

GORE TAG® Thoracic Endoprosthesis

Abstract

This annual clinical update provides a review of the ongoing experience with the GORE TAG® Thoracic Endoprosthesis. There have been more than 25,000 GORE TAG® Devices distributed worldwide as part of our IDE clinical trials and commercial experience through January 4, 2008. Results from our Pivotal (TAG 99-01), Confirmatory (TAG 03-03), and Treatment IDE (TAG 04-02) clinical studies, as well as our worldwide commercial experience are provided in this update. These results continue to support the treatment of descending thoracic aortic aneurysms with the GORE TAG® Thoracic Endoprosthesis.

Compared to open surgical repair, patients treated with the GORE TAG® Device have a consistently lower incidence of major adverse events (37% freedom from major adverse events in the Pivotal Study Test patients vs. 21% freedom from major adverse events in Pivotal Study Control patients through five years post-treatment) and improved aneurysm-related survival (96% freedom from aneurysm-related death among Pivotal Study Test patients vs. 88% for Pivotal Study Control patients through five years). Combined data from the Pivotal Study (five-year follow-up), Confirmatory Study (three-year follow-up), and Treatment IDE (two-year follow-up) test patients reveal a migration incidence of 0.4%, additional implantation incidence of 1.8%, rupture incidence of 1.1%, and a conversion incidence of 1.1%.

Worldwide commercial experience of approximately 25,000 GORE TAG® Devices continues to demonstrate a low incidence of reported adverse events and a successful treatment option for the repair of the descending thoracic aorta (DTA). This experience has identified 9 post-procedure ruptures of the descending thoracic aorta, 42 post-procedure conversions to surgical repair, 112 aneurysm-related deaths, 11 reported post-procedural migrations, 28 patients that experienced paraplegia or paraparesis, 32 patients with stroke, 95 device compressions, 45 devices with reported fractures, and 7 devices with deployment anomalies.

Long-term clinical data contained in this report, combined with the lower operative mortality and morbidity that have previously been reported, confirm that the GORE TAG® Device remains a safe and effective device in the treatment of thoracic aortic aneurysms.

Introduction

W. L. Gore & Associates, Inc. (Gore) Medical Products Division is pleased to provide this Annual Clinical Update of the ongoing clinical experience for this device. This report provides results from our Pivotal, Confirmatory, and Treatment IDE studies, as well as information from our worldwide commercial experience, which continue to indicate that the GORE TAG® Device is a safe and effective therapy option in the treatment of aneurysms of the DTA. Since its introduction in 1997, the GORE TAG® Device has proven to be effective in preventing aneurysm rupture. Additionally, it has provided patients with a means of aneurysm repair with far less morbidity and a faster return to normal activity than open surgical repair.

We are providing this information to assist you in making informed treatment decisions for thoracic aortic aneurysm patients and for you to share with your patients, referring

physicians, and hospital colleagues. Gore will provide an update to this report on an annual basis.

This report is divided into three sections.

- Section I includes the clinical results of the completed Pivotal Study through five years, the ongoing Confirmatory Study through three years, and the ongoing Treatment IDE through two years. All data are site-reported unless otherwise indicated.
- Section II includes a summary of Gore's worldwide commercial experience, in which approximately 25,000 devices have been distributed since 1997.
- Section III provides summaries of the data contained in Sections I and II as well as conclusions and information about patient selection and adverse event reporting.

Data contained in this document are current as of January 4, 2008.

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Device Description

The GORE TAG® Device is a flexible, self-expanding endoprosthesis that is constrained on the leading end of a delivery catheter. Endoprosthesis sizes range in diameter from 26 mm to 45 mm* and in length from 10 cm to 20 cm. The constrained profile of these devices on a delivery catheter ranges from 20 Fr to 24 Fr. The endoprosthesis consists of an expanded polytetrafluoroethylene (ePTFE) tube reinforced with ePTFE / FEP (fluorinated ethylene propylene) film and an external nitinol wire supporting structure that is attached circumferentially along the entire surface of the graft with ePTFE / FEP bonding tape. A circumferential PTFE sealing cuff is located on the external surface of the endoprosthesis at the base of each flared end to enhance sealing of the endoprosthesis to the wall of the aorta. In order to facilitate accurate endoprosthesis placement, two radiopaque gold bands

are attached to the graft at the base of each flared end. A sleeve constructed of ePTFE / FEP film constrains the endoprosthesis on the delivery catheter and is sewn closed using an ePTFE deployment line. The sleeve remains in situ between the endoprosthesis and the vessel wall following deployment. To deploy the endoprosthesis, the deployment knob on the catheter hub is turned and pulled, which removes the deployment line from the constrained endoprosthesis with unlacing initiating in the middle of the endoprosthesis and simultaneously extending toward both ends. This brief description of the device and its construction will facilitate interpretation of the clinical results in this report.

*Product listed may not be available in all markets pending regulatory clearance. The 45 mm GORE TAG® Device, treating internal diameters of 37 – 42 mm, is available in the US for investigational use only.

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Section I - Clinical Study Experience

Detailed clinical results for Pivotal (TAG 99-01), Confirmatory (TAG 03-03), and Treatment IDE (TAG 04-02) studies are included in this section. All data are site-reported unless otherwise indicated. The results from additional clinical studies are not included as explained below.

A summary of each clinical study is provided below.

Feasibility Study (TAG 97-01)

The Feasibility Trial (TAG 97-01) was the first clinical trial using the GORE TAG® Device at two investigational sites where 28 patients were enrolled. This non-controlled trial was designed to evaluate the safety of the device for treatment of patients with DTAs. The Feasibility Study demonstrated that the GORE TAG® Device and delivery system functioned as designed and warranted further investigation in a larger controlled pivotal study. This initial clinical use of the device also provided valuable testing of study parameters that were developed based on preclinical data. Data from the Feasibility Trial is not included in this report due to differences in study design and reporting requirements that result in the lack of poolability of this data.

Pivotal Study (TAG 99-01)

The Pivotal Study (TAG 99-01) was a non-randomized multicenter (17 sites) study comparing standard open surgical repair (Control, n = 94) to endovascular treatment using the GORE TAG® Device (Test, n = 140) in the treatment of aneurysms of the DTA. The primary endpoint compared major adverse event incidence between the Test and Control groups through one year post-treatment. Enrollment began in September 1999 and was completed in May 2001. Annual follow-up through five years post-treatment was completed in 2006. The study closed in June 2007. During the Pivotal Study, spine wire fractures were noted in a number of devices. The GORE TAG® Device was modified by removing the longitudinal spine wire and including a low permeability film layer to provide longitudinal stiffness for deployment accuracy and to minimize the potential for aneurysm expansion.

Confirmatory Study (TAG 03-03)

The Confirmatory Study (TAG 03-03) was designed to confirm the clinical performance of the GORE TAG® Device after the design modifications in response to the spine wire fractures. This study was a non-randomized multicenter (11 sites) study. The primary endpoint compared major adverse event incidence between the Test group (n=51) and the Pivotal Study Control group through 30 days post-treatment. Patient enrollment began in January 2004 and was completed in June 2004. Five-year follow-up is ongoing.

Complex Pathology Trial (TAG 04-01)

The Complex Pathology Trial (TAG 04-01) was a non-randomized multicenter study comparing open surgical repair (as reported in contemporary peer-reviewed literature) to endovascular treatment (GORE TAG® Device, n=59) in the treatment of complex pathologies of the DTA. Complex pathologies included ruptured

aneurysm of the DTA (n=20), traumatic aortic transection (n=20), and acute complicated type B dissection (n=19). The primary endpoint compared mortality and paraplegia incidence between the Test and Control groups through 30 days. The trial was initiated in 2004 and enrollment was completed in February 2007. Five-year follow-up is ongoing. This study is still under review by the FDA, therefore, data from this study are not included in this report.

Treatment IDE (TAG 04-02)

The Treatment IDE (TAG 04-02) was designed to provide clinical investigators access to the GORE TAG® Device while Gore awaited FDA approval. Eighty patients were enrolled at 13 sites under identical enrollment criteria to the Pivotal and Confirmatory Studies. Enrollment began in July 2004 and was completed in April 2005. Treatment IDE patients were followed per the Investigators' standard of care which was not defined in the protocol. Therefore, follow-up visits and associated imaging may not be available for Treatment IDE patients at all intervals.

Post-Approval Study (TAG 05-02)

The Post-Approval Study (TAG 05-02) is a non-randomized, multicenter (25 sites) study evaluating the long-term performance of the GORE TAG® Device in the primary treatment of DTA aneurysms and assessing the Physician Training Program. Long-term performance of the device will be evaluated by demonstrating that aneurysm-related death for patients treated with the GORE TAG® Device is not inferior to patients treated with open surgical repair. In addition, a subset of major adverse events including stroke, paraplegia, reintervention, and aneurysm-related death will be evaluated in patients treated with the GORE TAG® Device (n = 150) as compared to the open surgical control group from the TAG 99-01 study. This study was initiated in 2005 and completed enrollment in February of 2008. Five-year follow-up is ongoing. This study had not completed enrollment by the time of this report (January 4, 2008), therefore, data from this study are not included in this report.

45 mm GORE TAG® Device Study (TAG 06-02)

The 45 mm GORE TAG® Device Study (TAG 06-02) is a non-randomized multicenter study designed to assess the safety and efficacy of the 45 mm GORE TAG® Device (n=35) as compared to TAG 99-01 open surgical control group when used for the primary treatment of aneurysms of the DTA. Patient enrollment for TAG 06-02 began in February 2007 and is ongoing, therefore, data from this study are not included in this report.

Clinical Study Experience

Patient Accountability

Table 1 provides the patient disposition for Test and Control patients enrolled in the Pivotal Study (TAG 99-01), Confirmatory Study (TAG 03-03), and Treatment IDE (TAG 04-02) Test patients. Available patients are defined as those that are alive and participating in the study for that follow-up period. Patients in the Pivotal Study have completed their fifth and final year of follow-up. Confirmatory Study and Treatment IDE patients are in their third and second year of follow-up, respectively. For a given study period, data presented include the number of patients eligible for follow-up (e.g., number eligible from previous period minus patient deaths, patients discontinued or not yet due for their next follow-up visit).

Table 1: Patient Compliance and Disposition by Study Period

Study Period	Follow-Up Compliance			Events Prior to Next Interval			
	Eligible for Follow-Up	Patients with Visit in Window ^a	With CT ^a	With X-Ray Performed ^a	Death ^a	Discontinued ^a	Not Due for Next Follow-Up ^a
99-01 Open Surgical Control							
1 Month	94	93 (98.9%)	27 (28.7%)	72 (76.6%)	13 (13.8%)	0 (0.0%)	0 (0.0%)
6 Months	81	62 (76.5%)	18 (22.2%)	14 (17.3%)	6 (7.4%)	1 (1.2%)	0 (0.0%)
12 Months	74	54 (73.0%)	34 (45.9%)	8 (10.8%)	4 (5.4%)	1 (1.4%)	0 (0.0%)
24 Months	69	48 (69.6%)	27 (39.1%)	11 (15.9%)	5 (7.2%)	18 (26.1%)	0 (0.0%)
36 Months	46	29 (63.0%)	20 (43.5%)	2 (4.3%)	0 (0.0%)	6 (13.0%)	0 (0.0%)
48 Months	40	29 (72.5%)	21 (52.5%)	5 (12.5%)	2 (5.0%)	9 (22.5%)	0 (0.0%)
60 Months	29	24 (82.8%)	15 (51.7%)	4 (13.8%)	1 (3.4%)	1 (3.4%)	—
99-01 GORE TAG® Device							
1 Month	140	140 (100.0%)	123 (87.9%)	130 (92.9%)	3 (2.1%)	3 (2.1%)	0 (0.0%)
6 Months	134	117 (87.3%)	108 (80.6%)	83 (61.9%)	16 (11.9%)	1 (0.7%)	0 (0.0%)
12 Months	117	111 (94.9%)	103 (88.0%)	88 (75.2%)	9 (7.7%)	6 (5.1%)	0 (0.0%)
24 Months	102	90 (88.2%)	80 (78.4%)	75 (73.5%)	8 (7.8%)	18 (17.6%)	0 (0.0%)
36 Months	76	68 (89.5%)	64 (84.2%)	58 (76.3%)	3 (3.9%)	4 (5.3%)	0 (0.0%)
48 Months	69	62 (89.9%)	57 (82.6%)	54 (78.3%)	6 (8.7%)	10 (14.5%)	0 (0.0%)
60 Months	53	52 (98.1%)	47 (88.7%)	43 (81.1%)	0 (0.0%)	3 (5.7%)	—
03-03 GORE TAG® Device							
1 Month	51	51 (100.0%)	50 (98.0%)	51 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
6 Months ^b	51	15 (29.4%)	14 (27.5%)	12 (23.5%)	2 (3.9%)	0 (0.0%)	0 (0.0%)
12 Months	49	46 (93.9%)	45 (91.8%)	40 (81.6%)	2 (4.1%)	1 (2.0%)	0 (0.0%)
24 Months	46	40 (87.0%)	36 (78.3%)	36 (78.3%)	5 (10.9%)	0 (0.0%)	0 (0.0%)
36 Months	41	33 (80.5%)	31 (75.6%)	26 (63.4%)	2 (4.9%)	1 (2.4%)	0 (0.0%)
48 Months	38	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	38 (100.0%)
60 Months	—	—	—	—	—	—	—
04-02 GORE TAG® Device^c							
1 Month	80	75 (93.8%)	60 (75.0%)	57 (71.3%)	1 (1.3%)	1 (1.3%)	0 (0.0%)
6 Months	78	46 (59.0%)	41 (52.6%)	25 (32.1%)	7 (9.0%)	3 (3.8%)	0 (0.0%)
12 Months	68	58 (85.3%)	56 (82.4%)	38 (55.9%)	3 (4.4%)	2 (2.9%)	0 (0.0%)
24 Months	63	49 (77.8%)	49 (77.8%)	32 (50.8%)	5 (7.9%)	1 (1.6%)	0 (0.0%)
36 Months	57	9 (15.8%)	8 (14.0%)	7 (12.3%)	1 (1.8%)	0 (0.0%)	56 (98.2%)
48 Months	—	—	—	—	—	—	—
60 Months	—	—	—	—	—	—	—

Study period definitions: 1 Month (0-59 days), 6 Months (60-242 days), 12 Months (243-546 days), 24 Months (547-911 days), 36 Months (912-1275 days), 48 Months (1276-1640 days), 60 Months (1641-2006 days)

^a Denominators are based on number of patients eligible for follow-up.

^b A 6-month visit was not required as part of the TAG 03-03 Study.

^c Treatment IDE patients were followed per the Investigators' standard of care which was not defined in the protocol.

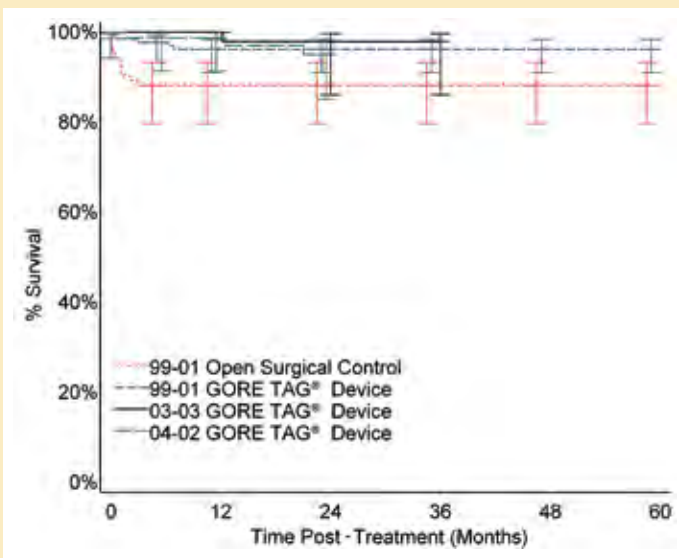
Clinical Study Experience

Aneurysm-Related Death

Figure 1 provides a Kaplan-Meier plot of aneurysm-related deaths in the Pivotal Study (TAG 99-01), Confirmatory Study (TAG 03-03), and Treatment IDE (TAG 04-02) patients. Aneurysm-related death is defined as death within 30 days of initial procedure or prior to hospital discharge, death within 30 days of a secondary procedure to treat the original aneurysm or prior to hospital discharge, or death

due to aneurysm rupture. Compared to open surgical repair, patients treated with the GORE TAG® Device have improved aneurysm-related survival (96% freedom from aneurysm-related death among Pivotal Study Test patients vs. 88% for Pivotal Study Control patients through five years post-treatment).

Figure 1: Aneurysm-Related Death Through Five Years



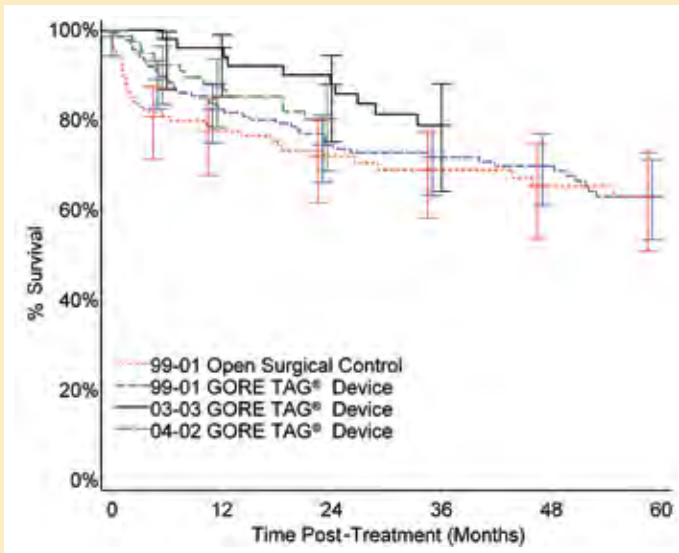
	Months After Procedure							
	Day 0	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months
99-01 Open Surgical Control								
Patients at Risk	94	88	75	72	60	42	33	17
% Survival	100%	94%	88%	88%	88%	88%	88%	88%
99-01 GORE TAG® Device								
Patients at Risk	140	135	122	109	88	73	66	33
% Survival	100%	99%	98%	96%	96%	96%	96%	96%
03-03 GORE TAG® Device								
Patients at Risk	51	51	50	48	43	23	—	—
% Survival	100%	100%	100%	100%	98%	98%	—	—
04-02 GORE TAG® Device								
Patients at Risk	80	80	70	63	35	—	—	—
% Survival	100%	100%	99%	99%	95%	—	—	—

Clinical Study Experience

All-Cause Mortality

Figure 2 provides a Kaplan-Meier plot of all-cause mortality in Pivotal Study (TAG 99-01), Confirmatory Study (TAG 03-03), and Treatment IDE (TAG 04-02) patients. At five years post-treatment, survival was 63% for both Pivotal Study Test and Control patients.

Figure 2: All-Cause Mortality Through Five Years



	Months After Procedure							
	Day 0	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months
99-01 Open Surgical Control								
Patients at Risk	94	88	75	72	60	42	33	17
% Survival	100%	94%	81%	78%	72%	69%	65%	63%
99-01 GORE TAG® Device								
Patients at Risk	140	135	122	109	88	73	66	33
% Survival	100%	99%	89%	82%	75%	72%	70%	63%
03-03 GORE TAG® Device								
Patients at Risk	51	51	50	48	43	23	—	—
% Survival	100%	100%	98%	96%	88%	79%	—	—
04-02 GORE TAG® Device								
Patients at Risk	80	80	70	63	35	—	—	—
% Survival	100%	100%	92%	88%	80%	—	—	—

Clinical Study Experience

Freedom from Major Adverse Events

Figure 3 provides a Kaplan-Meier plot of freedom from major adverse events (MAE) for Pivotal Study (TAG 99-01), Confirmatory Study (TAG 03-03), and Treatment IDE (TAG 04-02) patients. A patient experiencing more than one adverse event is counted only once for the occurrence of the first MAE in the Kaplan-Meier analysis. Standardized adverse event reporting criteria¹ were used to categorize events as Major or Minor. Patients treated with the GORE TAG® Device experienced an improved safety profile compared to patients undergoing open surgical repair throughout the follow-up

period based on the proportion of patients free from one or more MAE.

¹ Sacks D, Marinelli DL, Martin LG, et al. Reporting standards for clinical evaluation of new peripheral arterial revascularization devices. *Journal of Vascular & Interventional Radiology* 1997;8(1)Part 1:137-149.

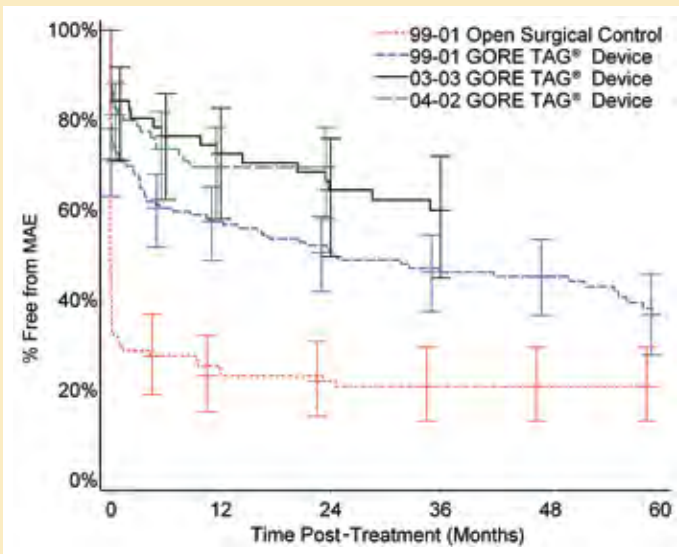
Major Adverse Event:

- a) requires therapy and short hospitalization (24 – 48 hours),
- b) requires major therapy, unplanned increase in level of care, prolonged hospitalization (> 48 hours),
- c) permanent adverse sequelae, or
- d) death.

Minor Adverse Event:

- a) no therapy, no consequence, or
- b) nominal therapy, no consequence; includes overnight admission for observation only.

Figure 3: Freedom From Major Adverse Events Through Five Years



	Months After Procedure							
	Day 0	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months
99-01 Open Surgical Control								
Patients at Risk	94	28	25	21	18	15	14	9
% Free from MAE	46%	30%	28%	23%	22%	21%	21%	21%
99-01 GORE TAG® Device								
Patients at Risk	140	98	83	78	63	50	45	21
% Free from MAE	82%	71%	60%	57%	51%	46%	45%	37%
03-03 GORE TAG® Device								
Patients at Risk	51	43	39	36	32	18	—	—
% Free from MAE	88%	84%	76%	73%	64%	60%	—	—
04-02 GORE TAG® Device								
Patients at Risk	80	65	57	50	30	—	—	—
% Free from MAE	90%	81%	74%	70%	70%	—	—	—

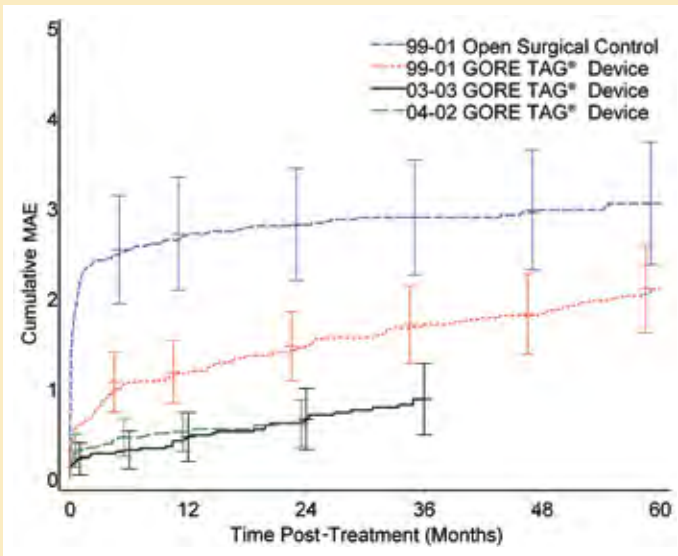
Clinical Study Experience

Cumulative Major Adverse Events

The time-related accumulation of MAEs for the Pivotal Study (TAG 99-01), Confirmatory Study (TAG 03-03), and Treatment IDE (TAG 04-02) patients through five years is presented in Figure 4. This figure represents average cumulative MAEs a patient experienced through a given time point. Patients

treated with the GORE TAG® Device experience fewer MAEs per patient than patients undergoing open surgical repair throughout the follow-up period (Pivotal Study Test, Confirmatory Study Test, or Treatment IDE patients vs. Pivotal Study Control patients).

Figure 4: Cumulative Major Adverse Events Through Five Years



	Months After Procedure							
	Day 0	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months
99-01 Open Surgical Control								
Patients at Risk	94	88	75	72	60	42	33	18
Cumulative MAE	0.72	2.21	2.55	2.73	2.83	2.91	3.00	3.07
99-01 GORE TAG® Device								
Patients at Risk	140	135	122	109	89	73	66	33
Cumulative MAE	0.28	0.62	1.09	1.20	1.49	1.73	1.84	2.12
03-03 GORE TAG® Device								
Patients at Risk	51	51	50	48	43	23	—	—
Cumulative MAE	0.14	0.24	0.33	0.48	0.68	0.90	—	—
04-02 GORE TAG® Device								
Patients at Risk	80	80	70	63	35	—	—	—
Cumulative MAE	0.15	0.33	0.47	0.53	0.63	—	—	—

Clinical Study Experience

Endoleak

Table 2 summarizes the endoleak incidence for the combined Pivotal (TAG 99-01), Confirmatory (TAG 03-03), and Treatment IDE (TAG 04-02) Test patient cohort. Overall, 39 (15.2%) patients have experienced an endoleak at any time during follow-up. Three Pivotal Study patients required additional GORE TAG® Device implants secondary to Type I endoleaks. One Confirmatory Study patient and one Treatment IDE Study patient required additional GORE TAG® Device implants due to Type I and Type II endoleak, respectively.

Table 2: Summary of Endoleaks by Study Period

	Months After Procedure							Overall Total
	1 Month	6 Months ^a	12 Months	24 Months	36 Months	48 Months	60 Months	
Pooled Test (TAG 99-01, 03-03, and 04-02)								
Number of Patients with CT Scan During Interval ^{a, b, c}	233	163	204	165	103	57	47	256
Patients with Endoleaks	25 (10.7%)	18 (11.0%)	17 (8.3%)	13 (7.9%)	6 (5.8%)	3 (5.3%)	2 (4.3%)	39 (15.2%)
Type Ia	11	9	5	1	0	1	1	16
Type Ib	2	3	2	3	3	2	0	5
Type II	6	3	6	5	3	0	1	14
Type III	3	1	1	2	0	0	0	4
Type IV	0	0	0	0	0	0	0	0
Indeterminate	4	3	3	3	0	0	0	7
Patients with Endoleaks Excluding Type II	20 (8.6%)	15 (9.2%)	11 (5.4%)	9 (5.5%)	3 (2.9%)	3 (5.3%)	1 (2.1%)	29 (11.3%)

Study period definitions: 1 Month (0-59 days), 6 Months (60-242 days), 12 Months (243-546 days), 24 Months (547-911 days), 36 Months (912-1275 days), 48 Months (1276-1640 days), 60 Months (1641-2006 days)

^a A 6-month visit was not required as part of the TAG 03-03 Study.

^b Patients are included in the denominator for analysis at each time period if there is a CT scan available during the given interval.

^c Treatment IDE patients were followed per the Investigators' standard of care which was not defined in the protocol.

Clinical Study Experience

Aneurysm Enlargement

Table 3 summarizes the changes in aneurysm size for Test patients in the Pivotal (TAG 99-01) and Confirmatory (TAG 03-03) Studies. Aneurysm size change was calculated by comparing the maximum aneurysm diameter at each follow-up visit to the baseline (one month follow-up). Post-treatment aneurysm diameters were not collected as part of the Treatment IDE.

Three Pivotal Study patients experienced aneurysm enlargement associated with endoleak. One patient with aneurysm enlargement at six months had a Type I endoleak that was not treated. Another patient received an additional GORE TAG® Device to treat aneurysm enlargement associated with Type I endoleak at 24 months. This patient was implanted with another GORE TAG® Device to treat aneurysm enlargement at 48 months that was not associated with endoleak. One other Pivotal Study patient with aneurysm enlargement at 48 months had a Type I endoleak that was not treated.

There were two Confirmatory Study patients with aneurysm enlargement associated with endoleak. One patient with aneurysm enlargement at six months had a Type I endoleak that was not treated. A second patient with aneurysm enlargement and associated Type II endoleak underwent conversion following subacute aneurysm rupture 35 months post-treatment.

The incidence of aneurysm growth ≥ 5 mm in Pivotal and Confirmatory Study Test subjects at three years was 16.4% and 6.5%, respectively. The GORE TAG® Device used in the Confirmatory Study was modified to include a low permeability film layer to provide longitudinal stiffness which also minimizes the potential for serous fluid migration through the graft material. The decreased aneurysm growth rates may be attributed to this low permeability film layer. This modified device is currently in commercial use.

Table 3: Change in Aneurysm Diameter From Baseline

	Months After Procedure					
	6 Months ^a	12 Months	24 Months	36 Months	48 Months	60 Months
99-01 GORE TAG® Device						
Number of Patients with Available Data ^b	88	86	70	55	51	42
Change in Aneurysm Diameter from Baseline						
≥ 5 mm Decrease in Diameter	31 (35.2%)	37 (43.0%)	32 (45.7%)	29 (52.7%)	23 (45.1%)	21 (50.0%)
< 5 mm Change in Diameter	49 (55.7%)	41 (47.7%)	29 (41.4%)	17 (30.9%)	17 (33.3%)	13 (31.0%)
≥ 5 mm Increase in Diameter	8 (9.1%)	8 (9.3%)	9 (12.9%)	9 (16.4%)	11 (21.6%)	8 (19.0%)
03-03 GORE TAG® Device						
Number of Patients with Available Data ^b	12	42	36	31	—	—
Change in Aneurysm Diameter from Baseline						
≥ 5 mm Decrease in Diameter	4 (33.3%)	25 (59.5%)	22 (61.1%)	20 (64.5%)	—	—
< 5 mm Change in Diameter	7 (58.3%)	17 (40.5%)	13 (36.1%)	9 (29.0%)	—	—
≥ 5 mm Increase in Diameter	1 (8.3%)	0 (0.0%)	1 (2.8%)	2 (6.5%)	—	—

Study period definitions: 6 Months (60-242 days), 12 Months (243-546 days), 24 Months (547-911 days), 36 Months (912-1275 days), 48 Months (1276-1640 days), 60 Months (1641-2006 days)

^a A 6-month visit was not required as part of the TAG 03-03 Study.

^b Patients must have a baseline (one month) and a post-baseline measurement to be available for evaluation.

Clinical Study Experience

Rupture

Three ruptures (1.1%) have been reported for the combined Pivotal, Confirmatory and Treatment IDE Study cohort.

Aneurysm ruptures have been reported for two patients enrolled in the Confirmatory Study. The first rupture occurred 12 months post-treatment and was located proximal to the GORE TAG® Device implanted at treatment. The patient subsequently died due to ruptured aneurysm secondary to periaortic abscess. The relation of the rupture to the GORE TAG® Device was inconclusive. The second rupture occurred 35 months post-treatment. The patient underwent conversion due to subacute aneurysm rupture and was discharged ten days later. Fresh thrombus was noted around the aneurysm sac and a Type II endoleak was ongoing at the time of rupture. An additional aneurysm rupture was reported for a patient enrolled in the Treatment IDE Study 12 months post-treatment. The patient subsequently died secondary to the ruptured aneurysm.

Conversion

Three conversions (1.1%) have been reported for the combined Pivotal, Confirmatory and Treatment IDE Study cohort.

One Pivotal Study patient was converted 74 days post-treatment due to suspected GORE TAG® Device infection. The patient died approximately three weeks following surgery due to cardiopulmonary failure, pulmonary insufficiency, and anoxic encephalopathy. One Confirmatory Study patient was converted 35 months post-treatment after subacute aneurysm rupture and discharged ten days later. Fresh thrombus was noted around the aneurysm sac and a Type II endoleak was ongoing at the time of rupture. One Treatment IDE Study patient was converted 21 months post-treatment due to hemoptysis and an infected GORE TAG® Device. The patient died four days later due to cardiopulmonary arrest.

Additional Implantations

Five patients (1.8%) in the Pivotal, Confirmatory and Treatment IDE cohort have undergone one or more additional implantations.

One Pivotal Study patient required an additional GORE TAG® Device implant at one month secondary to endoleak. This patient underwent an additional implantation at 36 months secondary to endoleak and device fracture. At 24 months, two Pivotal Study patients required additional

GORE TAG® Device implantations. One patient required an additional GORE TAG® Device implantation secondary to endoleak. The other patient required an additional GORE TAG® Device implantation secondary to endoleak with associated aneurysm enlargement. This patient also underwent an additional implantation 48 months post-treatment secondary to aneurysm enlargement without associated endoleak. One Confirmatory Study patient and one Treatment IDE Study patient required additional GORE TAG® Device implants due to endoleak at 6 and 30 months post-treatment, respectively.

Device Integrity

There have been 20 device fractures (14%) identified by Investigational Sites, the Core Laboratory, or the Sponsor in 19 patients in the Pivotal Study through five years post-treatment. One Pivotal Study patient received an additional GORE TAG® Device secondary to device fracture with concomitant proximal endoleak.

One deployment anomaly occurred in a patient enrolled in the Pivotal Study (TAG 99-01). The proximal end of the device did not fully deploy after deployment was initiated. The physician was able to successfully deploy the device and remove the delivery catheter by endovascular means.

There have been no device fractures or deployment anomalies reported for the Confirmatory and Treatment IDE Studies that used the modified, commercially available GORE TAG® Device.

Migration

Migration was defined as displacement of all or part of the device that is sufficient to be associated with another complication (e.g., endoleak); or longitudinal movement of all or part of the device for a distance > 1 cm as confirmed by CT scan and / or chest x-ray.

One migration (0.4%) has been reported for the combined Pivotal, Confirmatory and Treatment IDE Study cohort. One Pivotal Study patient experienced a device migration and Type I endoleak which required surgical intervention to resolve.

Section II - Worldwide Commercial Experience

There have been approximately 25,000 GORE TAG® Devices commercially distributed worldwide through January 4, 2008. This includes approximately 2,600 Original GORE TAG® Devices and 22,400 Modified GORE TAG® Devices with an average of 1.7 devices implanted per patient. Table 4 summarizes data from Gore's worldwide commercial experience with the GORE TAG® Device.

The information in this section includes worldwide reported data from the commercial use of the GORE TAG® Device as well as Physician Sponsored IDE (PSIDE) study data from three institutions treating patient populations with high risk aneurysmal and non-aneurysmal etiologies. This section does not include any IDE clinical trial data other than the PSIDE data.

Table 4: Summary of Worldwide Commercial Experience

Worldwide Commercial Experience	
Rupture (post-procedure)	9
Conversion (post-procedure)	41
Aneurysm-Related Death	112 ^a
Migration (post-procedure)	11
Paraplegia / Paraparesis	28
Stroke	32
Device Integrity:	
Compression	95
Fracture	45 ^b
Deployment Anomaly	7

^a Two deaths occurred greater than 30 days post-procedure; however, it is unknown whether or not the patients remained in the hospital prior to death due to significant comorbidities.

^b One reported fracture was confirmed to not be a fracture upon analysis.

Worldwide Commercial Experience

Rupture

Nine post-procedure ruptures of the DTA have been reported to Gore from the worldwide commercial experience of approximately 25,000 devices distributed. Three of these ruptures were associated with endoleaks: one rupture resulted from a Type II endoleak perfusing the aneurysmal sac, and two ruptures resulted from Type I endoleaks. Of these two ruptures that resulted from Type I endoleaks, one occurred two weeks post-implantation after the patient refused reintervention, and one occurred 11 months post-implantation which led to debranching of the aortic arch in order to gain adequate seal zone proximally. Four of the nine ruptures occurred in patients treated for dissections that had continued false lumen growth post-treatment leading to rupture. One patient had a pre-existing infection that led to complications with the device and surrounding tissue post-implantation resulting in the aneurysmal rupture. The ninth rupture was reported with no information regarding the cause of the rupture.

Conversion

There have been 41 post-procedure conversions to surgical repair reported to Gore from the worldwide commercial experience of approximately 25,000 devices distributed. See Table 5 for a breakdown of the causes of the conversions.

Table 5: Post-Procedure Commercial Conversions

Resolve Endoleaks	7
Device Compression	17
Progression of Dissection Disease	6
Rupture Caused by Type II Endoleak	1
Infection	7
Other	3

Of the seven patients converted due to infection, two were the result of infected aorto-esophageal fistulas, two were the result of infected aorto-bronchial fistulas, one was due to an infection that was present pre-implantation, one was the result of a PICC line infection that led to device infection, and one was the result of a patient that had contracted a salmonella bacterial infection. None of the reported infections originated from the implanted device.

Aneurysm-Related Death¹

There have been 112 aneurysm-related deaths reported to Gore from the worldwide commercial experience of approximately 25,000 devices distributed. See Table 6 for a breakdown of the causes of these aneurysm-related deaths.

Table 6: Aneurysm-Related Deaths in Commercial Experience

Pre-Procedure Ruptures	7
Comorbidities	54
Procedure-Related	36
Device-Related	6
Unknown Causes	9

The six aneurysm-related deaths attributed to device-related events include one in which a patient refused reintervention for a Type I endoleak, one related to complications with device compression resulting from oversizing of the GORE TAG® Device, one in which a patient, who was treated for a thoracic aortic aneurysm, presented 24 hours post-operatively with an ascending aortic dissection, two reports of proximal migrations of the device causing a stroke, and the sixth report due to an aorto-esophageal fistula formation at the location of the distal flares of the GORE TAG® Device.

Nine aneurysm-related deaths were caused by unknown reasons; two deaths were related to ruptures due to unknown causes, one death occurred in a patient with post-operative stroke at an unknown time post-implantation, one death occurred with a patient diagnosed with a type A dissection two days post-implantation of unknown cause, and five deaths were reported with no information on the cause of death.

¹ Chaikof EL, Blankensteijn JD, Harris PL, for the Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery of The Society for Vascular Surgery / American Association for Vascular Surgery. Reporting standards for endovascular aortic aneurysm repair. *Journal of Vascular Surgery* 2002;35(5):1048-1060.

Worldwide Commercial Experience

Migration

There have been 11 post-procedural device migrations reported to Gore from the worldwide commercial experience of approximately 25,000 devices distributed. However, only 5 of the 11 reported events have been confirmed. Of the confirmed migrations, two device migrations were reported to have been caused by device undersizing; one leading to a Type I endoleak and one leading to a device compression. One device was reported to have been oversized with a sealing zone length outside of the Instructions for Use (IFU). Another of the confirmed device migrations was an inter-component migration leading to a Type III endoleak. The fifth confirmed migration caused a Type I endoleak but sizing of the device could not be investigated due to inadequate imaging. The additional six device migrations reported to Gore could not be confirmed by Gore due to inadequate imaging or inability to acquire films.

Paraplegia / Paraparesis

There have been 28 cases of paraplegia / paraparesis that occurred during or after the procedure that have been reported to Gore from the worldwide commercial experience of approximately 25,000 devices distributed. There were 25 cases of post-implantation paraplegia reported; 17 of these paraplegia cases had no known recovery, 4 of these cases had full recovery of symptoms with placement of a spinal drain, 3 cases had partial recovery with placement of spinal drain and were discharged with varying degrees of paraparesis, and in 1 case the spinal drain reportedly caused transient paraplegia that reversed without intervention. The remaining three patients developed paraparesis post-implantation; two patients had full recovery with placement of spinal drain and one developed the paraparesis two months post-implantation and was diagnosed with spinal cord syndrome that resolved without intervention. In addition to these 28 patients, there were 6 patients that developed hemi- or mono-paralysis / paresis due to strokes and 2 patients that were diagnosed with quadriplegia from unknown causes.

Stroke

There have been 32 intra-operative or post-procedural cases of stroke reported to Gore from the worldwide commercial experience of approximately 25,000 devices distributed. Twenty-two of the strokes were reported in patients that were treated to the ostium of the left subclavian artery or further proximally. Two patients were reported to be treated in the descending thoracic aorta distal to the angulation of the aortic arch. The remaining eight patients have unknown treatment locations; this information was not reported nor were films provided that would facilitate acquiring this information. Six of the strokes were reported to have caused hemi- or mono-paralysis / paresis.

Worldwide Commercial Experience

Device Integrity:

Compression

There have been 95 device compressions reported to Gore from the worldwide commercial experience of approximately 25,000 devices distributed. For all compression events investigated by Gore, it has been determined that compressions occurred when devices were:

- not sized according to the device sizing guidelines specified in the Instructions For Use (IFU) and / or
- used in the treatment of pathologies other than degenerative, atherosclerotic aneurysms of the DTA.

Of the 95 device compressions reported, Gore has confirmed successful reinterventions in 71 cases, no known reinterventions in 13 cases, 5 cases resulting in patient deaths, the development of paraplegia in 2 cases, and 4 cases with unknown disposition of the patient.

Reinterventions include re-ballooning, placement of additional thoracic endoprostheses, placement of a bare metal stent, or surgical conversion. Of the five deaths, two were device-related. In both cases, the devices were used outside of the required IFU sizing guidelines. In one of these cases, the device was significantly undersized, and in the second, the device was significantly oversized. Of the three remaining deaths, two were procedure-related due to stroke and one occurred one month post-reintervention due to a comorbidity.

The root cause of device compression is multi-factorial, and has the highest reported incidence in young patients presenting with acute, traumatic transection of the thoracic aorta. Aortic diameters in these young patients are frequently less than 23 mm, and a typically tight radius of curvature of the aortic arch may predispose the device to a lack of circumferential apposition to the aortic wall on the lesser curve of the arch. Additionally, a unique physiologic characteristic of young patients is peak blood flow velocities up to twice that of older patients with degenerative, atherosclerotic aneurysmal disease.¹

As a result of the compression reports, Gore continues to emphasize to physician customers the importance of adhering to the intended use and sizing guidelines included in the IFU.

Fracture

There have been 45 devices reported to Gore with wire fractures from the worldwide commercial experience of approximately 25,000 devices distributed. Of the 45 devices reported to have fractures, 1 device was confirmed by Gore to have no fractures and 4 could not be confirmed as the imaging analysis was inconclusive. Eleven devices (modified design) reported to Gore were confirmed to contain wire fractures and these fractures were found to be consistent with fatigue failure due to cyclic radial compression. Twenty-nine devices with the original design (with spine wires) reported to have fractures were confirmed to have wire fractures attributed to anatomical conditions resulting in higher than expected strains where the spine wires may experience fatigue failure. There is no clear relationship between these device wire fractures and adverse clinical events.

Deployment Anomaly

There have been seven devices with deployment anomalies reported to Gore from the worldwide commercial experience of approximately 25,000 devices distributed. Deployment anomalies include difficulty in deploying the device, difficulty in withdrawing the delivery catheter, and partial deployment of the device. In five of the seven instances, the physician was able to successfully deploy the device. In the sixth instance, the physician was able to remove the undeployed device. The seventh device was surgically explanted.

¹ Salmasi AM and Dore' C. Variation of aortic blood velocity with age at rest and during exercise in normal subjects. *Clinical Autonomic Research*. 1995; 5: 19-23.

Section III - Summary and Conclusions

Summary of Clinical Study Experience

Compared to open surgical repair, patients treated with the GORE TAG® Device have a consistently lower incidence of major adverse events (37% freedom from major adverse events in the Pivotal Study Test patients vs. 21% freedom from major adverse events in Pivotal Study Control patients through five years post-treatment) and improved aneurysm-related survival (96% freedom from aneurysm-related death among Pivotal Study Test patients vs. 88% for Pivotal Study Control patients through five years post-treatment).

The following is a summary of the Pivotal Study (five-year follow-up), Confirmatory Study (three-year follow-up) and Treatment IDE (two-year follow-up) data of patients treated with the GORE TAG® Device:

- Aneurysm increase (≥ 5 mm) incidence in Pivotal and Confirmatory Study patients at three years was 16.4% and 6.5%, respectively.
- Rupture incidence for Pivotal, Confirmatory, and Treatment IDE patients was 1.1% (n=3).
- Conversion incidence for Pivotal, Confirmatory, and Treatment IDE patients was 1.1% (n=3).
- Additional implantation incidence for Pivotal, Confirmatory, and Treatment IDE patients was 1.8% (n=5).
- Twenty device fractures have been identified in 19 Pivotal Study patients. There have been no device fractures reported in either the Confirmatory or Treatment IDE Studies.
- One deployment anomaly has been reported in the Pivotal Study. There have been no deployment anomalies reported in either the Confirmatory or Treatment IDE Studies.
- One device migration has been reported in the Pivotal Study. There have been no device migrations reported in either the Confirmatory or Treatment IDE Studies.

Summary of Worldwide Commercial Experience

Approximately 25,000 GORE TAG® Devices have been distributed commercially worldwide through January 4, 2008. From the reported worldwide commercial experience through January 4, 2008, there have been:

- 9 post-procedure ruptures of the DTA
- 41 post-procedure conversions
- 112 aneurysm-related deaths
- 11 post-procedure reported migrations
- 28 incidents of paraplegia or paraparesis
- 32 incidents of stroke
- 95 device compressions
- 45 devices with reported fractures
- 7 deployment anomalies

Patient Follow-Up and Selection

Regular follow-up of all patients treated with the GORE TAG® Device is required. Physicians should tailor patient follow-up to the needs and circumstances of each individual patient.

As outlined in the IFU, critical factors for successful clinical outcomes include:

- Appropriate patient selection
- Device selection in accordance with the IFU
- Device deployment in accordance with the IFU
- Appropriate and timely patient follow-up

Adverse Event Reporting

Any adverse event involving the GORE TAG® Device should be reported to Gore immediately. To report an event in the US, call 800.437.8181. Outside of the US, contact your local Gore technical representative.

Conclusion

The Pivotal Study, Confirmatory Study, and Treatment IDE results as well as the worldwide commercial experience continue to support treatment of aneurysms of the DTA with the GORE TAG® Device as compared to open surgical repair. The GORE TAG® Device continues to perform as a safe and effective treatment of thoracic aortic aneurysms.

Gore is pleased to offer a device that has performed consistently since the introduction of the product several years ago. We remain committed to improving patient outcomes and delivering future innovations in this exciting field.

UNITED STATES INDICATIONS FOR USE

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

- Successful patient selection requires specific imaging and accurate measurements; please see Measurement Techniques and Imaging section below.
- The GORE TAG® Device is designed to treat aortic neck diameters no smaller than 23 mm and no larger than 37 mm. The GORE TAG® Device is designed to treat proximal and distal aortic neck lengths no less than 20 mm distal to either the left subclavian or left common carotid artery. Additional proximal aortic neck length may be gained by covering the left subclavian artery (with or without discretionary transposition) when necessary to optimize device fixation and maximize aortic neck length. Distal aortic neck length of at least 20 mm proximal to the celiac axis is required. These sizing measurements are critical to the performance of the endovascular repair.
- Adequate iliac or femoral access is required to introduce the device into the vasculature. Careful evaluation of vessel size, anatomy and disease state, is required to assure successful sheath introduction and subsequent withdrawal. A surgically created vascular conduit may be needed to achieve access in select patients.
- The safety and effectiveness of the GORE TAG® Device 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., Marfans and Ehlers-Danlos syndrome)

- patients with active systemic infections
- patients less than 21 years old
- pregnant or nursing females
- Differing proximal and distal neck diameters (aortic taper) outside the intended aortic diameter requirements for a single endoprosthesis diameter (Table 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® Device outside of the recommended anatomical sizing guidelines (Table 20) may result in potentially serious device-related events (e.g., device infolding, excessive device compression, endoleak, wire fracture, migration).
- If occlusion of the left subclavian artery ostium is required to obtain adequate neck length for fixation and sealing, transposition of the left subclavian artery should be considered.
- The GORE TAG® Device is not recommended in patients who cannot tolerate contrast agents necessary for intraoperative and post-operative follow-up imaging.
- The GORE TAG® Device is not recommended in patients with known sensitivities or allergies to ePTFE, FEP, nickel, or titanium.

Measurement Techniques and Imaging

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

• Diameter

A contrast-enhanced spiral CTA is required for aortic diameter measurements. Diameter measurements must be of the flow lumen not including vessel wall. The spiral CTA scan must include the great vessels through the femoral heads at an axial slice thickness of 3 mm or less.

• Length

Clinical experience indicates that 3-D CTA reconstruction is the required imaging modality to accurately assess proximal and distal neck lengths for the GORE TAG® Device. These reconstructions should be performed in sagittal, coronal and varying oblique views depending upon individual patient anatomy. If 3-D reconstruction is not available, the patient should be referred to a facility with these capabilities.

Device Selection:

- Healthy proximal and distal neck lengths of at least 20 mm are required. If aortic angulation is less than 60°, additional neck length may be required.
- Strict adherence to the GORE TAG® Device IFU sizing guide is required when selecting the appropriate device size (Table 20). The GORE TAG® Device is designed to be oversized from 7 to 18 %. Appropriate device oversizing has been incorporated into the IFU sizing guide. Sizing outside of this range can result in endoleak, fracture, migration, device infolding, or compression.
- Adverse clinical outcomes including significant distal vascular ischemic complications (bowel ischemia, paraplegia) and / or death have resulted from device use outside of the IFU sizing guide.
- Follow the Instructions for Use recommendations carefully using the sizing guide (Table 20) and aortic screening measurements (Figure 8) included in the IFU.

Implant Procedure

- Appropriate procedural imaging is required to successfully position the GORE TAG® Device in the neck and to assure appropriate apposition to the aortic wall.
- Device apposition to the inner curve of the aortic arch should be confirmed with procedural fluoroscopy and non-contrast radiography. If device apposition is not complete, the use of ballooning and / or additional GORE TAG® Device(s) has been reported by physicians to assure apposition of the GORE TAG® Device to the aortic wall in the acute setting.
- Clinicians recommend positioning the image intensifier (C-arm) so that it is perpendicular to the neck, typically 45-75 degrees left anterior oblique (LAO) for the arch.
- Systemic anticoagulation should be used during the implantation procedure based on hospital and physician preferred protocol. If heparin is contraindicated, an alternative anticoagulant should be considered.
- Minimize handling of the constrained endoprosthesis during preparation and insertion to decrease the risk of endoprosthesis contamination and infection.
- Do not rotate the delivery catheter while the endoprosthesis is inside the introducer sheath. Catheter breakage or inadvertent deployment may occur.
- Do not rotate the delivery catheter with device outside of the introducer sheath more than 180° in either direction. Catheter breakage or inadvertent deployment may occur.
- Do not attempt to reposition the endoprosthesis after deployment has been initiated. Vessel damage or endoprosthesis misplacement may result.
- Do not continue advancement of the guidewire, sheath, or delivery catheter if resistance is felt. Stop and assess the cause of resistance. Vessel or delivery catheter damage may occur.
- Incorrect deployment or migration of the endoprosthesis may require surgical intervention.
- Use caution if removing the undeployed endoprosthesis through the introducer sheath. Inadvertent endoprosthesis deployment may occur. If resistance is felt during removal of delivery catheter, stop and withdraw delivery catheter and introducer sheath together.
- Inadvertent partial deployment or migration of the endoprosthesis may require surgical removal.
- Do not cross significant arterial branches which do not have collateral or protected perfusion to end organs or body structures. Vessel occlusion may occur.

- When using the GORE Introducer Sheath with 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® Device in patients unable to undergo the necessary pre-operative and postoperative 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® Device 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® Device 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.

**W. L. GORE & ASSOCIATES, INC.**

Flagstaff, AZ 86004

+65.67332882 (Asia Pacific)

00800.6334.4673 (Europe)

800.437.8181 (United States)

928.779.2771 (United States)

goremedical.com

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