prior to Phase 1 procedure Phase 1 Evaluation at least 24 hours but no more than 60 days following the completion of the revascularization procedure: • Physical examination • Modified Rankin Scale

	• Spinal Cord Ischemia Scale • In addition, NIH Stroke Scale should be performed for any Subject suspected of having a stroke event that undergoes the treating site's stroke Protocol during the study interval from the initiation of surgical revascularization procedure until discharge post-index endovascular procedure, and it should be performed as soon as possible after learning of the event Phase 2 Procedure at least 24 hours but no more than 60 days following the completion of the revascularization procedure: • Endovascular repair with the TBE Device • Post deployment angiogram Post Procedure: *(Performed prior to discharge unless otherwise noted)* • Physical examination • Modified Rankin Scale • Spinal Cord Ischemia Scale • NIH Stroke Scale • In addition, NIH Stroke Scale should be performed for any Subject suspected of having a stroke event that undergoes the treating site's stroke Protocol during the study interval from the initiation of surgical revascularization procedure until discharge post-index endovascular procedure, and it should be performed as soon as possible after learning of the event Follow-Up Evaluations: Intervals: 1, 6, 12, 24, 36, 48, and 60 months post-treatment • Physical examination • Modified Rankin Scale (also completed at 3 months for Subjects suspected of experiencing a stroke event through 30 days) • Spinal Cord Ischemia Scale • NIH Stroke Scale (one month only) • Spiral CTA of the chest (contrast) • Dissection Subjects only: Spiral CTA of the chest, abdomen and pelvis (contrast) • Spiral CT of the chest (non-contrast – one month only, or if endoleak suspected) • Dissection Subjects only: Spiral CTA of the chest, abdomen and pelvis (non-contrast – one month only, or if endoleak suspected)

Additional Information	[redacted]