

INSTRUCTIONS FOR USE FOR:



T H O R A C I C
E N D O P R O S T H E S I S

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English

TABLE OF CONTENTS

DESCRIPTION.....	2
INDICATIONS FOR USE	2
CONTRAINDICATIONS	2
WARNINGS AND PRECAUTIONS.....	2
SUMMARY OF US CLINICAL STUDIES (TAG 99-01, TAG 03-03, TAG 04-01 AND TAG 06-02)	5
SUMMARY OF POST-APPROVAL STUDIES (TAG 05-02)	28
PATIENT SELECTION AND TREATMENT	28
PATIENT COUNSELING INFORMATION	29
HOW SUPPLIED.....	29
CLINICAL USE INFORMATION	29
DIRECTIONS FOR USE	30
IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP.....	32
DEVICE RELATED ADVERSE EVENT REPORTING.....	34
PATIENT TRACKING INFORMATION	34
DEFINITIONS	34

INSTRUCTIONS FOR USE

GORE® TAG® Thoracic Endoprosthesis

- **CAUTION – USA Federal law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.**
- **Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.**

DESCRIPTION

The GORE® TAG® Thoracic Endoprosthesis provides endovascular repair of aneurysms of the descending thoracic aorta (DTA). The GORE® TAG® Thoracic Endoprosthesis may be used as a single device or in multiple device combinations to accommodate the intended treatment site.

The endoprosthesis is comprised of an expanded polytetrafluoroethylene (ePTFE) tube reinforced with ePTFE / FEP (fluorinated ethylene propylene) film that is supported by a self-expanding nitinol (nickel titanium alloy) wire-frame (stent) along its external surface. The endoprosthesis contains radiopaque gold marker bands at the base of the device flares (**Figures 1 and 2**) approximately 1 cm from each end of the endoprosthesis. An implantable ePTFE / FEP sleeve is used to constrain the endoprosthesis on the leading end of the delivery catheter (**Figure 1**). Unlacing of the endoprosthesis initiates in the middle of the device and simultaneously extends toward both ends of the endoprosthesis. The ePTFE / FEP sleeve remains in-situ between the exterior surface of the endoprosthesis and the intimal surface of the aorta.

Two device introducer sheath caps are included with the GORE® TAG® Thoracic Endoprosthesis. These caps are only to be used with the GORE® Introducer Sheath with Silicon Pinch Valve to accommodate the delivery catheter. They are NOT compatible with the GORE® DrySeal Sheath.

Figure 1. GORE® TAG® Thoracic Endoprosthesis

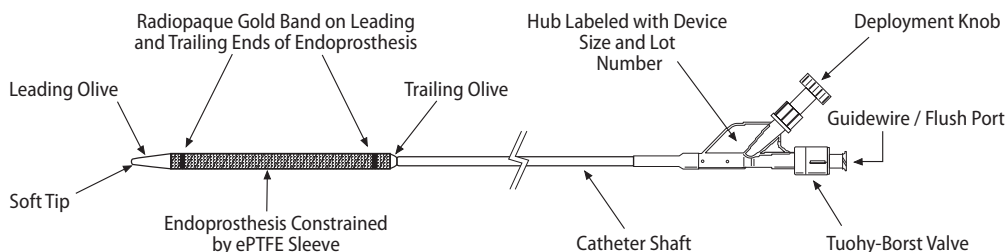
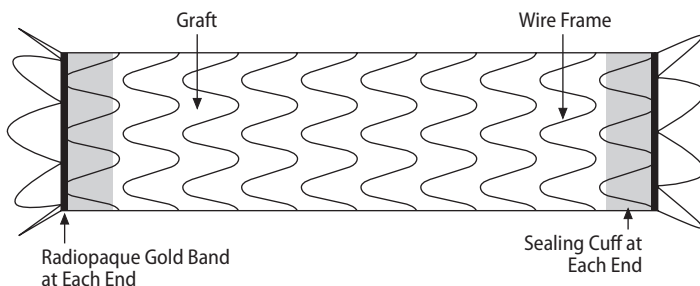


Figure 2. Deployed GORE® TAG® Thoracic Endoprosthesis



INDICATIONS FOR USE

The GORE® TAG® Thoracic Endoprosthesis is intended for endovascular repair of aneurysms of the descending thoracic aorta in patients who have appropriate anatomy, including:

- Adequate iliac / femoral access
- Aortic inner diameter in the range of 23-42 mm
- ≥ 2 cm non-aneurysmal aorta proximal and distal to the aneurysm

CONTRAINDICATIONS

The GORE® TAG® Thoracic Endoprosthesis is contraindicated in:

- Patients with known sensitivities or allergies to the device materials
- Patients with a systemic infection who may be at increased risk of endovascular graft infection

WARNINGS AND PRECAUTIONS

General

- Failure to properly follow the instructions, warnings, and precautions may lead to serious surgical consequences, injury to the patient or death. Compliance with device sizing recommendations is critical to optimal performance of the device.
- Read all instructions carefully, particularly the following sections: **Table 39: SIZING GUIDE**, and in the **DIRECTIONS FOR USE: Anatomical Requirements, and Using Multiple Devices**.
- The long-term performance of stent-grafts has not been established. All patients should be advised this treatment modality requires long-term, regular follow-up to assess patients' health status and stent-graft performance. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms) should receive enhanced follow-up (See **IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP**).
- The GORE® TAG® Thoracic Endoprosthesis should only be used by physicians experienced in vascular interventional techniques, and who have successfully completed the appropriate physician training program.
- The GORE® TAG® Thoracic Endoprosthesis is not recommended in patients unable to undergo, or who will not be compliant with, the necessary pre and post-operative imaging and follow-up described in **IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP**.

- The GORE® TAG Thoracic Endoprosthesis is only compatible with the GORE® Introducer Sheath with Silicone Pinch Valve or the GORE® DrySeal Sheath. Please refer to specific sheath IFU for instructions for use.
- Intervention or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aneurysms and / or endoleak. An increase in aneurysm size and / or persistent endoleak may lead to aneurysm rupture.
- Always have an appropriate surgical team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

Patient Selection and Treatment

- Successful patient selection requires specific imaging and accurate measurements; please see *Measurement Techniques and Imaging* section below.
- The GORE® TAG® Thoracic Endoprosthesis is designed to treat aortic neck diameters no smaller than 23 mm and no larger than 42 mm. The GORE® TAG® Thoracic Endoprosthesis is designed to treat proximal and distal aortic neck lengths no less than 20 mm distal to either the left subclavian or left common carotid artery. Additional proximal aortic neck length may be gained by covering the left subclavian artery (with or without discretionary transposition) when necessary to optimize device fixation and maximize aortic neck length. Distal aortic neck length of at least 20 mm proximal to the celiac axis is required. These sizing measurements are critical to the performance of the endovascular repair.
- Adequate iliac or femoral access is required to introduce the device into the vasculature. Careful evaluation of vessel size, anatomy and disease state, is required to assure successful sheath introduction and subsequent withdrawal. A surgically created vascular conduit may be needed to achieve access in select patients.
- The safety and effectiveness of the GORE® TAG® Thoracic Endoprosthesis have not been evaluated in the following patient etiologies:
 - acute and chronic dissections
 - aortic fistulas
 - aortitis or inflammatory aneurysms
 - intramural hematoma
 - mycotic aneurysms
 - penetrating ulcers
 - traumatic aortic transections
 - pseudoaneurysms resulting from previous graft placement
 - genetic connective tissue disease (e.g., Marfans and Ehlers-Danlos syndrome)
 - patients with active systemic infections
 - patients less than 21 years old
 - pregnant or nursing females
- Differing proximal and distal neck diameters (aortic taper) outside the intended aortic diameter requirements for a single endoprosthesis diameter (**Table 39**) requires the use of multiple endoprostheses of different diameters.
- Use of multiple devices with differing diameters require a treatment length of ≥ 13 cm.
- All lengths and diameters of the devices necessary to complete the procedure should be available to the physician, especially when pre-operative case planning measurements (treatment diameters / lengths) are not certain. This approach allows for greater intraoperative flexibility to achieve optimal procedural outcomes.
- Ilio-femoral access vessel size and morphology (e.g., minimal thrombus, calcium and / or tortuosity) should be adequate to accommodate the required introducer sheath diameters (**Table 39**) using appropriate vascular access techniques (including surgical conduit, if needed).
- Key anatomic elements that may affect successful exclusion of the aneurysm include severe neck angulation, short aortic neck(s) and significant thrombus and / or calcium at the arterial implantation sites. In the presence of anatomical limitations, a longer neck length may be required to obtain adequate sealing and fixation.
- Excessive thrombus or atherosclerotic plaque in the aortic arch may increase the risk of stroke.
- Use of the GORE® TAG® Thoracic Endoprosthesis outside of the recommended anatomical sizing guidelines (**Table 39**) may result in potentially serious device-related events (e.g., device infolding, excessive device compression, endoleak, wire fracture, migration).
- If occlusion of the left subclavian artery ostium is required to obtain adequate neck length for fixation and sealing, transposition of the left subclavian artery should be considered.
- The GORE® TAG® Thoracic Endoprosthesis is not recommended in patients who cannot tolerate contrast agents necessary for intraoperative and post-operative follow-up imaging.
- The GORE® TAG® Thoracic Endoprosthesis is not recommended in patients with known sensitivities or allergies to ePTFE, FEP, nickel, or titanium.
- ASA risk was higher in patients enrolled in the TAG 04-01 Ruptured Aneurysm Arm compared to patients enrolled in the TAG 99-01 and TAG 03-03 Aneurysm studies. Patients presenting with ruptured aneurysm may be at higher risk for complications associated with general anesthesia.

Measurement Techniques and Imaging

Clinical experience indicates that contrast-enhanced spiral computed tomographic angiography (CTA) with 3-D reconstruction is the required imaging modality to accurately assess patient anatomy prior to treatment for the GORE® TAG® Thoracic Endoprosthesis. If contrast-enhanced spiral CTA with 3-D reconstruction is not available, the patient should be referred to a facility with these capabilities. Clinicians recommend positioning of the image intensifier (C-arm) so that it is perpendicular to the neck, typically 45-75 degrees left anterior oblique (LAO) for the arch.

- **Diameter**
A contrast-enhanced spiral CTA is required for aortic diameter measurements. Diameter measurements must be of the flow lumen not including vessel wall. The spiral CTA scan must include the great vessels through the femoral heads at an axial slice thickness of 3 mm or less.
- **Length**
Clinical experience indicates that 3-D CTA reconstruction is the required imaging modality to accurately assess proximal and distal neck lengths for the GORE® TAG® Thoracic Endoprosthesis. These reconstructions should be performed in sagittal, coronal and varying oblique views depending upon individual patient anatomy. If 3-D reconstruction is not available, the patient should be referred to a facility with these capabilities.

Device Selection:

- Non-aneurysmal proximal and distal neck lengths of at least 20 mm are required. If aortic angulation is less than 60°, or if there is significant calcium and thrombus, additional neck length may be required.
- Strict adherence to the GORE® TAG® Thoracic Endoprosthesis IFU sizing guide is required when selecting the appropriate device size (**Table 39**). The GORE® TAG® Thoracic Endoprosthesis is designed to be oversized from 7 to 18 %. Appropriate device oversizing has been incorporated into the IFU sizing guide. Sizing outside of this range can result in endoleak, fracture, migration, device infolding, or compression.

- Adverse clinical outcomes including significant distal vascular ischemic complications (bowel ischemia, paraplegia) and / or death have resulted from device use outside of the IFU sizing guide.
- Follow the Instructions for Use recommendations carefully using the sizing guide (**Table 39**) and aortic screening measurements (**Figure 7**) included in the IFU.

Implant Procedure

- Appropriate procedural imaging is required to successfully position the GORE® TAG® Thoracic Endoprosthesis in the neck and to assure appropriate apposition to the aortic wall.
- Device apposition to the inner curve of the aortic arch should be confirmed with procedural fluoroscopy and non-contrast radiography. If device apposition is not complete, the use of ballooning and / or additional GORE® TAG® Device(s) has been reported by physicians to assure apposition of the GORE® TAG® Device to the aortic wall in the acute setting.
- The incidence of type I endoleak was higher in patients enrolled in the TAG 04-01 Ruptured Aneurysm Arm compared to patients enrolled in the TAG 99-01 and TAG 03-03 Aneurysm studies. More than 2 cm of proximal and distal neck length may help reduce the incidence of endoleak in patients who undergo endovascular repair for ruptured aortic aneurysm.
- Clinicians recommend positioning the image intensifier (C-arm) so that it is perpendicular to the neck, typically 45-75 degrees left anterior oblique (LAO) for the arch.
- Systemic anticoagulation should be used during the implantation procedure based on hospital and physician preferred protocol. If heparin is contraindicated, an alternative anticoagulant should be considered.
- Minimize handling of the constrained endoprosthesis during preparation and insertion to decrease the risk of endoprosthesis contamination and infection.
- Do not rotate the delivery catheter while the endoprosthesis is inside the introducer sheath. Catheter breakage or inadvertent deployment may occur.
- Do not rotate the delivery catheter with device outside of the introducer sheath more than 180° in either direction. Catheter breakage or inadvertent deployment may occur.
- Do not attempt to reposition the endoprosthesis after deployment has been initiated. Vessel damage or endoprosthesis misplacement may result.
- Do not continue advancement of the guidewire, sheath, or delivery catheter if resistance is felt. Stop and assess the cause of resistance. Vessel or delivery catheter damage may occur.
- Incorrect deployment or migration of the endoprosthesis may require surgical intervention.
- Use caution if removing the undeployed endoprosthesis through the introducer sheath. Inadvertent endoprosthesis deployment may occur. If resistance is felt during removal of delivery catheter, stop and withdraw delivery catheter and introducer sheath together.
- Inadvertent partial deployment or migration of the endoprosthesis may require surgical removal.
- Do not cross significant arterial branches which do not have collateral or protected perfusion to end organs or body structures. Vessel occlusion may occur.
- When using the GORE® Introducer Sheath with Silicone Pinch Valve, ensure that the pinch valve is not twisted, collapsed, or bent during advancing or withdrawing the delivery catheter. Device damage and / or delivery catheter breakage may occur.
- The GORE TAG Thoracic Endoprosthesis is only compatible with either the GORE® Introducer Sheath with Silicone Pinch Valve or the GORE® DrySeal Sheath. If an incompatible introducer sheath is used, damage may occur to the leading edge of the endoprosthesis, which may cause premature or inadvertent deployment.
- When catheters are in the body, manipulate only under fluoroscopic guidance.

Follow-Up

- Do not use the GORE® TAG® Thoracic Endoprosthesis in patients unable to undergo the necessary pre-operative and post-operative imaging. All patients should be monitored closely and checked periodically for a change in the condition of their disease and the integrity of the endoprosthesis.
- Wire fractures have been reported on this type of endoprosthesis and may be more likely to occur in conditions with excessive endoprosthesis oversizing, flexion, kinking, or bending with cardiac or respiratory cycles. Wire fractures may have clinical consequences which may include, but are not limited to endoleak, endoprosthesis migration, and / or adjacent tissue damage.
- A late type III endoleak was observed within 24 hours after DC cardioversion. Close surveillance is recommended to watch for symptoms of endoleaks post DC cardioversion or defibrillation.
- In patients enrolled in the TAG 04-01 Ruptured Aneurysm Arm, reintervention with a GORE® TAG® Thoracic Endoprosthesis was performed in three (15%) subjects through one year post-treatment. All reinterventions were performed within seven days of the initial procedure to treat endoleak.
- The incidence of type I endoleak was higher in patients enrolled in the TAG 04-01 Ruptured Aneurysm Arm compared to patients enrolled in the TAG 99-01 and TAG 03-03 Aneurysm studies. Additional radiologic follow-up may be warranted in patients who undergo endovascular repair for ruptured aortic aneurysm.
- Although the available data from use of the GORE® TAG® Thoracic Endoprosthesis 45 mm device supports similar outcomes compared to patients treated with smaller sized GORE® TAG® Devices, it is possible that patients with large aortic diameters represent a population for whom the aorta at that level is already diseased. Physicians should tailor patient follow-up to the needs and circumstances of each individual patient; patients with larger aortic diameters may represent a population for whom additional regular follow-up is warranted. Regular and consistent follow-up is a critical part of ensuring the safety and efficacy of aortic endovascular repair.
- Please refer to the IMAGING GUIDELINES and POST-OPERATIVE FOLLOW-UP for MRI safety and compatibility information.

Potential Device or Procedure Related Adverse Events

Complications associated with the use of the GORE® TAG® Thoracic Endoprosthesis may include but are not limited to:

- adynamic ileus,
- amputation,
- angina,
- atelectasis / pneumonia,
- bleeding (procedural and post-treatment),
- bowel (e.g., ileus, transient ischemia, infarction, necrosis),
- cardiac (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension or hypertension),
- change in mental status,
- coagulopathy,
- edema (e.g., leg),
- embolism (micro and macro) with transient or permanent ischemia,
- endoleak,
- endoprosthesis: improper placement; incomplete deployment; migration; material failure; occlusion; infection; stent fracture; dilatation; perigraft flow,
- erectile dysfunction,
- erosion,
- femoral neuropathy,
- fever and localized inflammation,
- fistula (aortoenteric, arteriovenous, aorto-esophageal, aortobronchial)
- genitourinary (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection),
- hematoma,
- infection (e.g., aneurysm, device or access sites),
- lymphocele / lymph fistula,
- myocardial infarction,
- neurologic damage, local or systemic (e.g., stroke, paraplegia, paraparesis),
- nerve injury,
- post-implant syndrome,
- prosthesis dilatation / rupture,
- prosthetic thrombosis,
- pseudoaneurysm,
- pulmonary complications (e.g., pneumonia, respiratory failure),
- pulmonary embolism,
- renal (e.g., artery occlusion, contrast toxicity, insufficiency, failure),
- reoperation,
- restenosis,
- surgical conversion,
- thrombosis,
- transient ischemic attack,
- vascular spasm or vascular trauma (e.g., ilio-femoral vessel dissection, bleeding, rupture),
- wound (e.g., infection, dehiscence),
- death

Device Related Adverse Event Reporting

Any adverse event involving the GORE® TAG® Thoracic Endoprosthesis should be reported to W. L. Gore & Associates immediately. To report an event in the US, call 800.437.8181.

SUMMARY OF US CLINICAL STUDIES (TAG 99-01, TAG 03-03, TAG 04-01 AND TAG 06-02)

Two US clinical studies were conducted to evaluate the safety and effectiveness of the GORE® TAG® Thoracic Endoprosthesis in non-ruptured aneurysms of the descending thoracic aorta. The first, referred to as TAG 99-01, evaluated the original design. The second US clinical study, referred to as TAG 03-03, evaluated a modified version of the device. TAG 99-01 and TAG 03-03 data are presented collectively. These data have been updated to reflect longer term follow-up that has become available since the original PMA and immediately follows. A third US clinical study, referred to as TAG 04-01, evaluated the use of the modified device in ruptured aneurysms of the DTA. This data is presented subsequent to those data summarized in TAG 99-01 and TAG 03-03. A fourth study, TAG 06-02, evaluated the use of the 45 mm GORE® TAG® Device for the repair of non-ruptured aneurysms of the DTA in subjects with aortas ranging from 37-42 mm. Data from this study follows the TAG 04-01 study data. This *Instructions for Use* contains the results of these US clinical studies.

Use of the GORE® TAG® Thoracic Endoprosthesis in Non-Ruptured Aneurysms of the Descending Thoracic Aorta: TAG 99-01 and TAG 03-03

TAG 99-01 Summary

TAG 99-01 was a non-randomized, multi-center clinical study designed to compare subjects treated with endovascular repair to an open surgical repair control group for repair of aneurysms of the DTA. Seventeen (17) US sites enrolled 140 GORE® TAG® Thoracic Endoprosthesis (GORE® TAG® Device) and 94 Open Surgical Control subjects. GORE® TAG® Device and Open Surgical Control subjects were required to meet the same inclusion / exclusion criteria with the exception of the anatomical criteria required for endovascular repair. The control group included both historical (50) and concurrent (44) surgical subjects; an analysis showed comparability between the two groups of surgical control subjects.

Subjects were assessed at pre-treatment, treatment, and hospital discharge and returned for follow-up visits at 1, 6, 12, 24, 36, 48, and 60 months post-treatment. Subject follow-up and accountability is presented in **Table 1**.

An imaging core laboratory provided an independent assessment of the imaging data collected during this study. Site evaluation is presented in this summary because the study hypotheses required an evaluation of the clinical significance of adverse events (i.e., major vs minor). Clinical events were adjudicated by a clinical events committee, and safety was monitored by a data safety monitoring board.

The primary objective of the study was to evaluate the safety and effectiveness of endovascular repair with the original GORE® TAG® Device as an alternative to open surgical repair. Safety was determined by comparing the proportion of subjects who experienced ≥ 1 major adverse event (MAE) through 12 months post-treatment between TAG 99-01 GORE® TAG® Device and TAG 99-01 Open Surgical Control subjects. Effectiveness was determined by evaluating the proportion of TAG 99-01 GORE® TAG® Device subjects free from a major device-related event through the 12-month follow-up visit in comparison to a predefined rate of success. Secondary objectives included an assessment of clinical benefit and quality-of-life measures. Enrollment began in September 1999 and was completed in May 2001. Annual follow-up through five years post-treatment was completed in 2006. The final study report was submitted in January 2007 and closed by the FDA in June 2007.

TAG 03-03 Summary

After completion of enrollment in TAG 99-01, breaks in the wire frame were identified. Modifications were made to the device to allow for removal of the component associated with the fractures. A risk analysis determined that modifications could potentially affect the deployment of the device. As such, TAG 03-03 was designed to confirm that the modifications did not adversely affect the perioperative (through 30 days) performance of the GORE® TAG® Thoracic Endoprosthesis.

The TAG 03-03 study enrolled 51 subjects who underwent endovascular repair at 11 investigational sites. The TAG 99-01 Open Surgical Control group served as the control. To support the comparability of the data between studies, the TAG 99-01 and TAG 03-03 studies used the same Inclusion / Exclusion criteria, screening assessments, clinical events committee, and imaging core laboratory. In addition, both studies collected identical study data (e.g., adverse events, device events).

Subjects were assessed at pre-treatment, treatment, and hospital discharge and returned for follow-up visits at 1, 6, 12, 24, and 36 months, with ongoing follow-up visits scheduled for 48 and 60 months post-treatment. Subject follow-up and accountability at 1, 6, 12, 24 and 36 months are presented in **Table 1**.

Safety was determined by comparing the proportion of subjects who experienced ≥ 1 MAE through 30 days post-treatment between TAG 03-03 GORE® TAG® Device subjects and TAG 99-01 Open Surgical Control subjects. Efficacy was the proportion of subjects who experienced ≥ 1 major device-related event in TAG 03-03 GORE® TAG® Device subjects through the 30 day follow-up visit. Efficacy data are presented descriptively. Secondary objectives included an assessment of clinical benefits and quality-of-life measures. At the time of database lock (July 18, 2008) three years of follow-up is complete.

Table 1 provides the subject disposition for subjects enrolled into the TAG 99-01 and TAG 03-03 clinical studies. Available subjects are defined as those that are alive and participating in the study for that follow-up period. TAG 99-01 subjects have completed their fifth, and final, year of follow-up. TAG 03-03 subjects are in their fourth year of follow-up. For a given study period, data presented include the number of subjects eligible for follow-up (e.g., number eligible from previous period minus subject deaths, subjects discontinued or not yet due for their next follow-up visit).

Table 1. Subject Disposition and Compliance by Study Period

Study Period	Eligible for Follow-Up	Follow-Up Compliance			Events Prior to Next Interval		
		Subjects with Visit in Window	CT Scan Performed ¹	X-Ray Performed ¹	Death ¹	Discontinued ¹	Not Due for Next Follow-Up ¹
TAG 99-01 Open Surgical Control							
1 Month	51	51 (100.0%)	50 (98.0%)	51 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
6 Months	51	15 (29.4%)	14 (27.5%)	12 (23.5%)	2 (3.9%)	0 (0.0%)	0 (0.0%)
12 Months	49	46 (93.9%)	45 (91.8%)	41 (83.7%)	2 (4.1%)	1 (2.0%)	0 (0.0%)
24 Months	46	40 (87.0%)	36 (78.3%)	36 (78.3%)	5 (10.9%)	0 (0.0%)	0 (0.0%)
36 Months	41	34 (82.9%)	32 (78.0%)	27 (65.9%)	2 (4.9%)	1 (2.4%)	0 (0.0%)
48 Months	38	19 (50.0%)	17 (44.7%)	16 (42.1%)	3 (7.9%)	0 (0.0%)	33 (86.8%)
60 Months	2	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
TAG 99-01 GORE® TAG® Device							
1 Month	94	93 (98.9%)	27 (28.7%)	72 (76.6%)	13 (13.8%)	0 (0.0%)	0 (0.0%)
6 Months	81	62 (76.5%)	18 (22.2%)	14 (17.3%)	6 (7.4%)	1 (1.2%)	0 (0.0%)
12 Months	74	54 (73.0%)	34 (45.9%)	8 (10.8%)	4 (5.4%)	1 (1.4%)	0 (0.0%)
24 Months	69	48 (69.6%)	27 (39.1%)	11 (15.9%)	5 (7.2%)	18 (26.1%)	0 (0.0%)
36 Months	46	29 (63.0%)	20 (43.5%)	2 (4.3%)	0 (0.0%)	6 (13.0%)	0 (0.0%)
48 Months	40	29 (72.5%)	21 (52.5%)	5 (12.5%)	2 (5.0%)	9 (22.5%)	0 (0.0%)
60 Months	29	24 (82.8%)	15 (51.7%)	4 (13.8%)	1 (3.4%)	1 (3.4%)	—
TAG 03-03 GORE® TAG® Device							
1 Month	140	140 (100.0%)	123 (87.9%)	130 (92.9%)	3 (2.1%)	3 (2.1%)	0 (0.0%)
6 Months	134	117 (87.3%)	108 (80.6%)	83 (61.9%)	16 (11.9%)	1 (0.7%)	0 (0.0%)
12 Months	117	111 (94.9%)	103 (88.0%)	88 (75.2%)	9 (7.7%)	6 (5.1%)	0 (0.0%)
24 Months	102	90 (88.2%)	80 (78.4%)	75 (73.5%)	8 (7.8%)	18 (17.6%)	0 (0.0%)
36 Months	76	68 (89.5%)	64 (84.2%)	58 (76.3%)	3 (3.9%)	4 (5.3%)	0 (0.0%)
48 Months	69	62 (89.9%)	57 (82.6%)	54 (78.3%)	6 (8.7%)	10 (14.5%)	0 (0.0%)
60 Months	53	52 (98.1%)	47 (88.7%)	43 (81.1%)	0 (0.0%)	3 (5.7%)	—
Study period definitions: 1 Month (0-59 days), 6 Months (60-242 days), 12 Months (243-546 days), 24 Months (547-911 days), 36 Months (912-1275 days), 48 Months (1276-1640 days), 60 Months (1641-2006 days)							
¹ Percentages are based on number of subjects eligible for follow-up. Compliance is based on site reported imaging assessments.							

Patient Demographics and Pretreatment History (TAG 99-01 and TAG 03-03)

Tables 2-3 compare subjects receiving the GORE® TAG® Thoracic Endoprosthesis (TAG 99-01 and TAG 03-03) and Open Surgical Control subjects (TAG 99-01)

Table 2. Subject Demographics

	TAG 03-03	TAG 99-01	TAG 99-01 Control
Subjects Enrolled	51	140	94
Gender			
Male	33 (64.7%)	80 (57.1%)	48 (51.1%)
Female	18 (35.3%)	60 (42.9%)	46 (48.9%)
Age (yrs)			
n	51	140	94
Mean (Std Dev)	71.2 (9.4)	70.9 (10.4)	68.6 (10.2)
Median	71.5	74.2	70.1
Range	(45.0, 86.3)	(30.7, 86.5)	(35.2, 88.1)
Ethnic Background			
White or Caucasian	47 (92.2%)	122 (87.1%)	81 (86.2%)
Black or African American	2 (3.9%)	11 (7.9%)	9 (9.6%)
Asian	1 (2.0%)	1 (0.7%)	2 (2.1%)
American Indian or Alaskan Native	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other	1 (2.0%)	6 (4.3%)	2 (2.1%)
Unknown	0 (0.0%)	0 (0.0%)	0 (0.0%)
Weight (kg)			
n	51	139	94
Mean (Std Dev)	80.8 (20.5)	76.2 (16.6)	77.6 (17.5)
Median	77.3	77.0	77.3
Range	(53.1, 145.0)	(40.0, 136.4)	(44.4, 136.0)
Height (cm)			
n	51	139	94
Mean (Std Dev)	171.0 (10.6)	169.5 (10.1)	169.5 (11.3)
Median	170.0	170.0	170.0
Range	(150.0, 193.0)	(137.0, 193.0)	(140.0, 196.0)

Table 3. Subject Pre-Treatment Medical History

	TAG 03-03	TAG 99-01	TAG 99-01 Control
Subjects Enrolled	51	140	94
Coronary Artery Disease	18 (35.3%)	69 (49.3%)	34 (36.2%)
Cardiac Arrhythmia	16 (31.4%)	33 (23.6%)	29 (30.9%)
Valvular Heart Disease	5 (9.8%)	9 (6.4%)	9 (9.6%)
Congestive Heart Failure	4 (7.8%)	13 (9.3%)	9 (9.6%)
Stroke	4 (7.8%)	14 (10.0%)	9 (9.6%)
Peripheral Arterial Occlusive Disease	7 (13.7%)	22 (15.7%)	10 (10.6%)
Prior Vascular Intervention	29 (56.9%)	63 (45.0%)	52 (55.3%)
Thromboembolic Event	4 (7.8%)	10 (7.1%)	6 (6.4%)
Aneurysm Symptomatic	14 (27.5%)	30 (21.4%)	36 (38.3%)
Aneurysm of Traumatic Origin	2 (3.9%)	8 (5.7%)	5 (5.3%)
Other Concomitant Aneurysm(s)	17 (33.3%)	40 (28.6%)	26 (27.7%)
COPD	22 (43.1%)	56 (40.0%)	36 (38.3%)
History of Smoking	43 (84.3%)	117 (83.6%)	77 (81.9%)
Renal Dialysis	2 (3.9%)	2 (1.4%)	0 (0.0%)
Paraplegia	0 (0.0%)	1 (0.7%)	0 (0.0%)
Erectile Dysfunction	1 (3.0%)	13 (16.3%)	5 (10.4%)
Hepatic Dysfunction	2 (3.9%)	3 (2.1%)	1 (1.1%)
Bleeding Disorder(s)	2 (3.9%)	4 (2.9%)	5 (5.3%)
Cancer	16 (31.4%)	27 (19.3%)	12 (12.8%)
NYHA Classification			
I	21 (41.2%)	39 (27.9%)	22 (23.4%)
II	14 (27.5%)	35 (25.0%)	14 (14.9%)
III	3 (5.9%)	7 (5.0%)	12 (12.8%)
IV	0 (0.0%)	0 (0.0%)	0 (0.0%)
N/A	13 (25.5%)	59 (42.1%)	46 (48.9%)
ASA Classification			
I	3 (5.9%)	2 (1.4%)	2 (2.1%)
II	4 (7.8%)	13 (9.3%)	5 (5.3%)
III	31 (60.8%)	90 (64.3%)	51 (54.3%)
IV	13 (25.5%)	35 (25.0%)	36 (38.3%)
V	0 (0.0%)	0 (0.0%)	0 (0.0%)
Summary SVS Risk Score			
n	51	140	94
Mean (Std Dev)	5.88 (2.84)	5.36 (2.84)	4.84 (2.76)
Median	6.00	5.71	4.00
Range	(0.00, 11.00)	(0.00, 13.00)	(0.00, 13.00)

Table 4 lists the initial aneurysm diameter sizes treated.

Table 4. Aneurysm Diameter Distribution

	TAG 03-03	TAG 99-01	TAG 99-01 Control
Subjects Enrolled	51	140	94
Diameter Range			
10-19 mm	0 (0.0%)	0 (0.0%)	0 (0.0%)
20-29 mm	0 (0.0%)	1 (0.7%)	1 (1.1%)
30-39 mm	0 (0.0%)	5 (3.6%)	3 (3.2%)
40-49 mm	5 (9.8%)	17 (12.1%)	5 (5.3%)
50-59 mm	14 (27.5%)	20 (14.3%)	17 (18.1%)
60-69 mm	23 (45.1%)	46 (32.9%)	30 (31.9%)
70-79 mm	7 (13.7%)	28 (20.0%)	16 (17.0%)
80-89 mm	1 (2.0%)	15 (10.7%)	8 (8.5%)
90-99 mm	1 (2.0%)	5 (3.6%)	2 (2.1%)
100-109 mm	0 (0.0%)	1 (0.7%)	1 (1.1%)
110-119 mm	0 (0.0%)	1 (0.7%)	2 (2.1%)
Missing	0 (0.0%)	1 (0.7%)	9 (9.6%)

Results

The primary and secondary objectives of TAG 99-01 and TAG 03-03 trials were met. Subjects treated with the GORE® TAG® Thoracic Endoprosthesis experienced a greater probability of remaining free from a MAE than subjects treated with open surgical repair. In addition, data from the TAG 99-01 and TAG 03-03 studies demonstrated that the GORE® TAG® Device subjects experienced a low incidence of major device-related events. Also, subjects treated with the endoprosthesis experienced less blood loss during the procedure, shorter ICU stay, shorter hospital stay and shorter time to return to normal daily activities than subjects treated with open surgical repair. The detailed results are separated into Safety, Efficacy and Secondary endpoints.

Table 5 lists the number of devices implanted for TAG 99-01 and TAG 03-03. More than 50% of subjects required more than one device (**Table 6**). Some subjects had more than one size device implanted.

Table 5. Devices Implanted

	TAG 03-03	TAG 99-01
Number of Devices	94	234
Endoprosthesis Diameter (mm)		
26	2 (2.1%)	9 (3.8%)
28	6 (6.4%)	9 (3.8%)
31	11 (11.7%)	32 (13.7%)
34	29 (30.9%)	102 (43.6%)
37	26 (27.7%)	41 (17.5%)
40	20 (21.3%)	41 (17.5%)

Table 6. Number of Endoprostheses Implanted at Initial Procedure

	TAG 03-03	TAG 99-01
Number of Subjects	51	140
Number of Devices Implanted		
0	0 (0.0%)	3 (2.1%) ¹
1	17 (33.3%)	61 (43.6%)
2	25 (49.0%)	60 (42.9%)
3	9 (17.6%)	11 (7.9%)
4	0 (0.0%)	5 (3.6%)

¹ There were three patients with access failures who did not receive a device.

Safety

Adverse events were characterized by severity, e.g., major or minor, as defined below:

Major

- Requires therapy, minor hospitalization (< 48 hours), or
- Major therapy, unplanned increase in level of care, prolonged hospitalization (> 48 hours), or
- Permanent adverse sequelae, or
- Death

Minor

- Requires no therapy, no consequence, or
- Nominal therapy, no consequence; includes overnight admission for observation only

The primary safety endpoint for the Pivotal Study (TAG 99-01), the proportion of subjects who experienced ≥ 1 MAE through one year post-treatment, was significantly lower ($p < 0.001$) in the TAG 99-01 GORE® TAG® Device group (42%) vs. the TAG 99-01 Open Surgical Control group (77%). Through 30-days post-treatment GORE® TAG® Device subjects experienced significantly fewer bleeding, pulmonary, renal, wound and neurological complications compared to Open Surgical Control subjects. This benefit was maintained throughout the five year follow-up period. Notably, among the clinically significant major complications, 4 / 140 (3%) in the 99-01 GORE® TAG® Device group and 13 / 94 (14%) in the TAG 99-01 Open Surgical Control group experienced paraplegia or paraparesis. **Tables 7–10** and **Figures 3-5** describe the morbidity and mortality outcomes for TAG 99-01 and TAG 03-03. The GORE® TAG® Device subjects experienced significantly less major adverse events for both TAG 99-01 and TAG 03-03. Aneurysm-related mortality is also less in the GORE® TAG® Device group. All-cause mortality is not different between the GORE® TAG® Device and Open Surgical Control groups.

Figure 3. Subjects Free of a Major Adverse Event

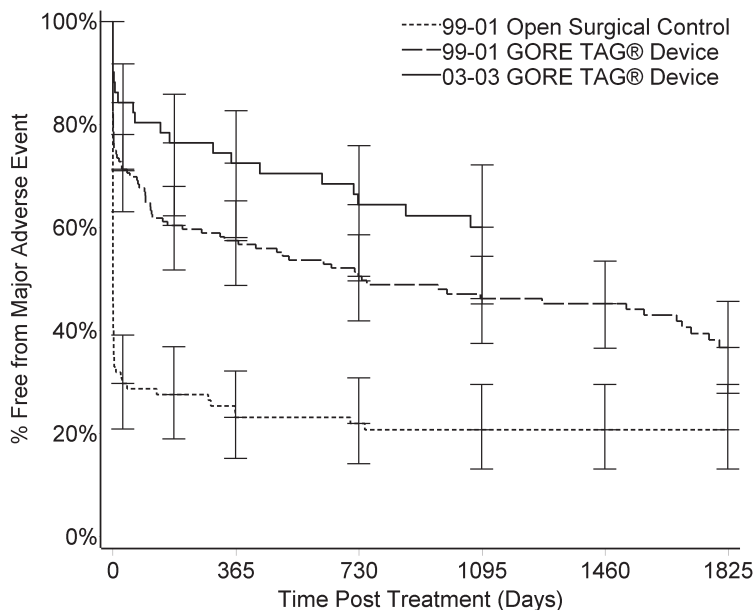


Table 7. Subjects Free of a Major Adverse Event

Time Post Treatment (Days)	N at Risk at Start of Interval	N Events During Interval ¹	N Censored During Interval ¹	% Free from Major Adverse Event	95% C.I. ²
TAG 99-01 Open Surgical Control					
0	94	51 (51)	0 (0)	0.457	(0.355, 0.554)
(0-30)	43	15 (66)	0 (0)	0.298	(0.209, 0.392)
(30-182)	28	2 (68)	1 (1)	0.276	(0.190, 0.369)
(182-365)	25	4 (72)	0 (1)	0.232	(0.152, 0.322)
(365-730)	21	1 (73)	2 (3)	0.220	(0.142, 0.309)
(730-1095)	18	1 (74)	2 (5)	0.208	(0.132, 0.296)
(1095-1460)	15	0 (74)	1 (6)	0.208	(0.132, 0.296)
(1460-1825)	14	0 (74)	14 (20)	0.208	(0.132, 0.296)
TAG 99-01 GORE TAG® Device					
0	140	25 (25)	0 (0)	0.821	(0.747, 0.876)
(0-30)	115	15 (40)	2 (2)	0.714	(0.631, 0.781)
(30-182)	98	15 (55)	0 (2)	0.604	(0.518, 0.680)
(182-365)	83	4 (59)	1 (3)	0.575	(0.488, 0.652)
(365-730)	78	9 (68)	6 (9)	0.506	(0.419, 0.586)
(730-1095)	63	5 (73)	8 (17)	0.462	(0.375, 0.544)
(1095-1460)	50	1 (74)	4 (21)	0.453	(0.366, 0.535)
(1460-1825)	45	7 (81)	38 (59)	0.368	(0.279, 0.457)
TAG 03-03 GORE TAG® Device					
0	51	5 (5)	0 (0)	0.902	(0.780, 0.958)
(0-30)	46	3 (8)	0 (0)	0.843	(0.711, 0.918)
(30-182)	43	4 (12)	0 (0)	0.765	(0.623, 0.859)
(182-365)	39	2 (14)	1 (1)	0.725	(0.581, 0.827)
(365-730)	36	4 (18)	0 (1)	0.645	(0.497, 0.759)
(730-1095)	32	2 (20)	30 (31)	0.601	(0.452, 0.722)

Pairwise Logrank p-values:

'99-01 GORE TAG® Device' '99-01 Open Surgical Control' p:<.001

'03-03 GORE TAG® Device' '99-01 Open Surgical Control' p:<.001

¹ Number in parentheses represents cumulative events or censored observations through end of interval.² At each time interval the 95% confidence intervals are provided to describe the variability associated with the estimated proportion of subjects remaining event free through that interval. The confidence intervals are produced using the complimentary log (log) transformation applied to the cumulative hazard function.

Table 8. Incidence of Major Adverse Events

	Post-Treatment Follow-Up Period (Days)					
	0-30	31-365	1-2 Years	2-3 Years	3-4 Years	4-5 Years
TAG 99-01 Open Surgical Control						
Number of Subjects	94	88	72	60	42	33
Any Major Adverse Event	66 (70.2%)	19 (21.6%)	4 (5.6%)	3 (5.0%)	1 (2.4%)	1 (3.0%)
Bleeding Complication	50 (53.2%)	1 (1.1%)	—	—	—	—
Coagulopathy	9 (9.6%)	—	—	—	—	—
Hematoma	1 (1.1%)	1 (1.1%)	—	—	—	—
Post-Procedure Bleeding	13 (13.8%)	—	—	—	—	—
Procedural Bleeding	39 (41.5%)	—	—	—	—	—
Neurologic Complication	30 (31.9%)	4 (4.5%)	1 (1.4%)	—	—	—
Cerebrovascular Accident	4 (4.3%)	3 (3.4%)	1 (1.4%)	—	—	—
Change Mental Status	16 (17.0%)	1 (1.1%)	—	—	—	—
Femoral Neuropathy	2 (2.1%)	—	—	—	—	—
Nerve Injury	3 (3.2%)	—	—	—	—	—
Paraplegia / Paraparesis	10 (10.6%)	—	—	—	—	—
Spinal Neurological Deficit	3 (3.2%)	—	—	—	—	—
Pulmonary Complication	31 (33.0%)	8 (9.1%)	—	2 (3.3%)	1 (2.4%)	—
Atelectasis / Pneumonia	17 (18.1%)	4 (4.5%)	—	1 (1.7%)	1 (2.4%)	—
Pulmonary Embolism	1 (1.1%)	1 (1.1%)	—	—	—	—
Respiratory Failure	19 (20.2%)	4 (4.5%)	—	1 (1.7%)	—	—
Renal Function Complication	12 (12.8%)	3 (3.4%)	—	—	—	—
Renal Failure	5 (5.3%)	2 (2.3%)	—	—	—	—
Renal Insufficiency	7 (7.4%)	2 (2.3%)	—	—	—	—
Vascular Complication	4 (4.3%)	2 (2.3%)	—	—	—	—
Embolism	1 (1.1%)	—	—	—	—	—
Restenosis	—	1 (1.1%)	—	—	—	—
Thrombosis	3 (3.2%)	1 (1.1%)	—	—	—	—
Cardiac Complication	19 (20.2%)	7 (8.0%)	2 (2.8%)	1 (1.7%)	—	1 (3.0%)
Arrhythmia	18 (19.1%)	3 (3.4%)	—	—	—	—
Congestive Heart Failure	2 (2.1%)	4 (4.5%)	—	1 (1.7%)	—	1 (3.0%)
Myocardial Infarction	1 (1.1%)	1 (1.1%)	2 (2.8%)	—	—	—
Wound Complication	11 (11.7%)	3 (3.4%)	1 (1.4%)	—	—	—
Dehiscence	3 (3.2%)	1 (1.1%)	—	—	—	—
Leg Edema	1 (1.1%)	—	—	—	—	—
Lymphocele / Lymph Fistula	1 (1.1%)	2 (2.3%)	1 (1.4%)	—	—	—
Wound Infection	10 (10.6%)	1 (1.1%)	—	—	—	—
Bowel Complication	6 (6.4%)	—	—	—	—	—
Adynamic Ileus	4 (4.3%)	—	—	—	—	—
Bowel Ischemia	2 (2.1%)	—	—	—	—	—
Bowel Obstruction	1 (1.1%)	—	—	—	—	—
Other Complication	1 (1.1%)	2 (2.3%)	—	—	—	—
Aortoenteric Fistula	—	1 (1.1%)	—	—	—	—
Prosthesis Infection	1 (1.1%)	1 (1.1%)	—	—	—	—

Table 8. Incidence of Major Adverse Events (continued)

	Post-Treatment Follow-Up Period (Days)					
	0-30	31-365	1-2 Years	2-3 Years	3-4 Years	4-5 Years
TAG 99-01 GORE® TAG® Device						
Number of Subjects	140	135	109	88	73	65
Any Major Adverse Event	40 (28.6%)	30 (22.2%)	13 (11.9%)	9 (10.2%)	5 (6.8%)	13 (20.0%)
Bleeding Complication	13 (9.3%)	3 (2.2%)	2 (1.8%)	—	—	—
Coagulopathy	—	1 (0.7%)	—	—	—	—
Hematoma	4 (2.9%)	2 (1.5%)	—	—	—	—
Post-Procedure Bleeding	4 (2.9%)	—	2 (1.8%)	—	—	—
Procedural Bleeding	7 (5.0%)	—	—	—	—	—
Neurologic Complication	11 (7.9%)	4 (3.0%)	3 (2.8%)	1 (1.1%)	—	3 (4.6%)
Cerebrovascular Accident	5 (3.6%)	2 (1.5%)	1 (0.9%)	—	—	2 (3.1%)
Change Mental Status	3 (2.1%)	2 (1.5%)	1 (0.9%)	—	—	—
Nerve Injury	1 (0.7%)	—	—	—	—	—
Paraplegia / Paraparesis	3 (2.1%)	—	—	—	—	—
Spinal Neurological Deficit	1 (0.7%)	—	1 (0.9%)	—	—	—
Transient Ischemic Attack	—	—	—	1 (1.1%)	—	1 (1.5%)
Pulmonary Complication	9 (6.4%)	13 (9.6%)	6 (5.5%)	2 (2.3%)	2 (2.7%)	5 (7.7%)
Atelectasis / Pneumonia	6 (4.3%)	11 (8.1%)	2 (1.8%)	2 (2.3%)	1 (1.4%)	3 (4.6%)
Pulmonary Embolism	—	—	1 (0.9%)	—	1 (1.4%)	1 (1.5%)
Respiratory Failure	6 (4.3%)	5 (3.7%)	4 (3.7%)	1 (1.1%)	—	2 (3.1%)
Renal Function Complication	2 (1.4%)	4 (3.0%)	1 (0.9%)	—	—	—
Renal Failure	1 (0.7%)	2 (1.5%)	1 (0.9%)	—	—	—
Renal Insufficiency	1 (0.7%)	2 (1.5%)	—	—	—	—
Vascular Complication	20 (14.3%)	5 (3.7%)	—	2 (2.3%)	2 (2.7%)	—
Embolism	3 (2.1%)	—	—	—	—	—
Pseudoaneurysm	—	2 (1.5%)	—	—	—	—
Thrombosis	6 (4.3%)	2 (1.5%)	—	1 (1.1%)	—	—
Vascular Trauma	14 (10.0%)	1 (0.7%)	—	1 (1.1%)	2 (2.7%)	—
Cardiac Complication	4 (2.9%)	18 (13.3%)	7 (6.4%)	5 (5.7%)	1 (1.4%)	4 (6.2%)
Angina	1 (0.7%)	—	—	1 (1.1%)	—	1 (1.5%)
Arrhythmia	3 (2.1%)	9 (6.7%)	6 (5.5%)	5 (5.7%)	—	—
Congestive Heart Failure	—	5 (3.7%)	2 (1.8%)	2 (2.3%)	—	2 (3.1%)
Myocardial Infarction	—	7 (5.2%)	1 (0.9%)	—	1 (1.4%)	1 (1.5%)
Wound Complication	8 (5.7%)	1 (0.7%)	1 (0.9%)	—	—	—
Dehiscence	3 (2.1%)	1 (0.7%)	1 (0.9%)	—	—	—
Lymphocele / Lymph Fistula	3 (2.1%)	—	—	—	—	—
Wound Infection	4 (2.9%)	1 (0.7%)	—	—	—	—
Bowel Complication	3 (2.1%)	3 (2.2%)	1 (0.9%)	—	1 (1.4%)	—
Adynamic Ileus	3 (2.1%)	1 (0.7%)	—	—	—	—
Bowel Ischemia	—	1 (0.7%)	—	—	—	—
Bowel Obstruction	—	1 (0.7%)	1 (0.9%)	—	1 (1.4%)	—
Other Complication	—	2 (1.5%)	—	—	—	—
Prosthesis Infection	—	2 (1.5%)	—	—	—	—
Additional Implantation	—	1 (0.7%)	1 (0.9%)	2 (2.3%)	—	1 (1.5%)

Table 8. Incidence of Major Adverse Events (continued)

	Post-Treatment Follow-Up Period (Days)					
	0-30	31-365	1-2 Years	2-3 Years	3-4 Years	4-5 Years
TAG 03-03 GORE® TAG® Device						
Number of Subjects	51	51	48	43	34	14
Any Major Adverse Event	8 (15.7%)	6 (11.8%)	5 (10.4%)	4 (9.3%)	3 (8.8%)	0 (0.0%)
Bleeding Complication	1 (2.0%)	1 (2.0%)	—	1 (2.3%)	—	—
Hematoma	1 (2.0%)	1 (2.0%)	—	1 (2.3%)	—	—
Neurologic Complication	2 (3.9%)	2 (3.9%)	1 (2.1%)	—	1 (2.9%)	—
Cerebrovascular Accident	2 (3.9%)	1 (2.0%)	—	—	—	—
Change Mental Status	—	2 (3.9%)	1 (2.1%)	—	1 (2.9%)	—
Pulmonary Complication	3 (5.9%)	2 (3.9%)	1 (2.1%)	3 (7.0%)	2 (5.9%)	—
Atelectasis / Pneumonia	3 (5.9%)	1 (2.0%)	—	2 (4.7%)	2 (5.9%)	—
Respiratory Failure	—	2 (3.9%)	1 (2.1%)	1 (2.3%)	—	—
Renal Function Complication	—	2 (3.9%)	—	—	—	—
Renal Failure	—	1 (2.0%)	—	—	—	—
Renal Insufficiency	—	1 (2.0%)	—	—	—	—
Vascular Complication	3 (5.9%)	—	1 (2.1%)	1 (2.3%)	—	—
Thrombosis	—	—	1 (2.1%)	1 (2.3%)	—	—
Vascular Trauma	3 (5.9%)	—	—	—	—	—
Cardiac Complication	1 (2.0%)	1 (2.0%)	3 (6.3%)	—	—	—
Angina	1 (2.0%)	—	1 (2.1%)	—	—	—
Arrhythmia	—	—	1 (2.1%)	—	—	—
Congestive Heart Failure	—	1 (2.0%)	1 (2.1%)	—	—	—
Wound Complication	1 (2.0%)	—	—	—	—	—
Wound Infection	1 (2.0%)	—	—	—	—	—
Bowel Complication	—	—	—	—	1 (2.9%)	—
Bowel Ischemia	—	—	—	—	1 (2.9%)	—
Additional Implantation	—	1 (2.0%)	—	—	—	—

Figure 4. Aneurysm-Related Mortality

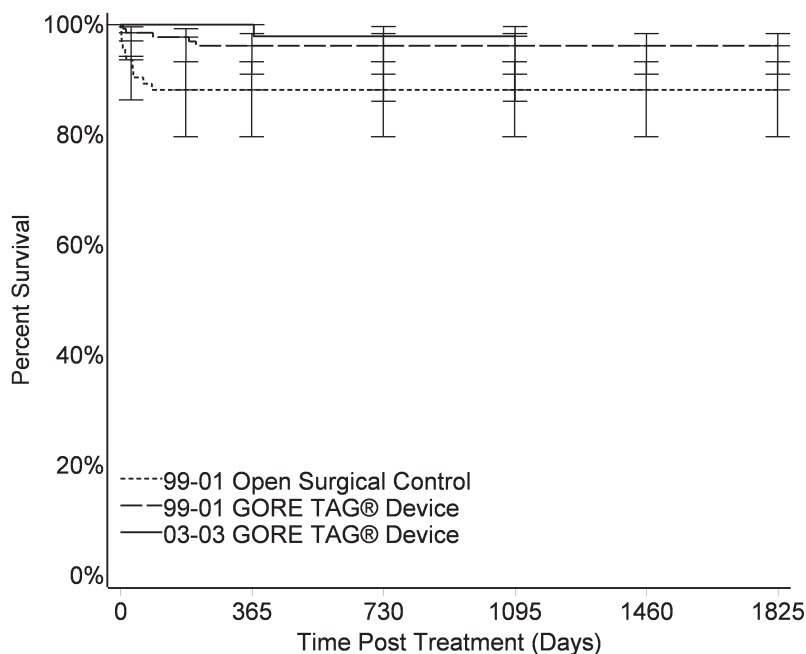


Table 9. Aneurysm-Related Mortality

Time Post Treatment (Days)	N at Risk at Start of Interval	N Events During Interval ¹	N Censored During Interval ¹	Percent Survival	95% C.I. ²
TAG 99-01 Open Surgical Control					
0	94	0 (0)	0 (0)	1.000	(1.000, 1.000)
(0-30]	94	6 (6)	0 (0)	0.936	(0.863, 0.971)
(30-182]	88	5 (11)	8 (8)	0.882	(0.797, 0.933)
(182-365]	75	0 (11)	3 (11)	0.882	(0.797, 0.933)
(365-730]	72	0 (11)	12 (23)	0.882	(0.797, 0.933)
(730-1095]	60	0 (11)	18 (41)	0.882	(0.797, 0.933)
(1095-1460]	42	0 (11)	9 (50)	0.882	(0.797, 0.933)
(1460-1825]	33	0 (11)	33 (83)	0.882	(0.797, 0.933)
TAG 99-01 GORE® TAG® Device					
0	140	0 (0)	0 (0)	1.000	(1.000, 1.000)
(0-30]	140	2 (2)	3 (3)	0.985	(0.943, 0.996)
(30-182]	135	1 (3)	12 (15)	0.978	(0.933, 0.993)
(182-365]	122	2 (5)	11 (26)	0.962	(0.910, 0.984)
(365-730]	109	0 (5)	21 (47)	0.962	(0.910, 0.984)
(730-1095]	88	0 (5)	15 (62)	0.962	(0.910, 0.984)
(1095-1460]	73	0 (5)	7 (69)	0.962	(0.910, 0.984)
(1460-1825]	66	0 (5)	66 (135)	0.962	(0.910, 0.984)
TAG 03-03 GORE® TAG® Device					
0	51	0 (0)	0 (0)	1.000	(1.000, 1.000)
(0-30]	51	0 (0)	0 (0)	1.000	(1.000, 1.000)
(30-182]	51	0 (0)	1 (1)	1.000	(1.000, 1.000)
(182-365]	50	0 (0)	2 (3)	1.000	(1.000, 1.000)
(365-730]	48	1 (1)	4 (7)	0.979	(0.861, 0.997)
(730-1095]	43	0 (1)	43 (50)	0.979	(0.861, 0.997)
Pairwise Logrank p-values: '99-01 GORE® TAG® Device' '99-01 Open Surgical Control' p:0.015 '03-03 GORE® TAG® Device' '99-01 Open Surgical Control' p:0.040					
¹ Number in parentheses represents cumulative events or censored observations through end of interval.					
² At each time interval the 95% confidence intervals are provided to describe the variability associated with the estimated proportion of subjects remaining event free through that interval. The confidence intervals are produced using the complimentary log (log) transformation applied to the cumulative hazard function.					

Figure 5. All-Cause Mortality

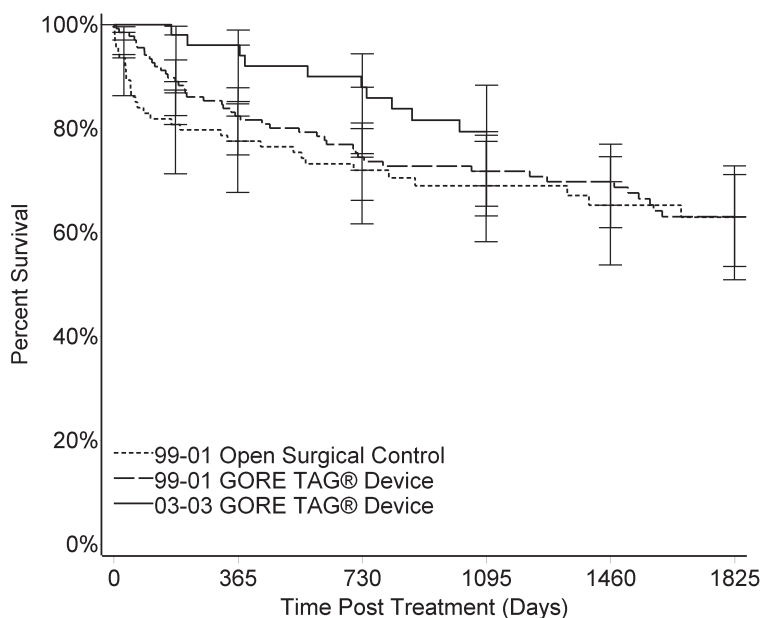


Table 10. All-Cause Mortality

Time Post Treatment (Days)	N at Risk at Start of Interval	N Events During Interval ¹	N Censored During Interval ¹	Percent Survival	95% C.I. ²
TAG 99-01 Open Surgical Control					
0	94	0 (0)	0 (0)	1.000	(1.000, 1.000)
(0-30]	94	6 (6)	0 (0)	0.936	(0.863, 0.971)
(30-182]	88	12 (18)	1 (1)	0.808	(0.713, 0.875)
(182-365]	75	3 (21)	0 (1)	0.776	(0.677, 0.848)
(365-730]	72	5 (26)	7 (8)	0.720	(0.617, 0.800)
(730-1095]	60	2 (28)	16 (24)	0.690	(0.582, 0.776)
(1095-1460]	42	2 (30)	7 (31)	0.653	(0.538, 0.746)
(1460-1825]	33	1 (31)	32 (63)	0.630	(0.509, 0.728)
TAG 99-01 GORE® TAG® Device					
0	140	0 (0)	0 (0)	1.000	(1.000, 1.000)
(0-30]	140	2 (2)	3 (3)	0.985	(0.943, 0.996)
(30-182]	135	13 (15)	0 (3)	0.891	(0.825, 0.932)
(182-365]	122	9 (24)	4 (7)	0.824	(0.749, 0.879)
(365-730]	109	10 (34)	11 (18)	0.745	(0.662, 0.811)
(730-1095]	88	3 (37)	12 (30)	0.718	(0.632, 0.787)
(1095-1460]	73	2 (39)	5 (35)	0.698	(0.609, 0.770)
(1460-1825]	66	6 (45)	60 (95)	0.630	(0.534, 0.712)
TAG 03-03 GORE® TAG® Device					
0	51	0 (0)	0 (0)	1.000	(1.000, 1.000)
(0-30]	51	0 (0)	0 (0)	1.000	(1.000, 1.000)
(30-182]	51	1 (1)	0 (0)	0.980	(0.869, 0.997)
(182-365]	50	1 (2)	1 (1)	0.961	(0.852, 0.990)
(365-730]	48	4 (6)	1 (2)	0.880	(0.752, 0.944)
(730-1095]	43	4 (10)	39 (41)	0.794	(0.651, 0.884)
Pairwise Logrank p-values: '99-01 GORE® TAG® Device' '99-01 Open Surgical Control' p:0.625 '03-03 GORE® TAG® Device' '99-01 Open Surgical Control' p:0.094					
¹ Number in parentheses represents cumulative events or censored observations through end of interval.					
² At each time interval the 95% confidence intervals are provided to describe the variability associated with the estimated proportion of subjects remaining event free through that interval. The confidence intervals are produced using the complimentary log (log) transformation applied to the cumulative hazard function.					

Table 11 delineates the incidence of aneurysm enlargement, rupture, conversion and additional GORE® TAG® Device implantations by study. TAG 99-01 and TAG 03-03 GORE® TAG® Device subjects experienced a low incidence of aneurysm rupture, conversion and additional implantation. TAG 03-03 GORE® TAG® Device subjects experienced lower aneurysm growth rate throughout all follow-up periods compared to TAG 99-01 GORE® TAG® Device subjects. TAG 03-03 GORE® TAG® Device subjects were treated with the GORE® TAG® Thoracic Endoprosthesis currently in commercial use.

Table 11. Aneurysm Enlargement, Rupture, Conversion and Additional GORE® TAG® Device Implantations

	0-30	31-365	366-730	731-1096	1097-1462	1463-1828
TAG 99-01						
Number of Subjects¹	140	135	109	88	73	65
Number of Subjects with Imaging²	—	106	76	64	51	48
Aneurysm Enlargement (≥ 5mm)	—	10 (9.4%)	7 (9.2%)	11 (17.2%)	7 (13.7%)	12 (25.0%)
Aneurysm Rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Conversion	0 (0.0%)	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Additional GORE® TAG® Device Implantation	0 (0.0%)	1 (0.7%)	1 (0.9%)	2 (2.3%)	0 (0.0%)	1 (1.5%)
TAG 03-03						
Number of Subjects¹	51	51	48	43	34	14
Number of Subjects with Imaging²	—	38	36	35	27	9
Aneurysm Enlargement (≥ 5mm)	—	1 (2.6%)	0 (0.0%)	2 (5.7%)	2 (7.4%)	0 (0.0%)
Aneurysm Rupture	0 (0.0%)	0 (0.0%)	1 (2.1%)	1 (2.3%)	0 (0.0%)	0 (0.0%)
Conversion	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.3%)	0 (0.0%)	0 (0.0%)
Additional GORE® TAG® Device Implantation	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
¹ Denominator for Aneurysm Rupture, Conversion, and Additional GORE® TAG® Device Implantation.						
² Denominator for Aneurysm Enlargement; Includes Subjects with CT or X-RAY assessments at baseline and in the given time window.						

Efficacy

The primary efficacy outcome of TAG 99-01 and TAG 03-03 was the proportion of subjects treated with the GORE® TAG® Thoracic Endoprosthesis free from a major device-related event as reported by the investigative sites. Since device-related events associated with endovascular therapy are different than those associated with open surgical repair, no meaningful efficacy comparisons may be made between the GORE® TAG® Device groups and the Open Surgical Control group.

An imaging core laboratory was used as part of TAG 99-01 and TAG 03-03 to provide an independent assessment of the imaging data collected during this study. Computed tomography films (CTA / CT) and radiographs (X-Ray) for study subjects were sent from the investigative sites to the imaging core laboratory to assess aortic morphology, vascular characteristics, and device integrity. Categories for endoleak are not mutually exclusive and therefore numbers of specific endoleak types may add to more than the total patients with endoleak.

There have been 20 device fractures (14%) identified by Investigational Sites, the Core Lab or W. L. Gore & Associates, Inc., in 19 subjects in the TAG 99-01 clinical study through five years post-treatment. One TAG 99-01 GORE® TAG® Device subject received an additional GORE® TAG® Thoracic Endoprosthesis secondary to device fracture with concomitant proximal endoleak. Following identification of these device fractures, the GORE® TAG® Thoracic Endoprosthesis was modified to reduce the failure mode. The modified device was used in the TAG 03-03 clinical study and is currently commercially available. No device fractures have been identified in any of the TAG 03-03 GORE® TAG® Device subjects.

Tables 12 and 13 summarize the incidence of site reported and Core Lab observations of device-related events in the TAG 99-01 and TAG 03-03 GORE® TAG® Device subjects by study period. The GORE® TAG® Thoracic Endoprosthesis demonstrated a low rate of device complications in both TAG 99-01 and TAG 03-03 clinical studies. Most major device-related events occurred during the first six months post-treatment. The definition of 'major' used for adverse events also applies to the device events used for the efficacy endpoint.

Table 12. Subjects With Major Device-Related Events by Follow-Up Periods (Site Reported)

TAG 03-03	Post-Treatment Follow-up Period						
	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months
Number of Subjects¹	51	51	49	45	37	25	0
Number of Subjects with Imaging²	51	14	45	38	33	18	0
Any Major Device Event	2 (3.9%)	1 (2.0%)	1 (2.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	—
Endoleak	2 (3.9%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Type I	1 (2.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Type IA	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Type IB	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Type II	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Type III	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Type IV	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Indeterminate	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Aneurysm Rupture	0 (0.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	—
Treatment Related Device Event	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Access Failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Deployment Failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Other Device Complication	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Unplanned Branch Vessel Occlusion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Lumen Obstruction	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Prosthesis Migration	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Prosthesis Material Failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Aneurysm Enlargement	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Extrusion / Erosion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Other Device Complication at Follow-Up	0 (0.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—

TAG 99-01	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months
Number of Subjects¹	140	134	117	102	76	69	53
Number of Subjects with Imaging²	136	113	106	86	66	61	49
Any Major Device Event	6 (4.3%)	2 (1.5%)	0 (0.0%)	3 (2.9%)	0 (0.0%)	1 (1.4%)	0 (0.0%)
Endoleak	3 (2.1%)	1 (0.7%)	0 (0.0%)	2 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type I	2 (1.4%)	1 (0.7%)	0 (0.0%)	1 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type IA	2 (1.4%)	1 (0.7%)	0 (0.0%)	1 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type IB	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type II	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type III	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type IV	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Indeterminate	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Aneurysm Rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Treatment Related Device Event	2 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Access Failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Deployment Failure	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other Device Complication	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unplanned Branch Vessel Occlusion	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Lumen Obstruction	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Prosthesis Migration	0 (0.0%)	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Prosthesis Material Failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Aneurysm Enlargement	1 (0.7%)	2 (1.5%)	0 (0.0%)	2 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Extrusion / Erosion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other Device Complication at Follow-Up	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)

¹ The number of subjects remaining in follow-up at the beginning of the interval is used to calculate percentage of device events.

² Device events such as endoleak, migration, material failure, and aneurysm enlargement should be considered with respect to number of subjects with imaging follow-up.

Time frames for each interval are as follows: 1 Month (0-59 days) 6 Months (60-242 days) 12 Months (243-546 days) 24 Months (547-911 days) 36 Months (912-1275 days) 48 Months (1276-1640 days) 60 Months (1641-2006 days)

Table 13. Subjects With Device-Related Events by Follow-Up Periods (Core Lab)

	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months
TAG 99-01							
Number of Subjects	140	140	140	140	140	140	140
Number of Subjects with CT Scan¹	109	104	97	73	47	42	24
Number of Subjects with Baseline and Post-Baseline CT Scans²	103	87	83	65	42	40	24
Number of Subjects with X-Ray³	119	80	80	64	42	37	26
Endoleak	11 (10.1%)	8 (7.7%)	6 (6.2%)	5 (6.8%)	0 (0.0%)	2 (4.8%)	1 (4.2%)
Type I	1	1	0	0	—	1	0
Type IA	1	1	0	0	—	1	0
Type IB	0	0	0	0	—	0	0
Type II	1	1	1	1	—	0	0
Type III	0	0	0	0	—	0	0
Type IV	0	0	0	0	—	0	0
Indeterminate	9	6	5	5	—	1	0
Unknown	0	0	0	0	—	0	1
Aneurysm Rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.4%)	0 (0.0%)
Fracture	0 (0.0%)	2 (2.5%)	6 (7.5%)	12 (18.8%)	6 (14.3%)	5 (13.5%)	3 (11.5%)
Change in Aneurysm Diameter							
Increase (≥ 5 mm)	2 (1.9%)	3 (3.4%)	5 (6.0%)	10 (15.4%)	5 (11.9%)	5 (12.5%)	3 (12.5%)
No Change	101 (98.1%)	62 (71.3%)	57 (68.7%)	31 (47.7%)	16 (38.1%)	16 (40.0%)	12 (50.0%)
Decrease (≥ 5 mm)	0 (0.0%)	22 (25.3%)	21 (25.3%)	24 (36.9%)	21 (50.0%)	19 (47.5%)	9 (37.5%)
Prosthesis Migration	0 (0.0%)	2 (1.9%)	0 (0.0%)	6 (8.2%)	3 (6.4%)	4 (9.5%)	0 (0.0%)
TAG 03-03							
Number of Subjects	51	51	51	51	51	51	51
Number of Subjects with CT Scan¹	50	13	45	29	28	0	0
Number of Subjects with Baseline and Post-Baseline CT Scans²	48	11	43	29	28	0	0
Number of Subjects with X-Ray³	51	9	42	28	20	2	0
Endoleak	3 (6.0%)	4 (30.8%)	4 (8.9%)	1 (3.4%)	0 (0.0%)	—	—
Type I	0	2	1	0	—	—	—
Type IA	0	2	1	0	—	—	—
Type IB	0	0	0	0	—	—	—
Type II	1	0	0	0	—	—	—
Type III	0	0	0	0	—	—	—
Type IV	0	1	0	0	—	—	—
Indeterminate	2	1	3	1	—	—	—
Unknown	0	0	0	0	—	—	—
Aneurysm Rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—	—
Fracture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Change in Aneurysm Diameter							
Increase (≥ 5 mm)	1 (2.1%)	1 (9.1%)	0 (0.0%)	1 (3.4%)	1 (3.6%)	—	—
No Change	47 (97.9%)	8 (72.7%)	21 (48.8%)	7 (24.1%)	8 (28.6%)	—	—
Decrease (≥ 5 mm)	0 (0.0%)	2 (18.2%)	22 (51.2%)	21 (72.4%)	19 (67.9%)	—	—
Prosthesis Migration	0 (0.0%)	0 (0.0%)	1 (2.2%)	1 (3.4%)	0 (0.0%)	—	—
Time frames for each interval are as follows: 1 Month (0-59 days), 6 Months (60-242 days), 12 Months (243-546 days), 24 Months (547-911 days), 36 Months (912-1275 days), 48 Months (1276-1640 days), 60 Months (1641-2006 days)							
¹ Denominator for Endoleak, Aneurysm Rupture, and Prosthesis Migration.							
² Denominator for Aneurysm Diameter Change.							
³ Denominator for Fracture.							

Four (4) GORE® TAG® Device subjects in TAG 99-01 and TAG 03-03 required implantation of an additional GORE® TAG® Device(s) post-operatively. These four subjects were implanted with seven additional GORE® TAG® Device(s) as listed in **Table 14**.

Table 14: Reasons for Implantation of Additional Devices

Reason for Intervention	Number of Devices
Endoleak	4
Endoleak and Aneurysm Enlargement	2
Aortic Dilation ¹	1
TOTAL	7 (4 total subjects)

¹ Aortic dilatation distal to treated aneurysm.

Table 15 lists the minor device-related events for both the TAG 99-01 and TAG 03-03 GORE® TAG® Device subjects. The majority of the minor device-related events occurred in the first 30 days.

Table 15. Subjects With Minor Device-Related Events by Follow-Up Periods (Site Reported)

TAG 03-03	Post-Treatment Follow-up Period						
	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months
Number of Subjects¹	51	51	49	45	37	25	0
Number of Subjects with Imaging²	51	14	45	38	33	18	0
Any Minor Device Event	9 (17.6%)	3 (5.9%)	2 (4.1%)	1 (2.2%)	0 (0.0%)	1 (4.0%)	—
Endoleak	6 (11.8%)	3 (5.9%)	2 (4.1%)	0 (0.0%)	0 (0.0%)	1 (4.0%)	—
Type I	5 (9.8%)	2 (3.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Type IA	4 (7.8%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Type IB	1 (2.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Type II	1 (2.0%)	0 (0.0%)	2 (4.1%)	0 (0.0%)	0 (0.0%)	1 (4.0%)	—
Type III	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Type IV	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Indeterminate	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Aneurysm Rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Treatment Related Device Event	2 (3.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Access Failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Deployment Failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Other Device Complication	2 (3.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Unplanned Branch Vessel Occlusion	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.2%)	0 (0.0%)	0 (0.0%)	—
Lumen Obstruction	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Prosthesis Migration	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Prosthesis Material Failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Aneurysm Enlargement	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Extrusion / Erosion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Other Device Complication at Follow-Up	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	—

TAG 99-01	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months
Number of Subjects¹	140	134	117	102	76	69	53
Number of Subjects with Imaging²	136	113	106	86	66	61	49
Any Minor Device Event	24 (17.1%)	2 (1.5%)	0 (0.0%)	6 (5.9%)	4 (5.3%)	3 (4.3%)	3 (5.7%)
Endoleak	21 (15.0%)	1 (0.7%)	0 (0.0%)	2 (2.0%)	1 (1.3%)	2 (2.9%)	1 (1.9%)
Type I	13 (9.3%)	1 (0.7%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (1.4%)	0 (0.0%)
Type IA	12 (8.6%)	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)
Type IB	2 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)
Type II	3 (2.1%)	0 (0.0%)	0 (0.0%)	1 (1.0%)	0 (0.0%)	1 (1.4%)	1 (1.9%)
Type III	3 (2.1%)	0 (0.0%)	0 (0.0%)	1 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type IV	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Indeterminate	4 (2.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Aneurysm Rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Treatment Related Device Event	4 (2.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Access Failure	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Deployment Failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other Device Complication	3 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unplanned Branch Vessel Occlusion	2 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.9%)
Lumen Obstruction	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Prosthesis Migration	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Prosthesis Material Failure	0 (0.0%)	1 (0.7%)	0 (0.0%)	3 (2.9%)	1 (1.3%)	0 (0.0%)	1 (1.9%)
Aneurysm Enlargement	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Extrusion / Erosion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other Device Complication at Follow-Up	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.6%)	2 (2.9%)	0 (0.0%)

¹ The number of subjects remaining in follow-up at the beginning of the interval is used to calculate percentage of device events.

² Device events such as endoleak, migration, material failure, and aneurysm enlargement should be considered with respect to number of subjects with imaging follow-up.

Time frames for each interval are as follows: 1 Month (0-59 days) 6 Months (60-242 days) 12 Months (243-546 days) 24 Months (547-911 days) 36 Months (912-1275 days) 48 Months (1276-1640 days) 60 Months (1641-2006 days)

Secondary Endpoints

Table 16 describes the peri-procedural secondary endpoints for TAG 99-01 and TAG 03-03 GORE® TAG® Device subjects as well as TAG 99-01 Open Surgical Control subjects. The GORE® TAG® Device groups had improved clinical benefit over the surgical control with respect to blood loss, length of ICU and hospital stay and the time to return to normal activities.

Table 16. Secondary Endpoints

	TAG 03-03	TAG 99-01	TAG 99-01 Control
Subjects Enrolled	51	140	94
Blood Loss During Procedure (mL)			
n	51	133	52
Mean (Std Dev)	222.4 (198.0)	472.1 (859.4)	2401.9 (2719.1)
Median	200.0	250.0	1850.0
Range	(0.0, 1000.0)	(0.0, 8000.0)	(0.0, 14000.0)
Length of ICU Stay (days)			
n	35	72	91
Mean (Std Dev)	1.7 (1.3)	5.0 (19.9)	5.1 (7.2)
Median	1.2	1.2	3.0
Range	(0.2, 5.9)	(0.5, 167.3)	(0.8, 54.7)
Length of Hospital Stay (days)			
n	51	140	94
Mean (Std Dev)	3.9 (3.3)	6.4 (17.5)	14.1 (14.2)
Median	3.0	3.0	9.0
Range	(1.0, 20.0)	(1.0, 190.0)	(1.0, 87.0)
Time to Return to Normal Daily Activities (days)			
n	49	114	52
Mean (Std Dev)	48.7 (100.0)	60.5 (82.6)	153.4 (201.3)
Median	18.0	30.0	80.0
Range	(3.0, 420.0)	(1.0, 413.0)	(17.0, 930.0)

Conclusions: TAG 99-01 and TAG 03-03

Data from TAG 99-01 and TAG 03-03 studies provide a reasonable assurance of safety and effectiveness of the GORE® TAG® Thoracic Endoprosthesis for the treatment of non-ruptured aneurysms of the descending thoracic aorta. Subjects treated with the GORE® TAG® Thoracic Endoprosthesis experienced a greater probability of remaining free from MAEs than subjects treated with open surgical repair. In addition, data from the TAG 99-01 and TAG 03-03 studies suggest that GORE® TAG® Thoracic Endoprosthesis subjects experienced a low incidence of major device-related events. Also, subjects treated with the GORE® TAG® Thoracic Endoprosthesis experienced less blood loss during the procedure, shorter ICU stay, shorter hospital stay and shorter time to return to normal daily activities than subjects treated with open surgical repair.

Use of the GORE® TAG® Thoracic Endoprosthesis in Ruptured Aneurysms of the Descending Thoracic Aorta: TAG 04-01

TAG 04-01 Rupture Arm Summary

TAG 04-01 is a non-randomized multi-center clinical trial designed to evaluate the safety and effectiveness of the GORE® TAG® Thoracic Endoprosthesis in the treatment of complex aortic pathologies. The data presented herein describe outcomes from a subset of 20 subjects treated for ruptured aneurysms of the DTA as part of this study. This cohort of subjects was enrolled at nine sites. Subjects were assessed at pre-treatment, treatment, and hospital discharge. Follow-up visits were scheduled at 1 month, 6 months, and annually thereafter through five years post-treatment. At the time of database lock (June 6, 2008) one year of follow-up is complete. Subject follow-up compliance and accountability through 12 months are presented in Table 17.

Data collected for these subjects included: subject characteristics, aneurysm diameter, device use, mortality, motor function evaluation, and adverse events (AEs). For a given study period, data presented include the number of subjects eligible for follow-up (e.g., number eligible from previous period minus subject deaths, subjects discontinued or not yet due for their next follow-up visit).

Table 17. Subject Status Through 12 Months

Study Period	Eligible for Follow-Up	Follow-Up Compliance				Events Prior to Next Interval		
		Subjects with Visit in Window	CT Scan Performed ¹	X-Ray Performed ¹	Baseline ² and Post-Baseline Aneurysm Max Diameter Measurement Available ³	Death ¹	Discontinued ¹	Not Due for Next Follow-Up ¹
Treatment	20	20 (100.0%)	17 (85.0%)	19 (95.0%)	—	3 (15.0%)	0 (0.0%)	0 (0.0%)
1 Month	17	17 (100.0%)	16 (94.1%)	16 (94.1%)	—	0 (0.0%)	2 (11.8%)	0 (0.0%)
6 Months	15	12 (80.0%)	11 (73.3%)	10 (66.7%)	9 (81.8%)	7 (46.7%)	1 (6.7%)	0 (0.0%)
12 Months	7	5 (71.4%)	5 (71.4%)	5 (71.4%)	4 (80.0%)	1 (14.3%)	1 (14.3%)	0 (0.0%)
24 Months	5	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (100.0%)	0 (0.0%)	1 (20.0%)	3 (60.0%)
36 Months	1	0 (0.0%)	0 (0.0%)	0 (0.0%)	0	0 (0.0%)	0 (0.0%)	1 (100.0%)
48 Months	0	0	0	0	0	0	0	0
60 Months	0	0	0	0	0	0	0	0

Study period definitions: Treatment (0-22 days), 1 Month (23-60 days), 6 Months (61-304 days), 12 Months (305-546 days), 24 Months (547-911 days), 36 Months (912-1275 days), 48 Months (1276-1640 days), 60 Months (1641-2006 days)

¹ Percentages for each entry are based on number of subjects eligible for follow-up. Compliance is based on site reported imaging assessments.

² Baseline is defined as the imaging assessment closest to 30 days post treatment between day 15 and day 60.

³ Denominator is number of subjects in visit window with CT scan performed.

Subject Characteristics

Tables 18 –19 show the demographics and pre-treatment medical history for the subset of TAG 04-01 subjects treated for ruptured aneurysms.

Table 18. Subject Demographics

Subjects Enrolled		20	
Gender			
Male		14	(70.0%)
Female		6	(30.0%)
Race			
Black or African American		3	(15.0%)
White or Caucasian		17	(85.0%)
Age (yrs)			
n		20	
Mean (Std Dev)		76.2 (10.7)	
Median		79.8	
Range		(50.6, 88.9)	
Height (cm)			
n		20	
Mean (Std Dev)		170.5 (14.0)	
Median		172.5	
Range		(140.0, 193.0)	
Weight (kg)			
n		20	
Mean (Std Dev)		79.6 (27.0)	
Median		68.3	
Range		(51.0, 159.0)	

Table 19. Subject Pre-Treatment Medical History

Subjects Enrolled	20
Risk Factors	
Coronary Artery Disease	7 (35.0%)
Coronary Artery Bypass Graft	1 (5.0%)
Hypercholesterolemia	9 (45.0%)
Chronic Obstructive Pulmonary Disease	6 (30.0%)
Congestive Heart Failure	2 (10.0%)
Hypertension	18 (90.0%)
Cigarette Smoking	13 (65.0%)
Renal Insufficiency	3 (15.0%)
Stroke	2 (10.0%)
Diabetes Mellitus	5 (25.0%)
Peripheral Vascular Disease	5 (25.0%)
Thoracotomy	4 (20.0%)
Signs and Symptoms	
Back Pain	9 (45.0%)
Chest Pain	10 (50.0%)
Abdominal Pain	5 (25.0%)
Hypotension	1 (5.0%)
Dysphagia	2 (10.0%)
Hemoptysis	4 (20.0%)
Dysphonia	0 (0.0%)
NYHA Classification	
I	5 (25.0%)
II	8 (40.0%)
III	1 (5.0%)
IV	0 (0.0%)
No Cardiac Disease	4 (20.0%)
NA	2 (10.0%)
ASA Anesthetic Classification	
I	0 (0.0%)
II	3 (15.0%)
III	8 (40.0%)
IV	9 (45.0%)
V	0 (0.0%)
NA	0 (0.0%)
Summary SVS Risk Score	
n	20
Mean (Std Dev)	7.6 (5.6)
Median	6.3
Range	(1.0, 24.0)

Table 20 shows a summary of the aneurysm diameters treated as part of the ruptured aneurysm cohort for the TAG 04-01 study.

Table 20. Aneurysm Diameter Measurements

Subjects Enrolled	20
Aortic Diameter (mm) Primary Lesion Maximum Outer Diameter	
n	20
Mean (Std Dev)	54.9 (22.1)
Median	59.5
Range	(10.0, 110.0)

Outcomes

Table 21 lists the number of devices implanted for the ruptured aneurysm subjects treated as part of the TAG 04-01 study. At initial procedure 50% of the subjects were treated with one device; 15% of the subjects required more than two devices.

Table 21. Devices Implanted

Number of Subjects with Successful Implant	20
Number of Implanted Endoprostheses (Total: Initial + Additional Implantation)*	
1	8 (40.0%)
2	8 (40.0%)
3	4 (20.0%)
4	0 (0.0%)
n	20
Mean (Std Dev)	1.8 (0.8)
Median	2.0
Range	(1.0, 3.0)

* Three patients had one additional device implanted.

Table 22 shows the treatment outcomes for the subset of subjects treated for ruptured aneurysms of the DTA as part of the TAG 04-01 Study.

Table 22. Treatment Outcomes

Subjects Enrolled	20	Estimated Blood Loss (ml)	
Endoprosthesis Access Method		n	20
Percutaneous	3 (15.0%)	Mean (Std Dev)	368.8 (507.4)
Cutdown	17 (85.0%)	Median	200.0
Procedure Time (min)		Range	(50.0, 2000.0)
n	20	Hospital Stay (Days)	
Mean (Std Dev)	133.0 (67.5)	n	20
Median	101.5	Mean (Std Dev)	7.2 (5.1)
Range	(55.0, 300.0)	Median	6.5
Anesthesia Time (min)		Range	(1.0, 21.0)
n	20	Subjects with ICU Stay	
Mean (Std Dev)	237.8 (92.7)	18 (90.0%)	
Median	193.5	ICU Stay (Days)	
Range	(132.0, 488.0)	n	18
Endoprosthesis Access Outcome		Mean (Std Dev)	3.9 (3.9)
Success (Implanted)	20 (100.0%)	Median	2.2
Failure (Discontinued)	0 (0.0%)	Range	(0.4, 13.7)

Mortality

Table 23 shows subject deaths for the subset of subjects treated for ruptured aneurysms of the DTA as part of the TAG 04-01 Study. No subject died intraoperatively. Through 30 days post-treatment there were three deaths, causes of death included: pre-existing osteomyelitis, myocardial infarction and cerebrovascular accident. Survival through 30 days post-treatment was 85%. The Kaplan-Meier survival estimate through one year post-treatment, which accounts for missing follow-up, was 37.4%.

Table 23. Subject Deaths

Days to Death	Cause of Death
1	Myocardial infarction
2	CVA, ischemic gut due to showering emboli
14	Osteomyelitis*
61	Subdural hematoma from a fall
101	Infected endograft**
106	Intracranial bleed
121	Cardiac arrest
164	Cardiac arrest
242	Pulmonary edema, cardiomyopathy
296	Pulmonary tuberculosis / pneumonia
360	Renal failure

* Subject initially presented with osteomyelitis. Aortic fistula suspected, but not confirmed, at treatment.
 ** Subject diagnosed with sepsis and endograft infection concomitantly. Cause of endograft infection was indeterminate.

Motor Function Evaluation

Subjects were assessed to determine the presence of paraplegia or paraparesis. No subject experienced paraplegia at any time. One subject experienced lower extremity weakness and left leg paraparesis during the one month follow-up period. This subject recovered without treatment from both incidences. No subject experienced paraparesis after the 30 day follow-up visit.

Adverse Events

All AEs were classified as major or minor based upon outcome and treatment required. A summary of the number of subjects that experienced ≥ 1 AE through one year is shown in Table 24. Most subjects that experienced a major or a device AE did so within five days of treatment. Only three subjects required re-intervention with a GORE® TAG® Device; all of these were to treat endoleaks and occurred within seven days of the initial procedure.

Table 24. Summary of All Adverse Events Through One Year Follow-up Visit

	Major			Minor			All		
	1 Month	6 Months	12 Months	1 Month	6 Months	12 Months	1 Month	6 Months	12 Months
Evaluable Subjects¹	20	15	7	20	15	7	20	15	7
Subjects with Imaging Assessment	19	12	5	19	12	5	19	12	5
Subjects with One or More Adverse Events	16 (80.0%)	9 (60.0%)	1 (14.3%)	11 (55.0%)	2 (13.3%)	—	18 (90.0%)	9 (60.0%)	1 (14.3%)
Subjects with One or More Implant-Related Adverse Events	5 (25.0%)	1 (6.7%)	—	6 (30.0%)	—	—	10 (50.0%)	1 (6.7%)	—
Endograft Infection	1 (5.0%)	1 (6.7%)	—	—	—	—	1 (5.0%)	1 (6.7%)	—
Access Failure	—	—	—	1 (5.0%)	—	—	1 (5.0%)	—	—
Endoleak	3 (15.0%)	—	—	6 (30.0%)	—	—	8 (40.0%)	—	—
Other Implant Related Complication	2 (10.0%)	—	—	—	—	—	2 (10.0%)	—	—
Subjects with One or More Deployment—Related Adverse Events	4 (20.0%)	—	—	—	1 (6.7%)	—	4 (20.0%)	1 (6.7%)	—
Operative Bleeding	2 (10.0%)	—	—	—	—	—	2 (10.0%)	—	—
Arterial Perforation or Rupture	3 (15.0%)	—	—	—	—	—	3 (15.0%)	—	—
Access Site Lymphocele, Lymphorrhea, Lymphedema	1 (5.0%)	—	—	—	—	—	1 (5.0%)	—	—
Fever of Unknown Origin	—	—	—	—	1 (6.7%)	—	—	1 (6.7%)	—
Subjects with One or More Systemic Adverse Events	14 (70.0%)	9 (60.0%)	1 (14.3%)	8 (40.0%)	1 (6.7%)	—	16 (80.0%)	9 (60.0%)	1 (14.3%)
Cardiac	4 (20.0%)	4 (26.7%)	1 (14.3%)	5 (25.0%)	—	—	8 (40.0%)	4 (26.7%)	1 (14.3%)
Pulmonary	7 (35.0%)	3 (20.0%)	—	7 (35.0%)	1 (6.7%)	—	13 (65.0%)	3 (20.0%)	—
Renal Insufficiency	1 (5.0%)	—	—	1 (5.0%)	—	—	2 (10.0%)	—	—
Cerebrovascular	1 (5.0%)	2 (13.3%)	—	—	—	—	1 (5.0%)	2 (13.3%)	—
Coagulopathy	1 (5.0%)	—	—	—	—	—	1 (5.0%)	—	—
Bowel Ischemia	1 (5.0%)	—	—	—	—	—	1 (5.0%)	—	—
Spinal Cord Ischemia	—	—	—	1 (5.0%)	—	—	1 (5.0%)	—	—
Other Systemic Complication	6 (30.0%)	3 (20.0%)	1 (14.3%)	—	—	—	6 (30.0%)	3 (20.0%)	1 (14.3%)

¹ Subjects are considered evaluable if date of last contact for the subject is on or after the first day of the given time window. The percentages for each entry are based on the number of evaluable subjects in that time window.

Note 1: An event with a '—' indicates no subjects reported the event.

Note 2: Device events such as endoleak should be considered with respect to number of subjects with imaging follow-up.

Note 3: Study period definitions: 1 Month (0 - 60 days), 6 Months (61 - 304 days), 12 Months (305 - 546 days). Events with onset date prior to study day 0 are recoded to study day 0 for analysis.

Table 25. Revisions

Days to Revision	Revision	Reason for Revision
2	Reintervention (Additional GORE® TAG® Device)	Other implant related complication: intramural hematoma
3	Additional GORE® TAG® Device deployed, coil embolization of left subclavian artery	Endoleak
7	Reintervention (Additional GORE® TAG® Device)	Endoleak
29	Explant	Other implant related complication: aorto-esophageal fistula
98	Embolization	Endoleak

TAG 06-02 45 mm GORE® TAG® Device Study and Emergency and Compassionate Use Summary

The 45 mm GORE® TAG® Device Study (TAG 06-02) is a non-randomized multicenter study designed to assess the safety and efficacy of the 45 mm GORE® TAG® Device when used for the primary treatment of aneurysms of the DTA. Patient enrollment for TAG 06-02 began in February 2007, enrolling 21 subjects. In addition, 13 subjects were treated with the 45 mm GORE® TAG® Device under the provisions of Emergency and Compassionate (E&C) use for pathologies that were not part of the study protocol, including rupture, elephant trunk procedures, debranching procedures, and treatment of aneurysms in which landing zones were outside of the recommended sizing guidelines (see Table 34). The data presented herein describe outcomes from both the 21 study subjects and the 13 patients treated with a 45 mm GORE® TAG® Device under the provisions of E&C use.

Table 26. Emergency and Compassionate Use Indications

	E&C Use Patients
Subjects Enrolled	13
E&C Use	
Rupture	5 (38.5%)
Elephant Trunk Procedure	3 (23.1%)
Debranching Procedure	3 (23.1%)
Landing Zone	2 (15.4%)

Tables 27 – 28 show the demographics and pre-treatment medical history for the TAG 06-02 study subjects and E&C patients.

Table 27. Subject Demographics

	TAG 06-02 Study Subjects	E&C Use Patients
Subjects Enrolled	21	13
Gender		
Male	18 (85.7%)	6 (46.2%)
Female	3 (14.3%)	7 (53.8%)
Ethnicity		
Hispanic or Latino	0 (0.0%)	0 (0.0%)
Not Hispanic or Latino	21 (100.0%)	13 (100.0%)
Race		
White or Caucasian	20 (95.2%)	12 (92.3%)
Black or African American	1 (4.8%)	1 (7.7%)
Asian	0 (0.0%)	0 (0.0%)
American Indian or Alaskan Native	0 (0.0%)	0 (0.0%)
Other	0 (0.0%)	0 (0.0%)
Unknown	0 (0.0%)	0 (0.0%)
Age (yrs)		
n	21	13
Mean (Std Dev)	78.2 (6.2)	77.7 (4.0)
Median	78.9	79.1
Range	(60.1, 87.1)	(69.6, 83.3)
Weight (kg)		
n	21	13
Mean (Std Dev)	85.0 (12.6)	75.5 (14.3)
Median	88.4	75.0
Range	(60.2, 110.0)	(50.0, 99.0)
Height (cm)		
n	21	13
Mean (Std Dev)	174.0 (9.0)	169.1 (9.3)
Median	175.0	165.0
Range	(157.0, 187.0)	(157.0, 185.0)

Table 28. Subject Pre-Treatment Medical History

	TAG 06-02 Study Subjects	E&C Use Patients
Subjects Enrolled	21	13
Risk Factors		
Coronary Artery Disease	14 (66.7%)	9 (69.2%)
Cardiac Arrhythmia	8 (38.1%)	7 (53.8%)
Valvular Heart Disease	5 (23.8%)	5 (38.5%)
Congestive Heart Failure	2 (9.5%)	3 (23.1%)
Stroke	2 (9.5%)	0 (0.0%)
Peripheral Arterial Occlusive Disease	3 (14.3%)	3 (23.1%)
Prior Vascular Intervention	16 (76.2%)	8 (61.5%)
Thromboembolic Event	0 (0.0%)	0 (0.0%)
Aneurysm Symptomatic	5 (23.8%)	7 (53.8%)
Aneurysm of Traumatic Origin	0 (0.0%)	0 (0.0%)
Other Concomitant Aneurysm(s)	7 (33.3%)	7 (53.8%)
COPD	10 (47.6%)	5 (38.5%)
History of Smoking	19 (90.5%)	11 (84.6%)
Renal Dialysis	0 (0.0%)	1 (7.7%)
Paraplegia	0 (0.0%)	0 (0.0%)
Erectile Dysfunction	2 (11.1%)	0 (0.0%)
Cancer	9 (42.9%)	5 (38.5%)
NYHA Classification		
I	12 (57.1%)	4 (30.8%)
II	8 (38.1%)	5 (38.5%)
III	1 (4.8%)	2 (15.4%)
IV	0 (0.0%)	0 (0.0%)
No Cardiac Disease	0 (0.0%)	0 (0.0%)
N/A	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	2 (15.4%)
ASA Anesthetic Classification		
I	1 (4.8%)	0 (0.0%)
II	5 (23.8%)	2 (15.4%)
III	13 (61.9%)	6 (46.2%)
IV	2 (9.5%)	3 (23.1%)
V	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	2 (15.4%)
Summary SVS Risk Score		
n	21	13
Mean (Std Dev)	7.39 (2.10)	6.54 (2.33)
Median	7.00	7.00
Range	(3.00, 11.00)	(3.00, 10.00)

Table 29 shows a summary of the aneurysm diameters treated as part of the TAG 06-02 study and E&C Use.

Table 29. Aneurysm Diameter Measurements

	TAG 06-02 Study Subjects	E&C Use Patients
Subjects Enrolled	21	13
Primary Lesion Maximum Outer Diameter		
n	21	11 ¹
Mean (Std Dev)	64.5(8.3)	72.5(8.6)
Median	63.0	70.0
Range	(46.0, 86.0)	(62.7, 90.0)

¹ Data is unavailable for two E&C use patients treated for rupture.

Outcomes

Table 30 lists the number of devices implanted for the TAG 06-02 study subjects and E&C patients. Two subjects (one study subject and one E&C patient) required additional implantations.

Table 30. Devices Implanted

	TAG 06-02 Study Subjects	E&C Use Patients
Number of Subjects with Successful Initial Implant	21 (100%)	13 (100%)
Number of Implanted Devices (Total - Initial + Additional Implantation)¹		
1	3 (14.3%)	2 (15.4%)
2	9 (42.9%)	2 (15.4%)
3	8 (38.1%)	7 (53.8%)
4	1 (4.8%)	0 (0.0%)
5	0 (0.0%)	1 (7.7%)
6	0 (0.0%)	1 (7.7%)
n	21	13
Mean (Std Dev)	2.3(0.8)	2.9(1.4)
Median	2.0	3.0
Range	(1.0, 4.0)	(1.0, 6.0)

¹ One TAG 06-02 study subject had an additional device implant at two days post-treatment; one E&C use patient had additional device implants at four months post-treatment.

Table 31 shows the treatment outcomes for the TAG 06-02 study subjects and E&C patients.

Table 31. Treatment Outcomes

	TAG 06-02 Study Subjects	E&C Use Patients
Subjects Enrolled	21	13
Conduit Use		
Yes	4 (19.0%)	2 (15.4%)
No	17 (81.0%)	8 (61.5%)
Missing	0 (0.0%)	3 (23.1%)
Procedure Time (min)		
n	20	13
Mean (Std Dev)	136.1(74.38)	206.1(85.19)
Median	107.0	192.0
Range	(73.0, 362.0)	(98.0, 373.0)
Estimated Blood Loss (ml)		
n	21	12 ¹
Mean (Std Dev)	328.6(383.92)	344.2(542.13)
Median	150.0	162.5
Range	(50.0, 1600.0)	(5.0, 2000.0)

¹ Data is unavailable for one E&C use patient.

Mortality

Table 32 shows subject deaths for the TAG 06-02 study subjects and E&C patients. No subject died intraoperatively. Through 30 days post-treatment there was one death in a study subject and two deaths in E&C patients.

Table 32. Subject Deaths

Cohort	Days to Death	Cause of Death
45 mm GORE® TAG® Device	11	Hematoma ¹
45 mm GORE® TAG® Device	51	Atelectasis / Pneumonia
45 mm GORE® TAG® Device	167	Sepsis
45 mm E&C	3	Sepsis
45 mm E&C	10	Other Multi-organ system failure
45 mm E&C	39	Respiratory Failure

¹ Subject developed epidural hematoma secondary to spinal drain.

Adverse Events

Major adverse events reported through one month are summarized in Table 33, with data from TAG 03-03 and TAG 99-01 provided for reference. Study subjects experienced bleeding, neurologic, pulmonary, vascular, and wound complications. Emergency & Compassionate use patients experienced pulmonary, vascular, cardiac, and wound complications. Of note, three study subjects experienced neurologic complications. One subject experienced paraplegia of both lower extremities one day post-treatment; a cerebrovascular accident (CVA) was confirmed three days post-treatment. This subject expired eleven days post-treatment (Table 32). Two additional subjects reported CVAs the day of treatment; one subject recovered within four days of initial onset and another subject reported the event as continuing. No neurologic complications were reported for E&C use patients.

No unanticipated adverse device events were reported. One major device event was reported for a study subject requiring an additional implantation of a GORE® TAG® Device for a Type III endoleak two days post-treatment. One E&C use patient experienced a major device event through 30 days post-treatment, a Type I endoleak on the day of treatment requiring embolization.

Available longer term follow-up includes one reported death in a TAG 06-02 study subject due to sepsis (Table 32) 167 days post-treatment and three additional GORE® TAG® Device implants in one E&C use patient to repair a Type III endoleak four months post-procedure with concomitant hematoma, renal failure, respiratory failure and atelectasis / pneumonia. Complete ascertainment of long-term follow-up for TAG 06-02 study subjects is ongoing.

No aneurysm ruptures or surgical conversions were reported in study subjects or E&C use patients.

Table 33. Short Term Major Adverse Events

	TAG 03-03 (N=51)	TAG 99-01 (N=140)	TAG 06-02 (N=21)	TAG 06-02 E&C (N=13)
Bleeding Complication	1 (2.0%)	13 (9.3%)	4 (19.0%)	0
Neurologic Complication	2 (3.9%)	11 (7.9%)	3 (14.3%)	0
Pulmonary Complication	3 (5.9%)	9 (6.4%)	2 (9.5%)	3 (23.1%)
Renal Function Complication	0	2 (1.4%)	0	0
Vascular Complication	3 (5.9%)	20 (14.3%)	1 (4.8%)	2 (15.4%)
Cardiac Complication	1 (2.0%)	4 (2.9%)	0	2 (15.4%)
Wound Complication	1 (2.0%)	8 (5.7%)	2 (9.5%)	1 (7.7%)
Bowel Complication	0	3 (2.1%)	0	0
Other Complication	0	0	0	0
Major Device Event¹	2 (3.9%)	6 (4.3%)	1 (4.8%)	1 (7.7%)
Additional Implantation ¹	0	0	1 (4.8%)	0

¹ data presented through one month time window (0-59 days)

SUMMARY OF POST-APPROVAL STUDIES (TAG 05-02)

As a condition of US FDA premarket approval, W. L. Gore & Associates was committed to conducting a post-approval study to evaluate the long-term performance of the GORE® TAG® Thoracic Endoprosthesis in the primary treatment of descending thoracic aortic (DTA) aneurysms and to assess the GORE® TAG® Device Physician Training Program. This study would enroll 150 subjects at up to 35 sites prospectively or retrospectively treated by clinicians participating in the training program.

The TAG 05-02 protocol was designed to evaluate the long-term performance of the GORE® TAG® Thoracic Endoprosthesis by demonstrating that aneurysm-related death for subjects treated with the device is not inferior to historical control subjects treated with open surgical repair. In addition, a subset of Major Adverse Events (MAEs) including stroke, paraplegia, re-intervention, and aneurysm-related death would be evaluated in subjects treated with the device and historical control subjects treated with open surgical repair.

The study was designed to assess the effectiveness of the training program by considering the incidence of Major Device-related Events (MDEs) through 30 days. Major Device-related Events include: unplanned branch vessel occlusion, endoleak, deployment failure, lumen obstruction, prosthesis material failure, aneurysm rupture, extrusion/erosion, prosthesis migration, prosthesis realignment and other device-related complications as specified by the investigator.

TAG 05-02 has completed enrollment, and all of the subjects enrolled into the study have passed the 30 day post-treatment follow-up interval. A summary of the results of the training program assessment is below, while evaluation of the long-term performance of the device continues for all eligible subjects.

Evaluation of the GORE® TAG® Device Physician Training Program

The GORE® TAG® Device Physician Training Program is categorized into four tiers. These tiers relate to a physician's prior endovascular experience with Tier I physicians being the most experienced and Tier IV physicians the least experienced. The objective of the training program is to adequately prepare qualifying physicians to safely implant the GORE® TAG® Thoracic Endoprosthesis in compliance with these Instructions for Use.

One hundred fifty subjects treated by physicians in Tiers I - III were evaluated. One subject treated by a Tier IV physician was included as a Tier III subject for ease of analysis. Eleven (7.3%) subjects overall experienced one or more MDEs during the 30 - day follow-up visit window. These MDEs were equally distributed across tiers.

There was no significant difference among the tiers in percentage of subjects free from MDEs through the 30 - day follow-up visit window, the percentage of which ranged from 91.2% to 93.8%.

In conclusion, the short term results reported suggest that the GORE® TAG® Device Physician Training Program is effective at preparing physicians of varying experience levels to use the GORE® TAG® Device.

PATIENT SELECTION AND TREATMENT (SEE WARNINGS AND PRECAUTIONS)

Gore recommends that the GORE® TAG® Thoracic Endoprosthesis be used in accordance with the Sizing Table (Table 34).

- The GORE® TAG® Thoracic Endoprosthesis is designed to treat:
 - Proximal and distal aortic neck lengths of ≥ 20 mm,
 - Proximal and distal aortic neck inner diameters between 23 and 42 mm.
- Differing proximal and distal neck diameters (aortic taper) outside the intended aortic diameter requirements for a single endoprosthesis diameter (Table 34) requires the use of multiple endoprostheses of different diameters.
- Use of multiple devices with differing diameters require a treatment length of ≥ 13 cm.
- All lengths and diameters of the devices necessary to complete the procedure should be available to the physician, especially when pre-operative case planning measurements (treatment diameters / lengths) are not certain. This approach allows for greater intraoperative flexibility to achieve optimal procedural outcomes.

The risks and benefits discussed in SUMMARY OF US CLINICAL STUDIES should be carefully considered for each patient before use of the GORE® TAG® Thoracic Endoprosthesis.

Additional considerations for patient selection include but are not limited to:

- Patient's age and life expectancy
- Co-morbidities (e.g., cardiac, pulmonary, renal)
- Patient's suitability for open surgical repair
- Patient's anatomical suitability for endovascular repair
- Risk of aneurysm rupture versus the risk of treatment with the GORE® TAG® Thoracic Endoprosthesis as listed in the WARNINGS and ADVERSE EVENTS sections
- Ability to tolerate general, regional or local anesthesia
- Iliofemoral access vessel size and morphology (minimal thrombus, calcium and / or tortuosity) should be compatible with vascular access techniques and accessories
- The final treatment decision is at the discretion of the physician and patient

The TAG 04-01 study protocol did not specify any differences in peri-operative care of patients with ruptured DTA aneurysm as compared to the TAG 99-01, 03-03 and 05-02 aneurysm trials. Medical management, anesthetic protocol, and all aspects of peri-operative care for these patients were left to the discretion of the implanting physician. Case planning guidelines were identical to those outlined for the treatment of DTA aneurysm in the GORE® TAG® Device Instructions for Use (IFU). Follow-up imaging requirements were also identical to the aneurysm patient guidelines outlined in the IFU. The primary outcome differences that were noted between patients with ruptured vs. intact DTA aneurysm were higher mortality, longer convalescence (median 7

day hospitalization vs. 3) and higher endoleak incidence (although most were incidentally noted). Compared to intact aneurysm patients, patients with ruptured DTA presented emergently, were older (median 79 years vs. 72-74), and were frequently symptomatic (chest and back pain most common).

PATIENT COUNSELING INFORMATION

The physician and patient should review the risks and benefits when discussing this endovascular device and procedure including:

- Risk and benefit differences between endovascular repair and open surgical repair
- Potential advantages and disadvantages of open surgical repair
- Potential advantages and disadvantages of endovascular repair
- The possibility that subsequent interventional or open surgical repair of the aneurysm may be required after initial endovascular repair

In addition to the risks and benefits of an endovascular repair, the physician should assess the patient's commitment and compliance to post-operative follow-up as necessary to ensure continuing safe and effective results. Listed below are additional topics to discuss with the patient as to expectations after an endovascular repair:

- **The long-term safety and effectiveness of endovascular repair has not been established.** Physicians should advise all patients that this treatment modality requires long-term, regular follow-up to assess patients' health status and stent-graft performance. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms) should receive enhanced follow-up. Patients should be counseled on the need for regular follow-up, even in the absence of obvious symptoms, e.g., pain, numbness, weakness (see IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP).
- Regular follow-up including imaging of the device should be performed at least every 12 months for all patients and at least every 6 to 12 months for patients with known endoleaks or aneurysm enlargement for the duration of the implant (see IMAGING GUIDELINES AND POST- OPERATIVE FOLLOW-UP).
- Physicians must advise all patients that it is important to seek prompt medical attention if he / she experiences signs of device occlusion, aneurysm enlargement or rupture. Signs of device occlusion include pain in the chest, abdomen or hip(s) or leg(s) during but may not be limited to activity. Aneurysm rupture may be asymptomatic, but usually presents as pain, numbness, weakness in the legs, any back, chest, abdominal, or groin pain, dizziness, fainting, rapid heartbeat, or sudden weakness.

Physicians are encouraged to refer the patient to the Patient Brochure regarding risks occurring during or after implantation of the device. Procedure related risks include cardiac, pulmonary, neurologic, bowel, and bleeding complications. Device related risks include occlusion, endoleak, aneurysm enlargement, fracture, potential for reintervention and open surgical conversion, rupture and death (See OBSERVED ADVERSE EVENTS and POTENTIAL DEVICE or PROCEDURE RELATED ADVERSE EVENTS). Physicians are encouraged to complete the Patient Wallet Card and give it to the patient so that he / she can carry it with them at all times. The patient should refer to the wallet card anytime they visit additional health practitioners, particularly for any additional diagnostic procedures (e.g., MRI).

HOW SUPPLIED

The GORE® TAG® Thoracic Endoprosthesis and introducer sheath caps are supplied sterile and non-pyrogenic.

Storage and Handling

- Do not resterilize; for single use only.
- Do not use if damaged or if sterile barrier has been compromised.
- Do not use after the "use by" (expiration) date printed on the label.
- Store in a cool, dry place.

CLINICAL USE INFORMATION

WARNING: Always have a surgical team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

WARNING: The GORE® TAG® Thoracic Endoprosthesis should only be used by physicians experienced in vascular interventional techniques, and who have successfully completed the appropriate physician training program.

The recommended skill / knowledge requirements for physicians using the GORE® TAG® Thoracic Endoprosthesis are outlined below:

Patient Selection

- Knowledge of the natural history of thoracic aortic disease and co-morbidities associated with endovascular repair of the descending thoracic aorta.
- Knowledge of radiographic image interpretation, device selection and sizing.

A multi-disciplinary team that has combined procedural experience with:

- Vascular access techniques
- Guidewire and catheter techniques
- Fluoroscopic and angiographic image interpretation
- Embolization
- Angioplasty
- Endovascular stent placement
- Snare techniques
- Appropriate use of contrast agents
- Techniques to minimize radiation exposure
- Expertise in necessary patient follow-up modalities

Materials Required for Device Placement

- GORE® TAG® Thoracic Endoprosthesis in the appropriate diameter(s) and length(s) (Table 34)
- GORE® Introducer Sheath Cap (two supplied with endoprosthesis)
- GORE® Tri-Lobe Balloon Catheter (supplied separately)
- GORE® Introducer Sheath with Silicone Pinch Valve or GORE® DrySeal Sheath of appropriate french size for the selected endoprosthesis diameter (supplied separately) (Table 34)
- Hemostatic vascular clamp with soft jaws
- 0.035" (0.89 mm) Medi-Tech Amplatz Super Stiff Guidewire or equivalent, 250 cm or longer
- Heparin and heparinized saline solution
- Contrast agents
- Sterile syringes
- 3-way stopcock
- Appropriate diagnostic catheters and accessories

Sizing

Table 34 indicates the appropriate diameter prosthesis for the intended aortic neck diameter. Aortic neck diameters should be measured from axial CTA films and should consist only of the flow lumen and not the adventitial layer. Three diameter measurements are required for both the proximal and distal necks (**Figure 7**). All measurements per neck must be within one Intended Aortic Inner Diameter range, as listed in **Table 34**. Appropriate oversizing (7-18%) is built into the recommended sizes. Therefore, do not incorporate additional oversizing in the selection of the endoprosthesis.

Table 34. Sizing Guide

Intended Aortic Inner Diameters ¹ (ID) (mm)	Endoprosthesis Diameter ² (mm)	Endoprosthesis Lengths ^{2,3} (cm)	Recommended GORE® Introducer Sheath Size (Fr)	GORE® Introducer Sheath with Silicone Pinch Valve Outer Diameter (OD) (mm)	GORE® DrySeal Sheath
23 - 24	26	10	20	7.6	7.5
24 - 26	28	10 / 15	20		
26 - 29	31	10 / 15	22	8.3	8.3
29 - 32	34	10 / 15 / 20	22		
32 - 34	37	10 / 15 / 20	24	9.2	9.1
34 - 37	40	10 / 15 / 20	24		
37 - 42	45	10 / 15 / 20	24		

¹ Appropriate oversizing is built into the recommended sizes.

² All dimensions are nominal.

³ A minimum of 20 mm non-aneurysmal aortic neck length is required both proximal and distal to the aneurysm. The length of the patient's aneurysm, plus a minimum of 4.0 cm for the non-aneurysmal necks, should be used when calculating the required endoprosthesis length. More than one endoprosthesis may be needed to cover the entire treatment area.

DIRECTIONS FOR USE

Anatomical Requirements

- Iliofemoral access vessel size and morphology (minimal thrombus, calcium and / or tortuosity) should be compatible with vascular access techniques and accessories.
- Proximal and distal aortic neck lengths should be a minimum of 20 mm.
- Aortic neck inner diameters (ID) in the range of 23–42 mm (**Table 34**).
- Differing proximal and distal neck diameters (aortic taper) outside the intended aortic diameter requirements for a single endoprosthesis diameter (**Table 34**) requires the use of multiple endoprostheses of different diameters.
- Use of multiple devices with differing diameters requires a treatment length of ≥ 13 cm.

Measurements to be taken during the pretreatment assessment are described below (**Figure 6**):

A, B, C. Proximal aortic neck diameter (minimum of 1 cm apart)

D. Maximum aneurysm diameter

E, F, G. Distal aortic neck diameter (minimum of 1 cm apart)

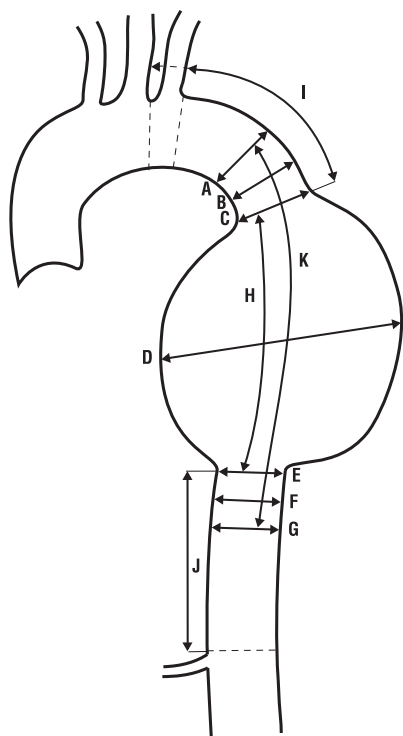
H. Length of the aneurysm measured along the greater curvature of the flow lumen

I. Distance between the left subclavian / left common carotid artery and the proximal end of the aneurysm (minimum of 2 cm)

J. Distance between the distal end of the aneurysm and the celiac axis (minimum of 2 cm)

K. Total treatment length

Figure 6. Aortic Screening Measurements

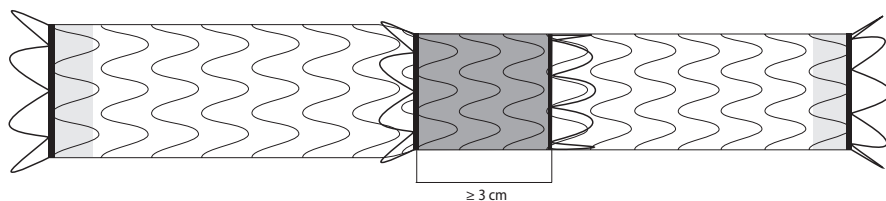


Using Multiple Devices

When multiple endoprostheses are used to compensate for aortic taper or treatment length, adhere to the sizing guide (Table 34) in conjunction with the recommended guidelines below:

- Overlapped endoprostheses in an aneurysmal section should be one to two sizes different in diameter with an overlap of at least 3 cm (gold band to gold band) (Figure 7).
- Always deploy the larger diameter endoprosthesis into the smaller diameter endoprosthesis.
- If overlapping devices of the same diameter, overlap by at least 5 cm.
- Use of multiple devices with differing diameters requires a treatment length of ≥ 13 cm.

Figure 8. Overlap Region When Using Multiple Devices



Catheter Preparation and Arterial Access

1. Obtain appropriate vascular access, according to standard practice.
2. Administer heparin, according to standard practice.
3. Perform angiography to determine the correct placement location of the device, according to standard practice.
4. Advance the appropriate introducer sheath through the vasculature, according to standard practice.
5. Remove the GORE® TAG® Thoracic Endoprosthesis delivery catheter from the packaging, and examine for possible damage.
6. Flush heparinized saline through the flushing port. The delivery catheter is now ready for use.
7. Attach appropriate device cap onto GORE® Introducer Sheath if using the GORE® Introducer Sheath with Silicone Pinch Valve. If using the GORE® DrySeal Sheath, refer to product instructions for use.

GORE® TAG® Thoracic Endoprosthesis Deployment

1. Insert the endoprosthesis delivery catheter over a 0.035" (0.89 mm) 'super-stiff' guidewire, through the introducer sheath into the aorta. **Warning: Do not rotate the delivery catheter while device is inside the introducer sheath. Catheter breakage or inadvertent deployment may occur.**
2. Position the endoprosthesis across the aneurysm using the radiopaque gold bands to identify the base of the flares which are located approximately 1 cm from each end of the endoprosthesis (Figure 2). The end of the endoprosthesis, including the flares, should extend at least 2 cm into non-aneurysmal proximal and distal necks. Care should be taken not to cover the origin of any major arterial branches in the vicinity of the treatment area. **Warning: Do not rotate the delivery catheter outside of the introducer sheath more than 180° in either direction. Catheter breakage or inadvertent deployment may occur.**
3. Stabilize the delivery catheter at the introducer sheath to prevent delivery catheter movement prior to deploying the endoprosthesis. Loosen the luer lock on the deployment knob. While maintaining the exposed delivery catheter as straight as possible, deploy the endoprosthesis by pulling the deployment knob in a steady, continuous motion. Deployment initiates from the middle of the device and extends simultaneously to the proximal and distal ends.

- Use fluoroscopic guidance during withdrawal of the delivery catheter to assure safe removal from the endoprosthesis.
- Additional endoprostheses may be deployed to treat longer segments. (Refer to *Using Multiple Devices* section).

Completion of Procedure

- After deployment, use the GORE® Tri-Lobe Balloon Catheter to smooth and seat the endoprosthesis against the aortic wall in the distal and proximal necks. Balloon the distal neck first, proximal neck second then overlap areas (if appropriate). Center the balloon at the radiopaque gold band on the endoprosthesis and inflate to the recommended volume (see GORE® Tri-Lobe Balloon Catheter Instructions for Use). Deflate the balloon, rotate the balloon approximately 60° and repeat the inflation. **Warning: If resistance is felt, stop and assess the cause. Otherwise, device displacement may occur.**
- Perform arteriography in two views to assess exclusion of the aneurysmal segment, luminal patency of the aorta, and endoprosthesis position.
- Close arterial access site, according to standard practice.

IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP

General

All patients should be advised this treatment modality requires long-term, regular follow-up to assess patients' health status and stent-graft performance. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms) should receive enhanced follow-up. Patients should be counseled on the need for regular follow-up, even in the absence of obvious symptoms (e.g., pain, numbness, weakness).

Regular and consistent follow-up is a critical part of ensuring continuing safety and efficacy of aortic endovascular repair.

Physicians should tailor patient follow-up to the needs and circumstances of each individual patient. In the US clinical studies, at least one annual physician visit and the imaging schedule (Table 35) were employed.

Follow-up modalities include CT / CTA, and four-view (AP, lateral, 45° LAO and 45° RAO) chest x-ray. Data from these modalities is acquired and used to compare changes over time and their effects on exclusion of the aneurysm.

Table 35. Recommended Schedule for Patient Imaging Follow-Up

Schedule for Patient Imaging Follow-up			
Visit	Angiogram	X-ray	CT Pre-Contrast and Contrast
Pre-Treatment	X ¹		X ¹
Treatment (Pre and Post Deployment)	X		
Discharge		X	
1 Month		X	X
3 Month			X ²
6 Month		X	X
12 Month (Annually Thereafter)		X	X

¹ Imaging should be performed < three months prior to the procedure
² Recommended if endoleak reported at one month

Angiographic Imaging

Angiographic images are recommended pre-treatment to evaluate the length and tortuosity of abdominal aorta, iliac and common femoral arteries.

- Images should include an angiographic marker catheter with incremental one centimeter markers over a 10-20 cm length.
- The following views are recommended for optimal evaluation and case planning:
 - Thoracic Chest; Supine-AP, Lateral, 45° LAO, and 45° RAO
 - Pelvis (to include bilateral common femorals); AP

Angiographic images are recommended during the treatment procedure both pre and post-deployment to evaluate device placement and orientation. Selective angiography during subsequent follow-up exams may provide useful device position and device integrity information.

CT / CTA Images

- Film sets should include all sequential images at lowest possible slice thickness (≤ 3 mm). Do NOT perform large slice thickness (> 3 mm) and / or omission of CT images / film sets (non-consecutive) as it prevents precise anatomical and device comparisons over time.
- All images should include a scale for each image / film. Images should be arranged no smaller than 20:1 images on 14" x 17" sheets if film is used.
- If an endoleak is suspected or there is aneurysm enlargement, it is recommended that pre-contrast and contrast runs be performed.**
- Pre-contrast and contrast run slice thickness and interval must match.
- DO NOT change patient orientation or re-landmark patient between non-contrast and contrast runs.
- Clinical experience indicates that 3-D CTA reconstruction is the required imaging modality to accurately assess proximal and distal neck lengths for the GORE® TAG® Thoracic Endoprosthesis. These reconstructions should be performed in sagittal, coronal and varying oblique views depending upon individual patient anatomy. If 3-D reconstruction is not available, the patient should be referred to a facility with these capabilities.

Non-contrast and contrast enhanced baseline and follow-up exams are important for optimal patient surveillance. For the best results, use the following CT / CTA imaging guidelines listed in Table 36.

Table 36. CT / CTA Imaging Guidelines

CT Imaging Protocol	
Injection Volume (ml)	150
Injection Rate (cc/sec)	3-4 (through \geq 20G IV)
Delay	SmarPrep ¹ or equivalent, 3 second delay
Start Position	Apices of lung (pre-contrast), 2 cm above aortic arch
End Position	Superior Mesenteric Artery
Scan Diameter (FOV)	Large
DFOV (cm)	24
Scan Type	Helical
Rotation Speed (sec)	0.8
Slice Thickness (mm)	\leq 3
Scan Mode	HS
Table Speed (mm/rot)	15
Interval (mm)	2

¹ **Baseline Location:** Thoracic Aorta, **ROI:** Ascending Aorta, **mA:** 40, **Monitor Delay:** 10 s, **Monitor ISD:** 3 s Scan, **Enhance Threshold:** 100 HU, **Scan Phase:** 3 s

Chest X-ray Film Series (plain film)

The following chest X-ray views are recommended for optimal visualization of the endograft.

- Supine – frontal (AP)
- Lateral
- 45 degree LPO
- 45 degree RPO

Ensure entire device is captured on each single image format lengthwise.

Set KvP to 75-85, maximizes device visualization.

If there is any concern about the device integrity (e.g., kinking, stent-wire breaks, relative component migration), it is recommended to use magnified views. The attending physician should evaluate films for device integrity (entire device length including components) using 2-4x magnification.

MRI Safety and Compatibility MR Conditional

Non-clinical testing has demonstrated that the GORE® TAG® THORACIC Endoprosthesis is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Spatial gradient field of \leq 720 Gauss / cm
- Maximum scanner displayed whole-body-averaged specific absorption rate (SAR) of 3.0 W / kg for 15 minutes of scanning.

3.0 Tesla Temperature Rise:

In non-clinical testing, the GORE® TAG® Thoracic Endoprosthesis produced a temperature rise of 1.9° C at an MR system reported maximum whole body averaged specific absorption rate (SAR) of 3.0 W / kg for 15 minutes of MR scanning in a 3.0 Tesla, Excite, General Electric active-shield, horizontal field MR scanner using G3.0-052B Software and placed in a worst-case location in a phantom designed to simulate human tissue. The SAR calculated using calorimetry was 2.8 W / kg.

1.5 Tesla Temperature Rise:

In non-clinical testing, the GORE® TAG® Thoracic Endoprosthesis produced a temperature rise of 1.8° C at an MR system reported maximum whole body averaged specific absorption rate (SAR) of 2.8 W / kg for 15 minutes of MR scanning in a 1.5 Tesla, Magnetom, Siemens Medical Solutions, active-shield, horizontal field MR scanner using Numaris / 4 Software and placed in a worst-case location in a phantom designed to simulate human tissue. The SAR calculated using calorimetry was 1.5 W / kg.

Image Artifact:

For each vascular device and assembly, the artifacts that appeared on the MR images were shown as localized signal voids (i.e., signal loss) that were minor in size relative to the size and shape of these implants. The gradient echo pulse sequence produced larger artifacts than the T1 – weighted, spin echo pulse sequence for the GORE® TAG® Thoracic Endoprosthesis. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the GORE® TAG® Thoracic Endoprosthesis. Therefore, it may be necessary to optimize the MR imaging parameters to compensate for the presence of this implant.

Additional Surveillance and Treatment

Additional surveillance and possible treatment is recommended for:

- Aneurysms with Type I endoleak
- Aneurysms with Type III endoleak
- Aneurysm enlargement, \geq 5 mm increase in maximum diameter (regardless of endoleak status) compared to any previous measurement

WARNING: A late type III endoleak was observed within 24 hours after DC cardioversion. Close surveillance is recommended to watch for symptoms of endoleaks post DC cardioversion or defibrillation.

Consideration for reintervention or conversion to open repair should include the attending physician's assessment of an individual patient's co-morbidities, life expectancy, and the patient's personal choices. Patients should be counseled as to the possibility of subsequent reinterventions including catheter based and open surgical conversion.

WARNING: Strict adherence to the GORE® TAG® Thoracic Endoprosthesis IFU sizing guide (Table 34) is required when selecting the appropriate device size. The GORE® TAG® Thoracic Endoprosthesis is designed to be oversized from 7 to 18% which has been incorporated into the IFU sizing guide. Use outside the IFU sizing guide can result in endoleak, fracture, migration, device infolding or compression. DO NOT treat patients with the GORE® TAG® Device if their anatomical measurements do not fall within the IFU sizing guide requirements.

- If device infolding or compression is observed, immediate conversion or other intervention to restore blood flow is essential.
- Adverse clinical outcomes including significant distal vascular ischemic complications (bowel ischemia, paraplegia) and / or death have resulted from device use outside of the IFU sizing guide.



















DEVICE RELATED ADVERSE EVENT REPORTING

Any adverse event involving the GORE® TAG® Thoracic Endoprosthesis should be reported to W. L. Gore & Associates immediately. To report an event in the US, call (800) 437-8181.

PATIENT TRACKING INFORMATION

In addition to these Instructions for Use, the GORE® TAG® Thoracic Endoprosthesis is packaged with a Device Tracking Form which US hospital staff are required to complete and forward to Gore for the purposes of tracking all patients who receive a GORE® TAG® Thoracic Endoprosthesis product (as required by US Federal Regulations).

DEFINITIONS

-  Use By
-  Caution
-  Consult Instructions for Use
-  Do Not Resterilize
-  Do Not Reuse
-  REF Catalogue Number
-  LOT Batch Code
-  MR Conditional
-  **R_x Only** CAUTION: USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.
-  STERILE Sterile
-  STERILE EO Sterilized using Ethylene Oxide
-  Do Not Use if Package is Damaged
-  Keep Dry
-  Store in a Cool Place
-  Catheter Working Length
-  Delivery Profile
-  Guidewire Compatibility
-  Manufacturer



AM0171-ML3



 Manufacturer

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Flagstaff, Arizona 86004 • USA

Order Information: Tel.: 928.526.3030 • Tel.: 800.528.8763

Technical Information: Tel.: 928.779.2771 • Tel.: 800.437.8181


For international contact and additional product information,
visit **www.goremedical.com**

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