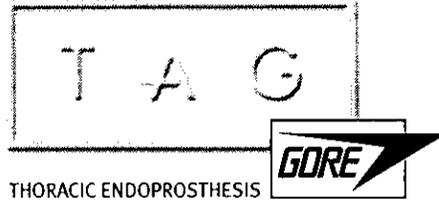


INSTRUCTIONS FOR USE FOR:



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English

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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 (Fig. 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 (Fig. 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.

A device introducer sheath cap is included with the GORE TAG Thoracic Endoprosthesis. This cap should be used with the GORE Introducer Sheath with Silicone Pinch Valve to accommodate the endoprosthesis delivery catheter.

Figure 1. GORE TAG Thoracic Endoprosthesis

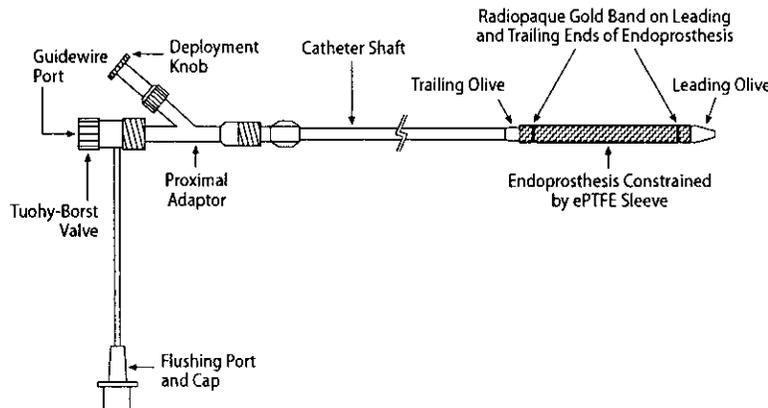
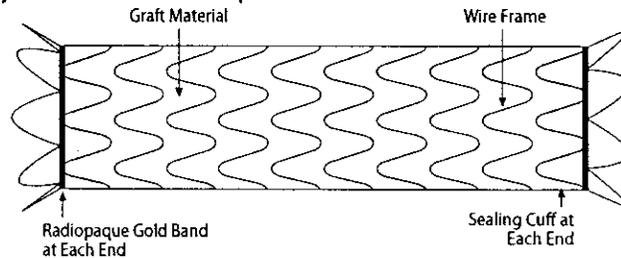


Figure 2. Deployed GORE TAG Thoracic Endoprosthesis



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 23-37 mm
- ≥ 2 cm non-aneurysmal aorta proximal and distal to the aneurysm

CONTRAINDICATIONS

- There are no known contraindications for this device.

WARNINGS AND PRECAUTIONS

General

- Read all instructions carefully, particularly the following sections: **Table 20: SIZING GUIDE**, and in the **DIRECTIONS FOR USE: Anatomical Requirements**, and **Using Multiple Devices**. Failure to properly follow the instructions, warnings, and precautions may lead to serious surgical consequences or injury to the patient. Compliance with device sizing recommendations is critical to performance of the device.
- 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 – page 17**).
- 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 – page 17**.
- 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

- The safety and effectiveness of the GORE TAG Thoracic Endoprosthesis has not been evaluated in the following patient populations:
 - acute and chronic dissections
 - aortic fistulas
 - aortitis or inflammatory aneurysms
 - Intramural hematoma
 - mycotic aneurysms
 - penetrating ulcers
 - ruptured aneurysms
 - traumatic aortic transections
 - pseudoaneurysms resulting from previous graft placement
 - genetic connective tissue disease (e.g., Marfan 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 20) 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 20) 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.
- Use of the GORE TAG Thoracic Endoprosthesis outside of the recommended anatomical sizing guidelines (Table 20) may result in potentially serious device-related events (e.g., device folding, 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.

Implant Procedure

- 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 a soft hemostasis pinch tube, ensure that the pinch tube is not twisted, collapsed, or bent during advancing or withdrawing the delivery catheter. Device damage and/or delivery catheter breakage may occur.
- Do not use an introducer sheath incompatible with the supplied introducer cap. 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.

MRI Safety and Compatibility

- Through non-clinical testing, the GORE TAG Thoracic Endoprosthesis has been shown to be MRI safe under the following conditions. Testing was performed at field strengths of 1.5 Tesla or less, a maximum spatial gradient of 450 gauss/cm and whole body averaged specific absorption rate (SAR) of 1.4 W/kg for 15 minutes of MRI. The GORE TAG Thoracic Endoprosthesis should not migrate in this environment. Non-clinical testing has not been performed to rule out the possibility of stent migration at field strengths higher than 1.5 Tesla or maximum spatial gradient magnetic fields of 450 gauss/cm.
- In this testing, the 5 overlapped endoprostheses produced a temperature rise of less than or equal to 0.9°C at a maximum SAR of 1.4 W/kg for 15 minutes of MRI.
- 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 endoprosthesis.

ADVERSE EVENTS (TAG 99-01 & TAG 03-03)

Two US clinical studies were conducted to evaluate the safety and effectiveness of the GORE TAG Thoracic Endoprosthesis. 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. This Instructions for Use contains the results of both of these US clinical studies.

Observed Adverse Events

For both clinical studies, 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 first study (TAG 99-01) conducted at 17 Investigational sites included 140 Test subjects (endovascular treatment) and 94 Control subjects (open surgical repair). The second study (TAG 03-03) conducted at 11 Investigational sites included 51 Test subjects (endovascular treatment). The incidence of major adverse events (MAE) is reported in Table 1. Specific key major adverse events are delineated in Table 2.

Table 1. Major Adverse Events from US Clinical Studies

Safety endpoints	Post-treatment follow-up period (days)						
	0 - 30		31 - 365		366 - 730		
	TAG 99-01 (N = 140) n (%)	TAG 99-01 Control (N = 94) n (%)	TAG 03-03 (N = 51) n (%)	TAG 99-01 (N = 134) n (%)	TAG 99-01 Control (N = 85) n (%)	TAG 99-01 (N = 106) n (%)	TAG 99-01 Control (N = 66) n (%)
All-cause deaths	2 (1)	6 (6)	0	22 (16)	14 (16)	10 (9)	4 (6)
Aneurysm related deaths	2 (1)	6 (6)	0	2 (1)	3 (4)	0	0
Any major adverse event	40 (29)	66 (70)	6 (12)	37 (28)	22 (26)	15 (14)	6 (9)
Bleeding complications	13 (9)	50 (53)	0	3 (2)	1 (1)	2 (2)	0
Pulmonary complications	9 (6)	31 (33)	2 (4)	13 (10)	8 (9)	6 (6)	0
Cardiac complications	4 (3)	19 (20)	1 (2)	18 (13)	7 (8)	7 (7)	2 (3)
Renal function complications	2 (1)	12 (13)	0	4 (3)	3 (4)	1 (1)	0
Wound complications	8 (6)	11 (12)	1 (2)	1 (1)	3 (4)	1 (1)	1 (2)
Bowel complications	3 (2)	6 (6)	0	3 (2)	0	1 (1)	0
Vascular complications	20 (14)	4 (4)	3 (6)	5 (4)	2 (2)	0	0
Neurologic complications	11 (8)	30 (32)	1 (2)	4 (3)	4 (5)	3 (3)	1 (2)
Other major complications*	0	1 (1)	1 (1)	2 (1)	2 (2)	0	0
Reoperation	4 (3)	0	0	2 (1)	0	0	0
Rupture	0	0	0	0	0	0	0

Note: The difference between the TAG 99-01 and TAG 99-01 Control groups for any major adverse event at 1-year is statistically significant (p<0.001).
The difference between the TAG 03-03 and TAG 99-01 Control groups for any major adverse event at 30 days is statistically significant (p<0.001).
*aortoenteric fistula, prosthesis infection

Table 2. Key Major Adverse Events, TAG 99-01 (through 1 year)

Safety endpoints	TAG Device (N = 140) n (%)	Surgical Control (N = 94) n (%)
Bleeding complications		
Coagulopathy	1 (1)	9 (10)
Procedural	7 (5)	39 (41)
Post-procedural	4 (3)	13 (14)
Neurologic complications		
Cerebrovascular accident	7 (5)	7 (7)
Paraplegia / paraparesis / spinal neurological deficit	4 (3)	13 (14)
Pulmonary complications		
Respiratory failure	11 (8)	22 (23)
Renal function complication		
Renal failure	3 (2)	7 (7)
Vascular complications		
Vascular trauma	15 (11)	0

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,
- aortoenteric fistula,
- arteriovenous fistula,
- 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,
- 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)

Two US clinical studies were conducted to evaluate the safety and effectiveness of the GORE TAG Thoracic Endoprosthesis. 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. This Instructions for Use contains the results of both of these US clinical studies.

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 descending thoracic aorta (DTA). Seventeen US sites enrolled 140 GORE TAG Thoracic Endoprosthesis and 94 surgical control subjects. GORE TAG Thoracic Endoprosthesis and 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.

The subjects were assessed at pre-treatment, treatment, and hospital discharge and returned for follow-up visits at 1, 6, 12, and 24 months, with additional visits scheduled for 36, 48, and 60 months post-treatment. Subject follow-up and accountability at 1 month, 6 months, 12 months and 24 months are presented in Table 3.

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). All 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 Thoracic Endoprosthesis 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 Test and TAG 99-01 Control subjects. Effectiveness was determined by evaluating the proportion of TAG 99-01 Test 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.

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 surgical 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).

Safety was determined by comparing the proportion of subjects who experienced ≥ 1 MAE through 30 days post-treatment between TAG 03-03 device subjects and TAG 99-01 Control subjects. Efficacy was the proportion of subjects who experienced ≥ 1 major device-related event in TAG 03-03 Test 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.

Table 3. Subject Status Through 24 Months

Subject disposition category*	Follow-up period**								
	1 month			6 months		12 months		24 months	
	TAG 99-01 (N=140)	TAG 99-01 Control (N=94)	TAG 03-03 (N=51)	TAG 99-01	TAG 99-01 Control	TAG 99-01	TAG 99-01 Control	TAG 99-01	TAG 99-01 Control
Available for visit	133	78	51	116	69	104	65	92	56
Expired ²	3	13	0	19	19	28	22	36	26
Withdrew or lost to follow-up ^{2,3}	4	3	0	5	6	8	7	12	12
Missed visit	12	19	3	15	25	2	13	8	10
Had a follow-up visit within window ¹	121	59	48	101	44	102	52	84	46
Had a follow-up visit outside window ¹	7	17	n/a	4	3	1	4	1	6
CT Imaging	110	12	48	100	15	103	34	80	27
X-ray imaging	24	26	48	76	7	88	8	75	11
Site evaluated for endoleak	110	n/a	48	100	n/a	103	n/a	80	n/a
Site evaluated for aneurysm enlargement	n/a	n/a	n/a	83	n/a	85	n/a	69	n/a

* Categories are mutually exclusive and exhaustive. Each successive category does not include subjects from the previous category.
¹ Data not included in study analyses.
² Cumulative; includes subjects from study start to end of indicated period.
³ If subject withdrew and had a follow-up visit within the same period, subject is included as having had a follow-up visit for that period. Subject is counted as withdrawn in the following period.
⁴ Aneurysm enlargement was evaluated for patients with adequate paired CT images.

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

Tables 4-6 compare subjects receiving the TAG Endoprosthesis (TAG 99-01 & TAG 03-03) and open surgical repair subjects.

Table 4. Subject Demographics

Variable	TAG 03-03 (N = 51)	TAG 99-01 (N = 139)	Surgical 99-01 (N = 94)	TAG 03-03 vs. TAG 99-01 p-value ¹	TAG 03-03 vs. Surgical 99-01 p-value ¹
Gender, n (%)				0.41	0.12
Female	18 (35)	59 (42)	46 (49)		
Male	33 (65)	80 (58)	48 (51)		
Age (years)	70.7 ± 9.4	70.4 ± 10.5	68.2 ± 10.2	0.88	0.15
Ethnicity, n (%)				0.66	0.77
Asian	1 (2)	1 (1)	2 (2)		
Black	2 (4)	11 (8)	9 (10)		
Caucasian	47 (92)	121 (87)	81 (86)		
Hispanic	1 (2)	3 (2)	1 (1)		
Other	0 (0)	3 (2)	1 (1)		
Weight (kg)	80.8 ± 20.5	76.5 ± 16.5	77.6 ± 17.5	0.14	0.34
Height (cm)	171.0 ± 10.6	169.6 ± 10.1	169.5 ± 11.3	0.39	0.44
BMI (kg/m ²)	27.5 ± 5.7	26.5 ± 4.7	26.9 ± 5.0	0.22	0.54

Notes: Denominators are the number of subjects who have each specific baseline variable available.
¹ p-values are based on Fisher's exact test for categorical variables and a two-sample t-test for continuous variables.

Table 5. Comparison of Subject Pre-treatment Medical History

Variable	TAG 03-03 (N = 51) n (%)	TAG 99-01 (N = 139) n (%)	TAG 99-01 Control (N = 94) n (%)	TAG 99-01 vs. TAG 99-01 Control p-value ¹	TAG 03-03 vs. TAG 99-01 p-value ¹	TAG 03-03 vs. TAG 99-01 Control p-value ¹
Coronary artery disease	18 (35)	69 (50)	34 (36)	0.060	0.10	1.00
Cardiac arrhythmia	16 (31)	33 (24)	29 (31)	0.23	0.35	1.00
Valvular heart disease	5 (10)	8 (6)	9 (10)	0.45	0.34	1.00
Congestive heart failure	4 (8)	13 (9)	9 (10)	1.00	1.00	1.00
Stroke	4 (8)	14 (10)	9 (10)	1.00	0.78	1.00
Peripheral arterial occlusive disease (infringuinal)	7 (14)	21 (15)	10 (11)	0.33	1.00	0.60
Prior vascular intervention	29 (57)	62 (45)	52 (55)	0.14	0.14	1.00
Thromboembolic event	4 (8)	10 (7)	6 (6)	1.00	1.00	0.74
Aneurysm symptomatic	13 (25)	30 (22)	36 (38)	0.007	0.56	0.14
Aneurysm of traumatic origin	2 (4)	8 (7)	5 (6)	1.00	0.73	0.71
Other concomitant aneurysm(s)	17 (33)	38 (27)	26 (28)	1.00	0.47	0.57
COPD	21 (41)	55 (40)	36 (38)	0.89	0.87	0.86
History of smoking (current or past)	43 (84)	116 (83)	77 (82)	0.86	1.00	0.82
Renal dialysis	2 (4)	2 (1)	0 (0)	0.52	0.29	0.12
Paraplegia	0 (0)	1 (1)	0 (0)	1.00	1.00	N/A ²
Erectile dysfunction	1 (3)	13 (16)	5 (10)	0.44	0.063	0.39
Hepatic dysfunction	2 (4)	3 (2)	1 (1)	0.65	0.61	0.28
Bleeding disorder(s)	2 (4)	4 (3)	5 (5)	0.49	0.66	1.00
Cancer	16 (31)	27 (19)	12 (13)	0.21	0.12	0.009
NYHA classification ³						
I	21 (55)	39 (48)	22 (46)			
II	14 (37)	35 (43)	14 (29)			
III	3 (8)	7 (9)	12 (25)			
N/A	13 (25)	58 (42)	46 (49)			
ASA classification				0.13	0.41	0.29
I	3 (6)	2 (1)	2 (2)			
II	4 (8)	13 (9)	5 (5)			
III	31 (61)	90 (65)	51 (54)			
IV	13 (25)	34 (24)	36 (38)			
Summary of mean SVS risk scores	0.7 ± 0.4	0.7 ± 0.3	0.6 ± 0.3	0.17	0.24	0.38
Note: Denominators are the number of subjects with known observations for each specific baseline variable. For N/A values, denominators are the number of subjects enrolled. ¹ p-values are based on Fisher's exact test for categorical variables and a two-sample t-test for the risk summary score. ² Not evaluable using Fisher's exact test. ³ NYHA was used to exclude Class IV patients from the studies and not to compare the distribution of the classification among groups.						

Table 6 lists the Initial aneurysm diameter sizes treated.

Table 6. Aneurysm Diameter Distribution

Diameter Range	TAG 99-01 N=140 n (%)	TAG 99-01 Surgical N=94 n (%)	TAG 03-03 N=51 n (%)
10 – 19 mm	0	1 1%	0
20 – 29 mm	1 1%	1 1%	0
30 – 39 mm	7 5%	3 4%	0
40 – 49 mm	18 13%	5 6%	5 10%
50 – 59 mm	18 13%	17 20%	14 27%
60 – 69 mm	45 32%	30 35%	23 45%
70 – 79 mm	28 20%	16 19%	7 14%
80 – 89 mm	15 11%	8 9%	0
90 – 99 mm	5 4%	2 2%	1 2%
100 – 109 mm	1 1%	1 1%	1 2%
110 – 119 mm	1 1%	1 1%	0

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 Thoracic Endoprosthesis 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 7 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 8). Some subjects had more than one size device implanted.

Table 7. Devices Implanted

Endoprosthesis Diameter (mm)	TAG 99-01 Number of devices (N = 234) n (%)	TAG 03-03 Number of devices (N = 93) n (%)
26	9 (4)	2 (2)
28	9 (4)	6 (6)
31	32 (14)	11 (12)
34	102 (44)	28 (30)
37	41 (18)	26 (28)
40	41 (18)	20 (22)

Table 8. Number of Endoprostheses Implanted at Initial Procedure

Number of devices implanted	TAG 99-01 Number of subjects (N = 137*) n (%)	TAG 03-03 Number of subjects (N = 51) n (%)
1	61 (45)	17 (33)
2	60 (44)	26 (51)
3	11 (8)	8 (16)
4	5 (4)	0

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

Safety

The primary safety endpoint for the Pivotal Study, the proportion of subjects who experienced ≥ 1 MAE through 1 year post-treatment, was significantly lower ($p < 0.001$) in the TAG 99-01 device (42%) vs. the TAG 99-01 surgical control (77%) group. The incidence of major bleeding (11% vs. 54%), pulmonary (13% vs. 38%), renal (4% vs. 15%), wound (6% vs. 15%), and neurological (11% vs. 33%) complications was lower in the TAG 99-01 device group through 1 year post-treatment. Among the clinically significant major neurologic complications, 4/140 (3%) in the 99-01 TAG Device group and 13/94 (14%) in the TAG 99-01 surgical control group experienced paraplegia or paraparesis.

Tables 9-14 and Figures 3-7 describe the morbidity and mortality outcomes for TAG 99-01 and TAG 03-03. The GORE TAG Thoracic Endoprosthesis 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 Thoracic Endoprosthesis group. All-cause mortality is not different between the GORE TAG Thoracic Endoprosthesis and surgical control. The proportion of TAG 99-01 and TAG 03-03 subjects that experienced ≥ 1 MAE through 30 days post treatment was less than TAG 99-01 surgical control subjects (Fig. 5).

Table 9: Summary of Kaplan-Meier Curves to 24 Months

	Total Number of Patients Reaching Follow-up			Aneurysm Rupture		Conversion to Surgical Repair	Death				Aneurysm Related Death ¹				Major Adverse Event				
	T1 N	C N	T2 N	T1 N	C N	T1 N	T1 N	T1 %	C N	C %	T1 N	T1 %	C N	C %	T1 N	T1 %	C N	C %	
Intra-operative	140	94	51	0	0	0	0	0	0	0	0	0	0	n/a ²	n/a ²				
≤ 30 Days	133	78	48	0	0	0	2	2%	6	5%	2	2%	6	5%	40	29%	66	47%	
> 30 Days to 12 Months	104	65	n/a	0	0	0	22	21%	14	13%	2	2%	3	3%	19	18%	6	6%	
12 Months to 24 Months	92	56	n/a	0	0	0	10	11%	4	4%	0	0	0	0	9	10%	1	1%	
Total Patients	140	94	51	0	0	0	34		24		4		9		68		6		
Kaplan-Meier Summaries				Freedom from Aneurysm Rupture		Freedom from Conversion	Probability of Survival		Freedom from Aneurysm Related Death		Freedom from Major Adverse Event								
12 Month Kaplan-Meier	104	65	n/a	100%	100%	100%	82%	78%	97%	90%	57% ³	23% ³							
24 Month Kaplan-Meier	92	56	n/a	100%	100%	100%	74%	72%	97%	90%	50% ³	21% ³							
T1 = TAG 99-01 C = TAG 99-01 Control T2 = TAG 03-03 ¹ Aneurysm related death is defined as all deaths due to aneurysm rupture, a primary or secondary procedure, surgical conversion, or within 30 days of the primary or secondary procedure. ² Major adverse events during the Intraoperative period are reported in the ≤ 30 day period. ³ Total number of patients with a first adverse event only.																			

Figure 3. Subjects Free of a Major Adverse Event (TAG 99-01)

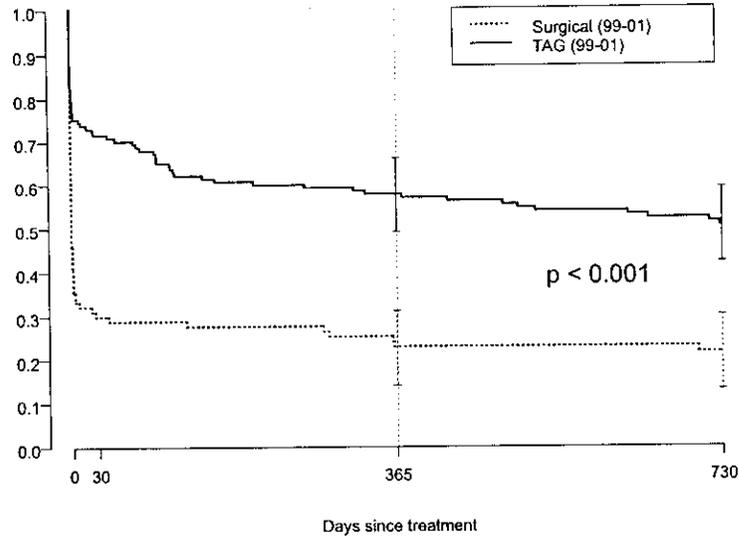


Table 10. Subjects Free of a Major Adverse Event (TAG 99-01)

Days from treatment ¹	Test (N= 140)		Control (N= 94)		Probability of remaining event-free from Day 0	
	Number event-free at start of interval	Number with event	Number event-free at start of interval	Number with event	Test	Control
[0, 30]	140	40	94	66	0.71	0.30
(30, 182]	98	15	27	2	0.60	0.27
(182, 365]	83	4	24	4	0.57	0.23
(365, 730]	76	9	19	1	0.50	0.21

¹ (lower endpoint, upper endpoint] denotes > lower endpoint and <= upper endpoint.
 Note: Column header are the number of subjects enrolled. Probability of remaining event-free is the Kaplan-Meier estimate.

Figure 4. Subjects Free of a Major Adverse Event (TAG 03-03)

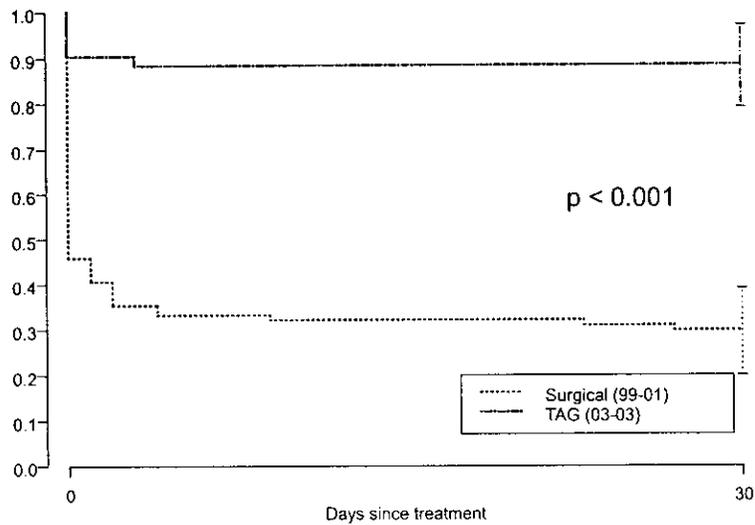


Table 11. Subjects Free of a Major Adverse Event (TAG 03-03)

Days from treatment ¹	TAG 03-03 (N= 51)		TAG 99-01 Control (N= 94)		Probability of remaining event-free from Day 0	
	Number event-free at start of interval	Number with event	Number event-free at start of interval	Number with event	TAG 03-03	TAG 99-01 Surgical
[0, 30)	51	6	94	66	0.88	0.30

¹ [lower endpoint, upper endpoint) denotes >= lower endpoint and < upper endpoint.
 Note: Column header are the number of subjects enrolled. Probability of remaining event-free is the Kaplan-Meier estimate.

Figure 5. Subjects Free of a Major Adverse Event Through 30-days Post-treatment

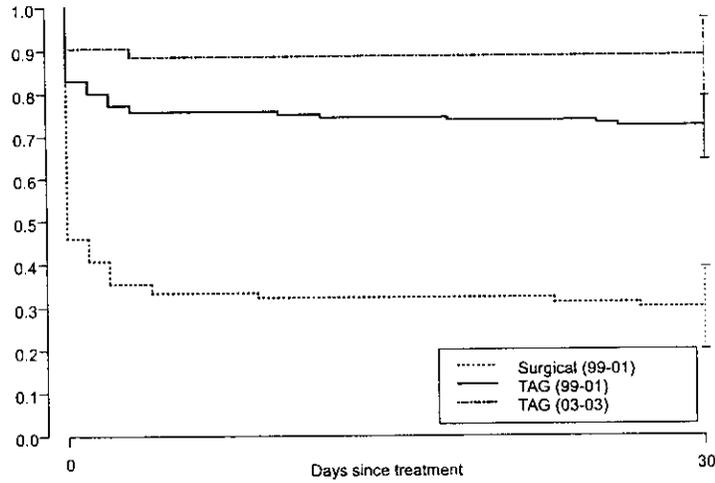


Table 12. Subjects Free of a Major Adverse Event Through 30 Days Post-treatment

Days from treatment ¹	Treatment group	Number event-free at start of interval	Number with event	Probability of remaining event-free from Day 0
[0, 30]	TAG 03-03 (N= 51)	51	6	0.88
[0, 30]	TAG 99-01 (N=139)	139	39	0.72
[0, 30]	TAG 99-01 Surgical (N=94)	94	66	0.30

Note: Probability of remaining event-free is the Kaplan-Meier estimate.
¹ [lower endpoint, upper endpoint] denotes >= lower endpoint and < upper endpoint.

Figure 6. Aneurysm-related Mortality Through 2 Years Post-treatment (TAG 99-01)

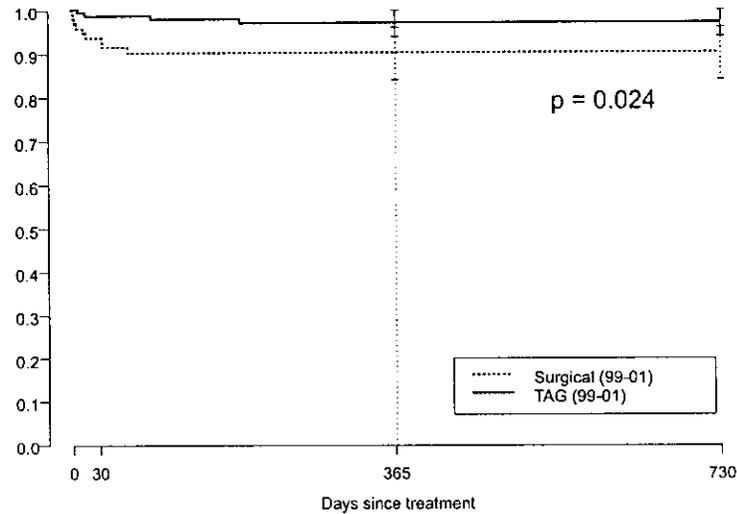


Table 13. Aneurysm-related Mortality Through 2 Years Post-treatment (TAG 99-01)

Days from treatment ¹	TAG 99-01 (N= 140)		TAG 99-01 Surgical (N= 94)		Probability of remaining alive from Day 0	
	Number alive at start of interval	Number died	Number alive at start of interval	Number died	TAG 99-01	TAG 99-01 Surgical
[0, 30]	140	2	94	6	0.99	0.94
(30, 182]	134	1	85	3	0.98	0.90
(182, 365]	120	1	66	0	0.97	0.90
(365, 730]	105	0	62	0	0.97	0.90

¹ (lower endpoint, upper endpoint) denotes > lower endpoint and <= upper endpoint.
 Note: Column header are the number of subjects enrolled. Probability of remaining alive is the Kaplan-Meier estimate.

Figure 7. All-cause Mortality Through 2 Years Post-treatment (TAG 99-01)

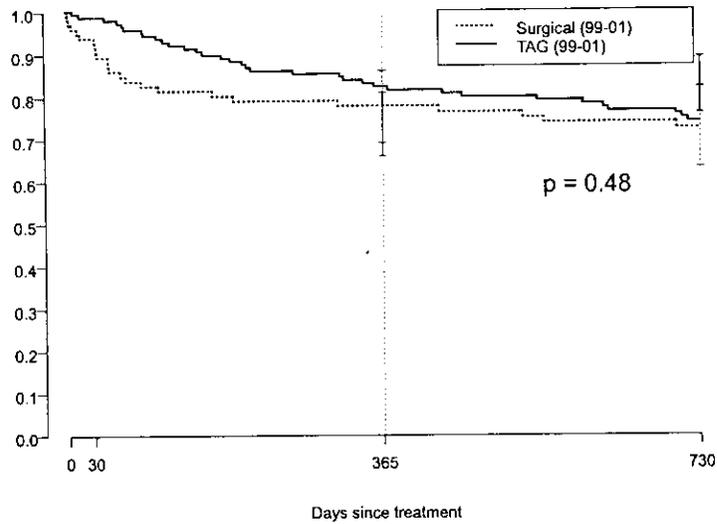


Table 14. All-cause Mortality Through 2 Years Post-treatment (TAG 99-01)

Days from treatment ¹	TAG Device (N= 140)		Surgical Control (N= 94)		Probability of remaining alive from Day 0	
	Number alive at start of interval	Number died	Number alive at start of interval	Number died	TAG Device	Surgical Control
[0, 30]	140	2	94	6	0.99	0.94
(30, 182]	134	13	85	12	0.89	0.80
(182, 365]	120	9	66	2	0.82	0.78
(365, 730]	105	10	62	4	0.74	0.72

¹ (lower endpoint, upper endpoint] denotes > lower endpoint and <= upper endpoint.
 Note: Column header are the number of subjects enrolled. Probability of remaining alive is the Kaplan-Meier estimate.

Efficacy

The primary efficacy outcome of this Pivotal Study was the proportion of subjects treated with the GORE TAG Thoracic Endoprosthesis free from a major device-related event through the 12-month follow-up visit 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 treatment groups.

An Imaging core laboratory was used as part of TAG 99-01 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. An analysis of subjects with an endoleak present at 12 months identified 2 of 7 or 29% had aneurysm enlargement.

Table 15 summarizes site and core lab findings from TAG 99-01. The difference in observed endoleaks was a result of periprocedural imaging which the core laboratory did not evaluate. The 6 additional wire-frame fractures and 1 additional migration identified by the core laboratory were not associated with clinical sequelae or reintervention. Site reported data for all other device-related events were worst case with respect to the number of events identified.

Table 15. Device-related Event Incidence: Core Lab and Site Data for Test Subjects Through the 12-month Follow-up Visit (TAG 99-01)

Device-related events	Core Lab	Site
	TAG 99-01 (N=131) n (%)	TAG 99-01 (N = 140) n (%)
Endoleak (by CT)	12/124 (10)¹	22/140 (16)
Type I	1/124 (1)	15/140 (11)
Ia (proximal)	n/a	14/140 (10)
Ib (distal)	n/a	2/140 (1)
Type II	1/124 (1)	3/140 (2)
Type III	0/124	3/140 (2)
Type IV	0/124	0/140
Indeterminate origin	10/124 (8)	4/140 (3)
Aneurysm rupture (by CT)	0/124¹	0/140
Fracture (by x-ray)²	7/126 (6)¹	1/140 (1)
Change in aneurysm diameter at 12 Month Visit from Month 1 visit (by CT)²		
Increase (≥ 5mm)	5/81 (6)	8/83 (10)
No change (increase or decrease < 5mm)	55/81 (68)	40/83 (48)
Decrease (≥ 5mm)	21/81 (26)	35/83 (42)
Prosthesis migration (by CT)⁴	2/124 (2)¹	1/140(1)
<p>Notes: Denominators are N specified for each subject period from readable scans. A subject is counted at most once in a period. Categories for endoleak are not mutually exclusive.</p> <p>¹ N at each follow-up period is the number of subjects with evaluations of the specified complication (documented presence or absence) by the indicated modality (i.e., CT or x-ray).</p> <p>² N at each follow-up period is the number of subjects with a complete data pair at both the Month 1 visit and the period indicated.</p> <p>³ All fractures identified were classified as minor</p> <p>⁴ All migrations identified were classified as minor</p>		

Tables 16 and 18 summarize all site reported device-related events. Site evaluation was used in the determination of efficacy because the study hypotheses required an evaluation of the clinical significance of device-related events (i.e., major vs minor).

Table 16 summarizes the incidence of major device-related events in the TAG 99-01 device group through the 12-month follow-up visit. The TAG Thoracic Endoprosthesis demonstrated a low rate of device complications in both TAG 99-01 and TAG 03-03 studies. Eight subjects (6%) experienced ≥ 1 major device-related event through the 12-month follow-up visit in TAG 99-01 and no subjects experienced major device-related events in TAG 03-03 through 30 days. The estimated 12-month freedom from a major device-related event was 0.94 in TAG 99-01. Only 1 additional major device-related event was reported from 12 to 24 months follow-up period of TAG 99-01. The definition of 'major' used for adverse events also applies to the device events used for the efficacy endpoint.

Table 16. Patients With Major Device-Related Events by Follow-up Periods (Site Reported)

Major device-related event ¹	Post-treatment follow-up period			
	Through Month 1 visit		> Month 1 visit to Month 12 visit	> Month 12 visit to Month 24 visit
	TAG 99-01 (N = 140) n (%)	TAG 03-03 (N = 51) n (%)	TAG 99-01 (N = 131) n (%)	TAG 99-01 (N = 100) n (%)
Any major device-related event	6 (4)	0	2 (2)	1 (1)
Endoleak	3 (2)	0	1 (1)	0
Type I	2 (1)	0	1 (1)	0
Ia (proximal)	2 (1)	0	1 (1)	0
Ib (distal)	0	0	0	0
Type II	0	0	0	0
Type III	0	0	0	0
Type IV	0	0	0	0
Indeterminate	1 (1)	0	0	0
Aneurysm rupture	0	0	0	0
Treatment-related device event	2 (1)	0	0	0
Access failure	0	0	0	0
Deployment failure	1 (1)	0	0	0
Other device complication at treatment ²	1 (1)	0	0	0
Unplanned occlusion of a branch vessel	1 (1)	0	0	0
Left subclavian	0	0	0	0
Left carotid	0	0	0	0
Celiac axis ³	1 (1)	0	0	0
Renal ³	1 (1)	0	0	0
Superior mesenteric ³	1 (1)	0	0	0
Non-specified	0	0	0	0
Lumen obstruction	0	0	0	0
Prosthesis migration	0	0	1 (1)	0
Prosthesis realignment	0	0	0	0
Fracture	0	0	0	0
Aneurysm enlargement⁴	1 (1)	0	2 (2)	1 (1)
Extrusion / erosion	0	0	0	0
Other device complication after treatment	0	0	0	0

¹ All events are based on the Sacks criteria for a major event.
² One right external iliac rupture during sheath removal.
³ Occurred in same patient.
⁴ Aneurysm enlargement is based on a change ≥ 5 mm from the Month 1 visit or the most recent scan.

Six subjects (4%) treated with the TAG Thoracic Endoprosthesis required implantation of an additional TAG Thoracic Endoprosthesis to treat the aneurysm through 1 year post-treatment. The reasons for these interventions are listed in Table 17.

Table 17: Reasons for Implantation of Additional Devices

Reason for Intervention	Number of patients
Deployment failure	1
Endoleak	1
Aneurysm Enlargement	1
Endoleak and Aneurysm Enlargement	2
Endoleak, Aneurysm Enlargement and Prosthesis Migration	1
TOTAL	6

Table 18 lists the minor device-related events for both the TAG 99-01 and TAG 03-03 device subjects. The majority of the minor device-related events in TAG 99-01 device subjects occurred in the first 30 days. Only 2% of patients experienced a minor device-related event between 1 month and 12 months and only 4% experienced a minor device-related event between 12 months and 24 months.

Table 18. Minor Device-related Events, Day 0 Through Month 24 Visit, Site-reported

Minor device-related event	Post-treatment follow-up period			
	Through Month 1 visit		> Month 1 visit to Month 12 visit	> Month 12 visit to Month 24 visit
	TAG 99-01 (N = 140) n (%)	TAG 03-03 (N = 51) n (%)	TAG 99-01 (N = 131) n (%)	TAG 99-01 (N = 100) n (%)
Any minor device-related event	22 (16)	10 (20)	2 (2)	4 (4)
Endoleak	19 (14)	6 (12)	1 (1)	2 (2)
Type I	11 (8)	4 (8)	1 (1)	0
Ia (proximal)	10 (7)	3 (6)	1 (1)	0
Ib (distal)	2 (1)	1 (2)	0	0
Type II	3 (2)	2 (4)	0	1 (1)
Type III	3 (2)	0	0	1 (1)
Type IV	0	0	0	0
Indeterminate	3 (2)	0	0	0
Treatment-related device event	4 (3)	3 (2)	0	0
Access failure	1 (1)	0	0	0
Deployment failure	0	0	0	0
Other device complication at treatment	3 (2)	3 (2)	0	0
Unplanned occlusion of a branch vessel	1 (1)	1 (1)	0	0
Left subclavian	0	0	0	0
Left carotid	0	0	0	0
Renal	1 (1)	1 (1)	0	0
Non-specified	0	0	0	0
Lumen obstruction	0	0	0	1 (1)
Prosthesis migration	1 (1)	1 (1)	0	0
Prosthesis realignment	0	0	0	0
Prosthesis material failure	0	0	1 (1)	1 (1)
Extrusion / erosion	0	0	0	0
Other device complication after treatment	0	0	0	0

Secondary Endpoints

Table 19 describes the peri-procedural secondary endpoints for TAG 99-01 and TAG 03-03 Test subjects as well as TAG 99-01 Control subjects. The GORE TAG Thoracic Endoprosthesis 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 19. Secondary Endpoints

Endpoint	TAG 03-03	TAG 99-01	TAG 99-01 Control	TAG 99-01 vs. TAG 99-01 Control p-value ¹	TAG 03-03 vs. TAG 99-01 Control p-value ¹
Blood loss during procedure (ml)	222.4 ± 198.0 (n = 51)	471.9 ± 862.7 (n = 132)	2402 ± 2719 (n = 52)		
Length of ICU stay (days)	1.2 ± 1.3 (n = 51)	2.7 ± 14.6 (n = 136)	5.2 ± 7.2 (n = 91)	< 0.001	< 0.001
Length of hospital stay (days)	4.8 ± 5.0 (n = 51)	7.4 ± 17.7 (n = 139)	14.4 ± 12.8 (n = 91)	< 0.001	< 0.001
Time to return to normal daily activities (days)	18.5 ± 15.9 (n = 42)	60.2 ± 82.7 (n = 114)	149.2 ± 201.0 (n = 51)		

¹ no test of significance due to high proportion of surgical (TAG 99-01) missing data.

Conclusions

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 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 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.

PATIENT SELECTION AND TREATMENT (SEE WARNINGS AND PRECAUTIONS)

Individualization of Treatment

Gore recommends that the GORE TAG Thoracic Endoprosthesis be used in accordance with the Sizing Table (Table 20).

- The GORE TAG Thoracic Endoprosthesis is designed to treat
 - Proximal and distal aortic neck lengths of ≥ 2.0 cm,
 - Proximal and distal aortic neck inner diameters between 23 and 37 mm.
- Differing proximal and distal neck diameters (aortic taper) outside the intended aortic diameter requirements for a single endoprosthesis diameter (Table 20) 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.

PATIENT COUNSELING INFORMATION

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

- Risks and differences between endovascular repair and open surgical repair.
- Potential advantages of open surgical repair.
- Potential advantages 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 - page 17).
- 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 - page 17).
- 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.

US 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 - page 4, and POTENTIAL DEVICE or PROCEDURE RELATED ADVERSE EVENTS - page 5). US 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 cap 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 20)
- GORE Introducer Sheath Cap (supplied with endoprosthesis)
- GORE Tri-Lobe Balloon Catheter (supplied separately)
- GORE Introducer Sheath with Silicone Pinch Valve 30 cm long of appropriate french size for the selected endoprosthesis diameter (supplied separately) (Table 20)
- Hemostatic vascular clamp with soft jaws
- 0.035" (0.89 mm) Med-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 20 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 (Fig. 8). All measurements per neck must be within one intended Aortic Inner Diameter range, as listed in Table 20. Appropriate oversizing (7-18%) is built into the recommended sizes. Therefore, do not incorporate additional oversizing in the selection of the endoprosthesis.

Table 20. Sizing Guide

Intended Aortic Inner Diameters* (ID) (mm)	Endoprosthesis Diameter ¹ (mm)	Endoprosthesis Lengths ^{1,2} (cm)	Recommended GORE Introducer Sheath Size (Fr)	Introducer Sheath Outer Diameter (OD) (mm)
23 - 24	26	10	20	7.6
24 - 26	28	10 / 15	20	
26 - 29	31	10 / 15	22	8.3
29 - 32	34	10 / 15 / 20	22	
32 - 34	37	10 / 15 / 20	24	9.2
34 - 37	40	10 / 15 / 20	24	

* Appropriate oversizing is built into the recommended sizes.

¹ All dimensions are nominal.

² A minimum of 2.0 cm 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 2.0 cm
- Aortic neck inner diameters (ID) in the range of 23–37 mm (Table 20)
- Differing proximal and distal neck diameters (aortic taper) outside the intended aortic diameter requirements for a single endoprosthesis diameter (Table 20) requires the use of multiple endoprostheses of different diameters
- Use of multiple devices with differing diameters require a treatment length of ≥ 13 cm.

Measurements to be taken during the pretreatment assessment are described below (Fig. 8):

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)

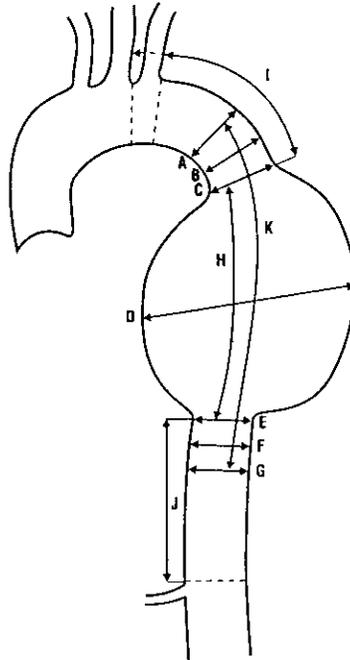
H. Length of the aneurysm measured along the greater curvature of the flow lumen

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 8. Aortic Screening Measurements

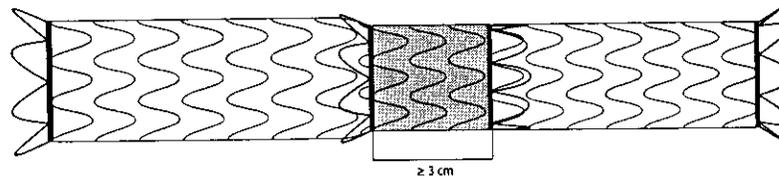


Using Multiple Devices

When multiple endoprostheses are used to compensate for aortic taper or treatment length, adhere to the sizing guide (Table 20) in conjunction with the recommended guidelines below:

- Overlapped endoprostheses in an aneurysmal section should be 1 to 2 sizes different in diameter with an overlap of at least 3 cm (gold band to gold band) (Fig. 9).
- 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 9. 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.

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

Completion of Procedure

1. 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.**
2. Perform arteriography in two views to assess exclusion of the aneurysmal segment, luminal patency of the aorta, and endoprosthesis position.
3. 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 21) 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 21. 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 ≤ 3 months prior to the procedure
² Recommended if endoleak reported at 1 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 film/image. 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.

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 22.

Table 22. CT/CTA Imaging Guidelines

CT Imaging Protocol	
Injection Volume (ml)	150
Injection Rate (cc/sec)	3-4 (through $\geq 20G$ IV)
Delay	SmarPrep1 or equivalent, 3 min 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)	≤ 3
Scan Mode	H5
Table Speed (mm/rot)	15
Interval (mm)	2
kVp	120
mA	300
Reconstruction (mm)	≤ 3
1 Baseline Location: Thoracic Aorta, RO: 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

- Through non-clinical testing, the GORE TAG Thoracic Endoprosthesis has been shown to be MRI safe under the following conditions. Testing was performed at field strengths of 1.5 Tesla or less, a maximum spatial gradient of 450 gauss/cm and whole body averaged specific absorption rate (SAR) of 1.4 W/kg for 15 minutes of MRI. The GORE TAG Thoracic Endoprosthesis should not migrate in this environment. Non-clinical testing has not been performed to rule out the possibility of stent migration at field strengths higher than 1.5 Tesla or maximum spatial gradient magnetic fields of 450 gauss/cm.
- In this testing, the 5 overlapped endoprostheses produced a temperature rise of less than or equal to 0.9°C at a maximum SAR of 1.4 W/kg for 15 minutes of MRI.
- 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 endoprosthesis.

Additional Surveillance and Treatment

Additional surveillance and possible treatment is recommended for:

- Aneurysms with Type I endoleak
- Aneurysms with Type III endoleak
- Aneurysm enlargement, ≥ 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.

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

 Attention, See Instructions for Use

 Do Not Re-Use

 Catalogue Number

 Batch Code



Contents sterile unless package has been opened or damaged.



Contents sterile unless enclosed package has been opened or damaged. Sterilized by ethylene oxide.

 Store in a cool dry place



AJ0076-EN2



W. L. Gore & Associates, Inc.
Flagstaff, Arizona 86004
USA

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800 / 942-5315 (Fax)
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www.goremedical.com

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MARCH 2005

An Endovascular Treatment for Thoracic Aortic Aneurysms
Patient Information Booklet

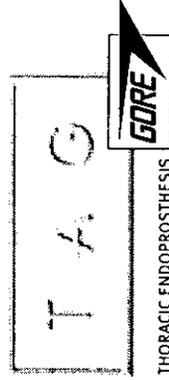


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This brochure has been provided as a courtesy by Gore & Associates (Gore). This brochure will help you learn more about risk factors, common symptoms as well as a less-invasive method of treating a thoracic aortic aneurysm (TAA). Whether you're trying to reduce your risk or supporting a loved one diagnosed with a TAA, we hope this information will be helpful for you and your family.

INTRODUCTION

A **thoracic aortic aneurysm (TAA)** is a bulge in the **aorta**, which could **rupture** with life-threatening results. If you or a loved one has this disease, you may be seeking information on how it can be treated. This brochure describes **TAA** and a relatively new way to treat them. One new treatment option is **endovascular repair** using an **endovascular graft**.

For your convenience, we have included a **Glossary of Medical Terms** on page 11 and space in this brochure on page 15 to jot down questions to discuss with your doctor. Words that are **BOLD** throughout the text can be found in the Glossary of Medical Terms.

This brochure is an informational and referral guide only, and is not intended to diagnose a medical condition. As with any surgery or medical procedure, the best resource for information and advice is your doctor.

WHAT IS A TAA?

A **TAA** is the swelling or ballooning of the thoracic aorta. The **aorta** is the main artery that carries oxygen-filled blood from the heart to all parts of the body. In the thorax (chest), once leaving the heart, blood travels upward through the ascending aorta turning into the **aortic arch** branching into the **innominate**, carotid and subclavian arteries. These branch vessels carry blood to the heart muscle, arms, shoulders, chest, neck, face, and head (including brain). Once past the **aortic arch**, the **aorta** turns downward turning into the **descending aorta** and carries blood to the intercostal arteries, spinal arteries, and ultimately other lower organs and areas of the body (see Figure 1).

An **aneurysm** is a ballooning of the **aorta** that results from a weakened section in the artery (see Figure 2).

While the thoracic aorta's diameter normally ranges from 1 to 1.5 inches (2 - 4 cm), an **aneurysm** can cause it to grow to several times its normal size. This condition, if not treated, could result in a **rupture** (bursting) of the **aorta** leading to internal bleeding.

The risk of **rupture** increases with **aneurysm** size and high blood pressure. Ruptured aneurysms are frequently fatal.

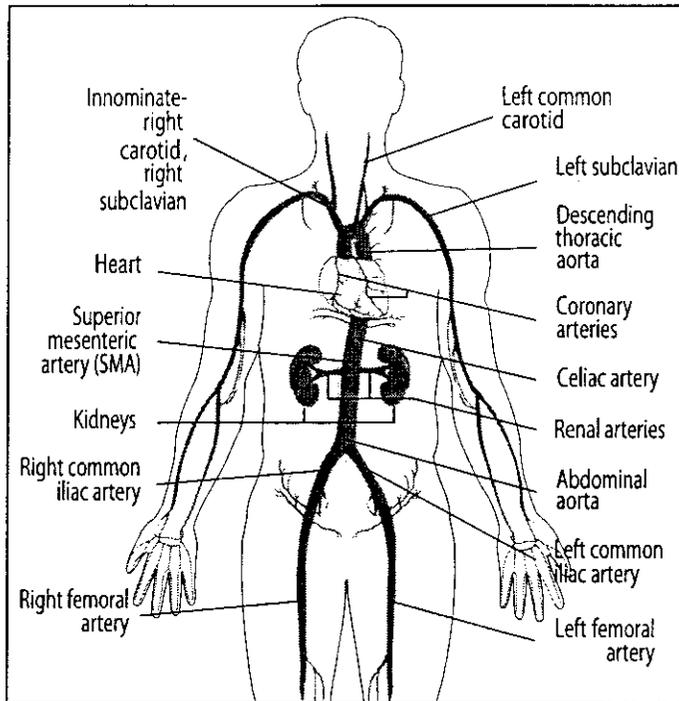


Figure 1

The **aorta** is the main artery that carries oxygen-filled blood from the heart. It is the largest artery in the body, starting in the chest, with branches into the arm, neck, head, and extending down to the abdomen where it then branches into the **iliac arteries** and into the legs.

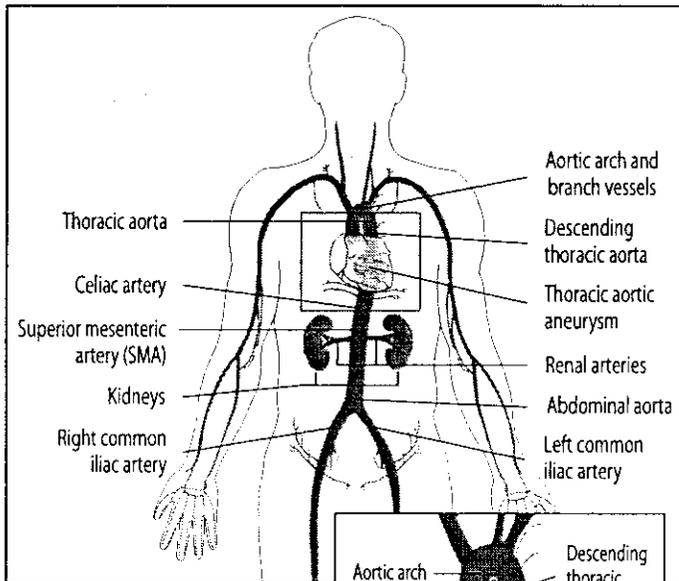


Figure 2

An **aneurysm** is the ballooning of the thoracic aorta. The weakened sections of the aortic wall may **rupture** (burst).

WHAT ARE SOME OF THE SYMPTOMS OF A TAA?

Many people do not experience any symptoms of a **TAA**. Because of this, it is very important to speak with your doctor about your risk of having or developing **TAA** disease. When symptoms do occur, pain is most commonly experienced. This can occur in the chest or back area, shoulders, neck and abdomen. Some patients describe the pain as anything from mild to severe, or a tenderness in the mid or upper chest, back or shoulders. Again, many people may not experience any of these symptoms, yet still be found to have a **TAA**. Your doctor may discover a **TAA** during a routine physical exam. Most often, **aneurysms** are found during a medical test such as a **CT** (Computed Tomography or CAT scan), **MRI** (Magnetic Resonance Imaging Scan) or cardiac catheterization (**angiogram**) procedure.

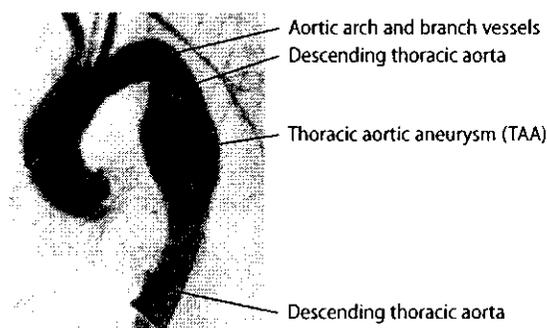


Figure 3
An angiogram of a TAA.

Your doctor may also recommend an **angiogram** (see Figure 3), or additional testing such as **CT** (Computed Tomography or CAT scan), **MRI** (Magnetic Resonance Imaging), or **IVUS** (Intravascular Ultrasound) to determine the precise location, size and shape of the **aneurysm** and your surrounding arteries.

WHAT CAUSES A TAA?

Over time, the weakening of the **aorta** due to vascular disease, injury (trauma), or a genetic (hereditary) defect of the tissue within the arterial wall can cause a **TAA**.

Continuous blood pressure against this weakened area can result in the ballooning (enlarging and thinning) of the aortic artery.

Risk factors for developing an **aneurysm** include heredity (family history), smoking, heart disease, high blood pressure, and high fat diet. Most doctors will advise simple preventative measures such as keeping your blood pressure under control, quitting smoking, reducing cholesterol in your diet and appropriate exercise. These lifestyle changes could also aid in preventing problems in the future.

If you are at risk for developing or have an **aneurysm**, your doctor may recommend periodic screening. This is commonly done with a simple physical exam and possibly a **CT Scan** or **transesophageal ultrasound (TEU)**. Your doctor may also prescribe medication to lower your blood pressure.

HOW DO DOCTORS TREAT A TAA?

The size and location of the **TAA** and your general health will determine how your **aneurysm** should be treated. When the **aneurysm** is small, your doctor may only recommend periodic check-ups to monitor the **aneurysm**. However, a larger, or rapidly growing (expanding) **aneurysm** poses more risk of bursting (**rupture**), and may require treatment.

Two procedural options are available if your doctor feels treatment is necessary; open surgical repair or **endovascular repair**.

WHEN TREATMENT BECOMES NECESSARY, WHAT ARE MY TREATMENT OPTIONS?

Medical Management -

Medical management is the first choice for treatment, including reducing blood pressure and minimizing other risk factors. Medical management usually includes keeping your blood pressure under control, quitting smoking and reducing cholesterol in your diet.

Open Surgical Repair -

Open surgical repair is an operation to remove the **TAA** when it is considered dangerous and at risk for **rupture**. During this type of operation, the doctor makes an incision (cut) in the chest (front or side) and repairs the **aorta** by replacing the diseased section (**aneurysm**) with a **synthetic graft** (tube) that is sewn into place with sutures. This procedure requires stopping the flow of blood through the **aorta** while the graft is being put into place. Open surgical repair is typically performed under general anesthesia and takes about 2 to 4 hours to complete. Patients usually spend some time in the intensive care unit (ICU) and another several days in the hospital for early recovery. Depending on how quickly your body heals and any other associated health issues, hospitalization and recovery time may take about 3 to 6 months. Currently, medical management and open surgical repair are standard of care for **TAA** and are proven medical therapies. However, both therapies have their limitations. Medical management does not fix the **aneurysm**, just reduces the stresses (i.e., blood flow pressure) on the **aneurysm**. Although open surgical repair is a proven treatment, not all patients can tolerate this major operation. Ask your doctor about the risks associated with an open procedure as they relate to your overall health condition.

Endovascular Repair -

Endovascular repair is a relatively new procedure for the treatment of **TAA**. Less invasive than open surgery, it involves excluding (sealing off) the **aneurysm** by placing an **endovascular graft** inside of the diseased **aorta**, re-lining and making a new path for blood flow. The **endovascular graft** (e.g., GORE TAG Thoracic Endoprosthesis) remains inside the **aorta** permanently through the use of a metal stent creating a tight fit and seal against the wall of the **aorta**. **Endovascular repair** may be performed under general, regional or local anesthesia. The procedure typically takes 1 to 3 hours to complete. Patients may

have a hospital stay of only a few days and can usually return to normal activity within 2-6 weeks after the procedure.

The endovascular procedure does require regular and routine follow-up visits with your doctor. Tests are performed to evaluate and monitor success of the treatment over time.

Please see the follow-up section on page 9 for further information. Not every patient is a candidate for **endovascular repair**. With this in mind, please check with your doctor to see if you are a candidate. If you would like to learn more about **TAA**, types of therapy, or more information about the GORE TAG Endoprosthesis, visit the websites listed on page 13.

WHAT IS THE GORE TAG THORACIC ENDOPROSTHESIS?

The GORE TAG Thoracic Endoprosthesis is an implantable device positioned by a **delivery catheter**. The **endovascular graft** is intended to exclude (seal off), the **aneurysm** by placing the **endovascular graft** inside the diseased **aorta** to make a new path for the blood to flow.

The GORE TAG Thoracic Endoprosthesis is a device that allows for **endovascular repair** of a **TAA**. The **endovascular graft** is a 1-piece, tube-shaped stent-graft that re-lines the **aorta** and extends from as high as the **aortic arch**, to as low as the abdomen above the celiac artery. The GORE TAG Thoracic Endoprosthesis is made of ePTFE (expanded polytetrafluoroethylene), with an outer metallic support structure known as a stent.

One or more GORE TAG Thoracic Endoprostheses would be placed in your thoracic aorta. The devices are placed to fit above, across and below the **aneurysm** portion of the **aorta** (see Figures 4, 5 and 6).

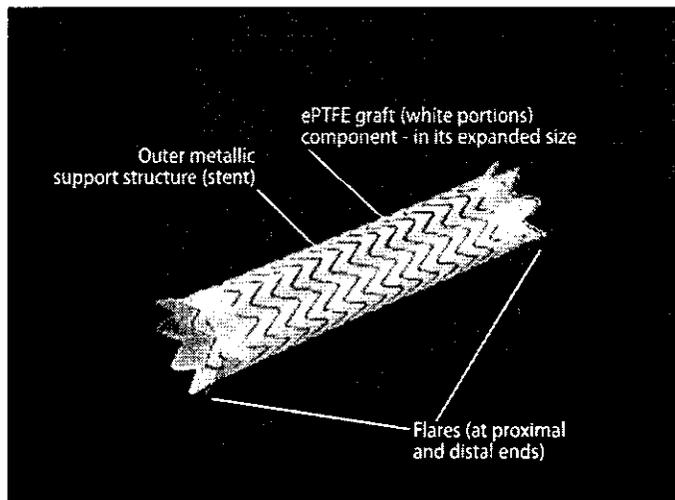


Figure 4
GORE TAG Thoracic Endoprosthesis

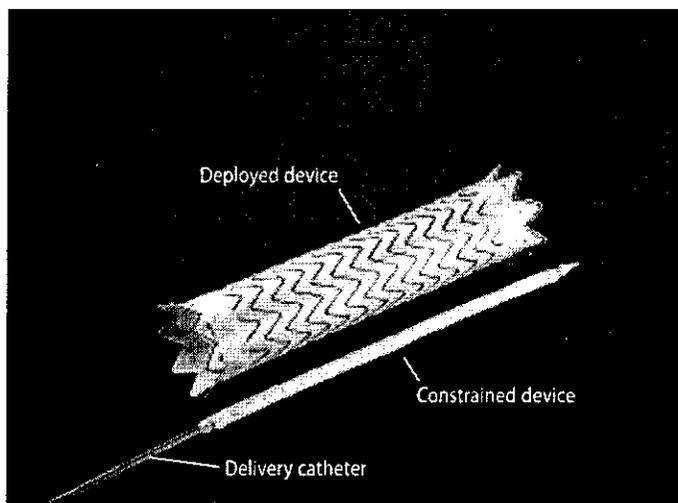


Figure 5
GORE TAG Thoracic Endoprosthesis (on and off delivery catheter)

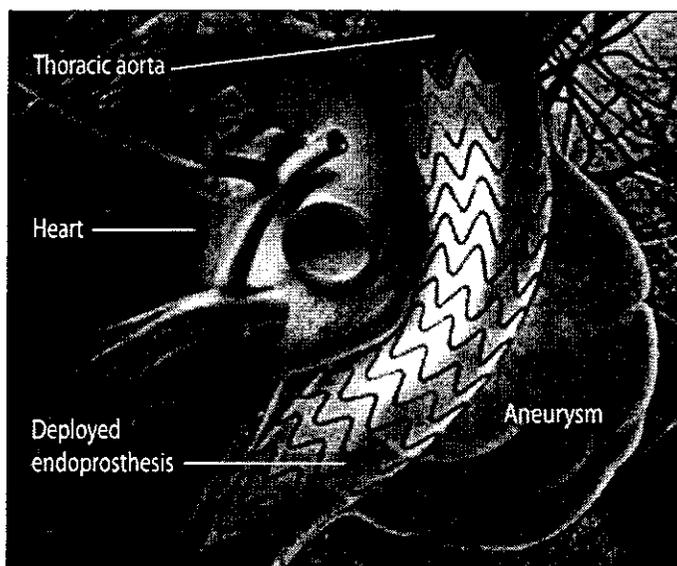


Figure 6
Artist's rendition of the delivery of a GORE TAG Thoracic Endoprosthesis allowing for endovascular repair of a TAA.

WHAT IS THE GORE TAG THORACIC ENDOPROSTHESIS (continued)?

Each **endovascular graft** is compressed into the end of a long, thin, tube-like device called a **delivery catheter**. The **delivery catheter** is used to deliver the **endovascular graft** at the **TAA** by making a small incision through an artery in the groin.

Diagnostic measurements (**CT, MRI, angiography** and **IVUS**) of the **aorta** prior to the procedure allow your doctor to visualize the **aneurysm** and your arteries to select the proper size of **endovascular graft** to fit your anatomy.

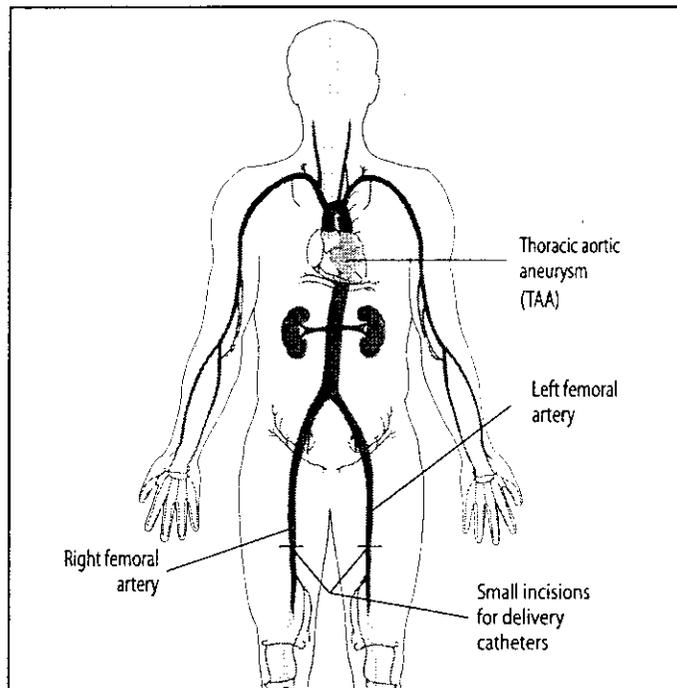


Figure 7
Insertion sites of **delivery catheters** for placement of GORE TAG Thoracic Endoprosthesis.

WHAT IS THE GORE TAG THORACIC ENDOPROSTHESIS PROCEDURE?

The GORE TAG Thoracic Endoprosthesis procedure consists of the implantation of a TAG Endoprosthesis to exclude a **TAA**. The **endovascular graft** is implanted using **fluoroscopy** (real-time x-ray images) viewed on a monitor in these steps:

1. A **delivery catheter** is inserted into the **femoral** or **iliac artery** through a small incision (cut) in the groin and carefully guided up the leg artery through the abdomen into the chest (near the heart) to the site of the **TAA** (Figure 7).
2. Once the **endovascular graft** is correctly positioned in the **aorta** (across the **aneurysm**), it is released or deployed from the **delivery catheter**.

3. The device self-expands inside the **aorta** to the diameter of your **aorta**. The placement of the **endovascular graft** is designed to exclude (seal off) the **aneurysm** and reline the artery wall.
4. The **delivery catheter** is withdrawn from the body.
5. Following deployment, an additional step is performed. This step is a ballooning of the device, which aids in sealing/seating of the device in the **aorta**.

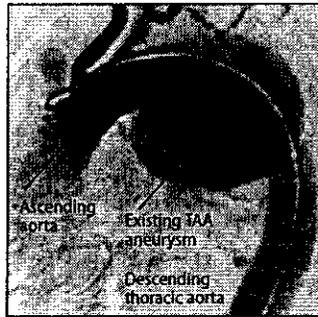


Figure 8a Pre-Op TAA

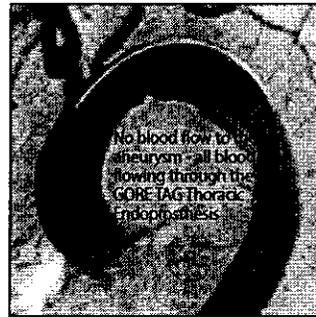


Figure 8b Post-Op TAA

These steps are the same for each device. At the end of the procedure, your doctor will confirm the position of the device and exclusion of blood flow to the **aneurysm** by using x-ray **angiography** (see Figures 8a and 8b). The doctor will then be able to determine whether the **aneurysm** has been successfully excluded before closing up the incision in each leg with a few sutures.

WHAT FOLLOW-UP EVALUATIONS WILL I HAVE?

Currently, follow-up is advised to include check-ups at 1 month, 6 months, 12 months and annually thereafter. It is very important that you go to all follow-up visits recommended by your doctor.

The follow-up exams will consist of routine x-rays, **CT Scans** and a physical exam. The exams may also include blood tests and **ultrasound** or **MRI** scans if other imaging methods are necessary. These follow-up exams carry some minimal risk, which should be discussed with your doctor. There is a rare risk of allergic reactions related to the **contrast (dye)** used in these **CT Scans**. Please ask your doctor if you have any concerns regarding these tests and exams.

These tests and exams are performed because they are necessary in evaluating the outcome of your treatment and any changes over time. Your doctor may also request additional evaluations based on findings at the follow-up visits. These may include finding a return of blood flow in the **aneurysm** and/or growth of the **aneurysm**. This type and frequency of follow-up visits are generally not required after open surgical repair.

WHEN SHOULD I CALL MY DOCTOR?

The long-term safety and effectiveness of **endovascular repair** has not been established. Some patients may require additional treatment for conditions such as:

Endoleak – An **endoleak** occurs when blood from the **aorta** continues to leak into the **thoracic aneurysm**. While most **endoleaks** do not cause any medical problem, a small number require additional treatment.

Aneurysm growth or rupture – Symptoms of **aneurysm** growth are not always present, but when they are, the most common symptom is pain, also numbness, and weakness in the legs, back, chest, or abdomen. **Aneurysm rupture** symptoms include dizziness, fainting, rapid heartbeat or sudden weakness.

Vessel occlusion – Symptoms include pain, numbness or weakness in the arm(s), hip(s) or leg(s), or discoloration or coolness of the arms(s), hand(s) or leg(s).

PATIENT COUNSELING INFORMATION

You and your doctor should review the following risks and benefits when discussing the **endovascular graft** and procedure:

- Risks and differences between **endovascular repair** and open surgical repair.
- Potential advantages of traditional open surgical repair.
- Potential advantages of **endovascular repair**.
- Potential risks of **endovascular repair** including; vascular trauma, **endoleak**, continued **aneurysm** growth, and device movement, etc.
- The possibility that additional endovascular treatment or surgery may be required after initial **endovascular repair**.

In addition to the risks and benefits of an **endovascular repair**, your doctor should consider your commitment and compliance to post-operative follow-up as necessary to ensure continuing safe and effective results.

In such cases, your doctor may recommend outpatient procedures and/or surgery. As with any surgery or medical procedure, there are potential complications with the treatment of a **TAA**. Discuss the risks and benefits with your doctor, and refer to this brochure for basic information. Contact your doctor immediately if you should experience any symptom potentially associated with your **TAA**. Remember, symptoms are not always present, but when they are, the most common symptom is pain, occurring in the chest, back, neck shoulders or abdominal area.

GLOSSARY OF MEDICAL TERMS

Aneurysm

A ballooning (enlarging and thinning) of a weakened area of a blood vessel.

Angiography/Angiogram

A method whereby dye is injected into the bloodstream to view blood flow through the blood vessels under x-ray. Utilizes contrast (dye) and small radiation exposure. The resulting image is an angiogram.

Aorta

The main artery that carries blood away from the heart to the rest of the body. It is the largest artery in the body.

Aortic Arch

A part of the main artery (aorta) that connects the ascending aorta with the descending aorta. Contains three branches: innominate, left common carotid and left subclavian arteries (see Figure 1).

Ascending Aorta

An artery that starts at the origin in the upper surface of the left ventricle (left side of the heart). It passes upward and turns into the arch of the aorta (see Figure 1).

Catheter

A slender, hollow, flexible tube that is inserted into the body.

Contrast (dye)

A drug injected into the vascular system to show blood flow through the blood vessels on the x-ray image and/or CT scan.

CT Scan (Computed Tomography Scan)

A computerized axial tomography scan is more commonly known by its abbreviated name, CAT scan or CT scan. It is an x-ray procedure that often utilizes contrast (dye) and combines many x-ray images with the aid of a computer to generate cross-sectional views and, if needed, three-dimensional images of the internal organs and structures of the body.

Delivery Catheter

A long, thin, tube-like tool that assists in the positioning and delivering of an endovascular graft through the vascular system. Also referred to as a catheter.

Descending Aorta

The descending aorta is part of the main artery (aorta) that starts at the aortic arch and runs down through the chest and the abdomen. The descending aorta starts after the arch of the aorta and ends by splitting into two great arteries (the common iliac arteries) that go to the legs. The descending aorta, by convention, is subdivided into the thoracic aorta and the abdominal aorta. The thoracic aorta, the part of the aorta that runs from the arch of the aorta to the diaphragm, gives off numerous branches that supply oxygenated blood to the chest cage and the organs within the chest.

Dilatation

The increase in size of a blood vessel.

Endoleak

Unwanted blood flow into the aortic aneurysm after placement of an endovascular graft.

Endoprosthesis

See definition under endovascular graft.

Endovascular Graft

A synthetic graft implanted within a diseased vessel intended to relieve weakened vessel walls without the use of open surgery techniques. Endovascular grafts are delivered to the diseased aorta at a small size and then are deployed or expanded to the size of the vessels in which it is placed. Also referred to as an endoprosthesis.

Endovascular Repair

Considered to be less invasive than open surgery, it involves the use of an endovascular graft to exclude (seal off) an aneurysm inside a diseased aorta, making a new path for blood to flow.

Through this technique, physicians can treat certain conditions through the skin that might otherwise require surgery.

Endovascular Treatment

The use of real time x-rays and guidewires to treat unhealthy arteries with an endovascular device delivered through small incisions in the iliac or femoral arteries.

Femoral Arteries

Two arteries located in each leg which carry blood to the femoral or thigh region of each leg. Doctors gain access to the iliac arteries and the aorta through the use of the femoral arteries (see Figure 7).

Fluoroscopy

A real time x-ray imaging method that helps physicians gain access to the vasculature and guide endovascular devices to their intended treatment area.

Guidewire

A long, flexible wire that is placed in an artery to track (or guide) a delivery catheter and other endovascular accessories used to implant an endovascular graft.

Iliac Arteries

Two arteries that deliver blood to the legs and connect the aorta to the femoral arteries in each leg. The iliac arteries begin from the bifurcation (separation) of the aorta, which occurs in your abdomen.

Innominate Artery

This is the first vessel to branch off the aortic arch. It divides into the right subclavian artery, which provides blood to the right arm and other areas, and the right common carotid artery which supplies blood to the right side of the head and neck (see Figure 1).

IVUS (Intravascular Ultrasound)

An ultrasound probe on a delivery catheter placed inside your arteries to see the vessel walls and measure diameters and lengths of your arteries.

Left Common Carotid Artery

One of the main branches off the aortic arch that supplies blood to the left side of the head and neck (see Figure 1).

Left Subclavian Artery

Provides blood for the left arm and portion of the thoracic area (see Figure 1).

MRI (Magnetic Resonance Imaging)

A procedure using magnetic fields and radio waves to form an image of structures inside the body.

Occlusion

The blocking of an artery, causing the stoppage of normal blood flow.

Radiation

A form of energy that allows your doctor to see blood vessel structures and other anatomy inside your body.

Rupture

A tear in the vessel wall near or at the location of the ballooning (enlarging and thinning) of the weakened area of the blood vessel allowing blood to leak into the areas around the heart, lungs or abdomen (hemorrhage).

Synthetic Graft

A man-made material in tube form intended to replace diseased human vessels.

Thoracic Aortic Aneurysm (TAA)

A ballooning (enlarging and thinning) of the aorta due to a weakening in the arterial wall that occurs in the chest area. This term is often abbreviated as "TAA".

Transesophageal Ultrasound (TEU)

Transesophageal Ultrasound is a useful tool used to evaluate the function and small detailed structures of the heart and associated vessels.

Transesophageal Ultrasound Examination

The TEU procedure uses ultrasound waves to produce images of the heart and aorta. Performing a TEU involves passing a tube into the esophagus.

Ultrasound

An image created through the use of high-frequency sound waves.

WHERE CAN I GET MORE INFORMATION?**Background Information on Thoracic Aneurysms**

<http://www.emedicine.com/emerg/topic942.htm>

<http://www.emedicine.com/MED/topic2783.htm>

<http://www.heartcenteronline.com/myheartdr/home/index.cfm>
(search - Aneurysm Center)

http://my.webmd.com/webmd_today/home/default.htm
(search - aneurysm)

American Heart Association

www.americanheart.org

Founded in 1924, today the American Heart Association is the largest voluntary health organization fighting cardiovascular diseases and stroke.

Mayo Clinic

www.mayoclinic.com/home

MayoClinic.com is the latest chapter in a long and successful consumer health publishing history of the Mayo Clinic. This presence on the web is a natural extension of Mayo's long-standing commitment to provide health education to patients and the general public.

Interventional Therapy**Society of Interventional Radiology**

www.sirweb.org

The Society of Interventional Radiology (SIR) is a professional society for doctors who specialize in interventional or minimally invasive procedures. SIR is a non-profit, national scientific organization deeply committed to its mission to improve health and the quality of life through the practice of cardiovascular and interventional radiology.

US National Library of Medicine

www.medlineplus.gov

The National Library of Medicine (NLM), on the campus of the National Institutes of Health in Bethesda, Maryland, is the world's largest medical library. The Library collects materials in all areas of biomedicine and health care, as well as works on biomedical aspects of technology, the humanities, and the physical, life, and social sciences.

Product Information**W. L. Gore & Associates, Inc.**

www.goremedical.com

The Gore Medical Products Division provides creative healing solutions to complex medical problems and provides such products as synthetic vascular grafts, interventional devices, surgical patches for hernia repair, and sutures for use in vascular, cardiac, general surgery and orthopedic procedures. With over 12 million implants, these devices have been saving and improving the quality of lives worldwide for 30 years.

US Department of Health and Human Services**Food and Drug Administration**

www.fda.gov

A US government agency intended to promote and protect the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after they are in use.

QUESTIONS FOR MY DOCTOR

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