

Abstract

This annual clinical update provides a review of the ongoing experience with the GORE® TAG® Thoracic Endoprosthesis. There have been more than 48,000 GORE® TAG® Devices distributed worldwide as part of our IDE clinical trials and commercial experience through January 26, 2011. Results from our Pivotal (TAG 99-01), Confirmatory (TAG 03-03), Treatment IDE (TAG 04-02), and Post-approval (05-02) 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® Device.

Compared to open surgical repair, patients treated with the GORE® TAG® Device have a consistently lower incidence of major adverse events. Freedom from major adverse events was 37% in the Pivotal and 45% in the Confirmatory Study Test

patients vs. 21% freedom from major adverse events in Pivotal Study Control patients through five years post-treatment. Patients treated with the GORE® TAG® Device also have an improved aneurysm-related survival (96% and 98% freedom from aneurysm-related death among Pivotal and Confirmatory Study Test patients, respectively vs. 88% for Pivotal Study Control patients through five years). Combined data from the Pivotal Study (five-year follow-up), Confirmatory Study (five-year follow-up), Treatment IDE (five-year follow-up) and Post-Approval Study (three-year follow-up) test patients reveal a migration incidence of 0.5%, additional implantation incidence of 5.0%, rupture incidence of 1.2% and a conversion incidence of 1.0%.

Worldwide commercial experience of more than 48,000 GORE® TAG® Devices distributed continues to demonstrate that endovascular

therapy with the GORE® TAG® Device is a successful treatment option for the repair of the descending thoracic aorta (DTA). Twenty-one post-procedure ruptures of the descending thoracic aorta, 95 post-procedure conversions to surgical repair, 343 aneurysm-related deaths, 27 reported post-procedural migrations, 74 patients that experienced paraplegia or paraparesis, 60 patients with stroke, 183 device compressions, 60 devices with reported fractures, and 7 devices with deployment anomalies have been reported.

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 therapy option 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, Treatment IDE and Post-Approval 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 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 four sections:

- Section I includes the clinical results of the completed Pivotal Study through five years, the ongoing Confirmatory Study through five years, and the ongoing Treatment IDE and Post-Approval Studies through five and three years, respectively. All data are site-reported unless otherwise indicated.
- Section II includes a summary of Gore's worldwide commercial experience, in which more than 48,000 devices have been distributed since 1997.
- Section III provides an analysis of all explanted devices returned to Gore as of January 26, 2011. Primary cause of explant and device durability are presented.
- Section IV provides summaries of the data contained in Sections I and II as well as conclusions and information about patient selection and adverse event reporting.

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† Data contained in this document are current as of January 26, 2011. All Adverse Event definitions follow those used in Gore's clinical study protocols.

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 ePTFE sealing cuff is located on the external surface of the endoprosthesis at the base of each flared end. 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 / FEP 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.

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Section I – Clinical Study Experience

Detailed clinical results for Pivotal (TAG 99-01), Confirmatory (TAG 03-03), Treatment IDE (TAG 04-02) and Post-Approval (TAG 05-02) 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 Study (TAG 97-01) was the first clinical study 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 aneurysms of the DTA. 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 Study are not included in this report due to differences in study design and reporting requirements that result in the lack of poolability of these 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. Modifications to the device design included removal of the spine wire and incorporation of a low permeability film layer. 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. Final data through five years are presented in this update.

Complex Pathology Trial (TAG 04-01)

The Complex Pathology Study (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 study was initiated in 2004 and enrollment was completed in February 2007. Five-year follow-up is ongoing.

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. Data through five years are presented in this update, however this database is not yet final.

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 GORE® TAG® Device 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 update will report three year follow-up data.

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

The 45 mm GORE® TAG® Device Study (TAG 06-02) was initiated to evaluate the device with a non-randomized multicenter study designed to assess the safety and efficacy of the 45 mm GORE® TAG® Device. Patient enrollment for TAG 06-02 began in February 2007 and is complete with a total of 23 patients enrolled. Five-year follow-up is ongoing, although this study is not included in this update. The larger size GORE® TAG® Device was approved by the FDA in March 2010.

Section I – 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), Treatment IDE (TAG 04-02) and Post-Approval Study (05-02) patients. Available patients are defined as those that are alive and participating in the study for that follow-up period. Patients in the Pivotal and Confirmatory Studies have completed their fifth and final year of follow-up. Treatment IDE patients are in their fifth year of follow-up. Patients in the Post-Approval Study are in their fourth year of follow-up. For a given study period, data presented include the number of patients eligible for follow-up (i.e., 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%) | 42 (85.7%) | 2 (4.1%) | 1 (2.0%) | 0 (0.0%) |
| 24 Months | 46 | 40 (87.0%) | 36 (78.3%) | 37 (80.4%) | 5 (10.9%) | 0 (0.0%) | 0 (0.0%) |
| 36 Months | 41 | 35 (85.4%) | 33 (80.5%) | 28 (68.3%) | 2 (4.9%) | 1 (2.4%) | 0 (0.0%) |
| 48 Months | 38 | 33 (86.8%) | 29 (76.3%) | 27 (71.1%) | 7 (18.4%) | 0 (0.0%) | 0 (0.0%) |
| 60 Months | 31 | 24 (77.4%) | 23 (74.2%) | 19 (61.3%) | 2 (6.5%) | 5 (16.1%) | — |
| 04-02 GORE® TAG® DEVICE^c | | | | | | | |
| 1 Month | 80 | 75 (93.8%) | 60 (75.0%) | 57 (71.3%) | 1 (1.3%) | 0 (0.0%) | 0 (0.0%) |
| 6 Months | 79 | 46 (58.2%) | 41 (51.9%) | 25 (31.6%) | 7 (8.9%) | 3 (3.8%) | 0 (0.0%) |
| 12 Months | 69 | 58 (84.1%) | 56 (81.2%) | 38 (55.1%) | 3 (4.3%) | 3 (4.3%) | 0 (0.0%) |
| 24 Months | 63 | 50 (79.4%) | 49 (77.8%) | 32 (50.8%) | 9 (14.3%) | 1 (1.6%) | 0 (0.0%) |
| 36 Months | 53 | 44 (83.0%) | 42 (79.2%) | 29 (54.7%) | 1 (1.9%) | 3 (5.7%) | 0 (0.0%) |
| 48 Months | 49 | 42 (85.7%) | 41 (83.7%) | 28 (57.1%) | 4 (8.2%) | 0 (0.0%) | 0 (0.0%) |
| 60 Months | 45 | 40 (88.9%) | 37 (82.2%) | 23 (51.1%) | 5 (11.1%) | 2 (4.4%) | — |
| 05-02 GORE® TAG® DEVICE | | | | | | | |
| 1 Month | 150 | 150 (100.0%) | 122 (81.3%) | 123 (82.0%) | 4 (2.7%) | 0 (0.0%) | 0 (0.0%) |
| 6 Months ^b | 146 | 77 (52.7%) | 72 (49.3%) | 35 (24.0%) | 3 (2.1%) | 0 (0.0%) | 0 (0.0%) |
| 12 Months | 143 | 126 (88.1%) | 119 (83.2%) | 80 (55.9%) | 8 (5.6%) | 2 (1.4%) | 0 (0.0%) |
| 24 Months | 133 | 109 (82.0%) | 104 (78.2%) | 76 (57.1%) | 12 (9.0%) | 6 (4.5%) | 0 (0.0%) |
| 36 Months | 115 | 82 (71.3%) | 77 (67.0%) | 57 (49.6%) | 7 (6.1%) | 4 (3.5%) | 16 (13.9%) |
| 48 Months | 88 | 56 (63.6%) | 53 (60.2%) | 38 (43.2%) | 6 (6.8%) | 1 (1.1%) | 27 (30.7%) |
| 60 Months | 54 | 16 (29.6%) | 12 (22.2%) | 9 (16.7%) | 5 (9.3%) | 0 (0.0%) | — |

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 six-month visit was not required as part of either the TAG 03-03 Study or the TAG 05-02 Study.

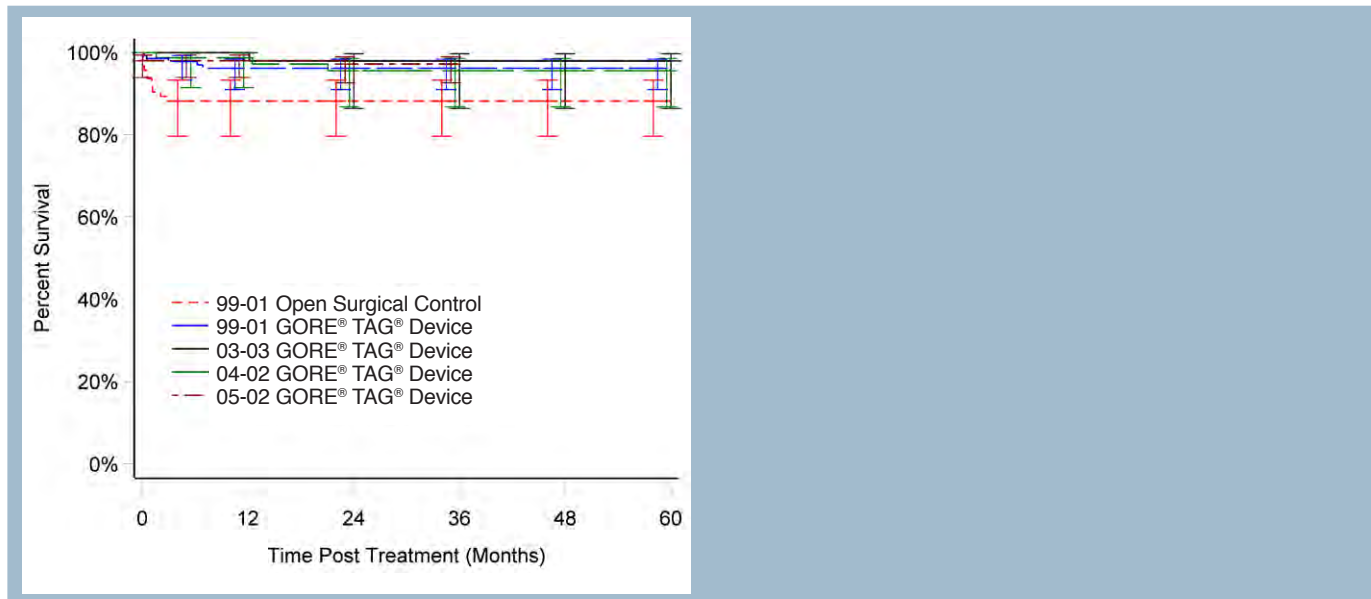
^c Treatment IDE patients were followed per the Investigators' standard of care which was not defined in the protocol.

Section I – 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), Treatment IDE (TAG 04-02), and Post-Approval Study (05-02) 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% and 98% freedom from aneurysm-related death among Pivotal and Confirmatory Study Test patients vs. 88% for Pivotal Study Control patients through five years post-treatment).

Figure 1: Aneurysm-Related Death Through Five Years



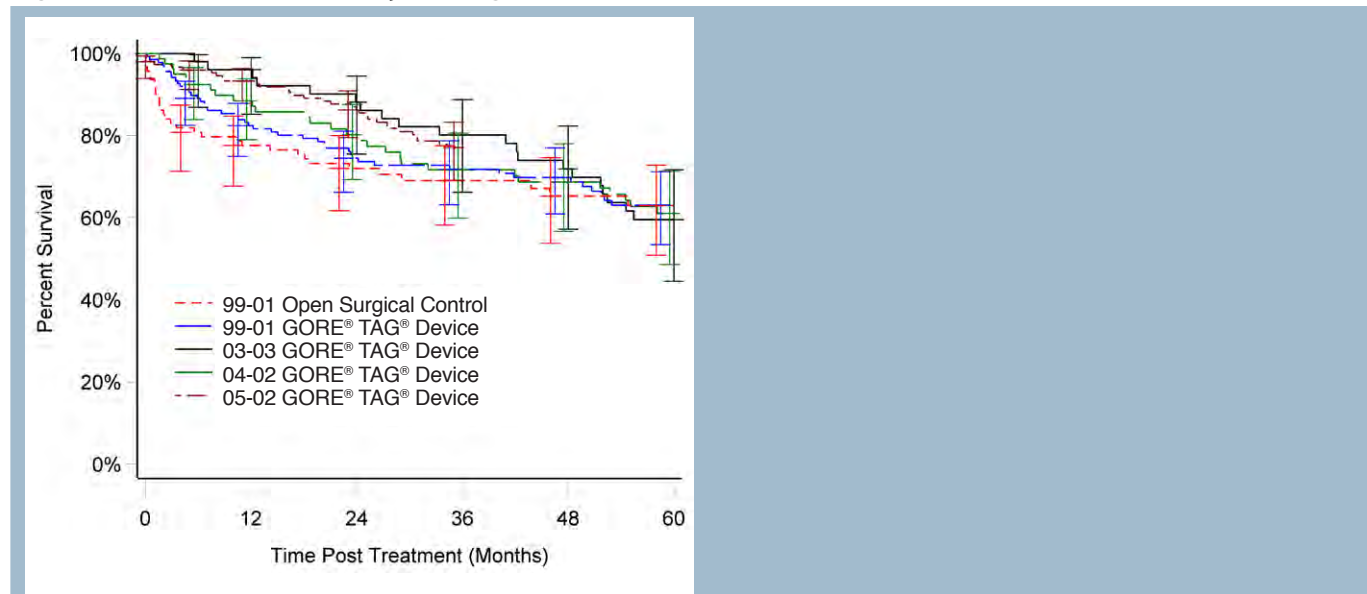
| | MONTHS AFTER PROCEDURE | | | | | | | |
|------------------------------------|------------------------|---------|----------|-----------|-----------|-----------|-----------|-----------|
| | DAY 0 | 1 MONTH | 6 MONTHS | 12 MONTHS | 24 MONTHS | 36 MONTHS | 48 MONTHS | 60 MONTHS |
| 99-01 OPEN SURGICAL 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 | 49 | 44 | 39 | 35 | 20 |
| % Survival | 100% | 100% | 100% | 100% | 98% | 98% | 98% | 98% |
| 04-02 GORE® TAG® DEVICE | | | | | | | | |
| Patients at Risk | 80 | 80 | 72 | 66 | 57 | 49 | 46 | 21 |
| % Survival | 100% | 100% | 99% | 99% | 96% | 96% | 96% | 96% |
| 05-02 GORE® TAG® DEVICE | | | | | | | | |
| Patients at Risk | 150 | 145 | 142 | 136 | 119 | 91 | — | — |
| % Survival | 100% | 98% | 98% | 98% | 97% | 97% | — | — |

Section I – 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), Treatment IDE (TAG 04-02), and Post-Approval Study (05-02) patients. All-cause mortality is defined as any death regardless of the relationship to device or procedure. At five years post-treatment, survival was 63% for both Pivotal Study Test and Control patients and 61% for Confirmatory Study Test patients. At three years post-treatment, survival was 77% for Post-Approval (05-02) 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 | 49 | 44 | 39 | 35 | 20 |
| % Survival | 100% | 100% | 98% | 96% | 88% | 80% | 72% | 60% |
| 04-02 GORE® TAG® DEVICE | | | | | | | | |
| Patients at Risk | 80 | 80 | 72 | 66 | 57 | 49 | 46 | 21 |
| % Survival | 100% | 100% | 92% | 88% | 80% | 72% | 69% | 61% |
| 05-02 GORE® TAG® DEVICE | | | | | | | | |
| Patients at Risk | 150 | 145 | 142 | 136 | 119 | 91 | — | — |
| % Survival | 100% | 98% | 96% | 93% | 86% | 77% | — | — |

Section I – 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), Treatment IDE (TAG 04-02), and Post-Approval (05-02) Study 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 criteria were used to categorize events as Major or Minor¹. 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.

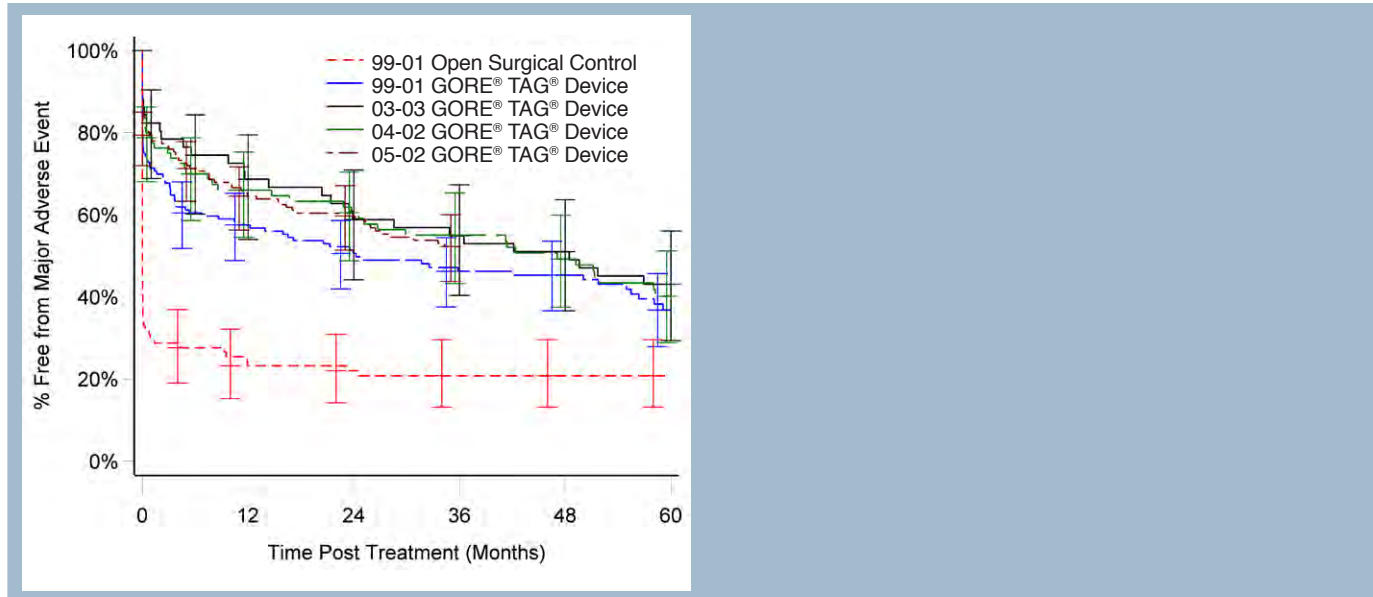
Major Adverse Event:

- 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 | 42 | 38 | 35 | 30 | 28 | 26 | 15 |
| % Free from MAE | 88% | 82% | 75% | 69% | 59% | 55% | 51% | 43% |
| 04-02 GORE® TAG® DEVICE | | | | | | | | |
| Patients at Risk | 80 | 63 | 55 | 50 | 44 | 39 | 34 | 15 |
| % Free from MAE | 89% | 79% | 70% | 66% | 61% | 55% | 49% | 40% |
| 05-02 GORE® TAG® DEVICE | | | | | | | | |
| Patients at Risk | 150 | 118 | 106 | 95 | 85 | 66 | — | — |
| % Free from MAE | 90% | 79% | 71% | 65% | 60% | 52% | — | — |

Section I – Clinical Study Experience

Cumulative Major Adverse Events

The time-related accumulation of major adverse events¹ for the Pivotal Study (TAG 99-01), Confirmatory Study (TAG 03-03), Treatment IDE (TAG 04-02) and Post-Approval Study (05-02) patients through five, four and two 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 experienced fewer major adverse events per patient than patients undergoing open surgical repair throughout the follow-up period (Pivotal Study Test, Confirmatory Study Test, Treatment IDE or Post-Approval patients vs. Pivotal Study Control patients).

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.

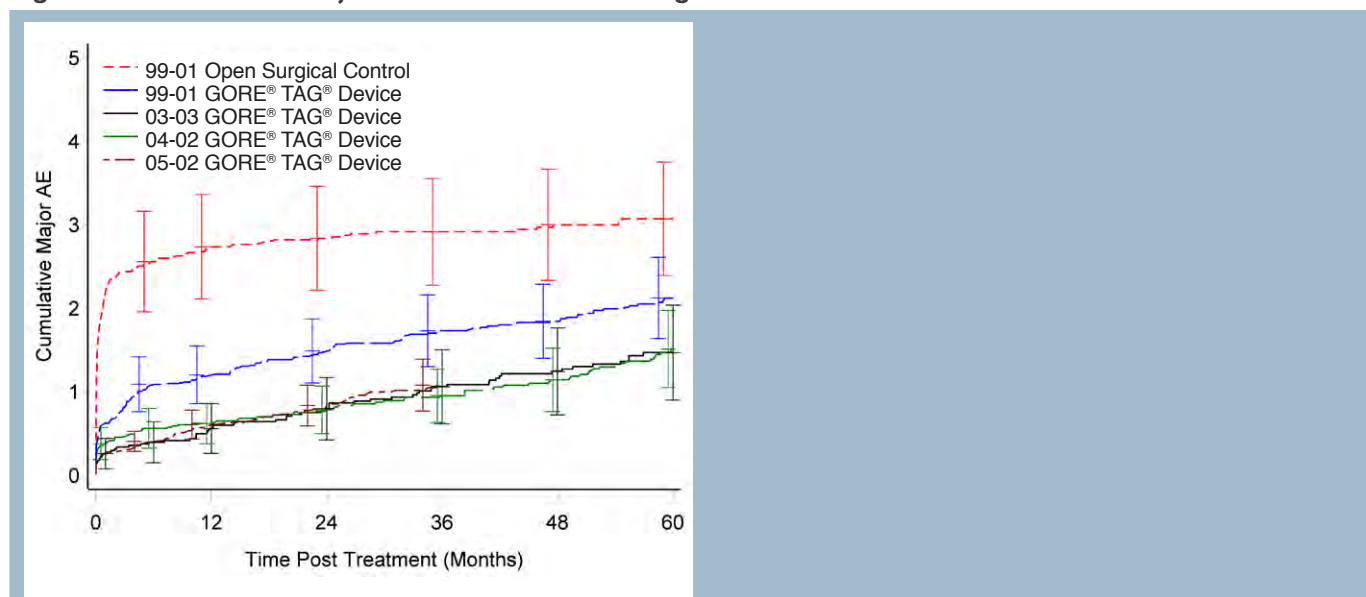
Major Adverse Event:

- 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 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 | 49 | 44 | 39 | 35 | 20 |
| Cumulative MAE | 0.14 | 0.25 | 0.39 | 0.56 | 0.79 | 1.06 | 1.24 | 1.46 |
| 04-02 GORE® TAG® DEVICE | | | | | | | | |
| Patients at Risk | 80 | 80 | 72 | 66 | 57 | 49 | 46 | 21 |
| Cumulative MAE | 0.18 | 0.38 | 0.56 | 0.62 | 0.78 | 0.95 | 1.14 | 1.51 |
| 05-02 GORE® TAG® DEVICE | | | | | | | | |
| Patients at Risk | 150 | 145 | 142 | 136 | 119 | 91 | — | — |
| Cumulative MAE | 0.12 | 0.26 | 0.40 | 0.60 | 0.83 | 1.08 | — | — |

Section I – Clinical Study Experience

Endoleak

Tables 2–5 summarize the endoleak incidence for the Pivotal (TAG 99-01), Confirmatory (TAG 03-03), Treatment IDE (TAG 04-02) and Post-Approval (05-02) Test patient cohorts, respectively. Overall, 116 (28.6%) patients have experienced an endoleak at any time during follow-up. Reports of Type I and Type III endoleaks are similar across the four cohorts with most of the reported Type I endoleaks considered proximal (Type IA) endoleaks. Type II endoleaks are more commonly reported in the Treatment IDE and Post-Approval Study when compared to the Confirmatory and Pivotal Study cohorts. 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 endoleaks, respectively. Fourteen Post-Approval Study patients required an additional thoracic stent-graft implant due to endoleak, with one patient requiring two reinterventions.

Table 2: Summary of Endoleaks^a by Study Period: TAG 99-01

| 99-01 GORE® TAG® DEVICE | TREATMENT | 1 MONTH | 6 MONTHS | 12 MONTHS | 24 MONTHS | 36 MONTHS | 48 MONTHS | 60 MONTHS | TOTAL |
|---|-------------|-------------|------------|------------|------------|------------|------------|------------|-------------|
| Patients Available at Beginning of Interval | 140 | 140 | 134 | 117 | 102 | 76 | 69 | 53 | 140 |
| Patients with Endoleak Evaluation or Ongoing Endoleak | 140 | 127 | 116 | 105 | 86 | 66 | 61 | 50 | 134 |
| Patients with One or More Endoleak Adverse Events Ongoing in Window | 14 (10.0%) | 21 (16.5%) | 22 (19.0%) | 18 (17.1%) | 17 (19.8%) | 16 (24.2%) | 15 (24.6%) | 11 (22.0%) | 24 (17.9%) |
| New | 14 (10.0%) | 7 (5.5%) | 2 (1.7%) | 0 (0.0%) | 3 (3.5%) | 1 (1.5%) | 2 (3.3%) | 1 (2.0%) | — |
| Ongoing | — | 14 (11.0%) | 21 (18.1%) | 18 (17.1%) | 16 (18.6%) | 15 (22.7%) | 15 (24.6%) | 11 (22.0%) | — |
| Type I | 9 (6.4%) | 13 (10.2%) | 15 (12.9%) | 12 (11.4%) | 11 (12.8%) | 10 (15.2%) | 11 (18.0%) | 8 (16.0%) | 18 (13.4%) |
| New | 9 (6.4%) | 4 (3.1%) | 2 (1.7%) | 0 (0.0%) | 1 (1.2%) | 1 (1.5%) | 1 (1.6%) | 0 (0.0%) | — |
| Ongoing | — | 9 (7.1%) | 13 (11.2%) | 12 (11.4%) | 10 (11.6%) | 9 (13.6%) | 10 (16.4%) | 8 (16.0%) | — |
| Type IA | 9 (6.4%) | 12 (9.4%) | 14 (12.1%) | 11 (10.5%) | 10 (11.6%) | 8 (12.1%) | 9 (14.8%) | 6 (12.0%) | 16 (11.9%) |
| New | 9 (6.4%) | 3 (2.4%) | 2 (1.7%) | 0 (0.0%) | 1 (1.2%) | 0 (0.0%) | 1 (1.6%) | 0 (0.0%) | — |
| Ongoing | — | 9 (7.1%) | 12 (10.3%) | 11 (10.5%) | 9 (10.5%) | 8 (13.1%) | 8 (13.1%) | 6 (12.0%) | — |
| Type IB | 1 (0.7%) | 2 (1.6%) | 2 (1.7%) | 2 (1.9%) | 2 (2.3%) | 3 (4.5%) | 3 (4.9%) | 3 (6.0%) | 3 (2.2%) |
| New | 1 (0.7%) | 1 (0.8%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 1 (1.5%) | 0 (0.0%) | 0 (0.0%) | — |
| Ongoing | — | 1 (0.8%) | 2 (1.7%) | 2 (1.9%) | 2 (2.3%) | 2 (3.0%) | 3 (4.9%) | 3 (6.0%) | — |
| Type II | 2 (1.4%) | 3 (2.4%) | 3 (2.6%) | 3 (2.9%) | 4 (4.7%) | 4 (6.1%) | 4 (6.6%) | 3 (6.0%) | 4 (3.0%) |
| New | 2 (1.4%) | 1 (0.8%) | 0 (0.0%) | 0 (0.0%) | 1 (1.2%) | 0 (0.0%) | 1 (1.6%) | 1 (2.0%) | — |
| Ongoing | — | 2 (1.6%) | 3 (2.6%) | 3 (2.9%) | 3 (3.5%) | 4 (6.1%) | 4 (6.6%) | 3 (6.0%) | — |
| Type III | 2 (1.4%) | 3 (2.4%) | 3 (2.6%) | 3 (2.9%) | 4 (4.7%) | 4 (6.1%) | 3 (4.9%) | 2 (4.0%) | 4 (3.0%) |
| New | 2 (1.4%) | 1 (0.8%) | 0 (0.0%) | 0 (0.0%) | 1 (1.2%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | — |
| Ongoing | — | 2 (1.6%) | 3 (2.6%) | 3 (2.9%) | 3 (3.5%) | 4 (6.1%) | 3 (4.9%) | 2 (4.0%) | — |
| Indeterminate | 2 (1.4%) | 4 (3.1%) | 4 (3.4%) | 2 (1.9%) | 2 (2.3%) | 1 (1.5%) | 1 (1.6%) | 1 (2.0%) | 4 (3.0%) |
| New | 2 (1.4%) | 2 (1.6%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | — |
| Ongoing | — | 2 (1.6%) | 4 (3.4%) | 2 (1.9%) | 2 (2.3%) | 1 (1.5%) | 1 (1.6%) | 1 (2.0%) | — |
| Patients with No Endoleak Adverse Events Ongoing in Window | 126 (90.0%) | 106 (83.5%) | 94 (81.0%) | 87 (82.9%) | 69 (80.2%) | 50 (75.8%) | 46 (75.4%) | 39 (78.0%) | 110 (82.1%) |

^a Type IV endoleak is not represented in the table, as no Type IV endoleaks were reported.

Table 3: Summary of Endoleaks^a by Study Period: TAG 03–03

| 03–03 GORE® TAG® DEVICE | TREATMENT | 1 MONTH | 6 MONTHS | 12 MONTHS | 24 MONTHS | 36 MONTHS | 48 MONTHS | 60 MONTHS | TOTAL |
|---|------------|------------|-----------|------------|------------|------------|------------|------------|------------|
| Patients Available at Beginning of Interval | 51 | 51 | 51 | 49 | 46 | 41 | 38 | 31 | 51 |
| Patients with Endoleak Evaluation or Ongoing Endoleak | 51 | 50 | 16 | 46 | 39 | 36 | 31 | 26 | 50 |
| Patients with One or More Endoleak Adverse Events Ongoing in Window | 2 (3.9%) | 6 (12.0%) | 8 (50.0%) | 9 (19.6%) | 8 (20.5%) | 7 (19.4%) | 6 (19.4%) | 5 (19.2%) | 11 (22.0%) |
| New | 2 (3.9%) | 4 (8.0%) | 3 (18.8%) | 2 (4.3%) | 0 (0.0%) | 0 (0.0%) | 1 (3.2%) | 0 (0.0%) | — |
| Ongoing | — | 2 (4.0%) | 6 (37.5%) | 7 (15.2%) | 8 (20.5%) | 7 (19.4%) | 5 (16.1%) | 5 (19.2%) | — |
| Type I | 2 (3.9%) | 5 (10.0%) | 6 (37.5%) | 5 (10.9%) | 4 (10.3%) | 3 (8.3%) | 3 (9.7%) | 3 (11.5%) | 6 (12.0%) |
| New | 2 (3.9%) | 3 (6.0%) | 2 (12.5%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | — |
| Ongoing | — | 2 (4.0%) | 5 (31.3%) | 5 (10.9%) | 4 (10.3%) | 3 (8.3%) | 3 (9.7%) | 3 (11.5%) | — |
| Type IA | 2 (3.9%) | 4 (8.0%) | 5 (31.3%) | 4 (8.7%) | 3 (7.7%) | 2 (5.6%) | 2 (6.5%) | 2 (7.7%) | 5 (10.0%) |
| New | 2 (3.9%) | 2 (4.0%) | 1 (6.3%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | — |
| Ongoing | — | 2 (4.0%) | 4 (25.0%) | 4 (8.7%) | 3 (7.7%) | 2 (5.6%) | 2 (6.5%) | 2 (7.7%) | — |
| Type IB | 0 (0.0%) | 1 (2.0%) | 2 (12.5%) | 2 (4.3%) | 1 (2.6%) | 1 (2.8%) | 1 (3.2%) | 1 (3.8%) | 2 (4.0%) |
| New | 0 (0.0%) | 1 (2.0%) | 1 (6.3%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | — |
| Ongoing | — | 0 (0.0%) | 1 (6.3%) | 2 (4.3%) | 1 (2.6%) | 1 (2.8%) | 1 (3.2%) | 1 (3.8%) | — |
| Type II | 0 (0.0%) | 1 (2.0%) | 1 (6.3%) | 3 (6.5%) | 3 (7.7%) | 3 (8.3%) | 3 (9.7%) | 2 (7.7%) | 4 (8.0%) |
| New | 0 (0.0%) | 1 (2.0%) | 0 (0.0%) | 2 (4.3%) | 0 (0.0%) | 0 (0.0%) | 1 (3.2%) | 0 (0.0%) | — |
| Ongoing | — | 0 (0.0%) | 1 (6.3%) | 1 (2.2%) | 3 (7.7%) | 3 (8.3%) | 2 (6.5%) | 2 (7.7%) | — |
| Type III | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| New | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | — |
| Ongoing | — | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | — |
| Indeterminate | 1 (2.0%) | 1 (2.0%) | 2 (12.5%) | 2 (4.3%) | 2 (5.1%) | 1 (2.8%) | 0 (0.0%) | 0 (0.0%) | 2 (4.0%) |
| New | 1 (2.0%) | 0 (0.0%) | 1 (6.3%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | — |
| Ongoing | — | 1 (2.0%) | 1 (6.3%) | 2 (4.3%) | 2 (5.1%) | 1 (2.8%) | 0 (0.0%) | 0 (0.0%) | — |
| Patients with No Endoleak Adverse Events Ongoing in Window | 49 (96.1%) | 44 (88.0%) | 8 (50.0%) | 37 (80.4%) | 31 (79.5%) | 29 (80.6%) | 25 (80.6%) | 21 (80.8%) | 39 (78.0%) |

^a Type IV endoleak is not represented in the table, as no Type IV endoleaks were reported.

Section I – Clinical Study Experience

Table 4: Summary of Endoleaks^a by Study Period: TAG 04–02

| 04–02 GORE® TAG® DEVICE | TREATMENT | 1 MONTH | 6 MONTHS | 12 MONTHS | 24 MONTHS | 36 MONTHS | 48 MONTHS | 60 MONTHS | TOTAL |
|---|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| Patients Available at Beginning of Interval | 80 | 80 | 79 | 68 | 62 | 52 | 48 | 44 | 80 |
| Patients with Endoleak Evaluation or Ongoing Endoleak | 80 | 62 | 48 | 60 | 52 | 45 | 44 | 39 | 75 |
| Patients with One or More Endoleak Adverse Events Ongoing in Window | 13 (16.3%) | 20 (32.3%) | 19 (39.6%) | 18 (30.0%) | 17 (32.7%) | 16 (35.6%) | 14 (31.8%) | 14 (35.9%) | 26 (34.7%) |
| New | 13 (16.3%) | 7 (11.3%) | 4 (8.3%) | 1 (1.7%) | 3 (5.8%) | 1 (2.2%) | 0 (0.0%) | 2 (5.1%) | — |
| Ongoing | — | 13 (21.0%) | 17 (35.4%) | 17 (28.3%) | 15 (28.8%) | 15 (33.3%) | 14 (31.8%) | 13 (33.3%) | — |
| Type I | 6 (7.5%) | 8 (12.9%) | 7 (14.6%) | 7 (11.7%) | 7 (13.5%) | 6 (13.3%) | 5 (11.4%) | 5 (12.8%) | 10 (13.3%) |
| New | 6 (7.5%) | 2 (3.2%) | 1 (2.1%) | 0 (0.0%) | 1 (1.9%) | 0 (0.0%) | 0 (0.0%) | 1 (2.6%) | — |
| Ongoing | — | 6 (9.7%) | 7 (14.6%) | 7 (11.7%) | 6 (11.5%) | 6 (13.3%) | 5 (11.4%) | 4 (10.3%) | — |
| Type IA | 6 (7.5%) | 8 (12.9%) | 7 (14.6%) | 7 (11.7%) | 6 (11.5%) | 5 (11.1%) | 4 (9.1%) | 5 (12.8%) | 9 (12.0%) |
| New | 6 (7.5%) | 2 (3.2%) | 1 (2.1%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 1 (2.6%) | — |
| Ongoing | — | 6 (9.7%) | 7 (14.6%) | 7 (11.7%) | 6 (11.5%) | 5 (11.1%) | 4 (9.1%) | 4 (10.3%) | — |
| Type IB | 1 (1.3%) | 1 (1.6%) | 1 (2.1%) | 1 (1.7%) | 2 (3.8%) | 2 (4.4%) | 2 (4.5%) | 1 (2.6%) | 2 (2.7%) |
| New | 1 (1.3%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 1 (1.9%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | — |
| Ongoing | — | 1 (1.6%) | 1 (2.1%) | 1 (1.7%) | 1 (1.9%) | 2 (4.4%) | 2 (4.5%) | 1 (2.6%) | — |
| Type II | 5 (6.3%) | 7 (11.3%) | 8 (16.7%) | 7 (11.7%) | 8 (15.4%) | 7 (15.6%) | 6 (13.6%) | 5 (12.8%) | 12 (16.0%) |
| New | 5 (6.3%) | 2 (3.2%) | 2 (4.2%) | 1 (1.7%) | 1 (1.9%) | 1 (2.2%) | 0 (0.0%) | 0 (0.0%) | — |
| Ongoing | — | 5 (8.1%) | 6 (12.5%) | 6 (10.0%) | 7 (13.5%) | 6 (13.3%) | 6 (13.6%) | 5 (12.8%) | — |
| Type III | 1 (1.3%) | 2 (3.2%) | 2 (4.2%) | 2 (3.3%) | 1 (1.9%) | 1 (2.2%) | 1 (2.3%) | 1 (2.6%) | 2 (2.7%) |
| New | 1 (1.3%) | 1 (1.6%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | — |
| Ongoing | — | 1 (1.6%) | 2 (4.2%) | 2 (3.3%) | 1 (1.9%) | 1 (2.2%) | 1 (2.3%) | 1 (2.6%) | — |
| Indeterminate | 1 (1.3%) | 3 (4.8%) | 4 (8.3%) | 3 (5.0%) | 3 (5.8%) | 3 (6.7%) | 3 (6.8%) | 3 (7.7%) | 6 (8.0%) |
| New | 1 (1.3%) | 2 (3.2%) | 2 (4.2%) | 0 (0.0%) | 1 (1.9%) | 0 (0.0%) | 0 (0.0%) | 1 (2.6%) | — |
| Ongoing | — | 1 (1.6%) | 2 (4.2%) | 3 (5.0%) | 2 (3.8%) | 3 (6.7%) | 3 (6.8%) | 3 (7.7%) | — |
| Patients with No Endoleak Adverse Events Ongoing in Window | 67 (83.8%) | 42 (67.7%) | 29 (60.4%) | 42 (70.0%) | 35 (67.3%) | 29 (64.4%) | 30 (68.2%) | 25 (64.1%) | 49 (65.3%) |

^a Type IV endoleak is not represented in the table, as no Type IV endoleaks were reported.

Table 5: Summary of Endoleaks^a by Study Period: TAG 05–02

| 05–02 GORE® TAG® DEVICE | TREATMENT | 1 MONTH | 6 MONTHS | 12 MONTHS | 24 MONTHS | 36 MONTHS | 48 MONTHS | 60 MONTHS | TOTAL |
|---|-------------|------------|------------|------------|------------|------------|------------|------------|------------|
| Patients Available at Beginning of Interval | 150 | 150 | 144 | 141 | 129 | 106 | 67 | 22 | 150 |
| Patients with Endoleak Evaluation or Ongoing Endoleak | 150 | 127 | 80 | 122 | 107 | 81 | 56 | 14 | 146 |
| Patients with One or More Endoleak Adverse Events Ongoing in Window | 26 (17.3%) | 40 (31.5%) | 33 (41.3%) | 32 (26.2%) | 21 (19.6%) | 14 (17.3%) | 13 (23.2%) | 3 (21.4%) | 55 (37.7%) |
| New | 26 (17.3%) | 21 (16.5%) | 10 (12.5%) | 6 (4.9%) | 4 (3.7%) | 4 (4.9%) | 3 (5.4%) | 0 (0.0%) | — |
| Ongoing | — | 25 (19.7%) | 27 (33.8%) | 26 (21.3%) | 19 (17.8%) | 12 (14.8%) | 10 (17.9%) | 3 (21.4%) | — |
| Type I | 17 (11.3%) | 18 (14.2%) | 14 (17.5%) | 14 (11.5%) | 9 (8.4%) | 6 (7.4%) | 5 (8.9%) | 2 (14.3%) | 26 (17.8%) |
| New | 17 (11.3%) | 2 (1.6%) | 5 (6.3%) | 2 (1.6%) | 1 (0.9%) | 2 (2.5%) | 1 (1.8%) | 0 (0.0%) | — |
| Ongoing | — | 16 (12.6%) | 10 (12.5%) | 12 (9.8%) | 9 (8.4%) | 5 (6.2%) | 4 (7.1%) | 2 (14.3%) | — |
| Type IA | 14 (9.3%) | 15 (11.8%) | 11 (13.8%) | 10 (8.2%) | 7 (6.5%) | 5 (6.2%) | 4 (7.1%) | 1 (7.1%) | 19 (13.0%) |
| New | 14 (9.3%) | 1 (0.8%) | 3 (3.8%) | 1 (0.8%) | 0 (0.0%) | 1 (1.2%) | 0 (0.0%) | 0 (0.0%) | — |
| Ongoing | — | 14 (11.0%) | 8 (10.0%) | 9 (7.4%) | 7 (6.5%) | 4 (4.9%) | 4 (7.1%) | 1 (7.1%) | — |
| Type IB | 3 (2.0%) | 3 (2.4%) | 4 (5.0%) | 4 (3.3%) | 3 (2.8%) | 2 (2.5%) | 2 (3.6%) | 1 (7.1%) | 9 (6.2%) |
| New | 3 (2.0%) | 1 (0.8%) | 2 (2.5%) | 1 (0.8%) | 1 (0.9%) | 1 (1.2%) | 1 (1.8%) | 0 (0.0%) | — |
| Ongoing | — | 2 (1.6%) | 2 (2.5%) | 3 (2.5%) | 2 (1.9%) | 2 (2.5%) | 1 (1.8%) | 1 (7.1%) | — |
| Type II | 6 (4.0%) | 16 (12.6%) | 15 (18.8%) | 16 (13.1%) | 12 (11.2%) | 8 (9.9%) | 7 (12.5%) | 0 (0.0%) | 27 (18.5%) |
| New | 6 (4.0%) | 11 (8.7%) | 5 (6.3%) | 3 (2.5%) | 3 (2.8%) | 1 (1.2%) | 2 (3.6%) | 0 (0.0%) | — |
| Ongoing | — | 6 (4.7%) | 12 (15.0%) | 13 (10.7%) | 9 (8.4%) | 7 (8.6%) | 5 (8.9%) | 0 (0.0%) | — |
| Type III | 1 (0.7%) | 4 (3.1%) | 2 (2.5%) | 1 (0.8%) | 2 (1.9%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 5 (3.4%) |
| New | 1 (0.7%) | 3 (2.4%) | 1 (1.3%) | 1 (0.8%) | 1 (0.9%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | — |
| Ongoing | — | 1 (0.8%) | 1 (1.3%) | 0 (0.0%) | 1 (0.9%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | — |
| Indeterminate | 3 (2.0%) | 10 (7.9%) | 7 (8.8%) | 4 (3.3%) | 2 (1.9%) | 2 (2.5%) | 2 (3.6%) | 1 (7.1%) | 12 (8.2%) |
| New | 3 (2.0%) | 7 (5.5%) | 0 (0.0%) | 0 (0.0%) | 1 (0.9%) | 1 (1.2%) | 0 (0.0%) | 0 (0.0%) | — |
| Ongoing | — | 3 (2.4%) | 7 (8.8%) | 4 (3.3%) | 1 (0.9%) | 1 (1.2%) | 2 (3.6%) | 1 (7.1%) | — |
| Patients with No Endoleak Adverse Events Ongoing in Window | 124 (82.7%) | 87 (68.5%) | 47 (58.8%) | 90 (73.8%) | 86 (80.4%) | 67 (82.7%) | 43 (76.8%) | 11 (78.6%) | 91 (62.3%) |

^a Type IV endoleak is not represented in the table, as no Type IV endoleaks were reported.

Section I – Clinical Study Experience

Table 6: 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 | 32 | 29 | 23 |
| Change in Aneurysm Diameter from Baseline | | | | | | |
| ≥ 5 mm Decrease in Diameter | 4 (33.3%) | 25 (59.5%) | 22 (61.1%) | 21 (65.6%) | 19 (65.5%) | 15 (65.2%) |
| < 5 mm Change in Diameter | 7 (58.3%) | 17 (40.5%) | 13 (36.1%) | 9 (28.1%) | 9 (31.0%) | 8 (34.8%) |
| ≥ 5 mm Increase in Diameter | 1 (8.3%) | — | 1 (2.8%) | 2 (6.3%) | 1 (3.4%) | — |
| 05-02 GORE® TAG® DEVICE | | | | | | |
| Number of Patients with Available Data ^b | 41 | 83 | 69 | 52 | 31 | 8 |
| Change in Aneurysm Diameter from Baseline | | | | | | |
| ≥ 5 mm Decrease in Diameter | 13 (31.7%) | 36 (43.4%) | 35 (50.7%) | 33 (63.5%) | 15 (48.4%) | 6 (75.0%) |
| < 5 mm Change in Diameter | 26 (63.4%) | 44 (53.0%) | 29 (42.0%) | 13 (25.0%) | 13 (41.9%) | 1 (12.5%) |
| ≥ 5 mm Increase in Diameter | 2 (4.9%) | 3 (3.6%) | 5 (7.2%) | 6 (11.5%) | 3 (9.7%) | 1 (12.5%) |
| 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 six-month visit was not required as part of either the TAG 03-03 Study or the TAG 05-02 Study. | | | | | | |
| ^b Patients must have a baseline (one month) and a post-baseline measurement to be available for evaluation. | | | | | | |

Aneurysm Enlargement

Table 6 summarizes the changes in aneurysm size for Test patients in the Pivotal (TAG 99-01), Confirmatory (TAG 03-03), and Post-Approval Studies (TAG 05-02). 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.

There were five Post-Approval Study patients with aneurysm enlargement associated with endoleak. One patient with aneurysm enlargement at six months had an indeterminate endoleak. Two patients had three endoleaks at two years

post-treatment. Two patients had endoleaks (one Type I and one indeterminate) at three years post-treatment.

The incidence of aneurysm growth ≥ 5 mm in Confirmatory and Pivotal Study Test patients at five years was 0% and 19%, respectively. The incidence at three years for the Post-Approval Study was 6.3%. The GORE® TAG® Device used in the Confirmatory and Post-Approval Studies 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. All GORE® TAG® Devices currently in commercial distribution incorporate the low permeability film layer.

Rupture

Five ruptures (1.2%) have been reported for the combined Pivotal, Confirmatory, Treatment IDE and Post-Approval 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

Section I – Clinical Study Experience

Table 7: Additional Thoracic Stent Graft Implants Through Five Years Post-Treatment

| | POST-TREATMENT FOLLOW-UP PERIOD | | | | | | | |
|-------------------------|---------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|------------------|
| | 1 MONTH | 6 MONTHS | 12 MONTHS | 24 MONTHS | 36 MONTHS | 48 MONTHS | 60 MONTHS | TOTAL |
| Number of Patients | 421 | 408 | 375 | 339 | 275 | 222 | 150 | 421 |
| 99-01 GORE® TAG® Device | 1 (0.2%) | 0 (0.0%) | 0 (0.0%) | 2 (0.6%) | 1 (0.4%) | 1 (0.5%) | 0 (0.0%) | 3 (0.7%) |
| 03-03 GORE® TAG® Device | 0 (0.0%) | 1 (0.2%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 1 (0.2%) |
| 04-02 GORE® TAG® Device | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 1 (0.3%) | 0 (0.0%) | 1 (0.5%) | 1 (0.7%) | 3 (0.7%) |
| 05-02 GORE® TAG® Device | 0 (0.0%) | 5 (1.2%) | 2 (0.5%) | 4 (1.2%) | 2 (0.7%) | 2 (0.9%) | 0 (0.0%) | 14 (3.3%) |
| TOTAL | 1 (0.2%) | 6 (1.5%) | 2 (0.5%) | 7 (2.1%) | 3 (1.1%) | 4 (1.8%) | 1 (0.7%) | 21 (5.0%) |

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).

post-treatment. The patient subsequently died secondary to the ruptured aneurysm. Two patients in the Post-Approval Study experienced aneurysm rupture. In the first patient there was a rupture of a thoracoabdominal aneurysm in addition to two endoleaks. The aneurysm and treatment area extended below the celiac artery which was covered with a GORE® TAG® Device. Although the patient did not meet the inclusion criteria, the patient was enrolled in the study. The two endoleaks and the rupture for this patient resolved following reintervention within the six-month follow-up window. A second patient reported a ruptured abdominal aortic aneurysm which resulted in death.

Conversion

Four conversions (1.0%) have been reported for the combined Pivotal, Confirmatory, Treatment IDE and Post-Approval 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. One Post-Approval patient was converted 24 months post-treatment due to an aortoenteric fistula. Upon explant it was noted that the patient also had a prosthesis infection. The patient died one day later.

Additional Implantations

A total of 21 patients (5.0%) in the Pivotal, Confirmatory, Treatment IDE, and Post-Approval Study cohort have undergone one or more additional thoracic stent graft implantations (Table 7). Most (n = 16) additional implantations were primarily performed to treat endoleak. Further reasons for additional implantation included migration with associated endoleak

(n = 1), prosthesis material failure (n = 1), pseudoaneurysm and penetrating ulcer distal to the initially treated aneurysmal segment (n = 1), and additional aneurysm treatment (n = 1). One additional implantation has no cause identified to date.

Device Integrity

There have been 20 device fractures (19 spine wire fractures; 1 apex wire) identified by Investigational Sites, the Core Laboratory, or the Sponsor in 19 of 140 patients enrolled in the Pivotal Study (14%) 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 was one reported prosthesis material failure in the Post-Approval Study. No source of endoleak could be identified so the investigator coded the event as prosthesis material failure. This event began as a minor event at the 30-Day visit but was upgraded to major when reintervention was performed at three years.

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.

Two migrations (0.5%) have been reported for the combined Pivotal, Confirmatory, Treatment IDE and Post-Approval Study cohort. One Pivotal Study patient experienced a device migration and Type I endoleak which required surgical intervention to resolve. One Post-Approval Study patient experienced a device migration at 12 months post-treatment due to aneurysmal degeneration of the graft seal zones which was resolved with additional GORE® TAG® Device implantation.

Section II – Worldwide Commercial Experience

There have been more than 48,000 GORE® TAG® Devices commercially distributed worldwide through January 26, 2011. This includes more than 2,000 Original GORE® TAG® Devices and more than 46,000 Current GORE® TAG® Devices with an average of 1.7 devices implanted per patient. **Table 8** provides a data summary of worldwide commercial events reported to Gore for the GORE® TAG® Device.

The information includes data from the commercial use of the GORE® TAG® Device and Physician Sponsored IDE (PSIDE) study data from three institutions treating patient populations with high-risk aneurysmal and non-aneurysmal etiologies.

Table 8: Summary of Worldwide Commercial Events Reported to Gore for the GORE® TAG® Device

| WORLDWIDE COMMERCIAL EXPERIENCE | |
|---------------------------------|------------|
| Rupture (post-procedure) | 21 |
| Conversion (post-procedure) | 95 |
| Aneurysm-Related Death | 343 |
| Migration (post-procedure) | 27 |
| Paraplegia / Paraparesis | 74 |
| Stroke | 60 |
| Device Integrity: | |
| Compression* | 183 |
| Fracture | 60 |
| Deployment Anomaly | 7 |
| Explants | 138 |

*More information is provided on Device Compression Events in the Device Integrity section of this document.

Rupture

Twenty-one post-procedure ruptures of the DTA have been reported to Gore. Eight of these ruptures were associated with endoleaks; one rupture resulted from a Type II endoleak perfusing the aneurysmal sac, six ruptures resulted from Type I endoleaks, and one rupture resulted from an unknown endoleak. Six of the remaining 13 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 six other ruptures were reported with no or incomplete information regarding the cause of the rupture.

Conversion

There have been 95 post-procedure conversions to surgical repair reported to Gore. **Table 9** provides a breakdown of the causes of the conversions.

Table 9: Post-Procedure Commercial Conversions

| | |
|------------------------------------|-----------|
| Resolve Endoleaks | 14 |
| Device Compression | 37 |
| Progression of Dissection Disease | 18 |
| Rupture Caused by Type II Endoleak | 4 |
| Infection | 12 |
| Other | 10 |
| TOTAL | 95 |

Of the twelve patients converted due to infection, one was the result of infected aorto-esophageal fistulas, three were the result of infected aorto-bronchial fistulas, two were due to an infection that was present pre-implantation, one was the result of a PICC line infection that led to device infection, one was the result of a patient that had contracted a salmonella bacterial infection, and four were of unknown causes. None of the reported infections were found to have originated from the implanted device. The “Other” category includes post-procedural conversions due to unsatisfactory device placement, dissection caused by placement of a PALMAZ® Stent, syncope, pulmonary aortic adhesions, and fistulas.

Section II – Worldwide Commercial Experience

Aneurysm-Related Death

There have been 343 aneurysm-related deaths reported to Gore. **Table 10** provides a breakdown of the causes of these aneurysm-related deaths.

Table 10: Aneurysm-Related Deaths in Commercial Experience

| | |
|------------------------|------------|
| Pre-Procedure Ruptures | 54 |
| Comorbidities | 141 |
| Procedure-Related | 92 |
| Device-Related | 13 |
| Unknown Causes | 43 |
| TOTAL | 343 |

The 13 aneurysm-related deaths attributed to device-related events include 2 attributed to untreated Type I endoleaks, 4 related to complications with device compression, and 3 cases in which patients, who were treated for a thoracic aortic aneurysm, presented post-operatively with an ascending aortic dissection. In addition, cases were reported of two proximal migrations of the device causing a stroke, one case of multi-organ failure suspected to be caused by coverage of spinal arteries, and the thirteenth report due to an aorto-esophageal fistula formation at the location of the distal flares of the GORE® TAG® Device.

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

Migration

There have been 27 post-procedural device migrations reported to Gore. However, only 11 of the 27 reported events have been confirmed. Of the confirmed migrations, three device migrations were reported to have been caused by device undersizing; one leading to a Type I endoleak and two leading to a device compression. Four devices were reported to have been oversized leading to device compression in three of the cases. Another of the confirmed device migrations was an inter-component migration leading to a Type III endoleak. Three confirmed migrations caused Type I endoleaks but sizing of the device could not be verified. The additional 16 device migrations reported to Gore could not be confirmed by Gore due to inadequate imaging or inability to acquire films. 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.

Paraplegia / Paraparesis

There have been 74 cases of paraplegia / paraparesis that occurred during or after the procedure that have been reported to Gore. There were 51 cases of post-implantation paraplegia reported; 40 of these paraplegia cases had no known recovery, 6 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. In another case, the spinal drain reportedly caused transient paraplegia that reversed without intervention, and in another, the patient recovered with drug treatment. Nine patients developed paraparesis post-implantation of which five patients had full recovery with placement of a spinal drain, two patients had no known recovery, and in two patients the paraparesis resolved without intervention. In addition to these 60 patients, there were 12 patients that developed hemi- or mono-paralysis / paresis due to strokes and 2 patients that were diagnosed with quadraplegia from unknown causes.

Section II – Worldwide Commercial Experience

Stroke

There have been 60 intra-operative or post-procedural cases of stroke reported to Gore. Forty-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 16 patients have unknown treatment locations; this information was not reported nor were films provided that would facilitate acquiring this information. Twelve of the strokes were reported to have caused hemi- or mono-paralysis / paresis.

Device Integrity

Compression

There have been 183 device compressions reported to Gore. Compression of a GORE® TAG® Device is defined as a failure of the device to maintain its intended expanded diameter post-implantation. Of the 183 device compressions reported, Gore has confirmed successful reinterventions in 126 cases, as well as 11 patient deaths, the development of paraplegia in 2 cases and fatal stroke experienced in 2 cases.

Reinterventions include re-ballooning, placement of additional thoracic endoprostheses, placement of a bare metal stent, or surgical conversion. In all 13 cases where the patient ultimately died, the devices were not sized according to the sizing guidelines specified in the *Instructions for Use* or the device was used in the treatment of pathologies other than degenerative, atherosclerotic aneurysms of the DTA. The highest reported incidence of device compression has been in young patients presenting with acute, traumatic transections 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 in these patients 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 physicians the importance of patient selection, and adhering to the intended use and sizing guidelines included in the IFU.

Fracture

There have been 60 devices reported to Gore with wire fractures. Of the 60 devices reported to have fractures, 1 device was confirmed by Gore to have no fractures and 9 could not be confirmed as the imaging analysis was inconclusive. Eighteen devices (current design) reported to Gore were confirmed to contain wire fractures; these fractures were identified throughout the device and were found to be consistent with fatigue failure associated with device compression events. Fourteen of the 18 devices were either oversized or undersized to the aorta; in the other 4 cases, the sizing could not be confirmed. Eleven of the cases were for the treatment of transections, 4 of the cases were for dissections, and the remaining 3 cases were for treatment of an aneurysm, a diseased aortic wall, and an ulcer. Thirty-two 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. Deployment anomalies include difficulty in deploying the device, difficulty in withdrawing the delivery catheter after an attempted deployment, and partial deployment of the device when attempting deployment. 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. In this case the leading end of the delivery catheter could not be separated from the trailing end of the device. This event was identified as a unique isolated incident associated with a single device. Modifications to the manufacturing procedure were made to prevent further occurrences.

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

Section III – Explant Analysis

Explant Analysis

There have been a total of 138 cases of GORE® TAG® Device explants reported to Gore. Sixty-seven of these total cases were returned to Gore for analysis and were evaluated for biologic response, material integrity, and overall device durability. The primary cause of explant was evaluated for these 67 cases which represent a total of 110 GORE® TAG® Devices.

Primary Cause of Explant

Of the 67 cases of device explant, etiology comprised of 33 aneurysms or pseudo-aneurysms, 12 dissections, 10 transections, and 8 ruptures. The remaining device explants were three cases of other etiologies and one case of unreported etiology. **Table 11** lists the primary cause of explant.

Table 11: Primary Cause of Explant

| NUMBER OF OCCURRENCES | |
|------------------------------------|-----------|
| REASON FOR EXPLANT | TOTAL |
| Implantation Difficulties | 12 |
| Rupture | 2 |
| Aneurysm Enlargement with Endoleak | 5 |
| Endoleak | 2 |
| Migration | 1 |
| Infection | 6 |
| Fistula | 4 |
| Dissection | 6 |
| Compression | 15 |
| Incidental Autopsy | 14 |
| Other | 2 |
| TOTAL CASES^a | 69 |

^a In two cases, the patient was reported to have more than one primary cause of explant (67 + 2 = 69). The explant analysis includes clinical trial data as well as commercial data.

Complications related to the explant procedure resulted in death in a total of two cases. Of the 15 compressions leading to explant, 12 were sized incorrectly and the sizing on 3 devices could not be verified. In all but six of the compression cases, the GORE® TAG® Devices were placed for the treatment of transections of the aorta. Implantation difficulties consisted predominantly of graft delivery issues associated with difficult anatomy as well as movement of the graft from the intended deployment site, due to post-deployment procedural manipulations.

Device Integrity Observations

Of the 67 cases of explanted devices returned to Gore for analysis, 40 cases were investigated and found to have no device integrity issues. In 25 cases, device integrity observations included wire fractures, including spine wire fractures (original GORE® TAG® Device), ePTFE holes from wire ends, ePTFE holes from frictional wear, as well as instrumentation-related observations likely occurring during device retrieval.

Table 12: Device Integrity Observations

| OBSERVATION | NUMBER OF CASES | | |
|----------------------------|--|--|-----------|
| | ORIGINAL GORE® TAG® DEVICE WITH SPINE WIRE (> 1,530 CASES) | CURRENT GORE® TAG® DEVICE (> 28,612 CASES) | TOTAL |
| Fracture | 5 | 16 | 21 |
| ePTFE Abrasion Holes | 3 | 6 | 9 |
| No Device Integrity Issues | 10 | 32 | 42 |
| TOTAL CASES | 15 | 52 | 67 |

Some cases of ePTFE abrasion holes were the same cases as that of fracture, resulting in the numbers in the first three rows adding up to a total higher than the total number of cases listed in the final row.

Section IV – 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% and 43% freedom from major adverse events in the Pivotal and Confirmatory 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% and 98% freedom from aneurysm-related death among Pivotal and Confirmatory Study Test patients vs. 88% for Pivotal Study Control patients through five years post-treatment).

Combined data from the Pivotal Study (five-year follow-up), Confirmatory Study (five-year follow-up), Treatment IDE (five-year follow-up) and Post-Approval Study (three-year follow-up) test patients reveal a migration incidence of 0.5%, additional implantation incidence of 5.0%, rupture incidence of 1.2% and a conversion incidence of 1.0%.

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

- Aneurysm increase (≥ 5 mm) incidence in Pivotal, Confirmatory and Post-Approval Study patients was 19.0% (n = 8), 0% and 11.5% (n = 6), respectively.
- Rupture incidence for Pivotal, Confirmatory, Treatment IDE and Post-Approval patients was 1.2% (n = 5) cumulative.
- Conversion incidence for Pivotal, Confirmatory, Treatment IDE and Post-Approval patients was 1.0% (n = 4) cumulative.
- Additional implantation incidence for Pivotal, Confirmatory, Treatment IDE and Post-Approval patients was 5.0% (n = 21) cumulative.
- Twenty device fractures have been identified in 19 Pivotal Study patients. There have been no device fractures reported in either the Confirmatory, Treatment IDE or Post-Approval Studies.
- One deployment anomaly has been reported in the Pivotal Study. There have been no deployment anomalies reported in either the Confirmatory, Treatment IDE or Post-Approval Studies.
- One device migration has been reported in each of the Pivotal and Post-Approval Studies (n = 2). There have been no device migrations reported in either the Confirmatory or Treatment IDE Studies.

Summary of Worldwide Commercial Experience

From the reported worldwide commercial experience through January 26, 2011, there have been:

- 21 post-procedure ruptures of the DTA
- 95 post-procedure conversions
- 343 aneurysm-related deaths
- 27 post-procedure reported migrations
- 74 incidents of paraplegia or paraparesis
- 60 incidents of stroke
- 183 device compressions
- 60 devices with reported fractures
- 7 deployment anomalies
- 138 explants

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, Treatment IDE, and Post-Approval Study 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 therapy option in the treatment of thoracic aortic aneurysms.

Gore is pleased to offer a device that has performed consistently since the introduction of the product in 1997. We remain committed to improving patient outcomes and delivering future innovations in this exciting field.

Section IV – Summary and Conclusions

UNITED STATES INDICATIONS FOR USE

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

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

CONTRAINDICATIONS

The GORE® TAG® Thoracic Endoprosthesis is contraindicated in:

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

WARNINGS AND PRECAUTIONS

General

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

Patient Selection and Treatment

- Successful patient selection requires specific imaging and accurate measurements; please see *Measurement Techniques and Imaging* section below.
- The GORE® TAG® Thoracic Endoprosthesis is designed to treat aortic neck diameters no smaller than 23 mm and no larger than 42 mm. The GORE® TAG® Thoracic Endoprosthesis is designed to treat proximal and distal aortic neck lengths no less than 20 mm distal to either the left subclavian or left common carotid artery. Additional proximal aortic neck length may be gained by covering the left subclavian artery (with or without discretionary transposition) when necessary to optimize device fixation and maximize aortic neck length. Distal aortic neck length of at least 20 mm proximal to the celiac axis is required. These sizing measurements are critical to the performance of the endovascular repair.
- Adequate iliac or femoral access is required to introduce the device into the vasculature. Careful evaluation of vessel size, anatomy and disease state, is required to assure successful sheath introduction and subsequent withdrawal. A surgically created vascular conduit may be needed to achieve access in select patients.
- The safety and effectiveness of the GORE® TAG® Thoracic Endoprosthesis have not been evaluated in the following patient etiologies:
 - acute and chronic dissections
 - aortic fistulas
 - aortitis or inflammatory aneurysms
 - intramural hematoma
 - mycotic aneurysms
 - penetrating ulcers
 - traumatic aortic transections
 - pseudoaneurysms resulting from previous graft placement
 - genetic connective tissue disease (e.g., Marfans and Ehlers-Danlos syndrome)
 - patients with active systemic infections
 - patients less than 21 years old
 - pregnant or nursing females

- Differing proximal and distal neck diameters (aortic taper) outside the intended aortic diameter requirements for a single endoprosthesis diameter 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 using appropriate vascular access techniques (including surgical conduit, if needed).
- Key anatomic elements that may affect successful exclusion of the aneurysm include severe neck angulation, short aortic neck(s) and significant thrombus and / or calcium at the arterial implantation sites. In the presence of anatomical limitations, a longer neck length may be required to obtain adequate sealing and fixation.
- Excessive thrombus or atherosclerotic plaque in the aortic arch may increase the risk of stroke.
- Use of the GORE® TAG® Thoracic Endoprosthesis outside of the recommended anatomical sizing guidelines may result in potentially serious device-related events (e.g., device infolding, excessive device compression, endoleak, wire fracture, migration).
- If occlusion of the left subclavian artery ostium is required to obtain adequate neck length for fixation and sealing, transposition of the left subclavian artery should be considered.
- The GORE® TAG® Thoracic Endoprosthesis is not recommended in patients who cannot tolerate contrast agents necessary for intraoperative and post-operative follow-up imaging.
- The GORE® TAG® Thoracic Endoprosthesis is not recommended in patients with known sensitivities or allergies to ePTFE, FEP, nickel, or titanium.
- ASA risk was higher in patients enrolled in the TAG 04-01 Ruptured Aneurysm Arm compared to patients enrolled in the TAG 99-01 and TAG 03-03 Aneurysm studies. Patients presenting with ruptured aneurysm may be at higher risk for complications associated with general anesthesia.

Measurement Techniques and Imaging

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

• Diameter

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

• Length

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

Device Selection:

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

Section IV – Summary and Conclusions

Implant Procedure

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

Follow-up

- Do not use the GORE® TAG® Thoracic Endoprosthesis in patients unable to undergo the necessary pre-operative and post-operative imaging. All patients should be monitored closely and checked periodically for a change in the condition of their disease and the integrity of the endoprosthesis.
- Wire fractures have been reported on this type of endoprosthesis and may be more likely to occur in conditions with excessive endoprosthesis oversizing, flexion, kinking, or bending with cardiac or respiratory cycles. Wire fractures may have clinical consequences which may include, but are not limited to endoleak, endoprosthesis migration, and / or adjacent tissue damage.

- A late type III endoleak was observed within 24 hours after DC cardioversion. Close surveillance is recommended to watch for symptoms of endoleaks post DC cardioversion or defibrillation.
- In patients enrolled in the TAG 04-01 Ruptured Aneurysm Arm, reintervention with a GORE® TAG® Thoracic Endoprosthesis was performed in three (15%) subjects through one year post-treatment. All reinterventions were performed within seven days of the initial procedure to treat endoleak.
- The incidence of type I endoleak was higher in patients enrolled in the TAG 04-01 Ruptured Aneurysm Arm compared to patients enrolled in the TAG 99-01 and TAG 03-03 Aneurysm studies. Additional radiologic follow-up may be warranted in patients who undergo endovascular repair for ruptured aortic aneurysm.
- Although the available data from use of the GORE® TAG® Thoracic Endoprosthesis 45 mm device supports similar outcomes compared to patients treated with smaller sized GORE® TAG® Devices, it is possible that patients with large aortic diameters represent a population for whom the aorta at that level is already diseased. Physicians should tailor patient follow-up to the needs and circumstances of each individual patient; patients with larger aortic diameters may represent a population for whom additional regular follow-up is warranted. Regular and consistent follow-up is a critical part of ensuring the safety and efficacy of aortic endovascular repair.
- Please refer to the IMAGING GUIDELINES and POST-OPERATIVE FOLLOW-UP for MRI safety and compatibility information.

MRI Safety and Compatibility

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

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

3.0 Tesla Temperature Rise:

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

1.5 Tesla Temperature Rise:

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

Image Artifact:

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

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