GORE® TAG® Thoracic Endoprosthesis
ANNUAL CLINICAL UPDATE†
SEPTEMBER 2018

Abstract

This annual clinical update provides a review of the ongoing experience with the GORE® TAG® Thoracic Endoprosthesis. There have been more than 146,000 GORE® TAG® Devices, including the GORE® TAG® Thoracic Endoprosthesis and the Conformable GORE® TAG® Thoracic Endoprosthesis, distributed worldwide as part of our IDE clinical trials and commercial experience through December 31, 2017. Information related to four events of incomplete deployment that resulted in a Class II recall (initiated September 25, 2017) is included in Section III of this report. This Class II recall resulted in an update to the Instructions for Use (IFU) and a physician safety letter. There was no removal of product from the market or explants of any devices associated with the recall. In the U.S., the GORE® TAG® Thoracic Endoprosthesis is indicated for the treatment of aneurysms of the descending thoracic aorta. The Conformable GORE® TAG® Thoracic Endoprosthesis is indicated for the treatment of isolated lesions and all Type B dissections. Synopses from our completed GORE® TAG® Device clinical and post-approval studies, final follow-up results from our Conformable GORE® TAG® Device Aneurysm Study (TAG 08-03), Traumatic Transection Study (TAG 08-02), and Acute Complicated Type B Dissection Study (TAG 08-01), and our worldwide commercial experience for the past two years (2016 and 2017) are provided in this update. These updated results continue to support the endovascular treatment of descending thoracic etiologies, including aortic aneurysms, isolated lesions, and Type B dissections of the descending thoracic aorta with the Conformable GORE® TAG® Device.

The Conformable GORE® TAG® Device was designed to improve device conformability and compression resistance while expanding treatment ranges. Data from three clinical studies using this device are included in this update. The Conformable GORE® TAG® Device Aneurysm Study (TAG 08-03) (five-year follow-up) was conducted to confirm the performance of the Conformable GORE® TAG® Device in the treatment of aneurysms. Data from Test patients reveal no device migrations, two ruptures, no conversions, and three patients requiring an additional implantation. The Conformable GORE® TAG® Device Traumatic Transection Study (TAG 08-02) (five-year follow-up) was conducted to evaluate the performance of the Conformable GORE® TAG® Device in the treatment of traumatic transection. Data from Test patients reveal no device migrations, no ruptures, no conversions, no device compressions, and no patients requiring additional thoracic stent graft implantation. The Conformable GORE® TAG® Device Acute Complicated Type B Dissection Study (TAG 08-01) (five-year follow-up) was conducted to evaluate the performance of the Conformable GORE® TAG® Device in the treatment of acute complicated Type B aortic dissection. Data from Test patients reveal no device migrations, two ruptures, no conversions, no device compressions, and six patients requiring additional thoracic stent graft implantation.

There have been more than 146,000 devices distributed worldwide, however, the number of patients treated is estimated to be less than the number of devices distributed. Reported events from the past two years of commercialization are as follows:

In 2016, there were 30 post-procedure ruptures of the descending thoracic aorta, 13 post-procedure conversions to surgical repair, 87 aneurysm-related deaths, 4 post-procedural migrations, 37 paraplegia or paraparesis patients, 33 stroke patients, 3 device compressions[1] reported, 1 device with reported fractures, and 0 devices with deployment anomalies reported.

Additionally, in 2017, there were 7 post-procedure ruptures of the descending thoracic aorta, 4 post-procedure conversions to surgical repair, 33 aneurysm-related deaths, 6 post-procedural migrations, 11 paraplegia or paraparesis patients, 9 stroke patients, 0 device compressions[1] reported, 0 devices with reported fractures, and 6 devices with a deployment anomaly reported.

Total occurrences within each category can and do fluctuate year to year. Increases from previous year, specifically the number of post-procedural ruptures and aneurysm-related deaths, was noted in 2016 and returned to lower levels in 2017. Overall endovascular treatment expansion, increased volume of devices implanted, and changes in regional reporting guidelines could account for the general fluctuations. Even with these increases, the worldwide commercial experience has remained consistent with the acceptable performance exhibited in previous years.

Based on available clinical study data and worldwide clinical experience to date, endovascular therapy with the GORE® TAG® Device, including the Conformable GORE® TAG® Device, continues to be a viable treatment option for the repair of the descending thoracic aorta (DTA).

Introduction

W. L. Gore & Associates, Inc. (Gore), Medical Products Division, is pleased to provide this clinical update of the ongoing clinical experience of the devices described above. This report provides synopses of the results from our completed GORE® TAG® Device clinical and post-approval studies, final results from our Conformable GORE® TAG® Device Aneurysm, Traumatic Transection, and Dissection 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 diseases of the descending thoracic aorta (DTA). The GORE® TAG® Device was introduced in 1997 with an indication for endovascular repair of aneurysms of the DTA. It has provided patients with a means of aneurysm repair with less morbidity than open surgical repair. The Conformable GORE® TAG® Device was approved for treatment of aneurysms of the DTA in August 2011. The indication was expanded to treatment of isolated lesions, including traumatic transections, penetrating aortic ulcers, intramural hematomas, and other pathologies of the descending thoracic aorta (dissections excluded), in January 2012, based on the submission of data for the treatment of traumatic transections. Expansion of the indication to include the treatment of Type B aortic dissections, was approved in September 2013. The inclusion of all types of Type B dissection was supported by pre-market studies in conjunction with an agreement to conduct post-market studies.

We are providing this information to assist you in making informed treatment decisions for thoracic aortic aneurysm, isolated lesion, and Type B dissection patients and for you to share with your patients, referring physicians, and hospital colleagues. This report is divided into six sections:

- Section I includes synopses of the Feasibility (TAG 97-01), Pivotal (TAG 99-01), Confirmatory (TAG 03-03), Complex Pathology (TAG 04-01), Treatment IDE (TAG 04-02), Post-Approval (TAG 05-02), and 45 mm GORE® TAG® Device (TAG 06-02) studies. Detailed clinical results for all of these studies may be found in the Conformable GORE® TAG® Thoracic Endoprosthesis IFU available on our website.
- Section II includes the clinical results of the Conformable GORE® TAG® Device studies for the treatment of aneurysms, traumatic transection, and Type B aortic dissections of the DTA. All data are site-reported unless noted.
- Section III includes a summary of worldwide commercial experience of the GORE® TAG® Thoracic Endoprosthesis and Conformable GORE® TAG® Thoracic Endoprosthesis for the past two years, in which more than 146,000 devices have been distributed since 1997
- Section IV provides an analysis of explanted devices returned to Gore in the past two years as of December 31, 2017
- Section V provides summaries of the data contained in Sections I, II, and III, as well as conclusions
- Section VI details patient selection and follow-up for commercial use of the GORE® TAG® Device and the Conformable GORE® TAG® Device

† Worldwide commercial data contained in this document are current as of December 31, 2017. All Adverse Event definitions follow those used in Gore's clinical study protocols.

[1] No device compressions were associated with the Conformable GORE® TAG® Device.

Device descriptions

GORE® TAG® Device

The GORE® TAG® Device is a flexible, self-expanding endoprosthesis that is constrained on the leading end of a delivery catheter and has a treatment range of 23 mm to 42 mm. 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. The GORE® TAG® Device is no longer sold in the U.S. but continues to be sold outside of the U.S.

Conformable GORE® TAG® Device

The Conformable GORE® TAG® Device has the characteristics of the GORE® TAG® Device with a modified design to increase compression resistance and conformability of the device and to expand the treatment range to 16 mm to 42 mm with expanded oversizing (6–33%). Design modifications include removal of the flared ends, an additional apex around the circumference of the nitinol stent, movement of the radiopaque gold bands to the edges of the ePTFE graft, and inclusion of partially uncovered stents on the proximal end of the device. Endoprosthesis sizes range in diameter from 21 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 18 Fr to 24 Fr.

These brief descriptions of the devices and their construction will facilitate interpretation of the clinical results in this report.

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Section I – GORE® TAG® Device clinical study experience

Synopses for Feasibility (TAG 97-01), Pivotal (TAG 99-01), Confirmatory (TAG 03-03), Complex Pathology (TAG 04-01), Treatment IDE (TAG 04-02), Post-Approval (TAG 05-02), and 45 mm (TAG 06-02) GORE® TAG® Device studies are included in this section. Detailed clinical results for all of these studies may be found in the Conformable GORE® TAG® Thoracic Endoprosthesis IFU available on our website.

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.

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. Annual follow-up through five years post-treatment was completed in August 2009.

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 aortic 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 was completed in October 2011.

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 have been available for Treatment IDE patients at all intervals.

Post-Approval Study (TAG 05-02)

The Post-Approval Study (TAG 05-02) was a non-randomized, multicenter (25 sites) study evaluating the long-term performance of the GORE® TAG® Device in the primary treatment of aneurysms of the DTA and assessing the GORE® TAG® Device physician training program. Long-term performance of the device was 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. For this comparison, 150 patients were enrolled in the TAG 05-02 study and combined with test patients enrolled in previous GORE® TAG® Device studies, resulting in a total test group of 449 patients. These previous studies included the Feasibility (TAG 97-01, n = 28), Pivotal (TAG 99-01, n = 140), Confirmatory (TAG 03-03, n = 51), and Treatment IDE (TAG 04-02, n = 80) studies. In addition, a subset of major adverse events including stroke, paraplegia, and reintervention were evaluated in patients treated with the GORE® TAG® Device in these studies as compared to the open surgical control group from the TAG 99-01 surgical patients. This study was initiated in 2005 and completed enrollment in February of 2008. Five-year follow-up was completed in July 2013.

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 completed. The larger size GORE® TAG® Device was approved by the FDA in March 2010.

Section II – Conformable GORE® TAG® Device clinical study experience

Detailed clinical results for the Conformable GORE® TAG® Device Aneurysm Study (TAG 08-03), the Conformable GORE® TAG® Device Traumatic Transection Study (TAG 08-02), and the Conformable GORE® TAG® Device Acute Complicated Type B Dissection Study (TAG 08-01) are included in this section. The data are reported independently from historical clinical study data collected for the GORE® TAG® Device as increased adoption and understanding of endovascular practices and outcomes led to advances in study design, data collection, and analyses performed for the Conformable GORE® TAG® Device. Not all previous studies included core lab data. Specifically, only the TAG 99-01 and TAG 03-03 studies used an independent core laboratory to assess aortic morphology, vascular characteristics, and device integrity, while all other studies reported site data. Site-reported data reflects physician resources and expertise for patient treatment, and is important to overall analysis. For consistency with the older studies, site-reported data was used for reporting in our Conformable GORE® TAG® Device studies, unless otherwise indicated. A summary of each clinical study is provided below.

Aneurysm Study (TAG 08-03)

The Conformable GORE® TAG® Device Aneurysm Study (TAG 08-03) was designed to confirm the clinical performance of the Conformable GORE® TAG® Device in aneurysms of the DTA. This was a non-randomized, multicenter study conducted at a total of 21 investigational sites designed to demonstrate that the proportion of patients experiencing a major device event through one-month post-procedure were similar to the results obtained in historical GORE® TAG® Device studies. A total of 51 patients were enrolled in the trial and 15 patients were enrolled under a continued access protocol. The study was initiated in October 2009 and completed enrollment in October 2010, with extended enrollment of patients concluding in September 2011. The Conformable GORE® TAG® Device was approved for the treatment of aneurysms of the DTA in August 2011. This update provides results through 60 months. Five-year follow-up is complete as of January 2017.

Traumatic Transection Study (TAG 08-02)

The Conformable GORE® TAG® Device Traumatic Transection Study (TAG 08-02) was designed to describe the short-term safety and effectiveness of the Conformable GORE® TAG® Device in the treatment of traumatic aortic transection. This was a non-randomized, multicenter study conducted at a total of 26 investigational sites. A total of 51 patients were enrolled in the trial and an additional 50 patients were enrolled under a continued access protocol. The study was initiated in December 2009 and completed enrollment in January 2011, with extended enrollment of patients concluding in November 2011. The study endpoints for traumatic transection patients were met, and the Conformable GORE® TAG® Device was approved for the treatment of isolated lesions (not including dissections) of the DTA in January 2012. This update provides results through 60 months. Five-year follow-up is complete as of February 2017.

Acute Complicated Type B Dissection Study (TAG 08-01)

The Conformable GORE® TAG® Device Acute Complicated Type B Dissection Study (TAG 08-01) was designed to describe the short-term safety and effectiveness of the Conformable GORE® TAG® Device in the treatment of acute complicated Type B aortic dissections of the DTA. This was a non-randomized, multicenter study conducted at 26 investigational sites with 50 patients enrolled. The primary safety endpoint of this study was all-cause mortality incidence through 30 days post-treatment. The study was initiated in January 2010. The study endpoints for acute complicated Type B aortic dissection patients were met and the Conformable GORE® TAG® Device was approved for the treatment of Type B aortic dissections in September 2013. This update provides results through 60 months. Five-year follow-up is complete as of February 2017.

Vascular Quality Initiative Post-Approval Dissection VQI Type B Dissection Post-Approval Surveillance Study (TAG 12-06)

The Vascular Quality Initiative (VQI), a Patient Safety Organization (PSO), in conjunction with the FDA and endovascular stent graft manufacturers, W. L. Gore & Associates, Inc. and Medtronic, Inc., agreed upon a Type B Dissection Post-Approval Surveillance Program that will make use of the VQI database to collect data regarding treatment of acute and chronic Type B aortic dissections with endovascular stent grafts.

Entry of patient data into the VQI Dissection Post-Approval Surveillance Program database began August 12, 2014. Patients treated for Type B aortic dissection beginning September 10, 2013 were eligible for inclusion in the data set.

The VQI data set consists of four cohorts: Acute Dissection with five-year follow-up; Chronic Dissection with five-year follow-up; Acute Dissection with one-year follow-up; and Chronic Dissection with one-year follow-up. Enrollment is now complete. No safety or effectiveness signals have been observed associated with the treatment of acute or chronic dissections for the Conformable GORE® TAG® Thoracic Endoprosthesis. Current efforts include focus on continued follow-up and surveillance. Refer to the *Journal of Vascular Surgery* article (2017;65(5):1280-1286) for more information regarding the study.

Section II – Conformable GORE® TAG® Device clinical study experience

Aneurysm study (TAG 08-03) results

Patient accountability

Table 1 provides the patient disposition for patients enrolled in the Conformable GORE® TAG® Device Aneurysm Study (TAG 08-03). Since the last update, 10 additional patients reported 60-month follow-up and 2 additional patients reported 48-month follow-up. Eligible patients are defined as those that are alive and participating in the study for that follow-up period. All eligible patients have completed the 60-month follow-up period. 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). The number of patients with adequate imaging to assess specific core lab parameters are described in **Table 2**.

Table 1: Patient compliance and disposition by study period

		Follow-up compliance[a]			Events prior to next interval[a]		
Study period	Eligible for follow-up	Patients with visit in window	With CT	With X-ray performed	Death	Discontinued[b]	Not due for next follow-up
TAG 08-03 Conformable GORE® TAG® Device Aneurysm Study							
Procedure	66	—[c]	—	—	0	0	0
Post-procedure	66	—	—	—	1 (1.5%)	1 (1.5%)	0
1 month	64	62 (96.9%)	60 (93.8%)	59 (92.2%)	1 (1.6%)	0	0
6 months	63	59 (93.7%)	59 (93.7%)	58 (92.1%)	3 (4.8%)	1 (1.6%)	0
12 months	59	58 (98.3%)	58 (98.3%)	55 (93.2%)	2 (3.4%)	0	0
24 months	57	51 (89.5%)	49 (86.0%)	47 (82.5%)	3 (5.3%)	1 (1.8%)	0
36 months	53	40 (75.5%)	39 (73.6%)	34 (64.2%)	5 (9.4%)	4 (7.5%)	0
48 months	44	35 (79.5%)	34 (77.3%)	27 (61.4%)	5 (11.4%)	3 (6.8%)	0
60 months	36	29 (80.6%)	28 (77.8%)	22 (61.1%)	4 (11.1%)	6 (16.7%)	—

Study period definitions: Procedure (0–0 days), post-procedure (1–14 days), 1 month (15–59 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] Percentages are based on number of patients in visit window. Compliance is based on site-reported imaging assessments.

[b] "Discontinued" refers to patients that no longer meet eligibility criteria due to voluntarily withdrawal or non-compliance. Patients no longer eligible due to death are provided separately. Changes in eligibility numbers are reflected in the subsequent follow-up window.

[c] A dash indicates information is not available.

Table 2: TAG 08-03 core lab adequate imaging

Study Period	Eligible for follow-up	Endoleak evaluable	DTA rupture evaluable	Wire fracture evaluable[1]	Extrusion/ erosion evaluable	Lumen obstruction/ compression/ thrombus evaluable	Migration evaluable	Diameters evaluable[2]
1 month	64	57 (89.1%)	60 (93.8%)	61 (95.3%)	60 (93.8%)	60 (93.8%)	59 (92.2%)	60 (93.8%)
6 months	63	54 (85.7%)	59 (93.7%)	59 (93.7%)	59 (93.7%)	59 (93.7%)	58 (92.1%)	59 (93.7%)
12 months	59	53 (89.8%)	57 (96.6%)	56 (94.9%)	56 (94.9%)	56 (94.9%)	54 (91.5%)	57 (96.6%)
24 months	57	43 (75.4%)	49 (86.0%)	48 (84.2%)	49 (86.0%)	49 (86.0%)	44 (77.2%)	49 (86.0%)
36 months	53	36 (67.9%)	39 (73.6%)	39 (73.6%)	39 (73.6%)	39 (73.6%)	37 (69.8%)	39 (73.6%)
48 months	44	30 (68.2%)	34 (77.3%)	34 (77.3%)	34 (77.3%)	34 (77.3%)	31 (70.5%)	34 (77.3%)
60 months	36	26 (72.2%)	28 (77.8%)	28 (77.8%)	28 (77.8%)	28 (77.8%)	25 (69.4%)	28 (77.8%)

Study period definitions: 1 month (15–59 days), 6 months (60–242 days), 12 months (243–546 days), 24 months (547–911 days), 36 months (912–1275 days), 48 months (1276–1640 days), 60 months (1641–2006 days)

[1] Wire fracture could be assessed by X-ray or CT.

[2] Maximum aneurysm diameters in axial and orthogonal views.

Section II – Conformable GORE® TAG® Device clinical study experience

Aneurysm-related death

Figure 1 provides a Kaplan-Meier plot of aneurysm-related deaths in the Conformable GORE® TAG® Device Aneurysm Study (TAG 08-03). There have been no new aneurysm-related deaths since the previous update. The following criteria were used to classify deaths as aneurysm-related:

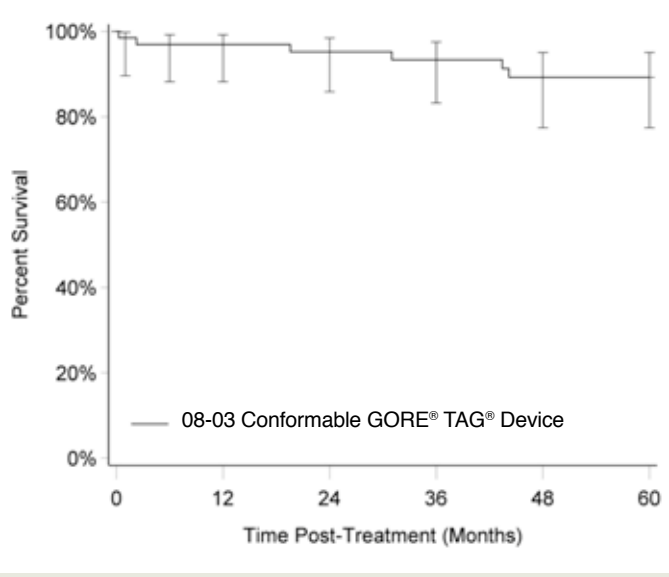
- Within 30 days of initial procedure or prior to hospital discharge
- Within 30 days of a secondary procedure to treat the original aneurysm or prior to hospital discharge for that procedure
- Adjudication by Clinical Events Committee or Office of Medical Affairs as device- or procedure-related

There have been six aneurysm-related deaths through 60 months:

- One at post-operative day (POD) eight due to multi-organ failure (occurring within 30 days of the initial procedure)
- One at POD 69 due to respiratory failure (occurring prior to hospital discharge)
- Two due to dissecting aortic aneurysm rupture at POD 1322 and 1345. More patient details are provided in TAG 08-03 Study Results – Rupture.
- One due to iliac disruption during a reintervention for endoleak (POD 596)
- One death associated with a device infection (POD 943)

Through 60 months, survival estimate was 89%.

Figure 1: Aneurysm-related death



	Months after procedure							
	Day 0	1 month	6 months	12 months	24 months	36 months	48 months	60 months
TAG 08-03 Conformable GORE® TAG® Device Aneurysm Study								
Patients at risk	66	64	59	58	54	50	41	21
Percent survival	100%	98%	97%	97%	95%	93%	89%	89%

Section II – Conformable GORE® TAG® Device clinical study experience

Freedom from major device-related events

Table 3 shows a summary of site-reported major device-related adverse events (MDE). There have been no new major device events since the previous update. Through 60-months post-treatment, six MDEs were reported in five patients. In one patient, at the time of the index procedure, several unsuccessful attempts were made to advance the device through access vasculature. The procedure was abandoned and patient was discontinued from the study. One patient reported a Type IA endoleak at 36 months and subsequent aortic rupture. The other three patients reported experiencing endoleaks of a Type IB at 36 months, Type II at 48 months, and an indeterminate location at 24 months, respectively. All resolved with successful treatment using an additional endovascular device.

Table 3: Summary of major device-related events

	Post-treatment follow-up period									
TAG 08-03 Conformable GORE® TAG® Device Aneurysm Study	Procedure	Post-procedure	1 month	6 months	12 months	24 months	36 months	48 months	60 months	Total
Number of patients	66	66	64	63	59	57	53	43	26	66
Number of patients with imaging evaluation or device event	66	62	61	59	58	51	40	33	19	66
Any major device event	1 (1.5%)[a]	0	0	0	0	1 (2.0%)	2 (5.0%)	1 (2.9%)	0	5 (7.6%)
Stent graft endoleak	0	—[b]	—	—	—	1 (2.0%)	2 (5.0%)	1 (2.9%)	—	4 (6.1%)
Stent graft endoleak	—	—	—	—	—	1 (2.0%)	0	0	—	1 (1.5%)
Stent graft endoleak Type IA	—	—	—	—	—	0	1 (2.5%)	0	—	1 (1.5%)
Stent graft endoleak Type IB	—	—	—	—	—	0	1 (2.5%)	0	—	1 (1.5%)
Stent graft endoleak Type II	—	—	—	—	—	0	0	1 (2.9%)	—	1 (1.5%)
Descending thoracic aorta rupture	0	—	—	—	—	0	1 (2.5%)	0	—	1 (1.5%)
Vascular access complication	1 (1.5%)	—	—	—	—	0	0	0	—	1 (1.5%)

Study period definitions: Procedure (0–0 days), post-procedure (1–14 days), 1 month (15–59 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), total (0–2006 days)

[a] Percentages are based on the number of patients with imaging follow-up, or device event in the given window.

[b] A dash indicates information is not available.

Endoleak

Table 4 summarizes the endoleak incidence for the Conformable GORE® TAG® Device Aneurysm Study (TAG 08-03). One new endoleak has been reported since the previous update, a minor Type II endoleak in the 60-month time period. This increased the total number of patients with Type II endoleak but did not affect the total with any endoleak, as this patient had previously reported a Type 1B endoleak in the 36-month time window. Overall, 13 (21.0%) patients have experienced an endoleak at any time during follow-up. Four of the 13 patients experienced a major endoleak, which are described in TAG 08-03 Study Results — Freedom from Major Device-Related Events. A "major" endoleak is one that: a) requires therapy and / or minor hospitalization < 48 hours; b) requires major therapy, unplanned increase in level of care, and / or prolonged hospitalization > 48 hours; c) results in permanent adverse sequelae; or d) results in death. The remaining 9 patients with endoleaks were not considered major. The majority of reported endoleaks (8 out of a total 13 patients) were identified within one month of the index procedure.

Table 4: Summary of endoleaks[a] by study period

TAG 08-03 Conformable GORE® TAG® Device Aneurysm Study	Procedure	Post-procedure	1 month	6 months	12 months	24 months	36 months	48 months	60 months	Total[b]
Patients available at beginning of interval	66	66	64	63	59	57	53	45	36	66
Patients with endoleak evaluation or ongoing endoleak	66	14	60	60	58	51	40	34	28	62
Patients with one or more endoleak adverse events ongoing in window	3 (4.5%)	3 (21.4%)	7 (11.7%)	6 (10.0%)	4 (6.9%)	4 (7.8%)	5 (12.5%)	5 (14.7%)	5 (17.9%)	13 (21.0%)
New	3 (4.5%)	0	5 (8.3%)	1 (1.7%)	1 (1.7%)	1 (2.0%)	2 (5.0%)	1 (2.9%)	1 (3.6%)	—[c]
Ongoing	—	3 (21.4%)	2 (3.3%)	5 (8.3%)	3 (5.2%)	3 (5.9%)	3 (7.5%)	4 (11.8%)	4 (14.3%)	—
Type I	1 (1.5%)	1 (7.1%)	3 (5.0%)	2 (3.3%)	1 (1.7%)	1 (2.0%)	3 (7.5%)	1 (2.9%)	1 (3.6%)	5 (8.1%)
New	1 (1.5%)	0	2 (3.3%)	0	0	0	2 (5.0%)	0	0	—
Ongoing	—	1 (7.1%)	1 (1.7%)	2 (3.3%)	1 (1.7%)	1 (2.0%)	1 (2.5%)	1 (2.9%)	1 (3.6%)	—
Type IA	1 (1.5%)	1 (7.1%)	3 (5.0%)	2 (3.3%)	1 (1.7%)	1 (2.0%)	2 (5.0%)	1 (2.9%)	1 (3.6%)	4 (6.5%)
New	1 (1.5%)	0	2 (3.3%)	0	0	0	1 (2.5%)	0	0	—
Ongoing	—	1 (7.1%)	1 (1.7%)	2 (3.3%)	1 (1.7%)	1 (2.0%)	1 (2.5%)	1 (2.9%)	1 (3.6%)	—
Type IB	0	0	0	0	0	0	1 (2.5%)	0	0	1 (1.6%)
New	0	0	0	0	0	0	1 (2.5%)	0	0	—
Ongoing	—	0	0	0	0	0	0	0	0	—
Type II	2 (3.0%)	2 (14.3%)	4 (6.7%)	4 (6.7%)	2 (3.4%)	1 (2.0%)	2 (5.0%)	3 (8.8%)	3 (10.7%)	9 (14.5%)
New	2 (3.0%)	0	3 (5.0%)	1 (1.7%)	0	0	1 (2.5%)	1 (2.9%)	1 (3.6%)	—
Ongoing	—	2 (14.3%)	1 (1.7%)	3 (5.0%)	2 (3.4%)	1 (2.0%)	1 (2.5%)	2 (5.9%)	2 (7.1%)	—
Type III	0	0	0	0	0	0	0	0	0	0
New	0	0	0	0	0	0	0	0	0	—
Ongoing	—	0	0	0	0	0	0	0	0	—
Indeterminate	0	0	0	0	1 (1.7%)	2 (3.9%)	1 (2.5%)	1 (2.9%)	1 (3.6%)	2 (3.2%)
New	0	0	0	0	1 (1.7%)	1 (2.0%)	0	0	0	—
Ongoing	—	0	0	0	0	1 (2.0%)	1 (2.5%)	1 (2.9%)	1 (3.6%)	—
Patients with no endoleak adverse events ongoing in window	63 (95.5%)	11 (78.6%)	53 (88.3%)	54 (90.0%)	54 (93.1%)	47 (92.2%)	35 (87.5%)	29 (85.3%)	23 (82.1%)	49 (79.0%)

Study period definitions: Procedure (0–0 days), post-procedure (1–14 days), 1 month (15–59 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), total (0–2006 days)

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

[b] Total number of patients with endoleak shown. The designation of "New" and "Ongoing" endoleak is only informative in the context of a specific follow-up window and therefore totals are not provided for these subcategories.

[c] Dashes in this column indicate that the information is not available relevant for procedural data.

Section II – Conformable GORE® TAG® Device clinical study experience

Aneurysm enlargement

Table 5 summarizes site-reported data for changes in the aneurysm size of patients in the Conformable GORE® TAG® Device Aneurysm Study (TAG 08-03). Change in aneurysm size was calculated by comparing the maximum aneurysm diameter at each follow-up visit to the baseline diameter measured at one-month follow-up. Each follow-up window is independently reported and indicates number of patients within each growth category over only that window; each patient may only be represented once within a follow-up window. Site reported observations include:

- One new patient experienced growth in the 48-month window and one new patient experienced growth in the 60-month window since the previous update
- Eleven total patients exhibiting aneurysm growth ≥ 5 mm during at least one follow-up visit
  - Of the 11 patients, only 4 had reported increases in aneurysm diameter at multiple time points
  - Three of the four patients demonstrating at growth at 60 months also saw growth at 48 months; two of those patients also had reported growth at 36 months
  - Three patients with multiple time points, demonstrated a reduction in aneurysm size after the initial reported increase in diameter. The aneurysm growth may be mainly attributed to endoleaks.
- A notable percentage increase in patients with aneurysm growth was observed at 48 and 60 months. Two factors may have contributed to the increase:
  - The patient follow-up attrition rate at the later time points; patients with endoleak are more likely to be followed by the site.
  - Identified Type II endoleaks; four of the six patients with growth in the 48 month time window had Type II endoleak reported at an earlier time point and two of these resolved without treatment several years prior to 48 month imaging.
- A total of 9 patients were reported by core lab to have aneurysm growth of 5 mm or greater at any time during follow-up using axial imaging. Core lab observations include:
  - Three of these nine patients had growth reported at multiple time points
  - Of the nine core lab reported patients with growth at any time, five patients were in common with site reporting
- Of the four site-reported patients who exhibited increases over multiple time points, growth was confirmed for two patients by core lab
  - Both had endoleaks that may have contributed to aneurysm enlargement
  - One patient had a Type II endoleak and one patient had a faint Type I endoleak which resolved by the one-month follow-up, but later had an undetermined endoleak which resolved by last reporting. No re-intervention was reported for the treatment for the endoleaks.
- At 60 months, over 85% of patients experienced ≤ 5 mm of diameter change or ≥ 5 mm decreased diameter of their aneurysms

Table 5: Change in aneurysm diameter from baseline

	Months after procedure					
TAG 08-03 Conformable GORE® TAG® Device Aneurysm Study	**6 months**	**12 months**	**24 months**	**36 months**	**48 months**	**60 months**
Number of patients with available data[a]	55	55	48	38	33	27
Change in aneurysm diameter from baseline						
≥ 5 mm decrease in diameter	24 (43.6%)	31 (56.4%)	30 (62.5%)	23 (60.5%)	17 (51.5%)	16 (59.3%)
≤ 5 mm change in diameter	28 (50.9%)	23 (41.8%)	17 (35.4%)	12 (31.6%)	10 (30.3%)	7 (25.9%)
≥ 5 mm increase in diameter	3 (5.5%)	1 (1.8%)	1 (2.1%)	3 (7.9%)	6 (18.2%)	4 (14.8%)

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). If multiple observations are contained within a single study window, the observation closest to the visit window date is used.
[a] Patients must have a baseline (one month) and a post-baseline measurement to be available for evaluation.

Rupture
There have been no new rupture events reported since the previous update. Two ruptures have been reported in the Conformable GORE® TAG® Device Aneurysm Study (TAG 08-03) through 60-months follow-up. One patient experienced a contained rupture of the descending thoracic aorta, underwent additional implantation, and subsequently experienced further rupture. The patient declined additional treatment and later died. Although the rupture was determined as unrelated to the device or procedure by the study site, internal review by Gore determined the event to be device-related because there was not sufficient evidence to absolve the device from the rupture and death. The other patient was reported to have a ruptured dissecting aneurysm also resulting in death. Information provided by the site indicated the location was in the ascending aorta, although the death certificate cited ruptured dissecting thoracic aortic aneurysm. The study site deemed the cause was indeterminate, while the internal review by Gore could not rule out a device-related death. Both rupture events are also captured as aneurysm-related deaths in TAG 08-03 Study Results – Aneurysm-Related Death. The rate of two ruptures in this study is consistent with previously reported data for the GORE® TAG® Device.

Conversion
No conversions to open surgical repair have been reported in the Conformable GORE® TAG® Device Aneurysm Study (TAG 08-03).

Additional Implantations
There have been no new additional implantations since the previous update. Three patients required additional thoracic stent graft implantations in the Conformable GORE® TAG® Device Aneurysm Study (TAG 08-03). The first patient experienced a progressive thoracoabdominal aneurysm one year after the initial treatment with the Conformable GORE® TAG® Device. The patient was treated for the thoracoabdominal aneurysm with visceral debranching and placement of additional thoracic stent grafts from another manufacturer. At two-years post-treatment, an indeterminate endoleak related to the additional stent grafts was detected and treated with an additional Conformable GORE® TAG® Device. The iliac artery was disrupted during this surgery and the patient subsequently died. The second patient had a Type IB endoleak without aneurysm enlargement reported at the 48-month follow-up visit and an additional Conformable GORE® TAG® Device was implanted. The third patient had a Type IA endoleak and contained rupture for which they received two additional Conformable GORE® TAG® Devices 36 months post-procedure. This patient died due to a subsequent rupture as discussed in the previous section.

Device Integrity
There have been no reports of device fractures or material failures in the Conformable GORE® TAG® Device Aneurysm Study (TAG 08-03).

Migration
There have been no reports of device migration in the Conformable GORE® TAG® Device Aneurysm Study (TAG 08-03).

Compression
There have been no reports of device compression in the Conformable GORE® TAG® Device Aneurysm Study (TAG 08-03).

Section II – Conformable GORE® TAG® Device clinical study experience

Traumatic Transection Study (TAG 08-02) results

Patient accountability

Table 6 provides the patient disposition for patients enrolled in the Conformable GORE® TAG® Device Traumatic Transection Study (TAG 08-02). Since the last update, 18 additional patients reported 60-month follow-up and 1 additional patient reported 48- month follow-up. Eligible patients are defined as those that are alive and participating in the study for that follow-up period. All eligible patients have completed the 60-month follow-up period. 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). Patients enrolled in this study had a median age of 39 and were unlikely to have evidence of progressive disease, which is an attribute of the patient population that expectantly resulted in lower patient compliance. The number of patients with adequate imaging to assess specific core lab parameters are described in **Table 7**. Note the combined column for lumen obstruction, compression, and thrombus and there were zero patients experiencing any such events. The thrombus assessment was defined as thrombus formation within the device resulting in hemodynamic compromise or clinical symptoms. Furthermore, there were no reports of intraluminal thrombus in the thoracic aorta per adverse event data collection.

Table 6: Patient compliance and disposition by study period

		Follow-up compliance[a]			Events prior to next interval[a]		
Study period	Eligible for follow-up	Patients with visit in window	With CT	With X-ray performed	Death	Discontinued[b]	Not due for next follow-up
TAG 08-02 Conformable GORE® TAG® Device Traumatic Transection Study							
Procedure	101	—[c]	—	—	0	0	0
Post-procedure	101	—	—	—	4 (4.0%)	0	0
1 month	97	94 (96.9%)	87 (89.7%)	84 (86.6%)	2 (2.1%)	0	0
6 months	95	80 (84.2%)	74 (77.9%)	71 (74.7%)	1 (1.1%)	1 (1.1%)	0
12 months	93	74 (79.6%)	74 (79.6%)	66 (71.0%)	1 (1.1%)	5 (5.4%)	0
24 months	87	58 (66.7%)	54 (62.1%)	45 (51.7%)	0	9 (10.3%)	0
36 months	78	52 (66.7%)	49 (62.8%)	47 (60.3%)	2 (2.6%)	15 (19.2%)	0
48 months	61	39 (63.9%)	39 (63.9%)	34 (55.7%)	0	14 (23.0%)	0
60 months	47	31 (66.0%)	28 (59.6%)	24 (51.1%)	0	16 (34.0%)	—

Study period definitions: Procedure (0–0 days), post-procedure (1–14 days), 1 month (15–59 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] Percentages are based on number of patients in visit window. Compliance is based on site-reported imaging assessments.
[b] "Discontinued" refers to patients that no longer meet eligibility criteria due to voluntarily withdrawal or non-compliance. Patients no longer eligible due to death are provided separately. Changes in eligibility numbers are reflected in the subsequent follow-up window.
[c] A dash indicates information is not available.

Table 7: TAG 08-02 core lab adequate imaging

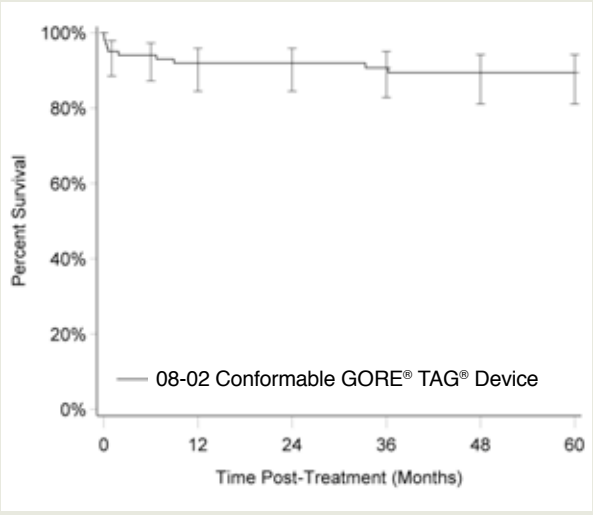
Study Period	Eligible for follow-up	Endoleak evaluable	DTA rupture evaluable	Wire fracture evaluable[1]	Extrusion/ erosion evaluable	Lumen obstruction/ compression/ thrombus evaluable	Migration evaluable	Diameters evaluable[2]
1 month	97	82 (84.5%)	8 (86.6%)	85 (87.6%)	84 (86.6%)	84 (86.6%)	81 (83.5%)	85 (87.6%)
6 months	95	70 (73.7%)	72 (75.8%)	73 (76.8%)	72 (75.8%)	72 (75.8%)	70 (73.7%)	73 (76.8%)
12 months	93	71 (76.3%)	74 (79.6%)	74 (79.6%)	74 (79.6%)	74 (79.6%)	67 (72.0%)	74 (79.6%)
24 months	87	50 (57.5%)	53 (60.9%)	54 (62.1%)	53 (60.9%)	53 (60.9%)	51 (58.6%)	53 (60.9%)
36 months	78	48 (61.5%)	49 (62.8%)	49 (62.8%)	49 (62.8%)	49 (62.8%)	48 (61.5%)	49 (62.8%)
48 months	61	38 (62.3%)	39 (63.9%)	39 (63.9%)	39 (63.9%)	39 (63.9%)	36 (59.0%)	39 (63.9%)
60 months	47	27 (57.4%)	28 (59.6%)	29 (61.7%)	28 (59.6%)	28 (59.6%)	28 (59.6%)	28 (59.6%)

Study period definitions: 1 month (15–59 days), 6 months (60–242 days), 12 months (243–546 days), 24 months (547–911 days), 36 months (912–1275 days), 48 months (1276–1640 days), 60 months (1641–2006 days)
[1] Wire fracture could be assessed by X-ray or CT.
[2] Maximum aneurysm diameters in axial and orthogonal views.

All-Cause mortality

Figure 2 provides a Kaplan-Meier plot of all-cause mortality in the Conformable GORE® TAG® Device Traumatic Transection Study (TAG 08-02). All-cause mortality is defined as any death regardless of the relationship to device or procedure. Through 60 months of follow-up, the survival estimate was calculated at 89%. No new deaths have been reported during the 60-month follow-up window.

Figure 2: All-Cause mortality



	Months after procedure							
	Day 0	1 month	6 months	12 months	24 months	36 months	48 months	60 months
08-02 Conformable GORE® TAG® Device Traumatic Transection Study								
Patients at risk	101	95	89	87	78	70	56	27
Percent survival	100%	95%	94%	92%	92%	91%	89%	89%

Freedom from major device-related events

Table 8 shows a summary of site-reported major device-related adverse events (MDE). No new MDEs have been reported since the previous update. Two MDEs have been reported in total. Two patients required additional endovascular techniques following unintentional partial obstruction of the left common carotid artery. Both patients received a stent placed in the left common carotid to ensure flow. No additional clinical sequela was noted. The patients tolerated the procedures. The Clinical Events Committee deemed the events as related to the device and the endovascular procedure.

Table 8: Summary of major device-related events

	Post-treatment follow-up period									
TAG 08-02 Conformable GORE® TAG® Device Traumatic Transection Study	Procedure	Post-procedure	1 month	6 months	12 months	24 months	36 months	48 months	60 months	total
Number of patients	101	101	97	93	88	82	76	58	47	101
Number of patients with imaging evaluation or device event	101	83	88	75	74	55	50	39	29	101
Any major device event	2 (2.0%)[a]	0	0	0	0	0	0	0	0	2 (2.0%)
Device placement at incorrect location	2 (2.0%)	—[b]	—	—	—	—	—	—	—	2 (2.0%)

Study period definitions: Procedure (0–0 days), post-procedure (1–14 days), 1 month (15–59 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), total (0-2006 days)

[a] Percentages are based on the number of patients with imaging follow-up, or device event in the given window.

[b] A dash indicates information is not available.

Section II – Conformable GORE® TAG® Device clinical study experience

Endoleak

Table 9 summarizes the endoleak incidence for the Conformable GORE® TAG® Device Traumatic Transection Study (TAG 08-02). No new endoleaks have been reported since the previous update. Overall, two (2.1%) patients have experienced an endoleak at any time during follow-up. One of these patients reported a minor Type III endoleak on day of procedure and the Clinical Events Committee noted this to be an indeterminate procedural endoleak that resolved at completion of procedure without treatment. The other patient reported a minor Type II endoleak on POD 14 which was not treated at the time of the patient's death on POD 57 due to worsening traumatic brain injury.

Table 9: Summary of endoleaks[a] by study period

TAG 08-02 Conformable GORE® TAG® Device Traumatic Transection Study	Procedure	Post-procedure	1 month	6 months	12 months	24 months	36 months	48 months	60 months	Total[b]
Patients available at beginning of interval	101	101	97	93	88	82	76	58	47	101
Patients with endoleak evaluation or ongoing endoleak	101	73	87	74	74	54	49	39	28	96
Patients with one or more endoleak adverse events ongoing in window	1 (1.0%)	2 (2.7%)	2 (2.3%)	0	0	0	0	0	0	2 (2.1%)
New	1 (1.0%)	1 (1.4%)	0	0	0	0	0	0	0	—
Ongoing	—[c]	1 (1.4%)	2 (2.3%)	0	0	0	0	0	0	—
Type I	0	0	0	0	0	0	0	0	0	0
New	0	0	0	0	0	0	0	0	0	—
Ongoing	—	0	0	0	0	0	0	0	0	—
Type IA	0	0	0	0	0	0	0	0	0	0
New	0	0	0	0	0	0	0	0	0	—
Ongoing	—	0	0	0	0	0	0	0	0	—
Type IB	0	0	0	0	0	0	0	0	0	0
New	0	0	0	0	0	0	0	0	0	—
Ongoing	—	0	0	0	0	0	0	0	0	—
Type II	0	1 (1.4%)	1 (1.1%)	0	0	0	0	0	0	1 (1.0%)
New	0	1 (1.4%)	0	0	0	0	0	0	0	—
Ongoing	—	0	1 (1.1%)	0	0	0	0	0	0	—
Type III	1 (1.0%)[d]	1 (1.4%)	1 (1.1%)	0	0	0	0	0	0	1 (1.0%)
New	1 (1.0%)	0 (0.0%)	0	0	0	0	0	0	0	—
Ongoing	—	1 (1.4%)	1 (1.1%)	0	0	0	0	0	0	—
Indeterminate	0	0	0	0	0	0	0	0	0	0
New	0	0	0	0	0	0	0	0	0	—
Ongoing	—	0	0	0	0	0	0	0	0	—
Patients with no endoleak ongoing in window	100 (99.0%)	71 (97.3%)	85 (97.7%)	74 (100.0%)	74 (100.0%)	54 (100.0%)	49 (100.0%)	39 (100.0%)	28 (100.0%)	94 (97.9%)

Study period definitions: Procedure (0–0 days), post-procedure (1–14 days), 1 month (15–59 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), total (0-2006 days)

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

[b] Total number of patients with endoleak shown. The designation of "New" and "Ongoing" endoleak is only informative in the context of a specific follow-up window.

[c] A dash indicates information is not available.

[d] Deployment of a second device was performed during the index procedure to treat what was thought to be a Type III endoleak.

Aortic enlargement

Table 10 summarizes site-reported changes in the aortic diameter at the level of the lesion for patients in the Conformable GORE® TAG® Device Traumatic Transection Study (TAG 08-02). While not a degenerative disease, transection is the result of a focal disruption of the aortic wall; this compromise of the aortic wall requires monitoring, as it may experience further distension or rupture. Size change was calculated by comparing the maximum diameter at the level of the lesion at each follow-up visit to the baseline measured at one-month follow-up.

- One new patient was reported to have growth in the six-month window (image was previously available from an outside facility but the missing data was entered recently as part of final study completion audit) and one new patient experienced growth in the 60-month window since the previous update
- According to site-reported data, a total of eight patients experienced diameter growth greater than or equal to 5 mm at any follow-up time point
- One report of growth appears to be a recording error. Five patients, including the recording error, had reported growth at only one time point, all reported before or at 36 months.
- The other three patients exhibited growth ≥ 5 mm over multiple time points; two of the three patients report a reduction in diameter at the last available follow-up
- Of the eight site-reported patients with growth, two were confirmed by core lab to have aortic enlargement of ≥ 5 mm at any time
  - — One patient had a measured increase of 5 mm at 12 months, with subsequent core lab reports of no change at 24 and 36 months
  - — The other patient had a measured increase of 5 mm during the 48-month window only, with core lab reporting a decrease in diameter in the 60-month window. Neither patient was reported to have an associated endoleak.
- None of the reported enlargements involved a device migration, endoleak, or other identifiable cause
- Further, no endoleaks were identified in any of the patients enrolled in TAG 08-02, but may not always be apparent in CTA imaging

Core lab measured maximum diameter using both axial and orthogonal images. Size change was taken at fixed bony landmarks. Even with guided techniques, growth was only identified in common by both site and core lab for two patients. Variation between site and core lab results highlight the difficulty in identifying growth and ascertaining a direct cause of aortic enlargement in these patients. There are no discernable trends in aortic diameter at the level of the lesion over time.

Table 10: Change in lesion diameter from baseline

	Months after procedure					
TAG 08-02 Conformable GORE® TAG® Device Traumatic Transection Study	6 months	12 months	24 months	36 months	48 months	60 months
Number of patients with available data[a]	70	69	51	47	37	27
Change in diameter from baseline						
≥ 5 mm decrease in diameter	3 (4.3%)	1 (1.4%)	1 (2.0%)	0 (0.0%)	1 (2.7%)	1 (3.7%)
≤ 5 mm change in diameter	63 (90.0%)	65 (94.2%)	47 (92.2%)	43 (91.5%)	34 (91.9%)	25 (92.6%)
≥ 5 mm increase in diameter	4 (5.7%)	3 (4.3%)	3 (5.9%)	4 (8.5%)	2 (5.4%)	1 (3.7%)

Study period definitions: 1 month (0–59 days), 6 months (60–242 days), 12 months (243–546 days), 24 months (547–911 days), 36 months (912–1275 days), 48 months (1276–1640 days), 60 months (1641–2006 days). If multiple observations are contained within a single study window, the observation closest to the visit window date is used.
[a] Patients must have a baseline (one month) and a post-baseline measurement to be available for evaluation.

Rupture

No ruptures have been reported in the Conformable GORE® TAG® Device Traumatic Transection Study (TAG 08-02).

Conversion

No conversions to open surgical repair have been reported in the Conformable GORE® TAG® Device Traumatic Transection Study (TAG 08-02).

Additional implantations

No patients have required additional thoracic stent graft implantations in the Conformable GORE® TAG® Device Traumatic Transection Study (TAG 08-02).

Device integrity

There have been no reports of device fractures or material failures in the Conformable GORE® TAG® Device Traumatic Transection Study (TAG 08-02).

Migration

There have been no reports of device migration in the Conformable GORE® TAG® Device Traumatic Transection Study (TAG 08-02).

Compression

There have been no reports of device compression in the Conformable GORE® TAG® Device Traumatic Transection Study (TAG 08-02).

Section II – Conformable GORE® TAG® Device clinical study experience

Acute Complicated Type B Dissection Study (TAG 08-01) results

Patient accountability

Table 11 provides the patient disposition for patients enrolled in the Conformable GORE® TAG® Device Acute Complicated Type B Dissection Study (TAG 08-01). Since the last update, 10 additional patients reported 60-month follow-up and 4 additional patients reported 48-month follow-up. Eligible patients are defined as those that are alive and participating in the study for that follow-up period. All eligible patients have completed the 60-month follow-up period. 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). Two patients survived the procedure but died on POD 0. The number of patients with adequate imaging to assess specific core lab parameters are described in **Table 12**.

Table 11: Patient compliance and disposition by study period

		Follow-up compliance[a]			Events prior to next interval[a]		
Study period	Eligible for follow-up	Patients with visit in window	With CT	With X-ray performed	Death	Discontinued[b]	Not due for next follow-up
TAG 08-01 Conformable GORE® TAG® Device Dissection Study							
Procedure	50	—[c]	—	—	2 (4.0%)	0	0
Post-procedure	48	—	—	—	2 (4.2%)	1 (2.1%)	0
1 month	45	45 (100.0%)	41 (91.1%)	39 (86.7%)	0	0	0
6 months	45	41 (91.1%)	38 (84.4%)	34 (75.6%)	2 (4.4%)	0	0
12 months	43	40 (93.0%)	38 (88.4%)	35 (81.4%)	1 (2.3%)	2 (4.7%)	0
24 months	40	32 (80.0%)	31 (77.5%)	28 (70.0%)	1 (2.5%)	3 (7.5%)	0
36 months	36	33 (91.7%)	31 (86.1%)	29 (80.6%)	2 (5.6%)	1 (2.8%)	0
48 months	33	27 (81.8%)	24 (72.7%)	20 (60.6%)	2 (6.1%)	2 (6.1%)	0
60 months	29	24 (82.8%)	23 (79.3%)	20 (69.0%)	1 (3.4%)	4 (13.8%)	—

Study period definitions: Procedure (0–0 days), post-procedure (1–14 days), 1 month (15–59 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] Percentages are based on number of patients in visit window. Compliance is based on site-reported imaging assessments.

[b] "Discontinued" refers to patients that no longer meet eligibility criteria due to voluntarily withdrawal or non-compliance. Patients no longer eligible due to death are provided separately. Changes in eligibility numbers are reflected in the subsequent follow-up window.

[c] A dash indicates information is not available.

Table 12: TAG 08-01 core lab adequate imaging

Study Period	Eligible for follow-up	Endoleak evaluable	DTA rupture evaluable	Wire fracture evaluable[1]	Extrusion/ erosion evaluable	Lumen obstruction/ compression/ thrombus evaluable	Migration evaluable	Diameters evaluable[2]
1 month	45	40 (88.9%)	41 (91.1%)	43 (95.6%)	41 (91.1%)	41 (91.1%)	41 (91.1%)	40 (88.9%)
6 months	45	33 (73.3%)	39 (86.7%)	39 (86.7%)	39 (86.7%)	39 (86.7%)	39 (86.7%)	37 (82.2%)
12 months	43	33 (76.7%)	39 (90.7%)	39 (90.7%)	39 (90.7%)	39 (90.7%)	39 (90.7%)	38 (88.4%)
24 months	40	30 (75.0%)	31 (77.5%)	31 (77.5%)	31 (77.5%)	31 (77.5%)	30 (75.0%)	31 (77.5%)
36 months	36	28 (77.8%)	31 (86.1%)	31 (86.1%)	31 (86.1%)	31 (86.1%)	29 (80.6%)	31 (86.1%)
48 months	33	23 (69.7%)	24 (72.7%)	24 (72.7%)	24 (72.7%)	24 (72.7%)	23 (69.7%)	24 (72.7%)
60 months	29	22 (75.9%)	23 (79.3%)	23 (79.3%)	23 (79.3%)	23 (79.3%)	22 (75.9%)	23 (79.3%)

Study period definitions: 1 month (15–59 days), 6 months (60–242 days), 12 months (243–546 days), 24 months (547–911 days), 36 months (912–1275 days), 48 months (1276–1640 days), 60 months (1641–2006 days)

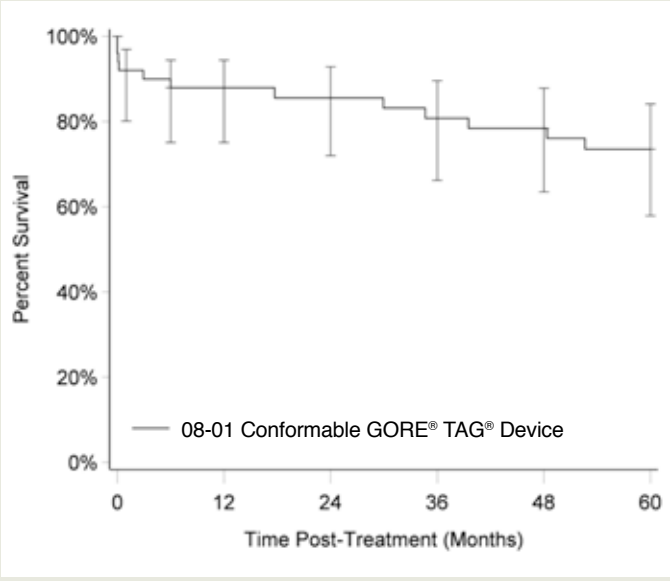
[1] Wire fracture could be assessed by X-ray or CT.

[2] Maximum false lumen diameters in axial and orthogonal views, and maximum overall diameters in treated area in axial and orthogonal views.

All-cause mortality

Figure 3 provides a Kaplan-Meier plot of all-cause mortality in the Conformable GORE® TAG® Device Acute Complicated Type B Dissection Study (TAG 08-01). All-cause mortality is defined as any death regardless of the relationship to device or procedure. One new death was reported since the previous update. Through 60 months, survival estimate was 73%.

Figure 3: All-cause mortality



	Months after procedure							
	Day 0	1 month	6 months	12 months	24 months	36 months	48 months	60 months
TAG 08-01 Conformable GORE® TAG® Device Dissection Study								
Patients at risk	50	45	43	39	36	34	33	22
Percent survival	96%	92%	88%	88%	86%	81%	78%	73%

Section II – Conformable GORE® TAG® Device clinical study experience

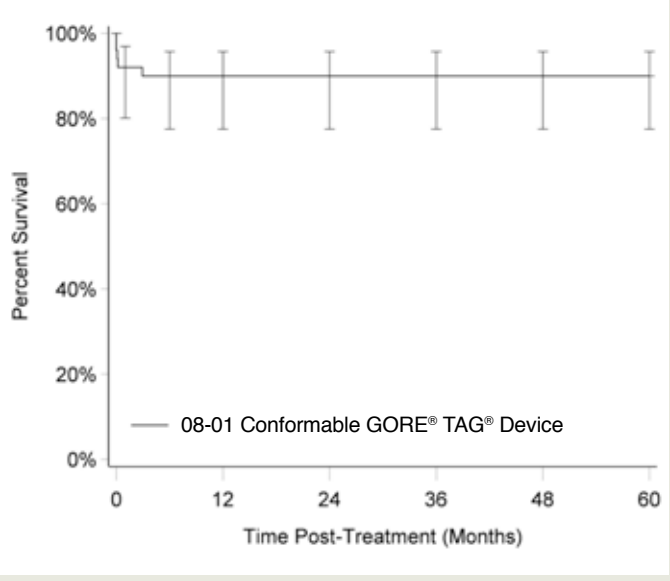
Dissection-related death

Figure 4 provides a Kaplan-Meier plot of dissection-related death in the Conformable GORE® TAG® Device Acute Complicated Type B Dissection Study (TAG 08-01). Dissection-related death includes death occurring within 30 days of treatment, death before hospital discharge, death occurring within 30 days of secondary treatment, and death directly caused by aortic dissection. There have been no new dissection-related deaths since the previous update. Through 60 months, dissection-related survival estimate was 90%. Per definition, five deaths were attributed to dissection-related death. All included deaths were Clinical Ethics Committee adjudicated.

Of the five deaths, four patients died during their initial hospital stay.

- Two patients died on POD 0: one due to a retrograde Type A dissection caused by the procedure and one due to an aortic rupture of an ulcerated lesion near the proximal landing of the implanted device
- One patient died on POD 3 following a pulmonary embolus and unsuccessful resuscitation
- One patient experienced multi-system organ failure as a result of the index Type B dissection and medical care was suspended on POD 5
- The remaining patient died on POD 89 due to a ruptured dissection in the proximal aortic arch which was undetermined to the treatment area or device. This patient would not have met the criteria for dissection-related death as defined in the Collaborative Type B Dissection Post-Approval Surveillance Program (TAG 12-06). In this post-approval study, the definition for dissection-related death excludes deaths due to dissections located in anatomic areas remote to the areas treated during the index dissection.

Figure 4: Dissection-related death



	Months after procedure							
	Day 0	1 month	6 months	12 months	24 months	36 months	48 months	60 months
TAG 08-01 Conformable GORE® TAG® Device Dissection Study								
Patients at risk	50	45	43	39	36	34	33	22
Percent survival	96%	92%	90%	90%	90%	90%	90%	90%

Freedom from major device-related events

Major device-related events (MDEs) were defined as a list of anticipated adverse device events which included endoleak, access and deployment failure, lumen obstruction (including device compression and thrombus), prosthesis material failure, extrusion / erosion, prosthesis migration, intercomponent migration, and wire fracture. MDEs required significant therapy, including unplanned increase in the level of care, permanent sequelae, hospitalization, or death. Subsequent sections include all events reported regardless of treatments or interventions. In the setting of aortic dissection, retrograde aortic dissection and rupture of the ascending aortic dissection may be considered device events and were therefore included even though they were not events specified in the protocol as device events. **Table 13** shows a summary of site-reported MDEs. Thirteen MDEs have been reported, with no new reports since the last clinical update. Three patients were previously discussed in TAG 08-01 Study Results — Dissection-Related Death.

- In one case, the valve of a GORE® Introducer Sheath with Silicone Pinch Valve was clamped prior to the full removal of the catheter from a deployed device, resulting in the leading olive separating from the catheter; the olive was retrieved using a snaring technique
- One patient had repairs on both a Type II endoleak originating from the left subclavian artery (treated with a series of embolization coils) and a Type IA endoleak (an additional Conformable GORE® TAG® Device was used) on POD 238 and 329, respectively
- One patient died POD 0 from a reported procedure-caused retrograde Type A dissection. The treating physician reported difficulty advancing the proximal device delivery catheter across the angulated aortic arch; review of procedural fluoroscopy imaging revealed that the retrograde Type A dissection was caused prior to Conformable GORE® TAG® Device deployment.
- One patient had a retrograde aortic dissection identified on POD 30, which the physician chose to monitor
- An additional patient had a retrograde ascending aortic dissection identified on POD 6 and treated with open repair of the ascending aorta on POD 18 with no intraoperative complications. During a later routine follow-up, the patient was found to have a Type II endoleak. On POD 1499, the patient was successfully treated with a plug to occlude the false lumen.
- One patient presented to the emergency room with a ruptured Type A aortic dissection due to apparent disease progression; the patient died during MRI imaging the same day (POD 89).
- An aortic rupture was reported as the cause of death for another patient treated for a Type B dissection with contained rupture. It was reported that post-deployment angiogram showed a Type I proximal endoleak that the physician elected not to balloon. The patient died the same day, with the autopsy report stating that a potential factor contributing to the rupture was a focal perforation located at the proximal landing zone of the implanted device.
- One patient died following 11 hours of malperfusion to the celiac, superior mesenteric, and renal arteries; it was reported that these arteries opened following endovascular device deployment, but the patient subsequently experienced decreased urine output, a rise in creatinine, lactate, and liver function tests, and necrotic colon and small bowel, leading to death on POD 5.
- A patient presented to the emergency department on POD 1221 with an acute retrograde Type A dissection. The patient's dissection and aortic root was repaired with open surgery.
- One patient verbally reported she had experienced a Type A dissection during an emergency department visit for chest pain. No imaging or medical records have been obtained to confirm the event.

Table 13: Summary of major device-related events

	Post-treatment follow-up period									
TAG 08-01 Conformable GORE® TAG® Device Dissection Study	**Procedure**	**Post-procedure**	**1 month**	**6 months**	**12 months**	**24 months**	**36 months**	**48 months**	**60 months**	**Total**
Number of patients	50	48	45	45	42	36	35	33	29	50
Number of patients with imaging evaluation or device event	50	41	43	40	39	31	31	24	23	50
Any major device event	4 (8.0%)[a]	1 (2.4%)	1 (2.3%)	2 (5.0%)	0	0	1 (3.2%)	2 (8.3%)	0	10 (20.0%)
Stent graft endoleak	1 (2.0%)	0	0	1 (2.5%)	—[b]	—	0	1 (4.2%)	—	3 (6.0%)
Stent graft endoleak Type IA	1 (2.0%)	—	—	1 (2.5%)	—	—	—	0	—	2 (4.0%)
Stent graft endoleak Type II	0	—	—	1 (2.5%)	—	—	—	1 (4.2%)	—	2 (4.0%)
Branch vessel occlusion	1 (2.0%)	0	0	0	—	—	0	0	—	1 (2.0%)
Carotid artery occlusion	1 (2.0%)	—	—	—	—	—	—	—	—	1 (2.0%)
Ascending aortic dissection	0	0	0	0	—	—	1 (3.2%)	1 (4.2%)	—	2 (4.0%)
Ascending aortic dissection rupture	0	0	0	1 (2.5%)	—	—	0	0	—	1 (2.0%)
Complication of device removal	1 (2.0%)	0	0	0	—	—	0	0	—	1 (2.0%)
Descending thoracic aorta rupture	1 (2.0%)	0	0	0	—	—	0	0	—	1 (2.0%)
Retrograde aortic dissection	1 (2.0%)	1 (2.4%)	1 (2.3%)	0	—	—	0	0	—	3 (6.0%)

Study period definitions: Procedure (0–0 days), post-procedure (1–14 days), 1 month (15–59 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), total (0-2006 days)

[a] Percentages are based on the number of patients with imaging follow-up, or device event in the given window.

[b] A dash indicates information is not available.

Section II – Conformable GORE® TAG® Device clinical study experience

Endoleak

Table 14 summarizes the endoleak incidence for the Conformable GORE® TAG® Device Acute Complicated Type B Dissection Study (TAG 08-01). Type I endoleaks described in this study include only those in which a compromised seal in the proximal or distal extents of the treatment zone were observed. No new endoleaks have been reported since the previous update. Overall, seven (15.2%) patients have experienced an endoleak at any time during follow-up. Two patients had two each endoleaks noted. Five patients experienced a Type II endoleak, three of which were confirmed or presumed to originate from the LSA. Any endoleak that required re-intervention is discussed as a major device-related event above.

Table 14: Summary of endoleaks[a] by study period

TAG 08-01 Conformable GORE® TAG® Device Dissection Study	Procedure	Post-procedure	1 month	6 months	12 months	24 months	36 months	48 months	60 months	Total[b]
Patients available at beginning of interval	50	48	45	45	42	36	35	33	29	50
Patients with endoleak evaluation or ongoing endoleak	50	33	42	39	39	31	31	24	23	46
Patients with one or more endoleak adverse events ongoing in window	1 (2.0%)	1 (3.0%)	2 (4.8%)	4 (10.3%)	4 (10.3%)	3 (9.7%)	3 (9.7%)	2 (8.3%)	0	7 (15.2%)
New	1 (2.0%)	1 (3.0%)	1 (2.4%)	2 (5.1%)	0	0	2 (6.5%)	1 (4.2%)	0	—
Ongoing	—[c]	0	1 (2.4%)	2 (5.1%)	4 (10.3%)	3 (9.7%)	1 (3.2%)	2 (8.3%)	0	—
Type I	1 (2.0%)	0	0	1 (2.6%)	1 (2.6%)	0	1 (3.2%)	1 (4.2%)	0	3 (6.5%)
New	1 (2.0%)	0	0	1 (2.6%)	0	0	1 (3.2%)	0	0	—
Ongoing	—	0	0	0	1 (2.6%)	0	0	1 (4.2%)	0	—
Type IA	1 (2.0%)	0	0	1 (2.6%)	1 (2.6%)	0	0	0	0	2 (4.3%)
New	1 (2.0%)	0	0	1 (2.6%)	0	0	0	0	0	—
Ongoing	—	0	0	0	1 (2.6%)	0	0	0	0	—
Type IB	0	0	0	0	0	0	1 (3.2%)	1 (4.2%)	0	1 (2.2%)
New	0	0	0	0	0	0	1 (3.2%)	0	0	—
Ongoing	—	0	0	0	0	0	0	1 (4.2%)	0	—
Type II	0	1 (3.0%)	2 (4.8%)	4 (10.3%)	4 (10.3%)	3 (9.7%)	1 (3.2%)	1 (4.2%)	0	5 (10.9%)
New	0	1 (3.0%)	1 (2.4%)	2 (5.1%)	0	0	0	1 (4.2%)	0	—
Ongoing	—	0	1 (2.4%)	2 (5.1%)	4 (10.3%)	3 (9.7%)	1 (3.2%)	0	0	—
Type III	0	0	0	0	0	0	0	0	0	0
New	0	0	0	0	0	0	0	0	0	—
Ongoing	—	0	0	0	0	0	0	0	0	—
Indeterminate	0	0	0	0	0	0	1 (3.2%)	1 (4.2%)	0	1 (2.2%)
New	0	0	0	0	0	0	1 (3.2%)	0	0	—
Ongoing	—	0	0	0	0	0	0	1 (4.2%)	0	—
Patients with no endoleak adverse events ongoing in window	49 (98.0%)	32 (97.0%)	40 (95.2%)	35 (89.7%)	35 (89.7%)	28 (90.3%)	28 (90.3%)	22 (91.7%)	23 (100.0%)	39 (84.8%)

Study period definitions: Procedure (0–0 days), post-procedure (1–14 days), 1 month (15–59 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), total (0-2006 days)

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

[b] Total number of patients with endoleak shown. The designation of "New" and "Ongoing" endoleak is only informative in the context of a specific follow-up window.

[c] A dash indicates information is not available.

Aortic enlargement

Table 15 summarizes aortic enlargement for patients in the Conformable GORE® TAG® Device Acute Complicated Type B Dissection Study (TAG 08-01). Size change was calculated by comparing the maximum diameter (within the treated segment) at each follow-up visit to the baseline established pre-treatment. Changes in diameter are reported for the treated segment of the aorta and comprise both the true lumen and false lumen. Transverse aortic expansion may have been the result of true lumen expansion without change in false lumen measurement. On average, the true lumen diameters increased and false lumen diameters decreased (**Figure 5**). Site-reported measurements for true lumen, false lumen, and total aortic diameters are maximum transverse diameters in the treated segment and are not all necessarily collected from the same location along the aorta. As diameter measurements were not exclusively collected for the untreated dissected aorta, information on aortic enlargement of the untreated aorta is not available in this report. Information on reinterventions for extended dissection coverage may be found under "Additional implantations".

One new patient experienced growth in the 48-month window and three new patients experienced growth in the 60-month window since the previous update. Twenty patients experienced aortic growth in the endovascularly treated segment of 5 mm or more at any time during follow-up. Nineteen of the 20 patients had site-reported increases in true lumen diameter.

- Core lab data reported false lumen growth in the treated aortic segment of 3 patients from the site-reported 20 patients with enlargement; all 3 patients had decreases in false lumen diameter at the last available follow-up
- Furthermore, of these 20 patients, 13 patients were treated with a single device and 7 were treated with 2 devices
- Three patients with reported enlargements also had reported endoleaks. One patient was treated for a Type IA and Type II endoleak. One patient was treated for a Type II endoleak and had a Type IB endoleak left untreated. The remaining patient had an infrarenal Type II endoleak that went untreated. Post-approval studies — including the Collaborative Type B Dissection Post-Approval Surveillance Program (TAG 12-06) — product surveillance, and additional clinical trials may continue to inform best practices for endovascular dissection treatment, including length of device coverage.

Table 15: Change in aortic diameter from baseline (within the treated segment)

	Months after procedure							
TAG 08-01 Conformable GORE® TAG® Device Dissection Study	Post-procedure	1 month	6 months	12 months	24 months	36 months	48 months	60 months
Number of patients with available data[a]	33	41	39	37	30	30	24	23
Change in aortic diameter from baseline								
≥ 5 mm decrease in diameter	7 (21.2%)	11 (26.8%)	16 (41.0%)	12 (32.4%)	12 (40.0%)	10 (33.3%)	10 (41.7%)	8 (34.8%)
≤ 5 mm change in diameter	17 (51.5%)	20 (48.8%)	15 (38.5%)	16 (43.2%)	11 (36.7%)	12 (40.0%)	7 (29.2%)	9 (39.1%)
≥ 5 mm increase in diameter	9 (27.3%)	10 (24.4%)	8 (20.5%)	9 (24.3%)	7 (23.3%)	8 (26.7%)	7 (29.2%)	6 (26.1%)

Study period definitions: Post-procedure (1–14 days), 1 month (15–59 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). If multiple observations are contained within a single study window, the best-case observation (e.g., decrease) is used.
[a] Patients must have a baseline (pre-treatment) and a post-baseline measurement to be available for evaluation.

Section II – Conformable GORE® TAG® Device clinical study experience

Rupture

Three ruptures have been reported in the Conformable GORE® TAG® Device Acute Complicated Type B Dissection Study (TAG 08-01). The latest of these was reported since the last update and occurred away from a treatment facility and was suspected as a ruptured aortic aneurysm and listed as aortic aneurysm on the death certificate. Without imaging or autopsy the specific location in the aorta could not be determined.

The first was reported as an aortic dissection rupture of the proximal arch on POD 89. This event was reported to be indeterminate as to the relationship to the device or endovascular procedure. The Clinical Events Committee agreed with the indeterminate relationship. The second was a reported finding of an aortic rupture in the descending thoracic aorta occurring on POD 0 and was reported to be related to the device and the endovascular procedure. Per the autopsy report, a possible contributing factor was the presence of an ulcerated lesion at the proximal landing zone of the device. The Clinical Events Committee found this event to be unrelated to the device or endovascular procedure.

Conversion

No conversions to open surgical repair have been reported in the Conformable GORE® TAG® Device Acute Complicated Type B Dissection Study (TAG 08-01).

Additional implantations

No new additional implantations were reported since the previous update. Six patients have required additional thoracic stent graft implantations in the Conformable GORE® TAG® Device Acute Complicated Type B Dissection Study (TAG 08-01). One of the patients received a GORE® TAG® Device deployed in the transverse aorta on the same day as index procedure as a life-saving measure to treat a procedure-caused retrograde Type A dissection. The other five cases extended distal coverage of the existing dissection (PODs 2, 49, 156, 238, and 1495), often in conjunction with embolic occlusion techniques. All five cases involved continued distal false lumen perfusion from uncovered fenestrations alone or in combination with perfusion from branch vessels. In addition to these six patients, another patient received an infrarenal abdominal device on POD 861 for distal perfusion of the false lumen. As previously described, post-approval studies, product surveillance, and additional clinical trials may continue to inform best practices for treatment length in the endovascular treatment of dissection.

Device integrity

There have been no reports of device fractures or material failures in the Conformable GORE® TAG® Device Acute Complicated Type B Dissection Study (TAG 08-01).

Migration

There have been no reports of device migration in the Conformable GORE® TAG® Device Acute Complicated Type B Dissection Study (TAG 08-01).

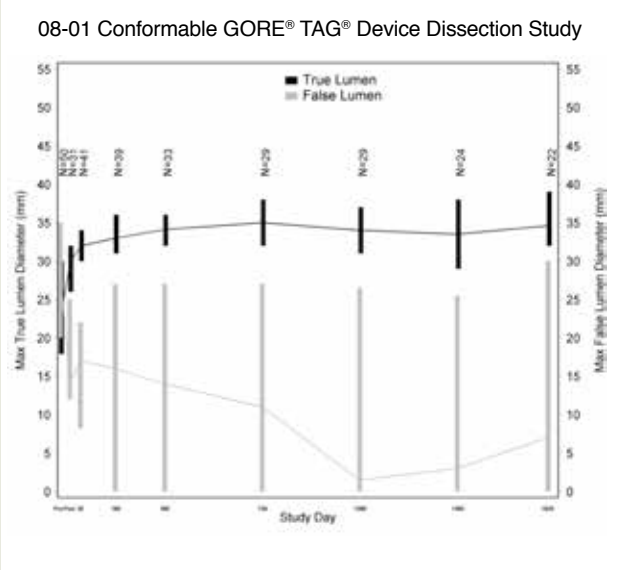
Compression

There have been no reports of device compression in the Conformable GORE® TAG® Device Acute Complicated Type B Dissection Study (TAG 08-01).

Aortic remodeling

Figure 5 demonstrates overall positive aortic remodeling for patients in the Conformable GORE® TAG® Device Acute Complicated Type B Dissection Study, as noted by site-reported increases in true lumen diameter and decreases in false lumen diameter.

Figure 5: Lumen diameters



False lumen patency

At 12 months, 38 patients had available imaging for core lab analysis of the false lumen. Twenty-nine (76.3%) patients were considered to have complete false lumen thrombosis adjacent to the stent graft, excluding the distal 2 cm of the device. An additional 6 (15.8%) patients had partial thrombosis with the presence of some blood flow in the false lumen. One patient (2.6%) was observed to have no false lumen thrombosis, and two patients (5.3%) had an unknown amount (e.g., non-contrast CT).

Additionally, at the same 12-month time point, the false lumen was evaluated distal to the endovascular treated segment. Twenty (52.6%) patients experienced partial thrombosis. A smaller patient subset of six patients (15.8%) had complete thrombosis of the false lumen distal to the treated segment. Five patients (13.2%) had no thrombosis and seven patients (18.4%) had an unknown amount of thrombosis.

At 60 months, 23 patients had available imaging for core lab analysis of the false lumen adjacent to the stent graft. At the time of last follow-up (45 patients with assessment), 38 (84.4%) had complete thrombosis, six (13.3%) partial thrombosis, zero with no thrombosis, and one (2.2%) was unknown. The percentage of patients with complete thrombosis tended to increase over time with lower values at follow-up occurring at 1 month and 6 months (63.4% and 61.5%) and higher values occurring at 36 months and 60 months (87.1% and 87.0%). Partial thrombosis tended to decrease over time with the highest value at follow-up occurring at 1 month (31.7%) and lower values occurring at 36 months and 60 months (12.9% and 13.0%).

Progression of aortic dissection data

Progressive aortic dissection was reported in seven patients, two of which are newly reported in the 36-month and 48-month periods since the previous update. Progressive aortic dissection includes retrograde Type A dissections caused by de novo disease progression, device placement, or the procedure. Three patients were determined to have retrograde Type A dissections, each within 30 days of index procedure. Of these three, one was related to the device and the procedure, one was confirmed to be a procedure-related event occurring before placement of the device and resulted in death, and one had an indeterminate cause.

Additionally, three patients experienced Type A dissection due to disease progression, two within the six month period, and one within the 36-month period. One patient had a reported pseudoaneurysm of the ascending aorta on POD 183 which was surgically repaired. The cause was independently adjudicated to be unrelated to the device or procedure. The second patient had dissection extension into the aortic root and involvement of the right common carotid artery on POD 1221, and underwent emergency open surgical repair of the dissection and aortic root replacement. The third patient had a ruptured Type A dissection due to apparent disease progression on POD 89 that resulted in death.

One patient had Type A dissection treated with additional endograft within the 48-month period reported from an outside facility that could not be confirmed by the study site or with imaging.

Additional dissection-based interventions

There were nine various additional dissection-based interventions, two of which are newly reported since the previous update. These surgical or adjunctive interventions may be a reflection of the disease state and not attributed to the repair the patient underwent. One of the newly reported interventions was late aortic root replacement and a subsequent carotid endarterectomy on POD 1233. Three patients had surgical procedures to remove necrotic tissue. One patient experienced lactic acidosis and gastrointestinal necrosis resulting in a right colon resection. Another patient underwent treatment with an additional Conformable GORE® TAG® Device for an endoleak (previously mentioned as an additional implantation on POD 2 and repeated here because CEC determined the event was related to dissection complication of rupture) and had a decortication due to a persistent hemothorax. One patient required multiple other surgical interventions, including a laparotomy excising the necrosed small bowel. The same patient had compartment syndrome resulting in a lower leg fasciotomy.

Four patients underwent additional interventional procedures. Of these four, two patients underwent additional stenting, one left and right renal angioplasty and stent placement (newly reported since last update) and the other patient was treated for peripheral artery stenosis four days after the index procedure. Another patient was identified with false lumen dilatation of the aortic dissection and underwent treatment with a stent graft in the right renal artery, coil embolization of the inferior mesenteric artery, and placement of an infrarenal aortic GORE® EXCLUDER® Device. An additional patient had both anuria and renal failure which was treated with a fenestration and endarterectomy of the left and right renal arteries. The final patient had thoracoabdominal surgical repair of an aneurysmal false lumen distal to the implanted device on POD 676.

Section III – Worldwide commercial experience

There have been more than 146,000 GORE® TAG® Devices distributed worldwide through December 31, 2017. This includes more than 65,000 GORE® TAG® Devices, and more than 80,000 Conformable GORE® TAG® Devices. **Table 16** provides a data summary of worldwide commercial events reported to Gore for the GORE® TAG® Device in 2016 and 2017. Fluctuations from previous years were observed where event rates were higher than usual in 2016 and returned to lower levels in 2017. Examples of this can be specifically seen in number of post-procedural ruptures and aneurysm-related deaths. Overall increases in total number of adverse events are likely due to an increase in adoption of endovascular therapy as a first line of treatment and continues to be a viable alternative for patients to open surgical repair. While the volume of cases using endovascular devices has increased, most of the 2016 increase can be attributed to a bolus in reports due to changes in regional reporting practices, that is, not due to device performance. Adverse event occurrences for 2017 are consistent with previous reported years. Therefore, even with the additional events and possible reasons for the fluctuations, the worldwide commercial experience remains acceptable to previous years.

Worldwide commercial experience has been collected through a variety of sources. Examples of reporting sources include publications, post-market surveillance studies, conference talks, and direct center reporting. Several attempts are made to complete reporting record. Index procedure dates and device information is not always available.

Table 16: Summary of 2016 and 2017 worldwide commercial events reported to Gore for the GORE® TAG® Device and Conformable GORE® TAG® Device

Year	2016		2017	
	GORE® TAG® Device	Conformable GORE® TAG® Device	GORE® TAG® Device	Conformable GORE® TAG® Device
Rupture (post-procedure)	20	10	3	4
Associated with endoleak	6	1	1	1
Conversion (post-procedure)	8	5	1	3
Associated with endoleak	1	1	1	0
Aneurysm-related death	44	43	8	25
Associated with endoleak	1	1	0	0
Migration (post-procedure)	3	1	1	5
Paraplegia / paraparesis	23	14	1	10
Stroke	19	14	2	7
Device integrity				
Compression	3	0	0	0
Fracture	1	0	0	0
Type III endoleak				
Tear / disruption in graft material	0	0	0	1
Unknown source	9	0	7	0
Deployment anomaly	0	0	0	6
Explants	8	7	1	3

Deployment-related Class II recall

There were four incomplete deployment events of a Conformable GORE® TAG® Thoracic Endoprosthesis received over eight months between December 2016 and July 2017. In each event, the physician observed that half of the Conformable GORE® TAG® Device deployed and half remained constrained to the delivery catheter. In three of the events, the physicians noted abnormal or inconsistent deployment line resistance during deployment initiation. Incomplete deployments are a known adverse event included in the IFU. However, this was the first time reports like these were received for Conformable GORE® TAG® Thoracic Endoprosthesis. While an extensive Corrective and Preventive Action (CAPA) investigation was performed, the root cause(s) of the incomplete deployments was not conclusive.

Of the four patients who have experienced an incomplete deployment, there were two serious adverse health consequences and one death reported:

- Patient (MDR # 2017233-2016-00950) required intra-operative surgical conversion and subsequently died
- Patient (MDR# 2017233-2017-00399) required intra-operative surgical conversion, and incurred temporary mesenteric and renal ischemia
- Patient (MDR# 2017233-2017-00184) required an additional surgical intervention and incurred temporary renal ischemia
- Patient (MDR# 2017233-2017-00275) sustained no injuries due to deployment during an open repair

For detailed information on each event, please refer to the FDA's Manufacturer and User Facility Device Experience (MAUDE) database for reporting complaints on medical devices.

Each of these events was considered an off-label procedure, but it is unclear at this time how this may have contributed to the outcomes.

A CAPA investigation has been completed that provided an in-depth analysis of the incomplete deployments. There were only two devices returned for evaluation. Engineering evaluations for two returned devices indicate that one partial or incomplete deployment was the result of an incorrect deployment line stitch pattern and another was the result of deployment line damage of unknown origin. An initial investigation began shortly after Gore was aware of the first event by reviewing the timeframe in which the devices at issue were manufactured, manufacturing processes, manufacturing training records and staffing, equipment records, device history records, and risk management documents; attempting to recreate potential failure modes; inspecting the returned devices and components; conducting interviews with operators; and reviewing process steps. In spite of these initial efforts, no root cause(s) was determined and a CAPA investigation continued to gather information about the events by performing the following activities to attempt to identify potential root causes:

- Benchmark other device deployment systems that use similar methods
- Implement trend watches to identify potential failure modes

- Complete Fishbone and Five Whys documentation
- Review for possible recent process changes
- Review for possible recent design changes

As a result of the CAPA investigation, no root cause(s) could be confirmed for the events. Gore continues to actively monitor reported events. To date, there have been no new incomplete deployment events reported.

Gore worked closely with the FDA and executed a corrective action which included a physician safety information letter and updated IFU warnings and precautions (below), with no removal of the device from commercial distribution. The physician safety information letters were sent to physicians globally starting on September 25, 2017.

Additional Warnings and Precautions:

- If abnormal or inconsistent deployment line resistance is felt during deployment initiation, STOP deployment action immediately. If device remains constrained, remove device through the introducer sheath. If resistance is felt during removal of the constrained endoprosthesis, stop and withdraw device and introducer sheath together.

  If the device is constrained or attached to the catheter and remains in a partially deployed state, physicians should strongly consider conversion to immediate open surgical repair in order to avoid additional procedure time and potential harm from additional endovascular maneuvers.

In the physician safety letter, Gore also recommended adherence to the approved Conformable GORE® TAG® Device indications and review of current Conformable GORE® TAG® Device IFU warnings. Gore emphasized the warning in the current IFU: Always have a surgical team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

An additional clarification to the IFU, not part of the physician safety information letter or corrective action, was also made to the Patient Counseling section to ensure that the potential for emergency conversion is discussed with the patients. View document online at https://www.goremedical.com/products/ctag---ifu/instructions.

Rupture

In the two year reporting time period from January 1, 2016 to December 31, 2017, a total of 37 patients were reported with a post-procedure rupture with a Gore thoracic device. Thirty were reported in 2016 related with the change in region reporting practices mentioned in the introductory paragraph at the beginning of Section III. A summary of the events are stated below by year and specific Gore thoracic device.

2016

GORE® TAG® Device

Twenty post-procedure ruptures of the DTA were reported to Gore in 2016 for the GORE® TAG® Device. Six of these ruptures were associated with various endoleaks. Five of these ruptures were associated with an infection of the aneurysm. Six were associated with "other" various causes such as revisions of non-Gore ruptures. In three patients, no cause of the rupture could be determined.

Conformable GORE® TAG® Device

Ten post-procedure ruptures of the DTA were reported to Gore in 2016 for the Conformable GORE® TAG® Device. One of these ruptures was caused by continued false lumen perfusion in a dissection patient. One of these ruptures was associated with and unspecified endoleak. One was associated with an infection. Of the remaining seven ruptures, in four cases no cause could be associated and the other three had various causes, such as an ascending aortic rupture following retrograde Type A dissection.

2017

GORE® TAG® Device

Three post-procedure ruptures of the DTA were reported to Gore in 2017 for the GORE® TAG® Device. One of these ruptures was associated with a Type I endoleak leading to eventual rupture. One was associated with an infection of the aneurysm occurring after a re-intervention to repair a Type I endoleak, while the other one reported rupture cause could not be determined.

Conformable GORE® TAG® Device

Four post-procedure ruptures of the DTA were reported to Gore in 2017 for the Conformable GORE® TAG® Device. One of these ruptures was caused by continued false lumen perfusion in a Type B dissection patient. One rupture was associated with a Type I endoleak. One rupture was unspecified and one was considered indeterminate with previous history of a re-intervention due to a Type II endoleak from the LSA. The patient underwent a coil embolization and months later expired due to a rupture.

Conversion

In the two year reporting time period from January 1, 2016 to December 31, 2017, a total of 17 patients were reported to have a post-procedure conversion with a Gore thoracic device. Thirteen of the 17 were reported in 2016, related with the change in region reporting practices mentioned in the introductory paragraph at the beginning of Section III. A summary of the events are stated below by year and specific Gore thoracic device.

2016

GORE® TAG® Device

Eight total post-procedure conversions were reported following treatment with the GORE® TAG® Device in 2016. **Table 17** provides a breakdown of the causes of the conversions. Of the six GORE® TAG® Devices converted due to infection; two were due to unknown causes, three were from a result of fistulas and one was suspected from suture used in an esophageal replacement surgery. None of reported infections were found to have originated from the implanted device. Of the remaining conversions one was due to aneurysm enlargement from a Type I endoleak and the other due to an aortoesophageal fistula. The physician chose to treat both surgically.

Conformable GORE® TAG® Device

Five post-procedure conversions were reported following treatment with the Conformable GORE® TAG® Device in 2016. **Table 17** provides a breakdown of the causes of the conversions. One was identified as a Type I endoleak, which the physician chose to treat surgically. Two others were considered progression of dissection. A post-procedure conversion of an ascending / arch open repair was conducted on one patient identified with a retrograde Type A dissection. The other continued to have false lumen perfusion and was treated surgically. The "Other" category includes two post-procedural conversions due to identification of a mycotic thoracoabdominal with contained rupture and removal after a Type IV endoleak of a non-Gore device.

Table 17: Primary cause of conversion in commercial experience

Number of occurrences				
Year	2016		2017	
Reason for explant	GORE® TAG® Device	Conformable GORE® TAG® Device	GORE® TAG® Device	Conformable GORE® TAG® Device
Endoleak	1	1	1	0
Device compression	0	0	0	0
Progression of dissection disease	0	2	0	0
Rupture caused by Type II endoleak	0	0	0	0
Infection	6	0	0	3
Fistula	1	0	0	0
Other	0	2	0	0
Total	8	5	1	3

2017

GORE® TAG® Device

One post-procedural conversions were reported to Gore in 2017 following treatment with the GORE® TAG® Device. In the emergent case, the device moved distally during ballooning which resulted in a proximal Type I endoleak, but the physician elected to conclude the procedure as the patient was stable; three days later, the devices were explanted and a vascular graft was implanted.

Conformable GORE® TAG® Device

Three post-procedural conversions were reported to Gore in 2017 following treatment with the Conformable GORE® TAG® Device. All three conversions were due to an infection, one of which was believed to have been caused by an aorto-esophageal fistula. The causes of the other two infections were unknown.

Aneurysm-related death

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. In the two year reporting time period from January 1, 2016 to December 31, 2017, an unusual amount of reported aneurysm-related death were reported. A total of eighty-seven aneurysm-related deaths were reported in 2016. The noticeable increases from previous years is thought to be related with the change in region reporting practices mentioned in the introductory paragraph at the beginning of Section III. In 2017, the occurrences returned to previous reported years. A summary of the events are stated below by year and specific Gore thoracic device. **Table 18** further details regarding the deaths and any comorbidities the patients had at the time of death.

2016

GORE® TAG® Device

Forty-four aneurysm-related deaths were reported following treatment with the GORE® TAG® Device in 2016. **Table 18** provides a breakdown of the causes of aneurysm-related death. Eight aneurysm-related deaths were attributed to device-related events including one late rupture from a Type IA endoleak, one stroke, one retrograde Type A dissection, two ruptures from disease progression, one from failed revision of previously implanted non-Gore device, one device infection and the last one could not have an assigned a specific cause. Ten were associated with treating a pre-treatment rupture. Eight occurred during the procedure and 13 were associated with patient co-morbidities. The remaining five could not be associated with a specific cause.

Conformable GORE® TAG® Device

Forty-three aneurysm-related deaths were reported following treatment with the Conformable GORE® TAG® Device in 2016. **Table 18** provides a breakdown of the causes of aneurysm-related death. Eight aneurysm-related deaths were attributed to a device-related events including one from visceral malperfusion, one from surgical conversion due to persistent Type I Endoleak, one from bowel ischemia, one suspected fistula, one rupture from surgical anastomosis site of concurrent Type A open repair, one retrograde Type A dissection and the other two could not be assigned to a specific cause. Five were associated with treating a pre-treatment rupture. Twenty occurred during the procedure and four were associated with patient co-morbidities. The remaining six could not be associated with a specific cause.

2017

GORE® TAG® Device

Eight aneurysm-related deaths were reported following treatment with the GORE® TAG® Device in 2017. **Table 18** provides a breakdown of the causes of aneurysm-related death. Two were associated with treating a pre-treatment rupture. One was procedure related and four were associated with patient comorbidities. The remaining one could not be associated with a specific cause.

Conformable GORE® TAG® Device

Twenty-five aneurysm-related deaths were reported following treatment with the Conformable GORE® TAG® Device in 2017. **Table 18** provides a breakdown of the causes of aneurysm-related death. Two aneurysm-related deaths were attributed to a device-related events including one from surgical explant due to late device infection, and one from access site rupture. Three were associated with treating a pre-treatment rupture. One was related to the procedure and six were associated with patient co morbidities. The remaining seven could not be associated with a specific cause.

Migration

In the two year reporting time period from January 1, 2016 to December 31, 2017, a total of 10 patients had a post-procedure device migration with a Gore thoracic device. A summary of the events are stated below by year and specific Gore thoracic device below.

2016

GORE® TAG® Device

There were three reported post-procedural device migrations of the GORE® TAG® Device reported to Gore in 2016. Two were thought to be associated with disease progression. The other was associated with a Type I endoleak with aneurysm enlargement.

Conformable GORE® TAG® Device

There was one post-procedural device migration of the Conformable GORE® TAG® Device reported to Gore in 2016. The migration was confirmed with imaging to be 10 mm from the original placement. The cause of the migration was undetermined.

2017

GORE® TAG® Device

There was one post-procedural device migration of the GORE® TAG® Device reported to Gore in 2017. The migration was revealed at the patient's four-year follow-up, reportedly due to a Type II endoleak that contributed to aneurysm enlargement. A Conformable GORE® TAG® Device was deployed distal to the existing device to resolve a Type I endoleak.

Conformable GORE® TAG® Device

There were five post-procedural device migrations of the Conformable GORE® TAG® Device reported to Gore in 2017. One migration was reportedly due to a short landing zone and / or an antegrade deployment approach; the patient was subsequently treated with two additional Conformable GORE® TAG® Devices to resolve a pseudoaneurysm. One migration occurred concurrently with a Type I endoleak treated with another device. One device was deployed in an elephant trunk technique which experienced proximal migration at three-year follow-up; the patient was treated with additional Conformable GORE® TAG® Devices. One device migrated in combination with aneurysm enlargement that was treated with additional Conformable GORE® TAG® Devices. The following two migrations occurred due to unknown causes that were resolved with additional devices.

Paraplegia / paraparesis*

In the two year reporting time period from January 1, 2016 to December 31, 2017, a total of 48 patients had reported cases of paraplegia or paraparesis after implants of a Gore thoracic device. Thirty-seven were reported in 2016 related with the change in region reporting practices mentioned in the introductory paragraph at the beginning of Section III. A summary of the events are stated below by year and specific Gore thoracic device.

2016

GORE® TAG® Device

There were 23 cases of paraplegia / paraparesis that were reported during or after the endovascular procedure that were reported to Gore in 2016 for the GORE® TAG® Device. Of the 23 cases of paraplegia / paraparesis involving the GORE® TAG® Device, five patients fully recovered, with no patients partially recovering. Eight patients exhibited no improvement. An additional 10 patients had no reports of their recovery.

Conformable GORE® TAG® Device

There were 14 cases of paraplegia / paraparesis that were reported during or after the procedure that were reported to Gore in 2016 for the Conformable GORE® TAG® Device. Of the 14 patients who received a Conformable GORE® TAG® Device and suffered a deficit, none fully recovered, 4 partially recovered, and 8 had no improvement. The additional two patients had unknown recovery.

2017

GORE® TAG® Device

There was one case of paraplegia / paraparesis that was reported during or after the endovascular procedure that was reported to Gore in 2017 for the GORE® TAG® Device. The patient was being treated for an impending rupture of a thoraco-abdominal aortic aneurysm. A spinal drain was placed post procedural without immediate recovery.

Conformable GORE® TAG® Device

There were 10 cases of paraplegia / paraparesis that were reported during or after the procedure that were reported to Gore in 2017 for the Conformable GORE® TAG® Device. Of the 10 patients who received a Conformable GORE® TAG® Device and suffered a deficit, 2 fully recovered, 2 partially recovered, and 1 had no improvement. Five patients had unknown recovery. Three were noted to have recovery or partial recovery and had received a post-procedural spinal drain.

Table 18: Aneurysm-related deaths in commercial experience

Number of occurrences				
Year	**2016**		**2017**	
	GORE® TAG® Device	**Conformable GORE® TAG® Device**	**GORE® TAG® Device**	**Conformable GORE® TAG® Device**
Pre-procedure ruptures	10	5	2	3
Comorbidities[a]	13	4	4	6
Procedure-related[b]	8	20	1	7
Device-related	8	8	0	2
Unknown causes	5	6	1	7
Total	44	43	8	25

[a] Cardiac events, sepsis, bowel occlusion, multi-organ dysfunction syndrome, pre-existing rupture, pre-existing bowel ischemia, rupture of untreated ascending aorta, pre-existing dissection, rupture of dissection, infection.

[b] Procedure-related death refers to events stemming from the endovascular procedure and determined unrelated to the endovascular device. Examples include complications resulting from dissections and surgical bypass or access and stroke.

* Paraplegia and paraparesis are used interchangeably by clinical sites and often are not distinguished from one another.

Section III – Worldwide commercial experience

Stroke

In the two-year reporting time period from January 1, 2016 to December 31, 2017, a total of 42 patients had a procedural or post-procedural stroke after implantation of a Gore thoracic device. Thirty-three were reported in 2016 related with the change in region reporting practices mentioned in the introductory paragraph at the beginning of Section III. A summary of the events are stated below by year and specific Gore thoracic device.

2016

GORE® TAG® Device

There were 19 cases of stroke that were reported during or after the procedure that were reported to Gore in 2016 for the GORE® TAG® Device. Fourteen of the strokes were reported in patients where the device was deployed proximal to the left subclavian ostium or further proximal. In the other five cases, the location was distal to the left subclavian artery.

Conformable GORE® TAG® Device

There were 14 cases of stroke that were reported during or after the procedure that were reported to Gore in 2016 for the Conformable GORE® TAG® Device. Eight of the strokes were reported in patients where the device was deployed proximal to the left subclavian ostium or further proximal. In the other 6 cases, the location was distal to the left subclavian artery. Eight of the strokes were reported to have caused hemi- or mono-paralysis / paresis.

2017

GORE® TAG® Device

There were two cases involving stroke that were reported during or after the procedure that were reported to Gore in 2017 for the GORE® TAG® Device. One stroke involved an emergent endovascular repair of a traumatic transection with the cause of the stoke unknown. The second patient involving a stroke was being treated for a ruptured thoracic arch aneurysm. The patient tolerated the procedure, but had a reported cerebral vascular accident. Both cases the devices were placed proximal to the left subclavian ostium or further proximal.

Conformable GORE® TAG® Device

There were seven cases of stroke that were reported during or after the procedure that were reported to Gore in 2017 for the Conformable GORE® TAG® Device. In five of the cases the devices were placed proximal to the left subclavian ostium or further proximal. The additional two reported cases the device location was distal to the left subclavian artery. One patient experienced paraparesis, while the other reportedly experienced right hemispheric stroke after a parallel graft procedure to treat a thoraco-abdominal aneurysm.

Device integrity

Compression

Compression of a GORE® TAG® Device is defined as a failure of the device to maintain its intended expanded diameter post-implantation. Reinterventions for device compression events include re-ballooning, placement of additional thoracic endoprostheses, placement of a bare metal stent, or surgical conversion.

Specific device modifications to improve device flexibility and resistance to compression were incorporated into the Conformable GORE® TAG® Device design. At the time of this analysis, no device compressions have been reported with more than 80,000 Conformable GORE® TAG® Devices distributed.

2016

GORE® TAG® Device

There were three device compressions of the GORE® TAG® Device reported to Gore in 2016. One incidence was reported from literature with 180 patients. Another was a reported in a trauma patient and the last was noted from a dissected aneurysm patient. Both were corrected with an additional stent graft devices.

Conformable GORE® TAG® Device

There were zero device compressions of the Conformable GORE® TAG® Device reported to Gore in 2016.

2017

GORE® TAG® Device

There were zero device compressions of the GORE® TAG® Device reported to Gore in 2017.

Conformable GORE® TAG® Device

There were zero device compressions of the Conformable GORE® TAG® Device reported to Gore in 2017.

Cumulative worldwide experience summary

There have been 207 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 207 device compressions reported, Gore has confirmed successful reinterventions in 144 cases, as well as 12 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 cases where the patient ultimately died, the devices were not sized according to the sizing guidelines specified in the IFU 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 was observed in young patients presenting with acute, traumatic transections of the thoracic aorta when using the GORE® TAG® Device. Aortic diameters in these young patients are frequently less than the 23 mm lowest treatment diameter of the GORE® TAG® Device. Typically these patients have a tight radius of curvature of the aortic arch which may predispose this 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. As a result of the compression reports for the GORE® TAG® Device, Gore continues to emphasize to physicians the importance of patient selection, and adhering to the intended use and sizing guidelines included in the IFU. After further investigation of these events, specific device modifications to improve device flexibility and resistance to compression were incorporated into the Conformable GORE® TAG® Device design. At the time of this analysis, no device compressions have been reported with more than 80,000 Conformable GORE® TAG® Devices distributed.

Fracture

2016

GORE® TAG® Device

There was one GORE® TAG® Device reported to Gore with wire fractures in 2016. Post-implantation CT revealed two wire fractures in the mid-body of the device. The treating physician noted a very oversized condition. The patient is doing well and will continue to be monitored.

Conformable GORE® TAG® Device

There were zero fractures reported to Gore in 2016 for the Conformable GORE® TAG® Device.

2017

GORE® TAG® Device

There were zero fractures reported to Gore in 2017 for the GORE® TAG® Device.

Conformable GORE® TAG® Device

There were zero fractures reported to Gore in 2017 for the Conformable GORE® TAG® Device.

Cumulative worldwide experience summary

Over Gore's 20 year history of endovascular treatment of thoracic diseases, 70 devices have been reported to Gore for wire fractures. Over 30 fracture reports were from early experience with our original GORE® TAG® Device with spine wires, and were confirmed to be attributed to anatomical conditions resulting in higher than expected strains on the spine wire, resulting in fatigue failure. There was no clear relationship between these device wire fractures and adverse clinical events. However, Gore decided to halt the pivotal study and redesign the GORE® TAG® Device by removing the spine wire. After the redesign, a confirmatory study was continued with approval of the GORE® TAG® Device in 2004. Other fractures reported to Gore for the GORE® TAG® Device were confirmed to have fatigue failure consistent with device compression events. Many were either implanted in oversized or undersized conditions in the aorta, associated with an early experience finding that physicians were treating younger patients off label in the arch for traumatic transections and dissections. Often, birdbeaking of the proximal end of the device resulted in compression of the leading end of the device, resulting in fatiguing the stent wire. There were no decisive characteristics from the other fractures reported for the GORE® TAG® Device. The GORE® TAG® Device is no longer available.

Only two cases of fracture reported to Gore involved the Conformable GORE® TAG® Device. One case was for the treatment of an aneurysm, with the fractures confirmed by imaging. A reintervention was performed with placement of additional devices. The other reported case involved a Conformable GORE® TAG® Device with an adjacent stent. A fracture was reported, but could not be confirmed on the Conformable GORE® TAG® Device and was unclear if it was instead on the adjacent stent.

Type III endoleaks

2016

GORE® TAG® Device

There were nine Type III endoleaks of an unknown source reported to Gore in 2016 for the GORE® TAG® Device. Of these nine patients, five of the endoleaks resolved without intervention, two were being monitored at last available follow-up and two patients received an additional device to resolve the endoleak.

Conformable GORE® TAG® Device

There were no Type III endoleaks reported for the Conformable GORE® TAG® Device in 2016.

2017

GORE® TAG® Device

There were seven Type III endoleaks of an unknown source reported to Gore in 2017 for the GORE® TAG® Device. Of these seven patients, five patients received no additional treatment, with three resolving and two with continued monitoring at last available follow-up. Two patients received an additional device with subsequent resolution of the endoleak.

Conformable GORE® TAG® Device

There was one graft material disruption / tear reported for Conformable GORE® TAG® Device in 2017. Two hours after the index procedure, the patient was identified with a reported Type III endoleak. The patient was treated the same day with an additional device extending proximal from the originally place device and the endoleak resolved. According to the physician the initial implantation was completed without issue. The source of the reported Type III could not be confirmed from the images provided.

Deployment anomaly

2016

GORE® TAG® Device

There were no deployment anomalies reported to Gore in 2016 for the GORE® TAG® Device.

Conformable GORE® TAG® Device

There were no deployment anomalies reported to Gore in 2016 for the Conformable GORE® TAG® Device.

2017

GORE® TAG® Device

There were no deployment anomalies reported to Gore in 2017 for the GORE® TAG® Device.

Conformable GORE® TAG® Device

There were a total of six deployment anomalies reported for Conformable GORE® TAG® Device in 2017. Two cases were associated with difficulties in withdrawing the catheter after deployment. The other four cases were related to the incomplete deployments previously noted.

Cumulative worldwide experience summary

There have been 15 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 8 of the 15 instances, the physician was able to successfully deploy the device. In one instance, the physician was able to remove the undeployed device. In one case the device was unable to track through a previously placed surgical graft and upon removal through the introducer sheath the device deployed. Four of the cases were associated with the incomplete deployments previously mentioned. Refer to the "Deployment-related Class II recall" section for more details.

Explants

Fifteen cases involving explants were reported in 2016 and six cases were reported in 2017. None of the devices were returned to Gore for analysis and were disposed at the site. Most of the 2016 reported cases were older dated cases related to the changes in the regional reported mentioned at the beginning of Section III. Explanted devices are often disposed at the site, therefore not returned to Gore for analysis. Refer to **Table 19** and summary for analyses on returned devices.

2016

GORE® TAG® Device

A total of eight total explants were reported following treatment with the GORE® TAG® Device in 2016. Of the six GORE® TAG® Devices converted due to infection; two were due to unknown causes, three were from a result of fistulas and one was suspected from suture used in an esophageal replacement surgery. None of reported infections were found to have originated from the implanted device. Of the remaining conversions one was due to aneurysm enlargement from a Type I endoleak and the other due to an aortoesophageal fistula. The physician chose to treat both surgically.

Conformable GORE® TAG® Device

A total of seven cases of Conformable GORE® TAG® Device explants were reported to Gore in 2016. One was identified as a Type I endoleak, which the physician chose to treat surgically. Two others were considered progression of dissection. A post-procedure conversions of an ascending / arch open repair was conducted on one patient identified with a retrograde Type A dissection. The other continued to have false lumen perfusion and was treated surgically. The "Other" category includes two post-procedural conversions due to identification of a mycotic thoracoabdominal with contained rupture and removal after a Type IV endoleak of a non-Gore device. Gore was made aware of complications related to the explant procedure that resulted in death in three cases.

2017

GORE® TAG® Device

One explant was reported to Gore in 2017 following treatment with the GORE® TAG® Device. In the emergent case, the device moved distally during ballooning which resulted in a proximal Type I endoleak, but the physician elected to conclude the procedure as the patient was stable; three days later, the devices were explanted and a vascular graft was implanted. This information was reported in the conversion section as it was the same.

Conformable GORE® TAG® Device

Three explants were reported to Gore in 2017 following treatment with the Conformable GORE® TAG® Device. Three explants were due to an infection, one of which was believed to have been caused by an aorto-esophageal fistula and the other two were unknown. This information was reported in the conversion section as it was the same.

Device integrity observations

One explanted device was returned to Gore for analysis. There were no device integrity observations.

Table 19: GORE® TAG® Device and Conformable GORE® TAG® Device summary of returned devices for analysis

Primary reason for explant	Total occurrences	GORE® TAG® Device	Conformable GORE® TAG® Device
Implantation difficulties	11	11	—
Rupture	2	2	—
Aneurysm enlargement with endoleak	6	6	—
Endoleak	2	2	—
Migration	1	1	—
Infection	9	7	2
Fistula	4	4	—
Dissection	5	5	—
Compression	15	15	—
Incidental autopsy	22	15	7[b]
Other comorbidities	4	3	1[c]
TOTAL CASES[a]	**81**	**71**	**10**

[a] Explant analyses include commercial and clinical trial devices
[b] Explant includes Conformable GORE® TAG® Device and GORE® TAG® Thoracic Branch Endoprosthesis (TBE)
[c] Explant of TBE extenders only

Explant analyses

Table 19 provides a historical summary of all explants returned to Gore for analysis since 2001. **Table 19** lists returned thoracic devices to Gore for evaluation over its 20 year implant history.

Figure 6 illustrates the timing of explants from GORE® TAG® Devices returned to Gore for analysis. The number to the right of the primary reason of explant represents the occurrences noted in **Table 19** above. The bar demonstrates the entire post-operative day (POD) range of the occurrences, while the tick within the bar denotes the average.

Figure 6: Timing of returned explants for the GORE® TAG® Device

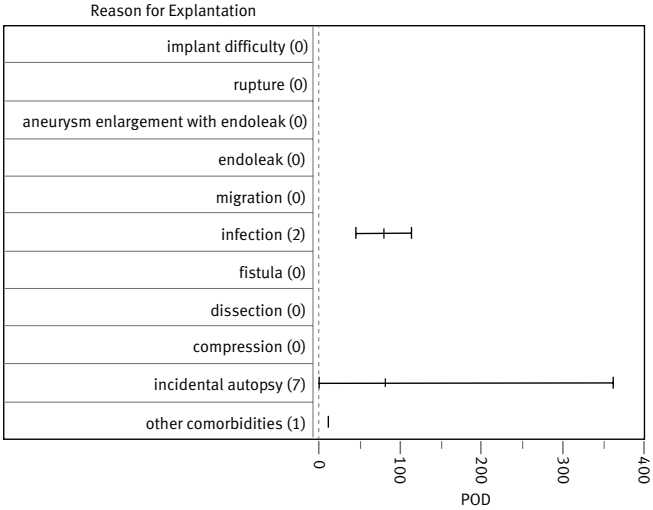
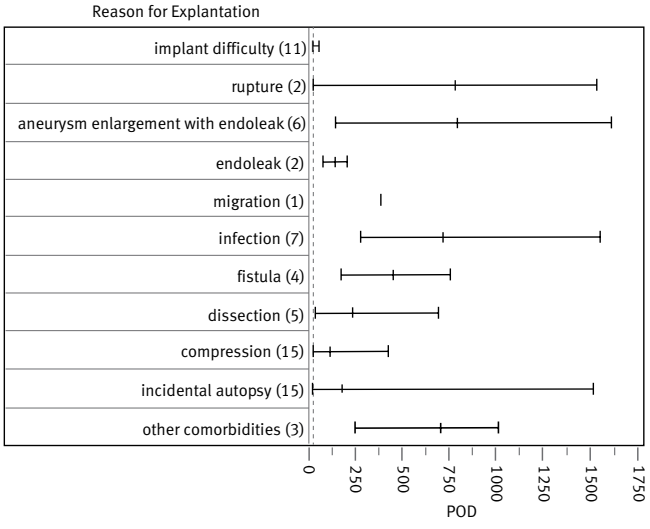


Figure 7 illustrates the timing of explants from Conformable GORE® TAG® Devices returned to Gore for analysis. The number to the right of the primary reason of explant represents the occurrences noted in the **Table 19** to the left. The bar demonstrates the entire post-operative day (POD) range of the occurrences, while the tick within the bar denotes the average.

Figure 7: Timing of returned explants for the Conformable GORE® TAG® Device



Gore has received ten explants, often multiple devices, containing the Conformable GORE® TAG® Devices, including investigation devices, for explant analysis. No wire fractures were observed consistent with wire fatigue. Explant instrument damage was observed on most explants resulting from removal from the patient. No wear related graft disruptions were identified on 9 of the 10 explants. One explant from a clinical study case (TAG 08-01) had three implanted devices and was noted to have holes consistent with material densification in all three devices in the overlap zones. The study patient had no history of endoleaks.

Explants not previously described

The four devices below were received from past years and had not yet been described in any previous annual clinical update.

Conformable GORE® TAG® Device Analysis

A total of three cases involving Conformable GORE® TAG® Devices had devices returned to Gore for analysis (received in 2014 and 2015). Two cases were related to clinical studies with one using the Conformable GORE® TAG® Devices as extension of treatment only of the feasibility study of GORE® TAG® Thoracic Branch Endoprostheses (TBE). The study patient (SSB 11-02) expired due to rupture. The other clinical study case (TAG 08-01) was a donation by the patient after expiring (POD 1602) from other causes not related to the dissection treatment. The third case involved treatment of a traumatic injury with a single Conformable GORE® TAG® Device and was later removed due to infection and noted abscess caused by a separate procedure. All devices were evaluated for biologic response, material integrity, and overall device durability. No unusual device or material durability observations were noted from the Conformable GORE® TAG® Devices included in the feasibility study or from the single device used to treat the traumatic transection. The Conformable GORE® TAG® Devices from the TAG 08-01 dissection study did have observations of material densification with holes in areas of device overlaps. All holes and densification (visual transparent material without evidence of holes or tears) noted did not penetrate the underlying graft material of the overlap stent-graft. No wire integrity observations were found, nor any clinical endoleak observed prior to explant.

The other explant received was from an early feasibility study (TBE 14-02) using TBE extenders. Eleven days post-op the physicians proceeded with open surgical repair due to an increase in aortic insufficiency based on TEE. The ascending aorta and proximal arch were replaced with a surgical graft, and the aortic root was reconstructed and the valve re-suspended. The patient tolerated the procedure. Upon evaluation, no wear related disruptions were identified. All material disruptions noted were consistent with surgical instrumentation during a surgical explant procedure.

Summary trends of explants

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 device from the intended deployment site, due to post deployment procedural manipulations. From the few Conformable GORE® TAG® Device explant analyses, no device integrity observations were found to impact device performance.

Section V – Summary and conclusions

Summary of clinical study experience

Summaries of five-year follow-up data from the Pivotal, Confirmatory, Treatment IDE, and Post-Approval Study for patients treated with the GORE® TAG® Device can be found in the previous published July 2013 GORE® TAG® Thoracic Endoprosthesis Annual Clinical Update (AS0089-EN1).

Five-year follow-up data from the Conformable GORE® TAG® Device Aneurysm Study (TAG 08-03), the Conformable GORE® TAG® Device Traumatic Transection Study (TAG 08-02), and the Conformable GORE® TAG® Device Acute Complicated Type B Dissection Study (TAG 08-01) reveal:

- No device migrations
- No conversions
- No device compressions
- 98% freedom from major device-related adverse events through 30 days in the Conformable GORE® TAG® Device Aneurysm Study (TAG 08-03)
- 100% procedural survival rate in the Conformable GORE® TAG® Device Traumatic Transection Study (TAG 08-02)
- 73.3% complete false lumen thrombosis at one year in the Conformable GORE® TAG® Device Acute Complicated Type B Dissection Study (TAG 08-01)

Summary of worldwide commercial experience

Key takeaways for the past two reporting years:

- A Class II recall occurred in 2017 due to incomplete deployment events which resulted in IFU changes and a physician safety communication letter
- There was an increase in the number of reported events in 2016 due to a change in regional reporting practices

From the worldwide commercial experience of 2016 and 2017 reporting periods, the following have been reported:

- 30 post-procedure ruptures of the DTA in 2016, 7 post-procedure ruptures of the DTA in 2017
- 13 post-procedure conversions in 2016, 4 post-procedure conversions in 2017
- 87 aneurysm-related deaths in 2016, 33 aneurysm-related deaths in 2017
- 4 post-procedure reported migrations in 2016, 6 post-procedure reported migrations in 2017
- 37 incidents of paraplegia or paraparesis in 2016, 11 incidents of paraplegia or paraparesis in 2017
- 33 incidents of stroke in 2016, 9 incidents of stroke in 2017
- 3 device compressions in 2016, 0 device compressions in 2017
- 1 device with reported fractures in 2016, 0 devices with reported fractures in 2017
- 0 deployment anomalies in 2016, 6 deployment anomalies in 2017
- 15 explants in 2016 and 4 explants in 2017

Conclusion

From our previous clinical study history and 20 years of worldwide commercial experience, the GORE® TAG® Thoracic Endoprosthesis continues to be effective in preventing aneurysm rupture and a viable alternative to open surgical repair. Endovascular repair of aortic pathologies has fast become the preferred treatment of choice in many centers. However, continued follow-up in treated patients is necessary, as complications may arise at longer term intervals. We continue to assess the performance of our devices through surveillance of our clinical studies, registries, and post-market studies. As physicians expand their treatment paradigms, especially in less-studied pathologies (e.g., chronic dissections), a further understanding may be obtained to help create tools and future devices for physicians and their patients. The Conformable GORE® TAG® Device is an approved, less-invasive treatment option for isolated lesions, including aneurysms and transections, and all Type B aortic dissections.

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 U.S., call 800.437.8181. Outside of the U.S., contact your local Gore technical representative.

GORE® TAG® THORACIC ENDOPROSTHESIS

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

Patient Selection and Treatment

- Successful patient selection requires specific imaging and accurate measurements; please see Measurement Techniques and Imaging section.
- 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
  - aortotitis 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).

Section VI – Patient follow-up and selection

- 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.

Follow-up

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

Potential Device or Procedure Related Adverse Events

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

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

CONFORMABLE *GORE® TAG®* THORACIC ENDOPROSTHESIS

UNITED STATES INDICATIONS FOR USE

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

- Adequate iliac / femoral access
- Aortic inner diameter in the range of 16–42 mm
- ≥ 20 mm non-aneurysmal aorta proximal and distal to the lesion

Type B dissections in patients who have appropriate anatomy, including:

- Adequate iliac / femoral access
- ≥ 20 mm landing zone proximal to the primary entry tear; proximal extent of the landing zone must not be dissected
- Diameter at proximal extent of proximal landing zone in the range of 16–42 mm

CONTRAINDICATIONS

The GORE® TAG® Thoracic Endoprosthesis is contraindicated in:

- Patients with known sensitivities or allergies to the device materials
- Patients who have a condition that threatens to infect the graft

WARNINGS AND PRECAUTIONS

General

- • Failure to properly follow the instructions, warnings, and precautions may lead to serious surgical consequences, injury to the patient or death. Compliance with device sizing recommendations is critical to optimal performance of the device.
- Read all instructions carefully, particularly the following sections: Table 99: 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 aortas) should receive enhanced follow-up (See IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP).
- The safety and effectiveness of the GORE® TAG® Thoracic Endoprosthesis to treat traumatic aortic transections and acute complicated Type B dissections was determined based on 30 day and 1 year follow-up data, respectively. Due to the short-term nature of this data, all patients should be advised that long-term, regular follow-up is necessary to assess patients' health status and stent graft performance.

- The GORE® TAG® Thoracic Endoprosthesis should only be used by physicians experienced in vascular interventional techniques, and who have successfully completed the appropriate physician training program.
- The GORE® TAG® Thoracic Endoprosthesis is not recommended in patients unable to undergo, or who will not be compliant with, the necessary pre and post-operative imaging and follow-up described in IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP. The GORE® TAG® Thoracic Endoprosthesis is not recommended in patients who cannot tolerate contrast agents necessary for intra-operative and post-operative follow-up imaging.
- Intervention or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aortas, endoleaks, dissection extension, or persistent false lumen perfusion. An increase in aortic diameter, persistent endoleak, or continued false lumen perfusion may lead to aortic rupture.
- Always have an appropriate surgical team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

Additional Warnings and Precautions added to IFU in 2017:

- • If abnormal or inconsistent deployment line resistance is felt during deployment initiation, STOP deployment action immediately. If device remains constrained, remove device through the introducer sheath. If resistance is felt during removal of the constrained endoprosthesis, stop and withdraw device and introducer sheath together.
- If the device is constrained or attached to the catheter and remains in a partially deployed state, physicians should strongly consider conversion to immediate open surgical repair in order to avoid additional procedure time and potential harm from additional endovascular maneuvers.

Patient Selection and Treatment

- Successful patient selection requires specific imaging and accurate measurements; please see Measurement Techniques and Imaging section below.
- For isolated lesions, the GORE® TAG® Thoracic Endoprosthesis is designed to treat aortic neck diameters no smaller than 16 mm and no larger than 42 mm. The GORE® TAG® Thoracic Endoprosthesis is designed to treat proximal 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 or bypass) 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.
- For Type B dissections, the GORE® TAG® Thoracic Endoprosthesis is designed to treat proximal aortic neck diameters no smaller than 16 mm and no larger than 42 mm and proximal landing zone lengths of ≥ 20 mm proximal to the primary entry tear, where the proximal extent of the intended landing zone is not dissected. Additional proximal landing zone length may be gained by covering the left subclavian artery (with or without discretionary transposition or bypass) when necessary to optimize device fixation and maximize aortic landing zone length. 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 ensure successful sheath introduction and subsequent withdrawal. A surgically created vascular conduit or vessel dilation 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:
  - chronic Type B dissections
  - acute uncomplicated Type B dissections
  - aortic fistulas
  - aortotitis or inflammatory aneurysms
  - intramural hematoma
  - mycotic aneurysms
  - penetrating ulcers
  - previous stent or stent graft or previous surgical repair in the descending thoracic aortic area
  - 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
- When treating isolated lesions, differing proximal and distal neck diameters (aortic taper) outside the intended aortic diameter requirements for a single endoprosthesis diameter (Table 99) requires the use of multiple endoprostheses of different diameters.
- Use of multiple devices with differing diameters requires 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 intra-operative 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 99) using appropriate vascular access techniques (including surgical conduit, if needed).
- Key anatomic elements that may affect successful treatment of the lesion 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 secondary to the implantation procedure.
- Adjunctive surgical or interventional procedures may be required to treat Type B dissections.
- When treating Type B dissections, the proximal extent of the intended proximal landing zone must not be dissected. For example, if the dissection or any hematoma in the proximal extent of the dissection extends up to the LSA, then coverage of the LSA would ensure the proximal end of the device lands in non-dissected tissue. Landing the proximal end of the device in dissected tissue could increase the risk of damage to the septum and could lead to new septal tears, aortic rupture, retrograde dissection, or other complications.
- Use of the GORE® TAG® Thoracic Endoprosthesis outside of the recommended anatomical sizing guidelines (Table 99) may result in potentially serious device-related events (e.g., device infolding, excessive device compression, endoleak, wire fracture, migration).
- If coverage of the left subclavian artery ostium is required to obtain adequate neck length for fixation and sealing, transposition or bypass of the left subclavian artery should be considered. In addition, consider occlusion of the ostium via surgical or endovascular means to avoid Type II endoleaks.
- When covering the left subclavian artery ostium without revascularization (e.g. transposition or bypass), there may be an increased risk of stroke due to decreased flow in the left vertebral artery. When treating emergent patients (e.g., ruptured aneurysms, traumatic transections, acute complicated Type B dissections) where revascularization may not be possible prior to stent graft placement due to the patient's condition, it is important to weigh this potential increased risk of stroke with the benefits of treatment.
- The GORE® TAG® Thoracic Endoprosthesis is not recommended in patients who cannot tolerate contrast agents necessary for intra-operative and post-operative follow-up imaging.
- The GORE® TAG® Thoracic Endoprosthesis is not recommended in patients with known sensitivities or allergies to ePTFE, FEP, gold, nickel, or titanium.
- ASA risk was higher in patients enrolled in the TAG 04-01 Ruptured Aneurysm Arm, TAG 08-02 Trauma study, and TAG 08-01 Acute Dissection study compared to patients enrolled in the TAG 99-01, TAG 03-03, and TAG 08-03 Aneurysm studies. Patients presenting with ruptured aneurysm, traumatic transection, and acute dissection may be at higher risk for complications associated with general anesthesia.

Section VI – Patient follow-up and selection

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, TAG 03-03, and TAG 08-03 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.
- Non-clinical testing has demonstrated that the GORE® TAG® Thoracic Endoprosthesis is MR Conditional. Please refer to the IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP for MR information.

Potential Adverse Events

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

- access, delivery and deployment events (e.g. access failure; deployment difficulties/failures; failure to deliver the stent graft; and insertion or removal difficulty)
- adynamic ileus
- allergic reaction (to contrast, anti-platelet therapy, stent graft material)
- amputation
- anesthetic complications
- aortic expansion (e.g., aneurysm, false lumen, landing zone, lesion)
- aortic rupture
- angina
- atelectasis / pneumonia
- bleeding (procedural and post-treatment)
- bowel (e.g., ileus, transient ischemia, infarction, necrosis)
- branch vessel occlusion or obstruction
- cardiac (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension or hypertension)
- catheter breakage
- change in mental status
- coagulopathy
- contrast toxicity
- death
- dissection, perforation, or rupture of the aortic vessel & surrounding vasculature
- edema (e.g., leg)
- embolism (micro and macro) with transient or permanent ischemia
- endoleak
- endoprosthesis: improper placement; incomplete deployment; migration; material failure; occlusion; infection; stent fracture; dilatation; perigraft flow
- erectile dysfunction
- erosion
- excessive or inappropriate radiation exposure
- femoral neuropathy
- fever and localized inflammation
- fistula (e.g., aortoeneteric, arteriovenous, aortoesophogeal, aortobronchial)
- genitourinary (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection)
- hematoma
- infarction
- infection (e.g., aneurysm, device or access sites)
- lymphocele / lymph fistula
- myocardial infarction
- neurologic damage, local or systemic (e.g., stroke, paraplegia, paraparesis)
- nerve injury
- peripheral malperfusion or ischemia
- persistent false lumen flow
- post-implant syndrome
- prosthesis dilatation / rupture
- prosthetic thrombosis
- pseudoaneurysm
- pulmonary complications (e.g., pneumonia, respiratory failure),
- pulmonary embolism
- renal (e.g., artery occlusion, contrast toxicity, insufficiency, failure)
- reoperation
- restenosis
- surgical conversion
- thrombosis
- transient ischemic attack
- vascular spasm or vascular trauma (e.g., ilio-femoral vessel dissection, bleeding, rupture)
- wound (e.g., infection, dehiscence)

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