GORE® TAG®
Thoracic Endoprosthesis

ANNUAL CLINICAL UPDATE

February 19, 2022 through
January 31, 2023

Together, improving life

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Overview

This annual clinical update provides a review of the ongoing experience with the GORE® TAG® Thoracic Endoprosthesis (TAG® Device) used in the treatment of all lesions of the descending thoracic aorta. The device has been commercially available in the United States since 2005. In this update, more than 20 years of worldwide commercial experience is presented. 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 TAG® Device. See *Table 1.* for a brief regulatory approval history of the TAG® Device in the United States.

The original 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. 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. 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 original TAG® Device is no longer sold.

The Conformable GORE® TAG® Thoracic Endoprosthesis (Conformable TAG® Device) has the characteristics of the original 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.

The GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System (TAG® Conformable Device with ACTIVE CONTROL System) has the same stent graft as the Conformable TAG® Device, which continues to have the same treatment range and indications, now paired with a modified delivery system. The modified delivery system was designed to enhance user control during thoracic endovascular aortic repair procedures by enabling a controlled and staged deployment paired with optional angulation control while maintaining the performance and safety of the Conformable TAG® Device. The modified delivery system consists of a multi-lumen catheter, two sewn deployment sleeves, deployment fibers, angulation fibers, a lockwire, and an integrated nested handle on the trailing end of the catheter.

Consult Instructions for Use
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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. "TAG"). Additional details on the Conformable TAG® 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
Original TAG® Device	Mar 2005	Descending thoracic aortic aneurysms
Conformable TAG® Device	Aug 2011 Jan 2012 Sept 2013	Descending thoracic aortic aneurysms Descending thoracic aortic isolated lesions Type B dissections
TAG® Conformable Device with ACTIVE CONTROL System	May 2019	All lesions of the descending thoracic aortic including isolated lesions and Type B dissections

Worldwide device distribution

There have been more than 260,000 TAG® Devices distributed worldwide as part of our IDE clinical trials and commercial experience through January 31, 2023. This includes almost 61,000 original TAG® Devices and more than 199,000 Conformable TAG® Devices. Of the Conformable TAG® Devices, more than 71,000 have been distributed with the GORE® ACTIVE CONTROL System.

This ACU covers the time period of February 19, 2022 - January 31, 2023, during which more than 25,000 Conformable TAG® Devices were distributed, of which more than 21,000 were with the ACTIVE CONTROL System.

Clinical evaluations

A list of the completed clinical evaluations can be found in *Table 2*. Summaries of the results of each can be found in the IFU or ClinicalTrials.gov. There is one ongoing post approval study (PAS) of the Conformable TAG® Device - the Vascular Quality Initiative (VQI) Post-Approval Dissection VQI Type B Dissection Post-Approval Surveillance Study (TAG 12-06).

Table 2: Completed clinical evaluations for the TAG® Devices

Device iterations	Clinical evaluation	Reference
Original TAG® Device	TAG 99-01 TAG 03-03 TAG 04-01 TAG 06-02	IFU
Conformable TAG® Device	TAG 08-01 TAG 08-02 TAG 08-03	IFU
TAG® Conformable Device with ACTIVE CONTROL System	TAG 15-03	ClinicalTrials.gov

VQI post approval study

The VQI, a Patient Safety Organization, 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 and five-year follow up is now complete. No safety or effectiveness signals have been observed associated with the treatment of acute or chronic dissections for the Conformable TAG® Device.[1] Refer to J Vasc Surg. 2017;65(5):1280-1286 for more information regarding the study.

Primary effectiveness endpoint

The primary effectiveness endpoint for the *1-year cohorts* has been defined as:

- All devices combined endpoint
  - Freedom from dissection-related mortality
- Device-specific endpoint
  - Device technical success

The primary effectiveness endpoint for the *5-year cohorts* has been defined as:

- All devices combined endpoint
  - Freedom from dissection-related mortality
- Device-specific endpoint
  - Device technical success
  - Device procedural success

Analyses of primary effectiveness endpoints from the VQI study specific to the Gore product, as of October 2022, are presented below in *Table 3* and *Table 4*.

Table 3: Primary efficacy endpoint: 1-year cohorts, acute and chronic

1-year cohorts	1-year cohort, acute % (m/n) [95% CI]	1-year cohort, chronic % (m/n) [95% CI]
Device technical success during the procedure	91.7% (44/48) [79.9%, 97.2%]	100% (29/29) [86.1%, 100%]

Table 4: Primary efficacy endpoint: 5-year cohorts, acute and chronic

5-year cohorts	5-year Cohort, Acute % (m/n) [95% CI]	5-year Cohort, Chronic % (m/n) [95% CI]
Device Technical Success During the Procedure	98.8% (84/85) [93%, 100%]	100% (65/65) [93.3%, 100%]
Successful delivery of the device	98.8% (84/85) [93%, 100%]	100% (65/65) [93.3%, 100%]
Successful and accurate deployment	98.8% (84/85) [93%, 100%]	100% (65/65) [93.3%, 100%]
Deployment of the endovascular device at the intended implantation site, covering the entry tear	98.8% (84/85) [93%, 100%]	100% (65/65) [93.3%, 100%]
Patency of the aortic endovascular device	100% (85/85) [94.8%, 100%]	100% (65/65) [93.3%, 100%]
Absence of inadvertent covering of aortic branch vessels	100% (85/85) [94.8%, 100%]	100% (65/65) [93.3%, 100%]
Successful withdrawal of the delivery system	100% (85/85) [94.8%, 100%]	100% (65/65) [93.3%, 100%]
Device Procedural Success at 30 days	92.2% (71/77) [83.7%,96.7%]	91.9% (57/62) [82.1%, 96.9%]
Freedom from retrograde extension of the dissection	95.2% (60/63) [86.4%, 98.9%]	100% (44/44) [90.4%, 100%]
Freedom from MAE	96.1% (73/76) [88.6%, 99.1%]	98.3% (59/60) [90.3%, 100%]
Freedom from unintentional dissection septum rupture	100% (63/63) [93.1%, 100%]	100% (43/43) [90.2%, 100%]
Freedom from PIT FLP	96.6% (56/58) [87.6%, 99.7%]	88.1% (37/42) [74.5%, 95.3%]

Freedom from dissection-related mortality

Analyses of freedom from dissection-related mortality from the VQI study specific to the Gore product, as of October 2022, are presented below in *Table 5* through *Table 8*.

Table 5: Freedom from dissection-related mortality: Chronic 1-year cohort

Freedom from dissection-related mortality	At 30 days	At 1 year
No. at risk	29	28
No. of events	0	0
No. censored	1	28
Kaplan-Meier estimate	1.000	1.000
Standard error	0.000	0.000

Study Windows: At 30 days (0-30), At 1 year (31-365)

Table 6: Freedom from dissection-related mortality: Acute 1-year cohort

Freedom from dissection-related mortality	At 30 days	At 1 year
No. at risk	48	44
No. of events	2	1
No. censored	2	43
Kaplan-Meier estimate	0.958	0.937
Standard error	0.029	0.035

Study Windows: At 30 days (0-30), At 1 year (31-365)

Table 7: Freedom from dissection-related mortality: Acute 5-year cohort

Freedom from dissection-related mortality	At 30 days	At 1 year	At 2 years	At 3 years	At 4 years	At 5 years
No. at risk	85	80	71	68	68	66
No. of events	5	0	2	0	0	1
No. censored	0	9	1	0	2	65
Kaplan-Meier estimate	0.941	0.985	0.985	0.914	0.914	0.900
Standard error	0.026	0.026	0.031	0.031	0.031	0.034

Study Windows: At 30 days (0-30), At 1 year (31-365), At 2 years (366-730), At 3 years (731-1095), At 4 years (1096-1460), At 5 years (1461-1825)

Table 8: Freedom from dissection-related mortality: Chronic 5-year cohort

Freedom from dissection-related mortality	At 30 days	At 1 year	At 2 years	At 3 years	At 4 years	At 5 years
No. at risk	65	63	62	59	58	54
No. of events	1	0	0	0	0	0
No. censored	1	1	3	1	4	54
Kaplan-Meier estimate	0.985	0.985	0.985	0.985	0.985	0.985
Standard error	0.015	0.015	0.015	0.015	0.015	0.015

Study Windows: At 30 days (0-30), At 1 year (31-365), At 2 years (366-730), At 3 years (731-1095), At 4 years (1096-1460), At 5 years (1461-1825)

Patient follow-up and compliance

Patient follow-up and compliance tables are presented below in *Table 9* through *Table 11*. It is important to note that patients are being followed per the standard of care at the site where they were treated. While sites are strongly encouraged to bring back patients within the broad visit windows allowed by the Post Approval Surveillance Program, they cannot be required to do so.

Table 9: Compliance: 1-year cohorts, acute and chronic

	1-year cohort, acute				1-year cohort, chronic			
1-year cohorts	**Enrolled**	**Pre-discharge**	**Discharge to 12 months**	**12-month**	**Enrolled**	**Pre-discharge**	**Discharge to 12 months**	**12-month**
Number of subjects available	48	48	45	40	29	29	29	27
Subjects discontinuing follow-up during interval								
Death during interval		3	5	1		0	2	1
Number with follow-up evaluation								
Follow-up completed in window		48	N/A	33		29	N/A	24
Missed follow-up visits		N/A	N/A	7		N/A	N/A	3
Subjects with pending evaluation		N/A	N/A	0		N/A	N/A	0
Subjects have not reached lower window of follow-up		N/A	N/A	0		N/A	N/A	0

Table 10: Compliance: 5-year cohort, acute

5-year cohort, acute	**Enrolled**	**Pre-discharge**	**1-month**	**12-month**	**24-month**	**36-month**	**48-month**	**60-month**
Number of subjects available	85	85	80	76	68	68	67	64
Subjects discontinuing follow-up during interval								
Death during interval		5	4	8	0	1	3	4
Number with follow-up evaluation								
Follow-up completed in window		85	77	63	47	50	43	43
Missed follow-up visits		N/A	3	13	21	18	24	21
Subjects with pending evaluation		N/A	0	0	0	0	0	0
Subjects have not reached lower window of follow-up		N/A	N/A	0	0	0	0	0

Table 11: Compliance: 5-year cohort, chronic

5-year cohort, acute	**Enrolled**	**Pre-discharge**	**1-month**	**12-month**	**24-month**	**36-month**	**48-month**	**60-month**
Number of subjects available	65	65	64	62	60	59	57	56
Subjects discontinuing follow-up during interval								
Death during interval		1	2	2	1	2	1	3
Number with follow-up evaluation								
Follow-up completed in window		65	62	54	47	38	31	37
Missed follow-up visits		N/A	2	8	13	21	26	19
Subjects with pending evaluation		N/A	0	0	0	0	0	0
Subjects have not reached lower window of follow-up		N/A	N/A	0	0	0	0	0

Notes for compliance *Table 9* through *Table 11*:

1. For the pre-discharge timepoint, "Missed follow-up visits", "Subjects with pending evaluation", and "Subjects have not reached lower window of follow-up" are populated with N/A because the pre-discharged information is associated with the VQI Procedure form; the procedure data cannot be submitted unless the pre-discharge information is complete.
2. For the 1-year cohorts there was no required 30-day timepoint; therefore, in the "Discharge to 12 Months" column all rows except "Death during interval" are populated with N/A. 3) For the 5-year cohorts the "1-Month" timepoint, "Subjects have not reached lower window of follow-up" is populated with N/A because the "1-Month" timepoint opens as soon as the patient has been discharged.

Worldwide recalls, safety communications and field safety notices

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

In September 2020, Gore instituted two Class II recalls for the TAG® Conformable Device with ACTIVE CONTROL System due to inability to complete secondary deployment and difficulty withdrawing the delivery catheter. Gore worked closely with the FDA and executed corrective actions for these Class II recalls, which included Medical Device Safety Correction Letters and updated IFU warnings with no device removal. Since then, Gore continues to monitor these events and has not observed any changes to its risk assessment related to these events. Further information can be found at goremedical.com.

In September 2017, A Class II recall for the Conformable TAG® Device occurred in 2017 due to incomplete deployment events. Gore worked closely with the FDA and executed a corrective action for this Class II recall, which included a Medical Device Safety Correction Letter and updated IFU warnings with no device removal. Since then, Gore continues to monitor these events and has not observed any changes to its risk assessment related to these events. Further information can be found at goremedical.com.

Worldwide commercial experience

The data presented in *Table 12* summarize patient adverse events from worldwide commercial experience that occurred in the past year from February 19, 2022–January 31, 2023. During this period, more than 25,000 Conformable TAG® Devices have been distributed, of which more than 21,000 were with the ACTIVE CONTROL System. Fluctuations of year-to-year event totals have occurred in previous years. Increased adoption of endovascular therapy as a viable alternative to open surgical repair and changes in regional reporting practices have been suspected for these observed fluctuations. Even with changes in year-to-year observations of 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. Several attempts are made to complete reporting record. Index procedure dates and device information are not always available.

Adverse event reports presented in *Table 12* are similar to those reported in prior annual clinical updates. Deployment anomalies capture events associated with the aforementioned Class II recalls as well as deployment anomalies that may be related to procedural or anatomical factors and will continue to be monitored. Each reported adverse event is not mutually exclusive and may contain multiple adverse events.

The worldwide commercial experience with the TAG® Devices has remained consistent with the acceptable performance exhibited in previous years.

Table 12: Summary of worldwide performance by patient for TAG® Devices in 2022

	Original TAG® Device	Conformable TAG® Device
Rupture (post-procedure)	2	13
Associated with endoleak	1	4
Conversion (post-procedure)	1	6
Associated with endoleak	0	2
Aortic-related death	0	23
Associated with endoleak	0	7
Migration (post-procedure)	2	5
Paraplegia/paraparesis	0	13
Stroke	0	6
Device integrity	0	1
Compression	0	0
Fracture	0	1
Deployment anomalies	0	4
Type III endoleak	2	4
Tear/disruption in graft material	1	0
Unknown source	1	3
Junction	0	1

Explant analysis

The data presented in *Table 13* summarizes the reason for explant in reported cases from February 19, 2022, to January 31, 2023. Of the five patients with explants, zero were returned to Gore for analysis. No device integrity observations were found to impact device performance.

Table 13: Summary of worldwide primary cause of explant by patient for TAG® Devices in 2022

1-year cohorts	Original TAG® Device	Conformable TAG® Device
Implantation difficulties	0	0
Rupture	0	0
Aneurysm enlargement without endoleak	0	1
Aneurysm enlargement with endoleak	0	0
Dissection	0	0
Endoleak	0	0
Migration	0	0
Infection	0	2
Aortoenteric fistula	0	0
Occlusion	0	0
Incidental autopsy	0	0
Other	1	1
Total cases	**1**	**4**

Literature review

A literature search was completed resulting in 65 articles published from February 19, 2022, to February 07, 2023. Refer to Section 4, for the bibliography and summary of information not previously submitted as part of the PMA. There were five articles, published over the last year, studying a large cohort specifically describing the use of the TAG® Device.

1. Trimarchi et al. published a study of patients from W. L. Gore's Global Registry for Endovascular Aortic Treatment (GREAT) who underwent thoracic endovascular aortic repair for acute type B aortic dissections were retrospectively analyzed. Results for complicated type B aortic dissections (cTBAD) versus uncomplicated acute type B aortic dissections (uTBAD) showed that 30-day mortality and perioperative complications were equally low for both. There was no statistically significant difference in 3-year follow-up outcomes between uTBAD and cTBAD.[2]
2. Böckler et al. published a single center retrospective study evaluating experience with the GORE TAG conformable thoracic aortic graft (CTAG), focusing on rupture-free survival, aortic-related reintervention, and device-related complications during midterm and long-term follow-up (FU). Out of the 194 patients treated with CTAG, overall survival rates were 75.8% and 56.6% at 12 and 60 months, respectively. Cumulative incidence for aortic rupture was 11.9% at 60 and 90 months, respectively. Cumulative incidence for aortic-related reintervention was 27.5% at 60 and 90 months. Cumulative incidence for migration was 2.8% and 3.9% at 60 and 90 months, respectively. The publication concluded that the device demonstrates appropriate persistent safety, efficacy, and clinical durability up to long-term follow-up in the treatment of diverse thoracic aortic pathologies.[3]
3. Farber et al. published on the 5-year follow-up results from the GORE Conformable TAG Thoracic Endoprosthesis for Treatment of Traumatic Transection (TAG 08-02) prospective, single-arm study. Out of 101 patients, the freedom from all-cause mortality was 95% and 89% at 1 month and 5 years after the procedure, respectively. There were two minor endoleaks. No aortic ruptures, wire frame fractures, erosions, lumen obstructions, device compressions, or thrombus-related events were reported. The publication concluded that the 5-year outcomes verify that the CTAG device is a safe, effective, and durable option for patients with blunt aortic injuries who are undergoing thoracic endovascular aortic repair.[4]
4. Panesar et al. summarized the clinical literature involving the GORE TAG Conformable Thoracic Stent Graft, focusing mainly on the publications that came from Gore's pre-market and post-market studies, including the Global Registry for Endovascular Aortic Treatment (GREAT), which is a large database of endovascular repair of various thoracic, abdominal and thoraco-abdominal aortic pathologies.[5]
5. Piazza et al. published their single-site experience with the Gore CTAG endograft with ACTIVE CONTROL System (ACS). Mean proximal and distal deployment accuracies were 1.89 ± 3.5 mm and 0.6 ± 1.4 mm, and were obtained in 93% and 100% of procedures, respectively. Mean proximal and distal wall apposition were 91 ± 17% and 98 ± 5.9%. Fifteen patients required an associated planned procedure. Two patients required reintervention during the same hospitalization because of type 1a endoleak onset. No further reinterventions were needed during follow-up. The publication concluded the analysis showed promising results using the Gore CTAG with ACS, with an optimal accuracy in deployment and wall apposition at both proximal and distal landing zones.[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 TAG® Device should be reported to Gore immediately. To report an event to W. L. Gore & Associates, in the United States:

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

Fax:
+1 928 864 4364

Email:
medcomplaints@wlgore.com

Conclusion

Based on a review of the literature, available clinical study data, and worldwide clinical experience to date, no issues have been identified regarding safety and effectiveness. Endovascular therapy with the TAG® Device continues to be a viable treatment option for all lesions of the descending thoracic aorta.

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.

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.

References

1. Beck AW, Lombardi JV, Abel DB, et al; Society for Vascular Surgery Vascular Quality Initiative TEVAR Surveillance Project Steering Committee. Innovative postmarket device evaluation using a quality registry to monitor thoracic endovascular aortic repair in the treatment of aortic dissection. *Journal of Vascular Surgery* 2017;65(5):1280-1286.

2. Spinelli D, Weaver FA, Azizzadeh A, *et al*. Endovascular treatment of complicated versus uncomplicated acute type B aortic dissection. *Journal of Thoracic & Cardiovascular Surgery* 2023;165(1):4-13.e1.

3. Skrypnik D, Bischoff MS, Meisenbacher K, Kronsteiner DB, Böckler D. A 10-year single-center experience with the GORE TAG conformable thoracic stent graft in the treatment of thoracic aortic disease. *Journal of Endovascular Therapy* 2022;29(3):370-380.

4. Farber MA, Krishnasastry KV, Desai N, Starnes BW, Matsumura JS, Tohill BC; TAG 08-02 Clinical Trial Investigators. Five-year outcomes with Conformable GORE® TAG® endoprosthesis used in traumatic aortic transections. *Annals of Thoracic Surgery* 2022;113(5):1536-1542. https://www.sciencedirect.com/science/article/pii/S0003497521010134

5. Panesar H, Simionian G, O'Connor D. GORE® TAG® Conformable Thoracic Stent Graft for the treatment of descending aortic pathologies. *Future Cardiology* 2022;18(5):431-441.

6. Antonello M, Squizzato F, Colacchio E, Spertino A, Grego F, Piazza M. Thoracic endovascular aortic repair using the C-TAG® device with ACTIVE CONTROL System. *Surgical Technology International*. In press.

Consult Instructions for Use
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INDICATIONS FOR USE IN THE U.S.: The GORE® TAG® Conformable Thoracic Stent Graft 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:** Patients with known sensitivities or allergies to the device materials; patients who have a condition that threatens to infect the graft. 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. $\mathrm{R}_{\mathrm{x\ Only}}$

Products listed may not be available in all markets.

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