GORE® TAG®
Thoracic Branch Endoprosthesis

ANNUAL CLINICAL UPDATE

March 2024 through
February 2025

Together, improving life

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Overview

This annual clinical update provides a review of the ongoing experience with the GORE® TAG® Thoracic Branch Endoprosthesis indicated for endovascular repair of lesions of the aortic arch and descending thoracic aorta, while maintaining flow into a single aortic arch branch vessel. The device has been commercially available in the United States as of August 2022.

The GORE® TAG® Thoracic Branch Endoprosthesis is a modular device consisting of the Aortic Component (AC), the Side Branch (SB) Component, and an optional Aortic Extender (AE), and their respective delivery systems. These components may be used together as a stand-alone device or in conjunction with the GORE® TAG® Conformable Thoracic Endoprosthesis (P040043) to accommodate the intended treatment site.

Each component of the endoprosthesis consists of an ePTFE/FEP graft supported over its entire length by a nitinol wire frame (stent). The AC incorporates an internal portal that opens to the outer device surface, allowing for seal and fixation of the SB Component. The SB Component includes the CBAS® Heparin Surface which consists of stable, covalent, end-point attached heparin of porcine origin. The Aortic Extender is a short, tubular device with radiopaque gold bands at each end for radiographic visibility. Both the leading and trailing ends consist of partially uncovered stent apices. This device is intended to be used to improve sealing of the Aortic Component and/or add seal length proximally within the aorta, if necessary.

Consult Instructions for Use
eifu.goremedical.com

INSTRUCTIONS FOR USE

The most up-to-date version of the *Instructions for Use* (IFU) can be found at https://eifu.goremedical.com and searching for the device part number or prefix (e.g. "TBE"). Additional details on the GORE® TAG® Thoracic Branch Endoprosthesis device can be found in the Summary of Safety and Effectiveness (SSED) for isolated lesions and type B dissections. Details on the original TAG® Device can be found in the SSED for aneurysms. These SSEDs are applicable for all TAG Devices.

Table 1: Brief regulatory approval history of the device in the United States

Device iterations	Approval	Indication
GORE® TAG® Thoracic Branch Endoprosthesis	May 2022	Descending thoracic aortic aneurysms, dissections, traumatic transection, and other isolated lesions.
	April 2025	This device is indicated for endovascular repair of lesions of the aortic arch and descending thoracic aorta, while maintaining flow into a single aortic arch branch vessel, in patients with appropriate anatomy.

Additional details on the GORE® TAG® Thoracic Branch Endoprosthesis for patients with treatment in the descending thoracic aorta can be found in the linked Summary of Safety and Effectiveness (SSED), PMA approval order, and Post Approval study webpage.

For patients treated with the GORE® TAG® Thoracic Branch Endoprosthesis in the aortic arch additional details can be found in the linked Summary of Safety and Effectiveness (SSED), PMA approval order, and Post Approval study webpage.

The Instructions for Use (IFU) all treatment areas can be found at https://eifu.goremedical.com.

Worldwide device distribution

The first commercial implant of the GORE® TAG® Thoracic Branch Endoprosthesis occurred on August 9, 2022. Data for this Annual Clinical Update was pulled from August 9, 2022, through February 28, 2025. During this period, there were 11,409 devices distributed globally consisting of 5,072 Aortic Components, 5,481 Side Branch Components, and 856 Aortic Extenders.

Clinical evaluations

A list of clinical evaluations can be found in **Table 2**. A summary of the results of each evaluation can be found in the IFU or ClinicalTrials.gov.

Table 2: Status clinical evaluations for the GORE® TAG® Thoracic Branch Endoprosthesis

Status	Reference	Name
Study Complete	NCT02021812	Evaluation of the GORE® TAG® Thoracic Branch Endoprosthesis in the Treatment of Proximal Descending Thoracic Aortic Aneurysms
Active, Follow-up ongoing	NCT02777593 (Zone 2) NCT02777528 (Zone 0/1)	Evaluation of the GORE® TAG® Thoracic Branch Endoprosthesis in the Treatment of Lesions of the Aortic Arch and Descending Thoracic Aorta, (SSB 11-02)
Active, Follow-up ongoing	SSB 22-05	GORE® TAG® Thoracic Branch Endoprosthesis Zone 2 Post-Market Surveillance Protocol
Protocol Pending	TBE 25-03	GORE® TAG® Thoracic Branch Endoprosthesis Zone 0/1 Post-Approval Study

Continued follow-up of pivotal study

This study is a non-randomized, multicenter, prospective study that consists of continued follow-up of all available subjects from the IDE Pivotal Study with treatment in the descending thoracic aorta and aortic arch.

The study design includes the assessment of the GORE® TAG® Thoracic Branch Endoprosthesis in treating lesions of the thoracic aorta in Zone 2. A total of 244 subjects were enrolled and eligible for analysis in the study across the 4 cohorts (including six continued access subjects).

The remaining subjects continue to be followed annually for 5 years. Clinical outcomes include Procedural Success (defined as Device Technical Success with the absence of serious adverse events at 30 days, including: death, disabling stroke, paraplegia, paraparesis, new onset renal failure requiring permanent dialysis, unanticipated reintervention related to the device or the procedure, new ischemia, distal device-related thromboembolic events requiring intervention, life threatening bleed, myocardial infarction, prolonged intubation, laryngeal or phrenic nerve injury, renal dysfunction or volume overload requiring ultrafiltration, severe heart failure or hypotension, aortic rupture or new dissection) and Treatment Success (defined as Device Technical Success, with absence of all of the following at all appropriate follow-up windows: lesion-related mortality, disabling stroke, paraplegia and paraparesis, protocol-defined reintervention, new ischemia, aortic rupture, loss of patency, fistula formation, loss of device integrity, device migration, new dissection, Type I/III endoleak, and aortic enlargement).

The study design also included the assessment of the GORE® TAG® Thoracic Branch Endoprosthesis in treating lesions of the aortic arch. A total of 77 subjects were enrolled and eligible for analysis in the study across the three cohorts. The remaining subjects will be followed annually for 5 years. Clinical outcomes include Procedural Success (defined as Device Technical Success with the absence of serious adverse events at 30 days, including: death, disabling stroke, paraplegia, paraparesis, new onset renal failure requiring permanent dialysis, unanticipated reintervention related to the device or the procedure, new ischemia, distal device-related thromboembolic events requiring intervention, life threatening bleed, myocardial infarction, prolonged intubation, laryngeal or phrenic nerve injury, renal dysfunction or volume overload requiring ultrafiltration, severe heart failure or hypotension, aortic rupture, new dissection, or extension of a dissection (Dissection Cohort only)) and Treatment Success (defined as Device Technical Success, with absence of all of the following at all appropriate follow-up windows: lesion-related mortality, disabling stroke, paraplegia and paraparesis, protocol-defined reintervention, new ischemia, aortic rupture, loss of patency, fistula formation, loss of device integrity, device migration, new dissection, Type I/III endoleak, aortic enlargement, extension of dissection (Dissection Cohort only), false lumen perfusion through primary entry tear (Dissection Cohort only), and false lumen perfusion through an aortic arch branch vessel (Dissection Cohort only). Other outcomes including Type II/IV Endoleak, false lumen status in treated and untreated segments and false lumen perfusion through a non-aortic arch branch vessel will also be evaluated at all appropriate follow up intervals.

The data was submitted under premarket approval application (P210032 and P210032/S015) which was approved on May 13, 2022 and April 11, 2025 and a summary of the data can be found in the IFU or SSEDs linked above.

The PMA submissions included 1 year data and since the approval, additional follow up information is available on the Zone 2 pivotal cohort.

Of the 248 Zone 2 subjects enrolled and eligible for analysis, 201 subjects have met the definition of Procedural Success and 175 subjects have met the definition of Treatment Success as of the data export on 15-Jan-2025 (those still in the study are in the 36-Month follow-up window or later). It should be noted that four additional dissection subjects were added to the study, and several events were re-adjudicated over the course of the study after the Procedural Success analysis data had been presented in the PMA. As a result, the updated Procedural Success was 81% in this cohort, with minimal changes to the procedural success component rates.

The Treatment Success was 72.0%. Sixty -eight subjects failed to meet the definition of Treatment Success due to the following adverse events:

- Device technical success failure: 10 subjects (4.0%),
- Lesion-related mortality: 4 subjects (1.6%),
- Disabling stroke: 4 subjects (1.6%),
- Paraplegia: 1 subject (0.4%),
- Paraparesis: 2 subjects (0.8%),
- Protocol-defined reintervention: 8 subjects (3.2%),
- New ischemia: 1 subject (0.4%),
- Aortic rupture: 3 subjects (1.2%),
- Loss of patency: 3 subjects (1.2%),
- Fistula formation: 1 subject (0.4%),
- New dissection: 26 subjects (10.5%),
- Type I/III endoleaks: 15 subjects (6.4%),
- Aortic enlargement: 13 subjects (6.5%),
- Extension of dissection (only in dissection cohort): 1 subject (0.8%).

Ongoing post approval study

The GORE® TAG® Thoracic Branch Endoprosthesis Zone 2 study is single-arm, non-randomized, multicenter registry designed to collect clinical outcomes and device performance data from patients who have been treated consecutively with the GORE® TAG® Thoracic Branch Endoprosthesis at participating centers in the SVS VQI within the United States of America. This study will enroll a minimum of 250 Patients and a maximum of 350 Patients treated with the GORE® TAG® Thoracic Branch Endoprosthesis with at least 100 Patients evaluable at five years post-implantation, and additional follow-up provided per the standard medical practice at each participating Site for all Patients enrolled to 10 years, unless lost to follow-up or Patient death. If a Patient does not return to the Site for follow-up evaluation, it is requested that the Site contact the Patient or Patient's next of kin/ representative for survival determination. Additional survival data may be obtained from the Social Security Death Index (SSDI) database.

Zone 2 treatment is defined as a Patient who requires proximal graft placement of the GORE® TAG® Thoracic Branch Endoprosthesis AC in Zone 2, with treatment of the LSA and there is an intent to use GORE® TAG® Thoracic Branch Endoprosthesis components for the index treatment (both AC and SB Components).

Primary endpoint

Patients will be followed per the standard medical practice at each participating Site for 10-years from the date of treatment with the GORE® TAG® Thoracic Branch Endoprosthesis. The following endpoints will be assessed:

Procedural success

Defined as Device Technical Success and the absence of the following through the 1-Month follow-up window (181 days) unless otherwise noted below:

- Mortality (device- and disease or treatment-related)
- Stroke (mRS ≥ 2) (through 30-days)
- Paraplegia / Paraparesis (through 30-days)
- Aortic rupture
- Type I/III endoleak
- Branch vessel occlusion requiring reintervention
- Additional surgical or interventional procedure related to the device or treatment (Reintervention)

Treatment success

Defined as Device Technical Success and absence of the following through all follow-up windows (unless indicated):

- Mortality (device- and disease or treatment-related)
- Stroke (mRS ≥ 2) (through 30-days only)
- Paraplegia / Paraparesis (through 30-days only)
- Aortic diameter enlargement > 5 mm in the region encompassed by the initial lesion
- Aortic rupture
- Type I/III endoleak
- New dissections

- Loss of device integrity
- Device migration
- Loss of aortic/aortic branch patency
- Additional surgical or interventional procedure related to the device or treatment (Reintervention)

The TBE Device Zone 2 Post-Market Surveillance (PMS) enrolled the first Patient on 01-May-2023 and the last patient on 15-August-2024, reaching a maximum enrollment of 350 Patients. Of the 350 Patients, 292 were enrolled in the study's Zone 2 ITT cohort, with the remaining 58 Patients enrolled into the study's Other Patients cohort. Of the 35 participating SVS VQI sites, 14 sites participated in the IDE study and 21 sites are new.

Compliance

Two hundred eighty-seven (287) enrolled Patients in the Zone 2 ITT cohort were eligible for a 1-Month follow-up visit, among which 163 (56.8%) Patients had data entered for the 1-Month visit; and 150 of these Patients (52.3%) had imaging. Two hundred seventy-four (274) Patients were eligible for a 12-Month follow-up visit, and 35 (12.8%) Patients had data entered for the 12-Month visit with 190 Patients still within the window; 33 of these Patients (12%) had imaging. No Patients have reached the 2-Year follow-up visit and there have been 10 deaths reported so far in this study.

Note: At the time of data export, 22 patients at 1-Month and 25 patients at 1-Year did not have data entered in the respective follow-up visit. The follow-up rate at 1-Month is 65.5% (185/287) and 21.9% (60/274) at 1-Year.

Primary Endpoint

Analyses of primary endpoints from the study are still on-going. A snapshot of current analyses, as of 06-Jan-2025, are presented below in the following tables.

Table 3: Device technical success for Zone 2 ITT

	Total Zone 2 ITT n/N (%)	Aneurysm n/N (%)	Chronic TBAD n/N (%)	Acute TBAD n/N (%)	Traumatic Transection n/N (%)	Other Isolated Lesions n/N (%)
Number of Patients	292	74	113	53	27	25
Device Technical Success During the Procedure	283/292 (96.9%)	70/74 (94.6%)	110/113 (97.3%)	52/53 (98.1%)	27/27 (100%)	24/25 (96%)

Note: This table was manually created.

Table 4: Procedural success through 1 month for Zone 2 ITT

	Total Zone 2 ITT n/N (%)	Aneurysm n/N (%)	Chronic TBAD n/N (%)	Acute TBAD n/N (%)	Traumatic Transection n/N (%)	Other Isolated Lesions n/N (%)
Number of Patients	292	74	113	53	27	25
Number of Patients with Imaging in Follow-Up Window	175	39	76	34	11	15
Number of Patients with Imaging or Site Reported Event in Window[1]	177	40	77	34	11	15
Procedural Success through 1-Month[2]	132/181 (72.9%)	25/43 (58.1%)	59/79 (74.7%)	26/35 (74.3%)	9/9 (100%)	13/15 (86.7%)

Table 4: Procedural success through 1 month for Zone 2 ITT *(continued)*

	Total Zone 2 ITT n/N (%)	Aneurysm n/N (%)	Chronic TBAD n/N (%)	Acute TBAD n/N (%)	Traumatic Transection n/N (%)	Other Isolated Lesions n/N (%)
Procedural Success Failure Components[3]						
Device Technical Success failure (Index Procedure only)	9/292 (3.1%)	4/74 (5.4%)	3/113 (2.7%)	1/53 (1.9%)	0/27 (0%)	1/25 (4%)
Aortic rupture	3/291 (1%)	1/74 (1.4%)	2/113 (1.8%)	0/53 (0%)	0/27 (0%)	0/24 (0%)
Lesion-related mortality	7/292 (2.4%)	5/74 (6.8%)	1/113 (0.9%)	1/53 (1.9%)	0/27 (0%)	0/25 (0%)
Stroke (mRS>2) (through 30-days)	5/292 (1.7%)	4/74 (5.4%)	1/113 (0.9%)	0/53 (0%)	0/27 (0%)	0/25 (0%)
Paraplegia (through 30-days)	0/292 (0%)	0/74 (0%)	0/113 (0%)	0/53 (0%)	0/27 (0%)	0/25 (0%)
Paraparesis (through 30-days)	2/292 (0.7%)	1/74 (1.4%)	0/113 (0%)	1/53 (1.9%)	0/27 (0%)	0/25 (0%)
Type I/III Endoleak	16/167 (9.6%)	4/37 (10.8%)	9/74 (12.2%)	2/33 (6.1%)	0/9 (0%)	1/14 (7.1%)
TBE Treated branch vessel occlusion requiring reintervention	0/292 (0%)	0/74 (0%)	0/113 (0%)	0/53 (0%)	0/27 (0%)	0/25 (0%)
Reintervention[4]	19/292 (6.5%)	6/74 (8.1%)	7/113 (6.2%)	5/53 (9.4%)	0/27 (0%)	1/25 (4%)

Note: This table was manually created.
[1]Site Reported Endpoint Event
[2]Denominator restricted to patients with all assessable procedural success failure components or had a failure event
[3]Through the 1-Month follow-up window (181 days) unless indicated
[4]Reintervention: Additional surgical or interventional procedure related to the device or procedure

Table 5: Treatment success by analysis study window for Zone 2 ITT

	Index Procedure n/N (%)	1-Month n/N (%)	1-Year n/N (%)	Total n/N (%)
Number of Patients	292	163	35	292
Number of Patients with Treatment Success Component Imaging in Follow-up Window	36	155	30	177
Number of Patients with Treatment Success Component Imaging or Endpoint Event in Window[1]	41	155	31	181
Treatment Success	N/A	N/A	21/28 (75%)	21/28 (75%)
Device Technical Success failure (Index Procedure only)	9/292 (3.1%)	N/A	N/A	9/292 3.1%)
Aortic rupture	2/291 (0.7%)	1/163 (0.6%)	0/34 (0%)	3/291 (1%)
Lesion-related mortality	5/292 (1.7%)	2/163 (1.2%)	0/35 (0%)	7/292 (2.4%)
Stroke (mRS>2) (through 30-days)	5/292 (1.7%)	0/105 (0%)	N/A	5/292 (1.7%)
Paraplegia (through 30-days)	0/292 (0%)	0/105 (0%)	N/A	0/292 (0%)
Paraparesis (through 30-days)	2/292 (0.7%)	0/105 (0%)	N/A	2/292 (0.7%)
Aortic Enlargement (> 5 mm)	N/A	1/16 (6.2%)	1/28 (3.6%)	2/43 (4.7%)
Type I/III Endoleak	4/34 (11.8%)	14/149 (9.4%)	2/29 (6.9%)	17/168 (10.1%)

Table 5: Treatment success by analysis study window for Zone 2 ITT *(continued)*

	Index Procedure n/N (%)	1-Month n/N (%)	1-Year n/N (%)	Total n/N (%)
New Dissections	3/292 (1%)	6/162 (3.7%)	2/34 (5.9%)	9/292 (3.1%)
Loss of Device Integrity	N/A	1/155 (0.6%)	0/30 (0%)	1/157 (0.6%)
Device Migration	N/A	0/14 (0%)	2/30 (6.7%)	2/43 (4.7%)
Loss of aortic / TBE treated aortic branch patency	1/292 (0.3%)	0/155 (0%)	0/32 (0%)	1/292 (0.3%)
Reintervention[2]	10/292 (3.4%)	9/163 (5.5%)	4/35 (11.4%)	23/292 (7.9%)

[1]Site Reported Endpoint Event
[2]Reintervention: Additional surgical or interventional procedure related to the device or procedure

Table 6: Primary efficacy endpoint: Treatment success by analysis study window for aneurysm

	Index Procedure n/N (%)	1-Month n/N (%)	1-Year n/N (%)	Total n/N (%)
Number of Patients	74	37	7	74
Number of Patients with Treatment Success Component Imaging in Follow-up Window	10	33	5	40
Number of Patients with Treatment Success Component Imaging or Endpoint Event in Window[1]	14	33	5	42
Treatment Success	N/A	N/A	3/4 (75%)	3/4 (75%)
Device Technical Success failure (Index Procedure only)	4/74 (5.4%)	N/A	N/A	4/74 (5.4%)
Aortic rupture	1/74 (1.4%)	0/37 (0%)	0/7 (0%)	1/74 (1.4%)
Lesion-related mortality	4/74 (5.4%)	1/37 (2.7%)	0/7 (0%)	5/74 (6.8%)
Stroke (mRS>2) (through 30-days)	4/74 (5.4%)	0/5 (0%)	N/A	4/74 (5.4%)
Paraplegia (through 30-days)	0/74 (0%)	0/5 (0%)	N/A	0/74 (0%)
Paraparesis (through 30-days)	1/74 (1.4%)	0/5 (0%)	N/A	1/74 (1.4%)
Aortic Enlargement (> 5 mm)	N/A	0/4 (0%)	0/4 (0%)	0/8 (0%)
Type I/III Endoleak	1/9 (11.1%)	3/32 (9.4%)	1/4 (25%)	4/37 (10.8%)
New Dissections	3/74 (4.1%)	3/37 (8.1%)	0/7 (0%)	4/74 (5.4%)
Loss of Device Integrity	N/A	0/33 (0%)	0/5 (0%)	0/34 (0%)
Device Migration	N/A	0/4 (0%)	0/5 (0%)	0/9 (0%)
Loss of aortic / TBE treated aortic branch patency	1/74 (1.4%)	0/34 (0%)	0/6 (0%)	1/74 (1.4%)
Reintervention[2]	5/74 (6.8%)	1/37 (2.7%)	1/7 (14.3%)	7/74 (9.5%)

[1]Site Reported Endpoint Event
[2]Reintervention: Additional surgical or interventional procedure related to the device or procedure

Table 7: Primary efficacy endpoint: Treatment success by analysis study window for chronic Type B dissection

	Index Procedure n/N (%)	1-Month n/N (%)	1-Year n/N (%)	Total n/N (%)
Number of Patients	113	70	19	113
Number of Patients with Treatment Success Component Imaging in Follow-up Window	16	70	17	77
Number of Patients with Treatment Success Component Imaging or Endpoint Event in Window[1]	17	70	18	79
Treatment Success	N/A	N/A	11/16 (68.8%)	11/16 (68.8%)
Device Technical Success failure (Index Procedure only)	3/113 (2.7%)	N/A	N/A	3/113 (2.7%)
Aortic rupture	1/113 (0.9%)	1/70 (1.4%)	0/19 (0%)	2/113 (1.8%)
Lesion-related mortality	1/113 (0.9%)	0/70 (0%)	0/19 (0%)	1/113 (0.9%)
Stroke (mRS>2) (through 30-days)	1/113 (0.9%)	0/69 (0%)	N/A	1/113 (0.9%)
Paraplegia (through 30-days)	0/113 (0%)	0/69 (0%)	N/A	0/113 (0%)
Paraparesis (through 30-days)	0/113 (0%)	0/69 (0%)	N/A	0/113 (0%)
Aortic Enlargement (> 5 mm)	N/A	1/10 (10%)	1/16 (6.2%)	2/25 (8%)
Type I/III Endoleak	3/16 (18.8%)	8/68 (11.8%)	0/17 (0%)	9/75 (12%)
New Dissections	0/113 (0%)	1/70 (1.4%)	2/19 (10.5%)	3/113 (2.7%)
Loss of Device Integrity	N/A	1/70 (1.4%)	0/17 (0%)	1/71 (1.4%)
Device Migration	N/A	0/8 (0%)	1/17 (5.9%)	1/24 (4.2%)
Loss of aortic / TBE treated aortic branch patency	0/113 (0%)	0/68 (0%)	0/18 (0%)	0/113 (0%)
Reintervention[2]	2/113 (1.8%)	5/70 (7.1%)	3/19 (15.8%)	10/113 (8.8%)

[1]Site Reported Endpoint Event
[2]Reintervention: Additional surgical or interventional procedure related to the device or procedure

Event rates for reintervention, Type I/III endoleaks, and lesion related mortality are higher in this study compared to the PMA Study. Several factors may explain these differences, including variations in patient populations, definitions and processes, core labs, reporting intervals between SVS VQI and the PMA study, and limited follow up data.

In the post market setting, broader patient selection allows treatment of higher risk individuals who were excluded from the PMA study. The PMS cohort had higher rates of prior aortic surgery, congestive heart failure, prior stroke, previous myocardial infarction, ASA IV/V status, and nicotine use. These differences suggest that increased lesion related mortality may reflect patient condition rather than TBE device safety or performance.

Because the PMS captured limited anatomic data, it is unclear whether elevated event rates relate to potential off label TBE use. Incomplete follow up inherent to the PMS also limits definitive conclusions regarding endoleak rates. Although PMS enrollment is complete, core lab imaging analysis is still lagging.

Early prioritization of baseline imaging may create a follow up bias, with more early post procedure CT scans increasing hospital detection of endoleaks. This is expected to normalize as full follow up is completed. Additionally, the PMS core lab is reporting fewer indeterminate endoleaks than the PMA core lab, indicating differences in imaging interpretation which may influence overall rates given incomplete data.

Review of PMS reinterventions thus far show that none were attributed to "device contributing factors" such as device deformation, inadequate seal, incorrect sizing, migration, conformability issues, loss of integrity, or penetration. This suggests that sites are planning cases effectively in the post market setting.

Based on the available information, Gore has not identified any factors associated with these events aside from patient selection and low follow-up. These outcomes will continue to be monitored during the PMS as well as through commercial complaint reporting processes. Gore would like to emphasize to implanting physicians the importance of regular follow-up to ensure timely identifications of these and other events; refer to the following statements in the IFU:

- 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 lesions) should receive enhanced follow-up (see IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP).
- The GORE® TAG® Thoracic Branch 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.
- Do not use the GORE® TAG® Thoracic Branch 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.
- Regular follow-up including imaging of the device should be performed at least every 12 months for all patients and at least every 6 to 12 months for patients with known endoleaks or lesion enlargement for the duration of the implant (see IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP).

Worldwide recalls, safety communications and field safety notices

There have been no new worldwide recalls, safety communications, or field safety notices in the applicable period of this report.

Worldwide commercial experience

The first commercial implant of the GORE® TAG® Thoracic Branch Endoprosthesis occurred on August 9, 2022 in the United States. Other geographies approved at the time of this report in addition to the US include Canada, European Union, Japan, China, Australia, and Taiwan. The data presented in **Table 8** summarizes patient adverse events from commercial complaints received by Gore, that occurred in the past year from March 1, 2024, through February 28, 2025.

Table 8. Summary of clinical events from worldwide commercial complaints received by Gore for TAG® TBE from March 1, 2024, through February 28, 2025

	TAG® TBE Device
Rupture (post-procedure)	0
Conversion (post-procedure)	0
Aortic-related Death	4
Migration (post-procedure)	0
Paraplegia / paraparesis	3
Stroke	6
Proximal new dissection	6

ADVERSE EVENT REPORTING

The accurate and timely reporting of adverse events by users is critical for monitoring device performance and detection of device-related safety issues. Any adverse event involving a GORE® TAG® Thoracic Branch Endoprosthesis should be reported to Gore immediately. To report an event to W. L. Gore & Associates in the United States:

Call:
+1 800 528 1866, Ext. 44922 or
+1 928 864 4922

Fax:
+1 928 864 4364

Email:
medcomplaints@wlgore.com

Table 8. Summary of clinical events from worldwide commercial complaints received by Gore for TAG® TBE from March 1, 2024, through February 28, 2025 *(continued)*

	TAG® TBE Device
Device integrity	5
Side Branch Occlusion	4
Side Branch Compression	1
Deployment anomalies	8
Type I Endoleak	10
Type III Endoleak	6
At Junction	5

Please note these complaints are an estimate and may be under-reported. Gore continues to monitor the safety of the GORE® TAG® Thoracic Branch Endoprosthesis.

Explant analysis

From March 1, 2024 through February 28, 2025, there was one patient that required explant of the GORE® TAG® Thoracic Branch Endoprosthesis. The device was explanted due to infection; however, the physician stated that the infection was not deemed to be related to the initial implant procedure or to the reintervention. The physician reported that although it was suspected that the lesion had been mycotic prior to the index procedure, it was not confirmed before the GORE® TAG® Thoracic Branch Endoprosthesis procedure. It was reported that the pre-existing infection was confirmed by the physician upon review of the pre-implant imaging at a later date.

Literature review

There were 16 peer-reviewed literature articles, published over the last year describing the use of the GORE® TAG® Thoracic Branch Endoprosthesis.

1. DiLosa K, Anaya D, Gifford S, Heafner T, Maximus S. Use of the GORE Thoracic Branched Endoprosthesis in combination with branched/fenestrated physician-modified endografts in the treatment of Extent I and II thoracoabdominal aneurysms. *J Vasc Surg.* 2024;79(6):e132-e133.
2. DiLosa K, Pozolo C, Heafner T, Humphries M, Kwong M, Maximus S. Early experience with the GORE TAG Thoracic Branch Endoprosthesis for treatment of acute aortic pathology. *J Vasc Surg Cases Innov Tech.* 2023;10(1):101363. doi:10.1016/j.jvscit.2023.101363
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These peer-reviewed publications demonstrate that the GORE® TAG® Thoracic Branch Endoprosthesis continues to show acceptable durability and remains a safe and effective device for the treatment of thoracic aortic disease.

Conclusion

Based on available clinical study data and worldwide clinical experience to date, endovascular therapy with the GORE® TAG® Thoracic Branch Endoprosthesis continues to be a viable treatment for endovascular repair of lesions of the descending thoracic aorta, while maintaining flow into the left subclavian artery.

Patient follow-up and selection

Regular follow-up of all patients treated with the TAG® Device is required. Worldwide commercial experience and clinical data over the last 20 years demonstrate that some adverse events may become apparent over time, however, Gore's post market surveillance program monitors complaints for frequency and severity to determine potential impact on safety. As stated in the IFU, regular and consistent follow-up is a critical part of ensuring continuing safety and efficacy of aortic endovascular repair. Patients with specific clinical findings such as endoleak and/or aneurysm enlargement should receive enhanced follow-up. Physicians should tailor patient follow-up to the needs and circumstances of each individual patient.

[1]Referenced scientific publications focus primarily on off-label device use.

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

- Patient selection
- Device selection
- Device deployment
- Patient follow-up

Please refer to the IFU at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available.

Consult Instructions for Use
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Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

INDICATIONS FOR USE: The GORE® TAG® Thoracic Branch Endoprosthesis is indicated for endovascular repair of lesions of the aortic arch and descending thoracic aorta, while maintaining flow into a single aortic arch branch vessel in patients who have: Adequate iliac/femoral access; Proximal Aortic Landing Zones: For Isolated Lesion Patients: Proximal landing zone cannot be aneurysmal, dissected, heavily calcified or heavily thrombosed; For Dissection Patients: Primary entry tear must be distal to the target branch vessel and the proximal extent of the landing zone must not be dissected; Aortic inner diameter range 16-42 mm; Proximal segment length (length from distal edge of target branch vessel to the midpoint of any proximal branch vessel) of at least 2.0-4.0 cm, depending on Aortic Component selection; Proximal covered length (measured from distal edge of target branch vessel to the distal edge of any proximal branch vessel) of at least 15–36 mm, depending on Aortic Component selection; For patients with prior ascending aorta or aortic arch repair with surgical graft: at least 2 cm landing zone proximal to the distal anastomosis; Target Branch Vessel Landing Zone: Landing zone cannot be aneurysmal, dissected, heavily thrombosed and severely tortuous (180 degree turn within the treated length); Target branch vessel inner diameter of 6–18 mm, depending on Side Branch Portal diameter selected; Target branch vessel minimum length of 2.5–3.0 cm, depending on Side Branch Portal diameter selected. Distal Landing Zone (Isolated Lesion Patients only): Outer curve length must be ≥ 2 cm proximal to celiac artery; Aortic inner diameter range 16-42 mm; Cannot be aneurysmal, dissected, heavily calcified or heavily thrombosed; Native Aorta or previously placed GORE® TAG® Conformable Thoracic Stent Graft. **CONTRAINDICATIONS:** The GORE® TAG® Thoracic Branch Endoprosthesis is contraindicated in: Patients with known sensitivities or allergies to the device materials [ePTFE (polytetrafluoroethylene), FEP (fluoroethylpropylene), Nitinol (nickel, titanium), Gold, SB Component only - Heparin (CBAS® Heparin Surface)]; Patients who have a condition that threatens to infect the graft; Patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II.

Products listed may not be available in all markets.

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