GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System

Value Analysis Committee reference guide

GORE
Creative Technologies Worldwide

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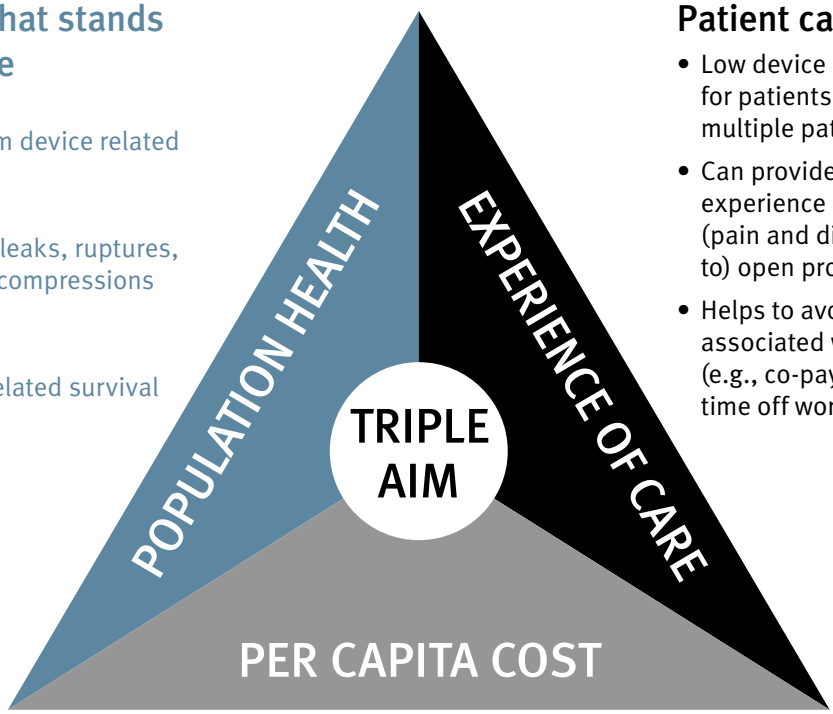
Executive summary

Value analysis

GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System is designed to support the Triple Aim.

Performance that stands the test of time

- **Aneurysm**
  97% freedom from device related reintervention[1]
- **Transection**
  Zero Type III endoleaks, ruptures, device fractures, compressions or conversions[1]
- **Dissection**
  97% dissection related survival



Patient care

- Low device reintervention for patients treated across multiple pathologies
- Can provide a better experience of care by avoiding (pain and discomfort related to) open procedure
- Helps to avoid costs associated with reintervention (e.g., co-payments, time off work)

Cost savings

- 8%–23% reduction in devices used per case[2]
- 67% reduction in vertical storage space
- 55–73 fewer codes in inventory to treat same vessel diameters (versus competition)

1. The GREAT Registry is a prospective, observational, multi-center registry to actively track Gore commercial aortic endovascular device performance and associated patient outcomes in global markets with 10 years of follow-up. Data June 2017. Through 2-year follow up. Aneurysm n=316; Transection n=53; Type B dissection n=269.
2. W. L. Gore & Associates. Observational Registry Characterizing the Performance and Feature Use of the GORE® TAG®Conformable Thoracic Stent Graft Featuring ACTIVE CONTROL System. Bethesda, MD: National Library of Medicine; 2010. Available from: https://clinicaltrials.gov/ct2/show/NCT03286400. NLM Identifier: NCT03286400. Published September 18, 2017. Updated January 7, 2019. Accessed May 13, 2019.

Disease state and treatment options

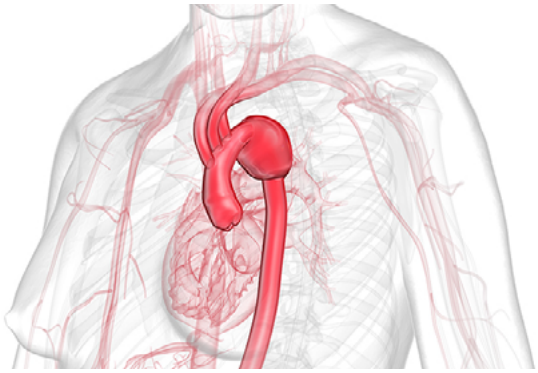
Disease state / condition to treat

Types of descending thoracic aortic diseases and treatment options*

The aorta is the main artery that carries oxygenated blood from the heart to the rest of the body. Patients can experience three conditions that require treatment: aneurysms, transections and type B dissections.

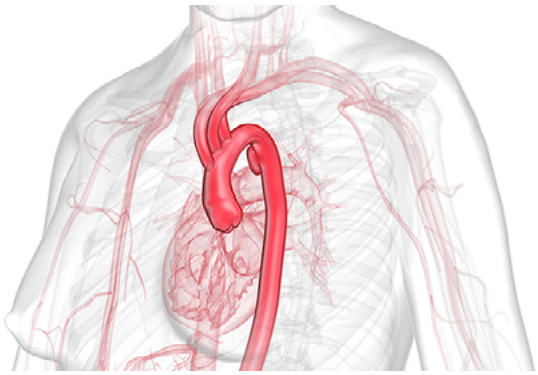
GORE® TAG® Conformable Stent Graft with ACTIVE CONTROL System is FDA approved to treat the following therapeutic treatment options:

Aneurysm



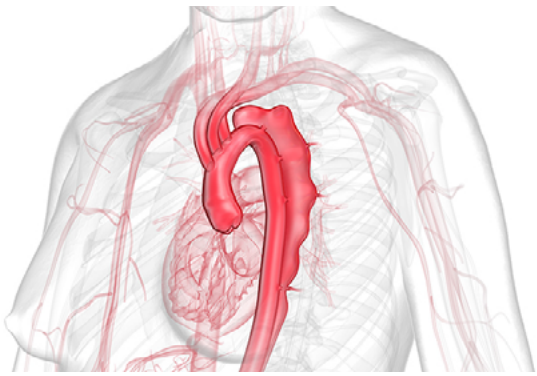
- A ballooning (enlarging and thinning) of a weakened area of a blood vessel
- Aneurysms are typically asymptomatic until there is a high risk of rupture and are associated with older age (> 65–75 years) and any history of smoking

Transection



- A near-complete tear through all the layers of the aorta due to a trauma
- Approximately 70% of transections are due to motor vehicle accidents or other sudden deceleration events
- Click here to see a video from a survivor of a trauma

Type B Dissection



- A serious condition in which the inner layer of the aorta, the large blood vessel branching off the heart, tears. Blood surges through the tear, causing the inner and middle layers of the aorta to separate (dissect).
- Dissection tears can block blood flow to branch vessels that carry blood to end-organs
- Most Type B dissections require ongoing medication and / or surgery

* Torsello GB, Austermann M, Torsello GF. Early experience using the GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System: why it is my preferred TEVAR device. *Endovascular Today* 2018;17(3)Supplement:4-7.

Disease state and treatment options[1,2,3,4]

Treatment options

Treating patients to optimize patient satisfaction and outcomes.

Minimally invasive surgery
Thoracic endovascular aortic repair (TEVAR)

Minimally invasive surgery used to place a stent graft in the affected area

- Smaller incision size
- Less invasive procedure
- Fewer hospital intensive care unit (ICU) days
- Faster recovery rate

Patient experience

Traditional open surgery

Traditional surgery where an incision is made in the chest or abdomen to expose the affected area and place a stent graft

- Larger incision size
- More invasive procedure
- More hospital ICU days
- Slower recovery rate

Patient experience

1. Johns Hopkins Medicine. Thoracic Endovascular Aortic Repair. Johns Hopkins Medicine Web site. https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/thoracic-endovascular-aortic-repair. Accessed June 7, 2019.
2. Mancini M, Taylor W. Thoracic Aortic Aneurysm and Aortic Dissection. University of Rochester Medical Center Web site. https://www.urmc.rochester.edu/encyclopedia/content.aspx?contenttypeid=85&contentid=p08258 . Accessed June 7, 2019.
3. Iannacone E, Girardi L. Thoracic endovascular aortic repair (TEVAR) versus open versus medical management of type B dissection. *Journal of Visualized Surgery* 2018;4:8. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5803117/
4. Lee HC, Joo HC, Lee SH, *et al*. Endovascular repair versus open repair for isolated descending thoracic aortic aneurysm. *Yonsei Medical Journal* 2015;56(4):904-912.

Product overview

The GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System

Listening carefully to our physician partners, we have applied our spirit of innovation to the complexities of endovascular repair.

Now, endovascular repair of aneurysms, transections and Type B dissections can be carried out with greater precision than ever.

Controlled

The GORE® ACTIVE CONTROL System is a new delivery system that offers controlled, staged deployment.

Conformable

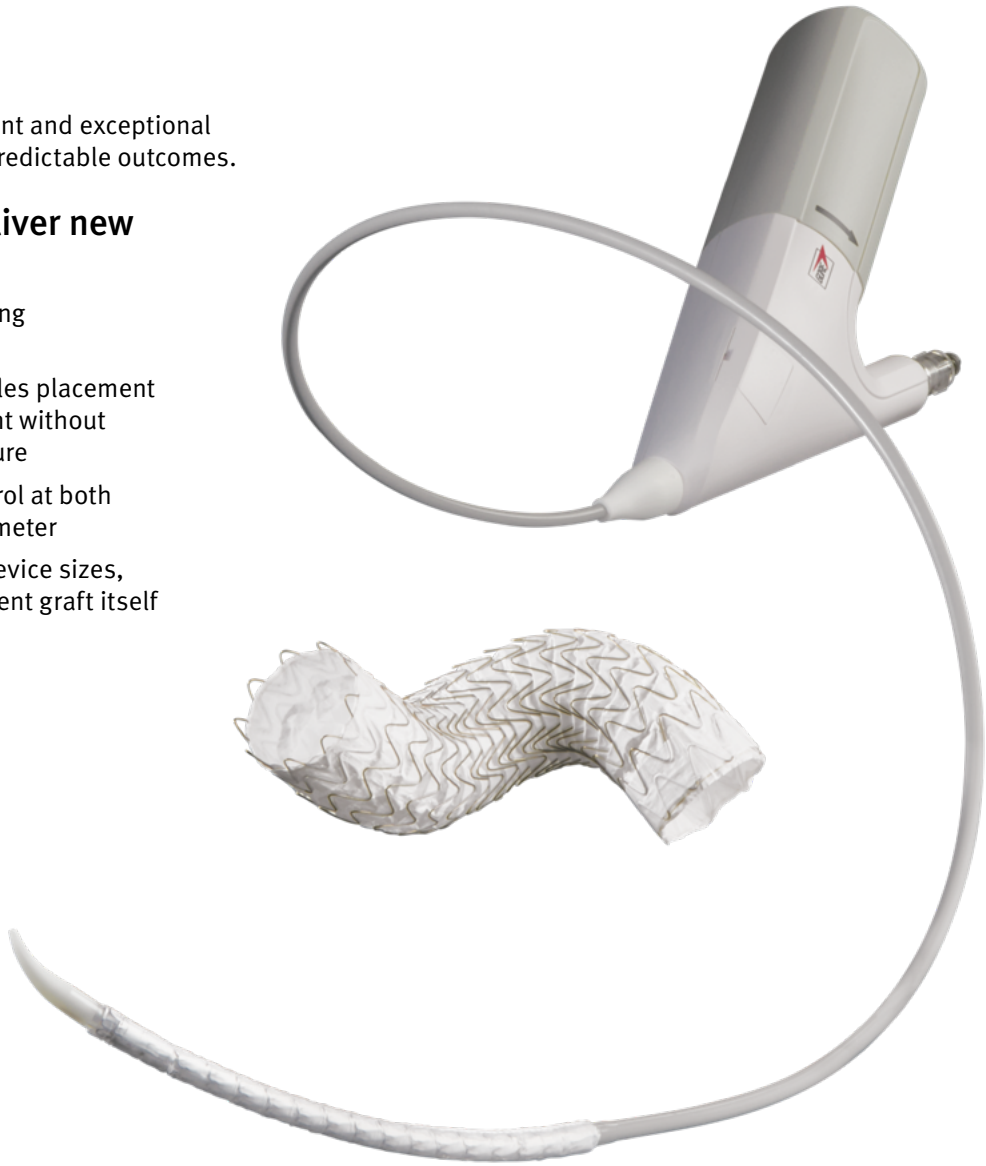
The GORE® ACTIVE CONTROL System enhances the exceptional conformability of the stent graft; facilitating the optimized wall apposition.

Predictable

Combining precise placement and exceptional conformability to achieve predictable outcomes.

Purpose-built to deliver new levels of control

- Accurate device positioning pre-deployment
- Staged deployment enables placement and angulation refinement without alteration of blood pressure
- Optional angulation control at both intermediate and full diameter
- Reduced profiles on 10 device sizes, with no changes to the stent graft itself



Product overview

Product summary

Built on the established success of the Conformable GORE® TAG® Device

The Conformable GORE® TAG® Device is indicated for endovascular repair of the descending thoracic aorta, including aneurysms, transections and type B dissections. It is a PMA-approved, Class III medical device.

Most studied TEVAR device

- Ten clinical studies
- Global Registry for Endovascular Aortic Treatment (GREAT)[1]
- European post-market registry (SURPASS)[2]
- Twenty years of clinical experience

Designed for multiple etiologies with proven results.

Confidence is earned over time

- Supported by more than 20 years of clinical experience
- Over 125,000 devices distributed

1st
Approved device
in the U.S., Europe and Japan

1st
Approved device
for endovascular treatment of aneurysm, transection and Type B dissection

20+
Years
clinical history

A legacy of firsts

1998 **FIRST** thoracic stent graft to receive CE Mark in Europe

2005 **FIRST** thoracic stent graft approved in the U.S.

2008 **FIRST** thoracic stent graft approved in Japan

2009 **NEXT-GENERATION** thoracic stent graft receives CE Mark*

2011 **APPROVED BY FDA** for treatment of aneurysms*

2012 **FIRST** thoracic stent graft approved in the U.S. for isolated lesions including traumatic transections*

2013 **FIRST** stent graft approved in the U.S. for acute and chronic Type B Dissections*

2016 **FIRST** thoracic stent graft to reach 100,000 devices distributed

2017 **FIRST** thoracic stent graft to feature a new delivery system that offers controlled, staged deployment to receive CE Mark in Europe

2019 **FDA approval for GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System in U.S. and PMDA approval in Japan**

* Conformable GORE® TAG® Device

1. The GREAT Registry is a prospective, observational, multi-center registry to actively track Gore commercial aortic endovascular device performance and associated patient outcomes in global markets with 10 years of follow-up. Data June 2017.
2. W. L. Gore & Associates. Observational Registry Characterizing the Performance and Feature Use of the GORE® TAG®Conformable Thoracic Stent Graft Featuring ACTIVE CONTROL System. Bethesda, MD: National Library of Medicine; 2010. Available from: https://clinicaltrials.gov/ct2/show/NCT03286400. NLM Identifier: NCT03286400. Published September 18, 2017. Updated January

Product overview

GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System—same proven device, new delivery system

Device adapts to natural anatomy as opposed to the anatomy adapting to the device.

Wall apposition in highly angulated anatomy

Designed for 360°
aortic wall apposition even in *angulated anatomy*

reducing the need for proximal extensions

Partially uncovered stents help achieve better wall apposition*

Designed to decrease risk of septum perforation

Fully covered distal end provides a transition between the stent frame and the septum,

decreasing the risk of septum perforation

in the treatment of Type B dissection

* Partially uncovered stents are designed to allow maximum seal zone on the inner curve with no compromise to aortic blood flow or to seal.

Product overview

The GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System leverages the performance legacy of Conformable GORE® TAG® Thoracic Endoprosthesis and offers the same:

- Stent graft material construction and design
- Conformability
- Radial fit (broad oversizing windows, low spring-back force)

Proven clinical performance with durable and long-term outcomes

- History of clinical trials in multiple etiologies
- Outcomes from real-world registries
- Low rates of reintervention (3%)[1]

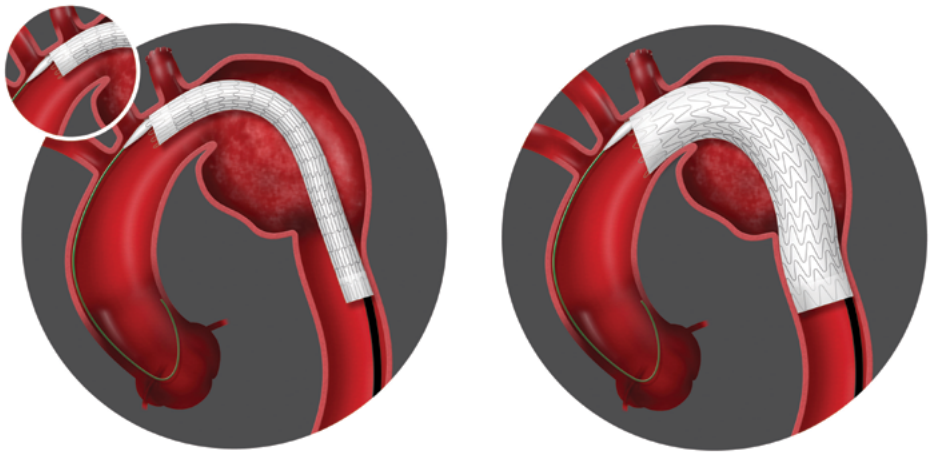
1. W. L. Gore & Associates. 'GREAT' Global Registry for Endovascular Aortic Treatment -Outcomes Evaluation. Bethesda, MD: National Library of Medicine; 2012. Available from: https://clinicaltrials.gov/ct2/show/NCT01658787. NLM Identifier: NCT01658787. Published August 3, 2012. Updated: October 27, 2016. Accessed: Accessed June 22, 2017

Product overview

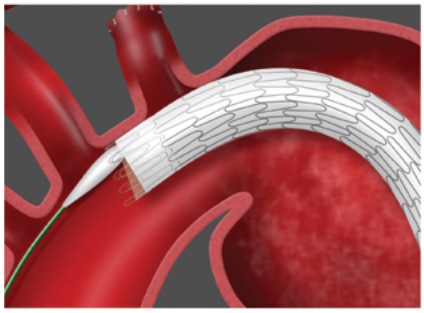
Where conformability meets control—Enhanced deployment system enables optimized placement

- Combines the proven conformability of the Conformable GORE® TAG® Device with an enhanced deployment system that offers physicians new levels of control
- Features advanced technology to improve deployment predictability through accuracy and control

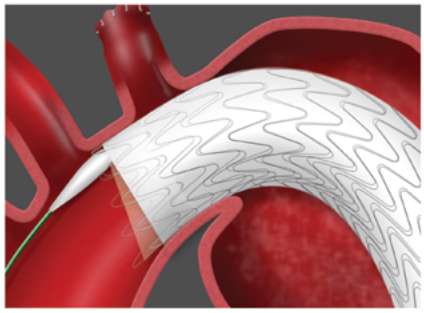
Staged deployment



Angulation control



At intermediate diameter



At full diameter

Staged deployment and angulation control

A unique combination of stent graft and deployment technologies allows active positioning of the stent graft for optimal seal in a variety of aortic anatomies.

- Intuitive deployment system allows physicians to focus on the patient, not deployment
- Clinician can visualize and refine device placement, optimizing angulation and seal to patient anatomy
- Continuous blood flow through deployment
- Designed to minimize the 'wind sock' effect increasing physician satisfaction and confidence in deployment[1]

Example of wind sock effect

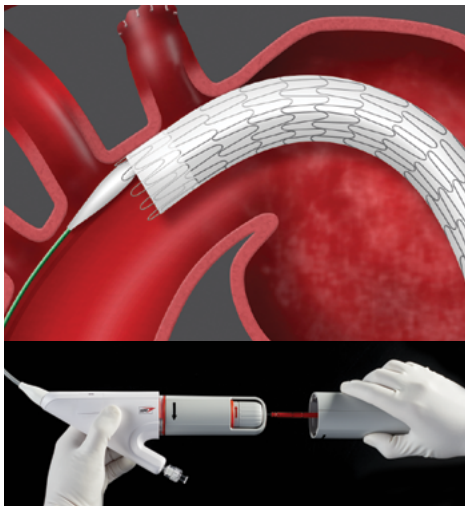
1. Moore JE Jr. Biomechanical issues in endovascular device design. *Journal of Endovascular Therapy* 2009;(1)Supplement:1-11.

Product overview

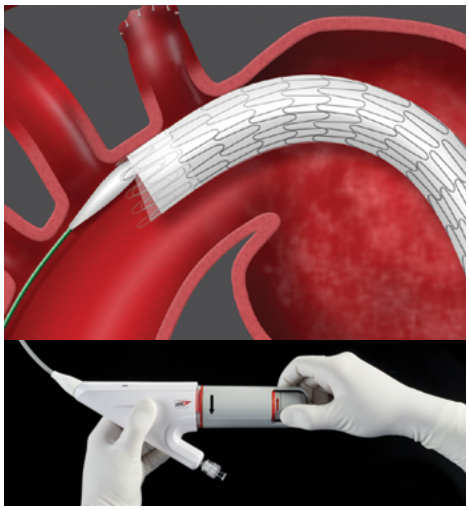
Two deployment stages

Stage 1 — Intermediate diameter

- At intermediate diameter, the stent graft is open, allowing continuous blood flow and promoting hemodynamic stability throughout the procedure
- During this stage, the stent graft position can be refined and C-arm position adjusted to ensure precise positioning in the aorta
- Optional angulation control at this point helps promote optimal seal



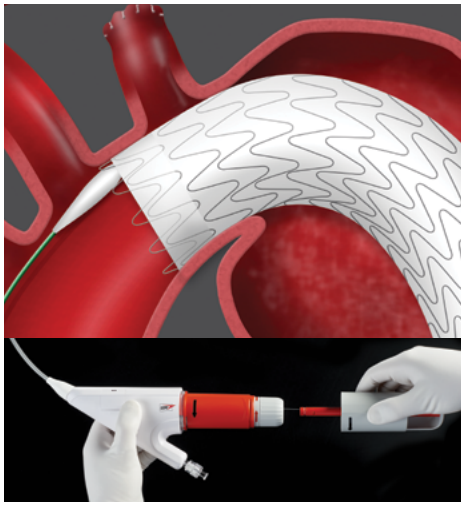
Deployment to intermediate diameter



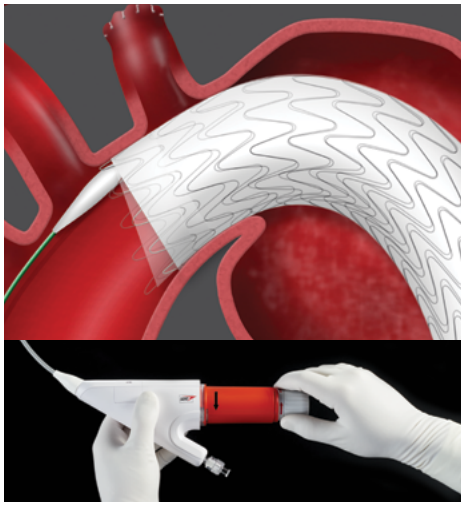
Angulation control at intermediate diameter

Stage 2 — Full diameter

- The stent graft expands to full diameter, precisely maintaining its position within the aorta during deployment — the stent graft is open allowing continuous blood flow during this step
- Optional angulation control at this point helps optimize the proximal seal for 360° wall apposition



Deployment to full diameter

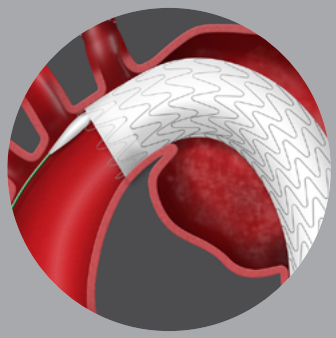


Angulation control at full diameter to finalize proximal seal

Tap here to watch the deployment video.

Product overview

Where conformability meets control — Enhanced deployment system enables optimized placement



Combines the proven conformability of the **Conformable GORE® TAG® Device** with an **enhanced deployment system** optimizing control and confidence

Staged deployment—
Allows for **continuous blood flow to patient** and multiple opportunities for the physician to **place device exactly where intended**

Angulation control—
Physicians have **two opportunities to optimize placement** in the anatomy

> The [GORE® TAG® Conformable Device] deployed exactly at the intended position, with no change in position during the different deployment steps"[1]

"Importantly, the system remains easy to use and the handle operation is intuitive"[1]

"We were able to achieve perfect positioning of the first stent graft… without any movement"[1]

1. Verhagen HJM, Raa ST, van Rijn MJ. Precision and accuracy in the distal landing zone. *Endovascular Today* 2018;17(3)Supplement:8-11. Gore Supplement

Product overview

Patient population and impact

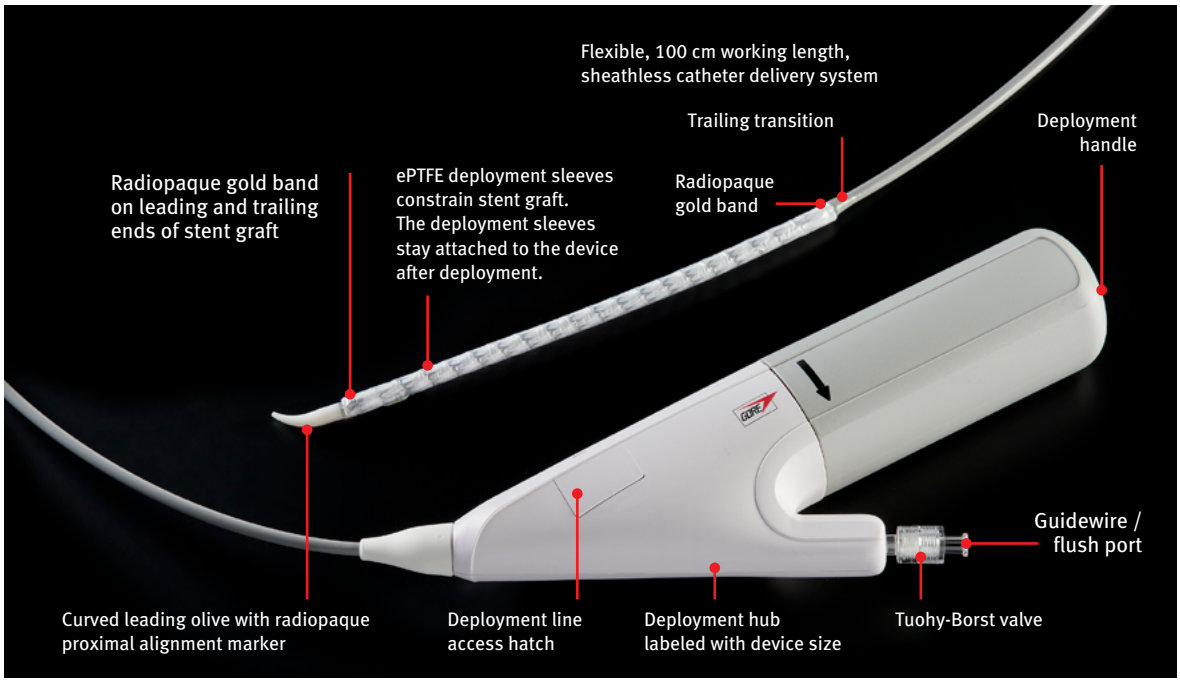
Patient population

Able to treat a broader range of disease states

- Small diameter and tapered devices offer a large treatment range
- Broad 6–33% oversizing windows allow physicians to choose device with optimal radial fit for patient anatomy
- Larger device oversizing windows engineered, tested and proven to accommodate differences in proximal and distal landing zone diameters

Patient impact

- Low device reintervention for patients treated across multiple pathologies
- Can provide a better experience of care by avoiding (pain and discomfort related to) open procedure
- Helps to avoid costs associated with reintervention (e.g., co-payments, time off work)



Product overview

Target user

Primary user for GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System:

- Vascular Surgeons
- Cardiothoracic Surgeons
- Interventional Radiologists
- Interventional Cardiologists

Physician benefits

- Low rates of reintervention (3%)[1] achieved by adapting to patient anatomy
- Staged and controlled deployment helps reduce the potential for complications
- With the GORE® ACTIVE CONTROL System, physicians are able to make refinements during the procedure, including those patients with angulated anatomy

1. W. L. Gore & Associates. 'GREAT' Global Registry for Endovascular Aortic Treatment -Outcomes Evaluation. Bethesda, MD: National Library of Medicine; 2012. Available from: https://clinicaltrials.gov/ct2/show/NCT01658787. NLM Identifier: NCT01658787. Published August 3, 2012. Updated: October 27, 2016. Accessed: Accessed June 22, 2017

Value analysis

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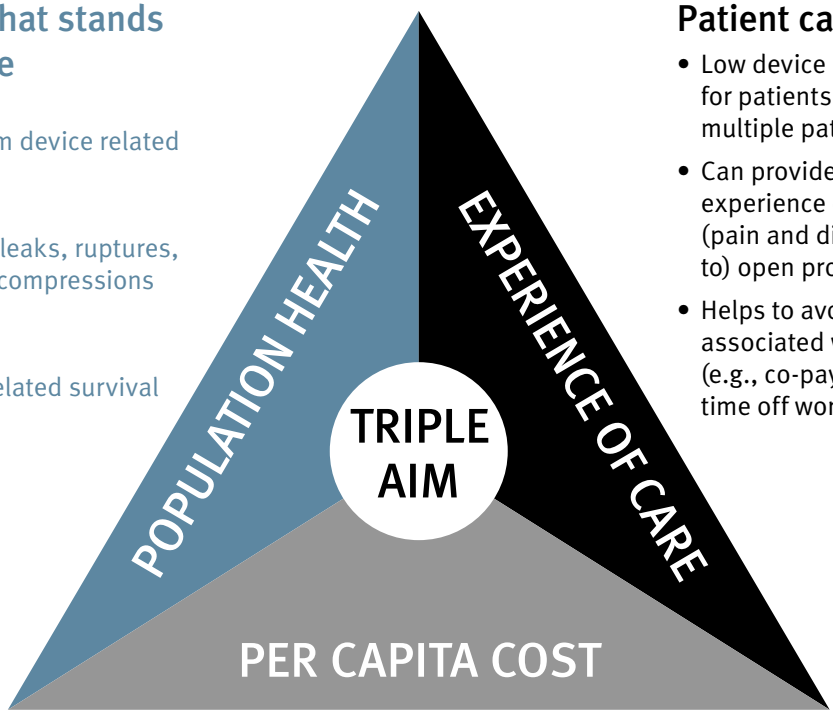

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Cost savings

- 8%–23% reduction in devices used per case[2]
- 67% reduction in vertical storage space
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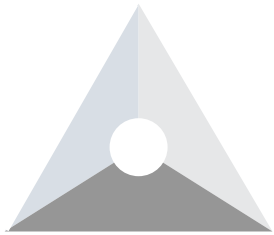
Value analysis

Economic impact

Continued innovation leads to enhanced value with the GORE® ACTIVE CONTROL System

Reducing the number of devices used per case can lead to overall cost savings. The GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System has shown to reduce devices / case by 8–23%.[1]



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Device	Average devices per case	Device per case impact
GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System[2]	**1.38**	**8%–23% reduction**
Conformable GORE® TAG® Thoracic Endoprosthesis[2]	1.6	–
Competitor A[3, 4]	1.8	–
Competitor B[5]	1.5	6% reduction

Data shown represents information publicly available by disease state.

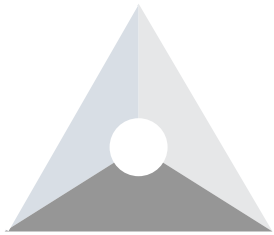
1. W. L. Gore & Associates. Observational Registry Characterizing the Performance and Feature Use of the GORE® TAG® Conformable Thoracic Stent Graft Featuring ACTIVE CONTROL System. Bethesda, MD: National Library of Medicine; 2010. Available from: https://clinicaltrials.gov/ct2/show/NCT03286400. NLM Identifier: NCT03286400. Published September 18, 2017. Updated January 7, 2019. Accessed May 13, 2019.
2. Global Registry for Endovascular Aortic Treatment (GREAT) is a prospective, observational, multicenter registry to actively track Gore commercial aortic endovascular device performance and associated patient outcomes in global markets with 10 years of follow-up. Results as of June 2017.
3. U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data MEDTRONIC VALIANT Thoracic Stent Graft with the CAPTIVIA® Delivery System. October 26, 2012. Retrieved March 8, 2019 from HYPERLINK "https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100040S012c.pdf"
4. U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data MEDTRONIC VALIANT Thoracic Stent Graft with the CAPTIVIA® Delivery System. April 1, 2011. Retrieved March 8, 2019 from www.accessdata.fda.gov/cdrh_docs/pdf10/P100040b.pdf.
5. U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data MEDTRONIC VALIANT Navion Thoracic Stent Graft System. October 19, 2018. Retrieved May 23, 2019 from https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100040S036B.pdf.

Value analysis

Supply chain economic advantages

Minimizing inventory and improving efficiency in storage with fewer SKUs

The management and stocking of SKUs requires time and valuable warehouse or stockroom space. With the GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System, stock fewer devices while treating a broad range of patients.



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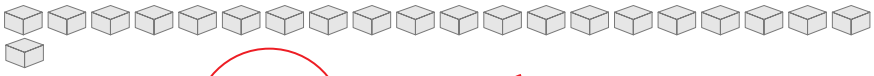
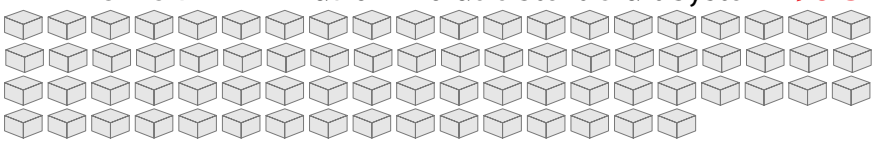
GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System–21 SKUs*



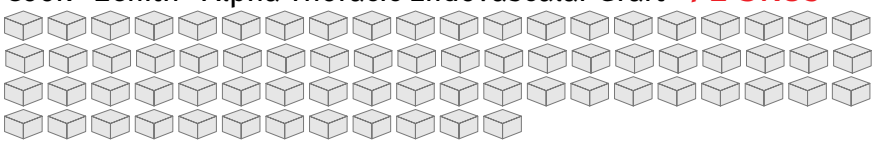
21
Part numbers

16–42 mm
Widest diameter range with fewest part numbers

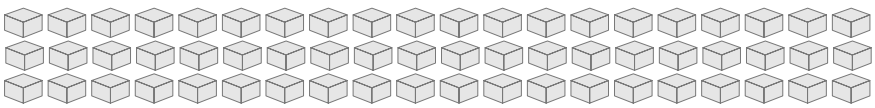
MEDTRONIC VALIANT Navion Thoracic Stent Graft System—76 SKUs*



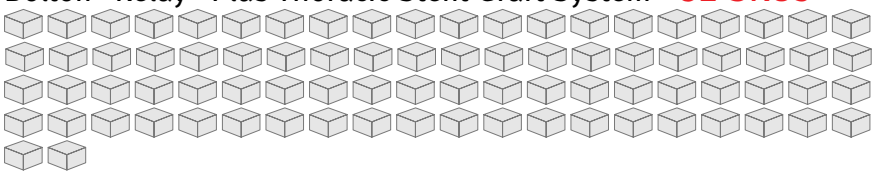
Cook® Zenith® Alpha Thoracic Endovascular Graft—72 SKUs*



Cook® Zenith® TX2® Dissection Endovascular Graft—60 SKUs*



Bolton® Relay® Plus Thoracic Stent Graft System—82 SKUs*



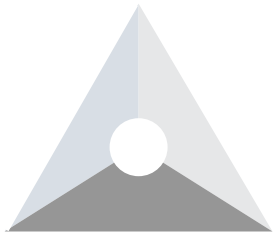
* Assumes rounding of measured vessel diameter (mm) to nearest whole number within IFU sizing range for aneurysm.

Value analysis

Supply chain economic advantages

Improving packaging to optimize storage

The GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System has revised packaging to better align with standard shelving designs, which is another way that Gore listens to your needs. The new packaging reduces vertical storage space requirements by 67% (33.8 inches), conforms to standard shelf height and includes a flexible box configuration that can accommodate stacking or hanging.



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67% less
vertical storage space needed

1. W. L. Gore & Associates. Observational Registry characterizing the performance and feature use of the GORE® TAG® Conformable Thoracic Stent Graft featuring ACTIVE CONTROL System. Bethesda, MD: National Library of Medicine; 2010. Available from: https://clinicaltrials.gov/ct2/show/NCT03286400 . NLM Identifier: NCT03286400. Published September 18, 2017. Updated January 7, 2019. Accessed May 13, 2019.

Value analysis

Population health: Quality outcomes

Performance that stands the test of time

Long-term freedom from device-related reintervention—important for clinicians, hospitals and patients

Performance that stands the test of time

- **Aneurysm:** 97% freedom from device related reintervention[1]
- **Transection:** Zero Type III endoleaks, ruptures, device fractures, compressions or conversions[1]
- **Dissection:** 97% dissection related survival

Real-world[1] treatment using GORE® TAG® Conformable Device

Aneurysms

97%

Freedom

from device-related reintervention

Serious device events:

2 Type IA serious endoleaks*

5 Type IB serious endoleaks*

3 Type II serious endoleaks*

1 Migration reported

Transection

ZERO

Type III endoleaks*
Ruptures
Device fractures
Compressions
Conversions

Device events in other areas:

1 Type I endoleak

2 Migrations

Type B dissection

100%

Procedural survival

97%

Dissection-related survival

Adverse events:

1.1% Retrograde Type A dissection

1.5% Stroke

2.2% Type IA endoleaks*

0% Device compression

1.9% Paraparesis / Paralysis

2.2% Conversion

* Endoleak requiring intervention. No endoleaks persisted past one month or required intervention.

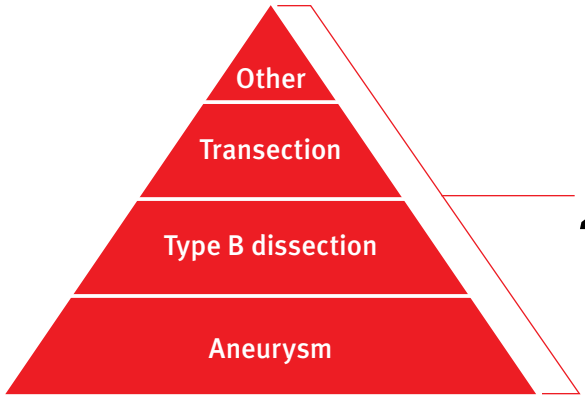
1. The GREAT Registry is a prospective, observational, multi-center registry to actively track Gore commercial aortic endovascular device performance and associated patient outcomes in global markets with 10 years of follow-up. Data June 2017.
Through 2-year follow up. Aneurysm n=316; Transection n=53; Type B dissection n=269.CAPTIVIA® and VALIANT are trademarks of Medtronic Vascular, Inc.

Value analysis

Device related reintervention at 30 days

Therapeutic areas included

GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System



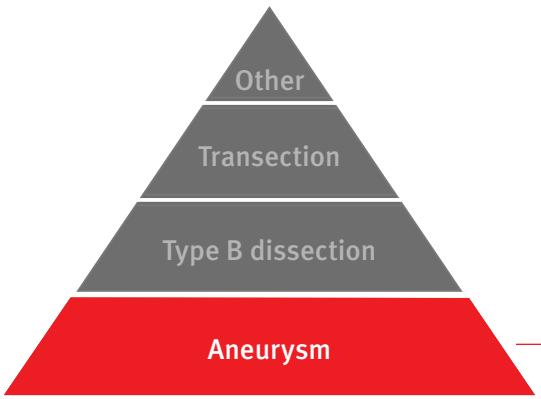
2.4%[2] n = 127

Real-world registry. Participants included were identified by physician and not determined by clinical trial guidelines.

Performance that stands the test of time

- **Aneurysm:** 97% freedom from device related reintervention[1]
- **Transection:** Zero Type III endoleaks, ruptures, device fractures, compressions or conversions[1]
- **Dissection:** 97% dissection related survival

MEDTRONIC VALIANT® NAVION Thoracic Stent Graft System



2.3%[3] n = 87

Inclusion defined by clinical trial guidelines. Data shown represents information publicly available by disease state.

1. The GREAT Registry is a prospective, observational, multi-center registry to actively track Gore commercial aortic endovascular device performance and associated patient outcomes in global markets with 10 years of follow-up. Data June 2017. Through 2-year follow up. Aneurysm n=316; Transection n=53; Type B dissection n=269.
2. W. L. Gore & Associates. Observational Registry characterizing the performance and feature use of the GORE® TAG® Conformable Thoracic Stent Graft featuring ACTIVE CONTROL System. Bethesda, MD: National Library of Medicine; 2010. Available from: https://clinicaltrials.gov/ct2/show/NCT03286400 . NLM Identifier: NCT03286400. Published September 18, 2017. Updated January 7, 2019. Accessed May 13, 2019.
3. U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data MEDTRONIC VALIANT Navion Thoracic Stent Graft System. October 19,2018. Retrieved May 23, 2019 from https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100040S036B.pdf.

Value analysis

Patient satisfaction: Experience of care

Hospitals can count on efficient and reliable TEVAR outcomes even in challenging patient anatomies with the unique combination of deployment and trusted conformability of the GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System.

The GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System has predictable outcomes demonstrating long-term freedom from device-related reintervention (93.1%) and low complication rates (zero migrations, fractures or compressions)* for enhanced patient experience and outcomes.

Patient care

- Low device reintervention for patients treated across multiple pathologies
- Can provide a better experience of care by avoiding (pain and discomfort related to) open procedure
- Helps to avoid costs associated with reintervention (e.g., co-payments, time off work)

ZERO*

- Type Ia and Type III endoleaks
- Device compressions
- Fractures
- Ruptures

100% Successful deployment

98.4% With no device related issues

97.2% Freedom from serious access complications

SURPASS[1] is an observational, prospective, single-arm post-market registry. 20 European sites in 7 countries are included.

* Consolidated site reported outcomes following 5 years of follow-up in TAG 08-01, TAG 08-02, TAG 08-03 clinical studies.

1. W. L. Gore & Associates. Observational Registry characterizing the performance and feature use of the GORE® TAG® Conformable Thoracic Stent Graft featuring ACTIVE CONTROL System. Bethesda, MD: National Library of Medicine; 2010. Available from: https://clinicaltrials.gov/ct2/show/NCT03286400 . NLM Identifier: NCT03286400. Published September 18, 2017. Updated January 7, 2019. Accessed May 13, 2019.

Surgeon and staff support resources

Education and surgical case support

Case planning support

- Provided by a highly skilled team of specialists
- Case planning pre-procedure
- Intra-procedural technical device expertise

Gore MEDICAL MASTERY Series

- Educational content available both online and through in-person training
- Physician led content discussing procedural considerations for different etiologies
- Technical resource on device use and keys to success

Product training

- Training is provided by certified trainers at a company sponsored course at the account
- FDA requires physicians must be certified by a Gore certified trainer before using the device

Materials management information

Catalogue numbers / size chart / configurations

GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System							
Catalogue number	Intended aortic diameter (mm)	Proximal diameter (mm)	Distal diameter (mm)	Endoprosthesis length (cm)	Recommended GORE® Dryseal Flex Introducer Sheath size (Fr)	Oversizing range (%)	Partially uncovered stent length (mm)
TGM212110	16–19.5	21	21	10	18	8–31	3
TGM262110	19.5–24 / 16–19.5	26	21	10	20	8–33	4
TGM262610	19.5–24	26	26	10	20	8–33	4
TGM282810	22–26	28	28	10	20	8–27	4
TGM282815	22–26	28	28	15	20	8–27	4
TGMR312610	24–29 / 19.5–24	31	26	10	20	7–33	4
TGMR313110	24–29	31	31	10	20	7–29	4
TGMR313115	24–29	31	31	15	20	7–29	4
TGMR313120	24–29	31	31	20	20	7–29	4
TGM343410	27–32	34	34	10	22	6–26	5
TGM343415	27–32	34	34	15	22	6–26	5
TGM343420	27–32	34	34	20	22	6–26	5
TGMR373710	29–34	37	37	10	22	9–28	5
TGMR373715	29–34	37	37	15	22	9–28	5
TGMR373720	29–34	37	37	20	22	9–28	5
TGMR404010	31–37	40	40	10	22	8–29	6
TGMR404015	31–37	40	40	15	22	8–29	6
TGMR404020	31–37	40	40	20	22	8–29	6
TGM454510	34–42	45	45	10	24	7–32	6.5
TGM454515	34–42	45	45	15	24	7–32	6.5
TGM454520	34–42	45	45	20	24	7–32	6.5

For Europe, Australia and New Zealand, add E at the end of the catalogue number.

Materials management information

Stent graft size* — Reduced profile without device compromise

Catalogue number[1]	Labeled diameter (mm)	Intended aortic diameter (mm)	Device length (cm)	Device profile (fr)	Oversizing range (%)	Partially uncovered stent length (mm)
TGM	21	16–19.5	10	18	8–31	3
TGM	26	19.5–24	10	20	8–33	4
TGM	28	22–26	10, 15	20	8–27	4
TGMR	31	24–29	10, 15, 20	20	7–29	4
TGM	34	27–32	10, 15, 20	22	6–26	5
TGMR	37	29–34	10, 15, 20	22	9–28	5
TGMR	40	31–37	10, 15, 20	22	8–29	6
TGM	45	34–42	10, 15, 20	24	7–32	6.5
TGM	26 × 21	19.5–24 / 16–19.5	10	20	8–33	4
TGMR	31 × 26	24–29 / 19.5–24	10	20	7–33	4

- Same sizing chart for Type B dissections as for isolated lesions
- If there are two or three device options per *Instructions for Use* (IFU) for a given aortic diameter, the physician can choose which device will be optimal for the patient's anatomy

Product specifications

Product dimensions 16.38″H × 12.38″W × 2.56″D

Material composition

This device is a flexible, self-expanding stent graft that is constrained on the leading end of a delivery catheter.

- The stent graft consists of an ePTFE / FEP graft supported over its entire length by a nitinol wire frame (stent)
- A radiopaque gold band is embedded in the graft material at each end for device imaging
- The stent is attached to the external surface of the graft by laminated ePTFE / FEP bonding tape
- The proximal end of the stent graft consists of exposed stent apices, while the distal end of the stent is in line with the graft material
- An ePTFE sealing cuff is attached over the stent at each end

GORE® TAG® Conformable Thoracic Stent Graft Materials†
ePTFE (polytetrafluoroethylene)
FEP (fluoroethylpropylene)
Nitinol (Nickel, Titanium)
Gold

* If aortic angulation is < 60°, additional neck length may be required.

† This product not made with natural rubber latex.

Materials management information

Coding and reimbursement

For coding and/or reimbursement support contact Coding Strategies (888-812-0322) or visit (www.codingstrategies.com/wl-gore). The direct reimbursement page for the GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System can also be found at https://www.goremedical.com/coding and https://www.goremedical.com/products/ctagac.

Instructions for Use

DESCRIPTION

The GORE® TAG® Conformable Thoracic Stent Graft provides endovascular repair of the descending thoracic aorta (DTA). The GORE® TAG® Conformable Thoracic Stent Graft may be used as a single device or in multiple device combinations to accommodate the intended treatment site.

This device is a flexible, self-expanding stent graft that is constrained on the leading end of a delivery catheter. The system consists of two parts, the stent graft and the delivery system. Stent graft sizes range in diameter from 21 to 45 mm and in length from 10 to 20 cm. The compressed profile of these devices on a delivery catheter ranges from 18 to 24 Fr.

The stent graft consists of an ePTFE/FEP graft supported over its entire length by a nitinol wire frame (stent). A radiopaque gold band is embedded in the graft material at each end for device imaging. The stent is attached to the external surface of the graft by laminated ePTFE/FEP bonding tape. The proximal end of the stent graft consists of exposed stent apices, while the distal end of the stent is in line with the graft material. An ePTFE sealing cuff is attached over the stent at each end. For delivery, the stent graft is mounted onto the delivery system.

The delivery system consists of a PEBA multi-lumen catheter, two sewn deployment sleeves, and an integrated handle featuring the GORE® ACTIVE CONTROL System to provide the user with controlled deployment. The catheter is compatible with a 0.035" guidewire. A curved leading olive and a trailing transition longitudinally restrain and protect the stent graft during introduction. The leading olive is curved to facilitate appropriate device placement and orientation. The leading olive is constructed using a radiopaque material with a radiopaque lockwire termination feature acting as an alignment marker for visualization of device placement and orientation. The stent graft is constrained by the sewn deployment sleeves and is mounted on the leading end of the catheter. The GORE® ACTIVE CONTROL System features a nested handle on the trailing end of the catheter that enables a stepwise operation of deployment steps.

The primary sleeve constrains the stent graft at the delivery profile and the secondary sleeve constrains the stent graft at an intermediate diameter that is approximately half of the nominal device diameter. Actuating the Primary Deployment Handle (attached to the primary sleeve deployment line) unlaces the primary sleeve, from leading to trailing end, and allows the self-expanding stent graft to deploy into the secondary sleeve (intermediate diameter). Actuating the Angulation Control Dial (attached to the angulation fibers) angulates the proximal end of the stent graft. Actuating the Secondary Deployment Handle (attached to the secondary sleeve deployment line) unlaces the secondary sleeve, from trailing to leading end, to deploy the device to full diameter. Actuating the Angulation Control Dial at full diameter further angulates the proximal end of the stent graft. After device positioning at full diameter is complete, the lockwire and angulation fibers are removed from the catheter. Both deployment sleeves are secured to the stent graft and remain implanted between the device and the vessel wall. The delivery hub is equipped with a Deployment Line Access Hatch to expose all the lines needed to complete deployment.

INDICATIONS FOR USE

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

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

Materials management information

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® Conformable Thoracic Stent Graft is designed to treat aortic neck diameters no smaller than 16 mm and no larger than 42 mm. The GORE® TAG® Conformable Thoracic Stent Graft 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® Conformable Thoracic Stent Graft 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® Conformable Thoracic Stent Graft 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 stent graft diameter requires the use of multiple stent grafts 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 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® Conformable Thoracic Stent Graft outside of the recommended anatomical sizing guidelines may result in potentially serious device-related events (e.g., device infolding, excessive device compression, endoleak, wire fracture, migration).
- If 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® Conformable Thoracic Stent Graft is not recommended in patients who cannot tolerate contrast agents necessary for intra-operative and post-operative follow-up imaging.
- The GORE® TAG® Conformable Thoracic Stent Graft 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.

Measurement Techniques and Imaging

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

- Diameter
  A contrast-enhanced spiral CTA is required for aortic diameter measurements. Diameter measurements must be of the flow lumen not including vessel wall. The spiral CTA scan must include the great vessels through the femoral heads at an axial slice thickness of 3 mm or less.
- Length
  Clinical experience indicates that 3-D CTA reconstruction is the required imaging modality to accurately assess proximal and distal neck lengths for the GORE® TAG® Conformable Thoracic Stent Graft. These reconstructions should be performed in sagittal, coronal and varying oblique views depending upon individual patient anatomy. If 3-D reconstruction is not available, the patient should be referred to a facility with these capabilities.

Materials management information

Device Selection

- If aortic angulation is less than 60°, or if there is significant calcium or thrombus, additional neck length may be required.
- Strict adherence to the GORE® TAG® Conformable Thoracic Stent Graft IFU sizing guide is required when selecting the appropriate device size. The GORE® TAG® Conformable Thoracic Stent Graft is designed to be oversized from 6 to 33%. Appropriate device oversizing has been incorporated into the IFU sizing guide. Sizing outside of this range may result in endoleak, fracture, migration, device infolding, or compression.
- Adverse clinical outcomes including significant distal vascular ischemic complications (bowel ischemia, paraplegia) and / or death have resulted from device use outside of the IFU sizing guide.
- Follow the Instructions for Use recommendations carefully using the sizing guide and aortic screening measurements included in the IFU.

Implant Procedure

- Appropriate procedural imaging is required to successfully position the GORE® TAG® Conformable Thoracic Stent Graft in the landing zone and to improve apposition to the aortic wall.
- Device apposition to the inner curve of the aortic arch should be confirmed with procedural fluoroscopy and non-contrast radiography. If device apposition is not complete, the use of ballooning and / or additional GORE® TAG® Device(s) has been reported by physicians to ensure apposition of the GORE® TAG® Device to the aortic wall in the acute setting.
- The incidence of type I endoleak was higher in patients enrolled in the TAG 04-01 Ruptured Aneurysm Arm compared to patients enrolled in the TAG 99-01, TAG 03-03, and TAG 08-03 Aneurysm studies. More than 2 cm of proximal and distal neck length may help reduce the incidence of endoleak in patients who undergo endovascular repair for ruptured aortic aneurysm.
- Clinicians recommend positioning the image intensifier (C-arm) so that it is perpendicular to the neck, typically 45-75 degrees left anterior oblique (LAO) for the arch.
- Systemic anticoagulation should be used during the implantation procedure based on hospital and physician preferred protocol. If heparin is contraindicated, an alternative anticoagulant should be considered.
- Consider use of cerebrospinal fluid drainage or other spinal protection measures when treating a patient with risk of paraplegia / paraparesis.
- Minimize handling of the constrained stent graft during preparation and insertion to decrease the risk of device contamination and infection.
- Do not rotate the delivery catheter while the stent graft is inside the introducer sheath. Catheter breakage or inadvertent deployment may occur.
- Do not rotate the delivery catheter with device outside of the introducer sheath more than 180° in either direction. Catheter breakage or inadvertent deployment may occur.
- Do not attempt to reposition the stent graft after deployment to full diameter has been initiated. Vessel damage or stent graft misplacement may result.
- Do not continue advancement or retraction of the guidewire, sheath, or delivery catheter if resistance is felt. Stop and assess the cause of resistance. Vessel, stent graft, or delivery catheter damage may occur.
- Incorrect deployment or migration of the stent graft may require endovascular or surgical intervention.
- Use caution if removing the undeployed stent graft through the introducer sheath. Inadvertent stent graft deployment may occur. If resistance is felt during removal of delivery catheter, stop and withdraw delivery catheter and introducer sheath together.
- Inadvertent partial deployment or migration of the stent graft may require surgical removal.
- Do not cross significant arterial branches which do not have collateral or protected perfusion to end organs or body structures. Vessel occlusion may occur.
- If resistance is felt, stop and assess the cause. Otherwise, device displacement may occur.
- If resistance is felt during removal of the trailing packaging sleeve toward the tip of the device, do not force removal. Damage to the device could occur. If resistance is felt, slide the packaging sleeve in the opposite direction towards the delivery handle. If full working length of the catheter is needed, the packaging sleeve may be carefully excised (e.g., using Mayo scissors), taking care not to damage the catheter.
- Consider adjunctive procedures to restore blood flow to malperfused branch vessels. Additional procedures during treatment in the TAG 08-01 Dissection study included, but are not limited to fenestration, aortic stenting, peripheral stenting, surgical bypass, and angioplasty.
- When treating ruptured dissections, consider extended coverage of the dissection distally to the celiac in order to promote thrombosis of the false lumen and decrease the risk of perfusion of the ruptured false lumen through distal fenestrations in the septum.
- When treating acute dissections with multiple devices, always deploy the proximal device first. Inadvertent pressurization of the false lumen may result in retrograde dissection.
- When treating dissections, ensure the distal end of the device is in a straight portion of the aorta in order to reduce risk of septum damage.
- When treating dissections, consider coverage of ≥ 10 cm distal to the primary entry tear to ensure adequate coverage to stabilize the septum and promote thrombosis of the false lumen.
- The GORE® TAG® Conformable Thoracic Stent Graft is only compatible with the GORE® DrySeal Introducer Sheath family of devices. Compatibility with other sheaths has not been established. If an incompatible introducer sheath is used, damage may occur to the stent graft, delivery system, or catheter, which may cause premature or inadvertent deployment, or breakage. Please refer to specific sheath IFU for instructions for use.
- *In vitro* testing has shown that the GORE® TAG® Thoracic Endoprosthesis is not compatible with introducer sheaths that have multi-layer silicone disc valves. Catheter breakage has been observed in clinical use with such valves.
- When catheters are in the body, manipulate only under fluoroscopic guidance.
- Gore recommends the GORE® Tri-Lobe Balloon Catheter for use with the GORE® TAG® Conformable Thoracic Stent Graft. Data is not available for use of other balloon catheters with the GORE® TAG® Conformable Thoracic Stent Graft. Follow the Instructions for Use supplied with the GORE® Tri-Lobe Balloon Catheter.
- Care should be taken when ballooning in patients with a history of aortic dissection. Over inflation of the balloon in dissection patients could lead to aortic damage including retrograde dissection and damage to the septum. Ballooning should only be completed when necessary such as treatment of an endoleak. When ballooning in dissection patients, balloon the proximal landing zone first and then overlapped areas (if appropriate). Do not balloon the distal neck of dissections. Inadvertent pressurization of the false lumen may result in retrograde dissection or damage to the septum.
- To avoid vessel trauma, do not over inflate the GORE® Tri-Lobe Balloon Catheter in relation to the diameter of the artery or the GORE® TAG® Conformable Thoracic Stent Graft.
- Do not inflate the GORE® Tri-Lobe Balloon Catheter in areas of significant calcified plaque. Balloon rupture and / or vessel damage may occur.
- Care should be taken not to balloon outside of the GORE® TAG® Conformable Thoracic Stent Graft. Ballooning native vessel could lead to vessel damage, rupture, or death.

Follow-Up

- Do not use the GORE® TAG® Conformable Thoracic Stent Graft 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 stent graft.
- Wire fractures have been reported on this type of stent graft and may be more likely to occur in conditions with excessive stent graft 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, stent graft 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.

Materials management information

- 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® Conformable Thoracic Stent Graft 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® Conformable Thoracic Stent Graft 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 (e.g., 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,
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,
stent graft: improper placement; incomplete deployment; migration; material failure; occlusion; infection; stent fracture; dilatation; perigraft flow,
surgical conversion,
thrombosis,
transient ischemic attack,
vascular spasm or vascular trauma (e.g., ilio-femoral vessel dissection, bleeding, rupture),
wound (e.g., infection, dehiscence)

Device Related Adverse Event Reporting

Any adverse event involving the GORE® TAG® Conformable Thoracic Stent Graft should be reported to W. L. Gore & Associates immediately. To report an event in the US, call 800.528.1866 Ext. 44922 or email medcomplaints@wlgore.com. Outside the US, contact your local technical representative.

SUMMARY OF US CLINICAL STUDIES

A series of US clinical studies were conducted to evaluate the safety and effectiveness of the various versions of the GORE® TAG® Conformable Thoracic Stent Graft in aneurysm, traumatic aortic transection, and dissection patient populations. A summary of these studies is provided below followed by study information and clinical data from each of the studies which supports the safety and effectiveness claims and the approved indications for use statement for the GORE® TAG® Conformable Thoracic Stent Graft. Two US clinical studies were conducted to evaluate the safety and effectiveness of the GORE® TAG® Thoracic Endoprosthesis in aneurysms of the descending thoracic aorta (DTA). The first, referred to as TAG 99-01, evaluated the original device design. The second US clinical study, referred to as TAG 03-03, evaluated a modified version of the device. TAG 99-01 and TAG 03-03 data are presented collectively. These data have been updated to reflect longer term follow-up that has become available since the original PMA and immediately follows. After approval of the GORE® TAG® Thoracic Endoprosthesis for treatment of aneurysms of the DTA, Gore conducted a third US clinical study, referred to as TAG 04-01, to evaluate the use of the modified device in ruptured aneurysms of the DTA. This data is presented subsequent to those data summarized in TAG 99-01 and TAG 03-03. In order to expand the treatment range from 23-37 mm to 23-42 mm diameter aortas, Gore conducted a fourth clinical study, TAG 06-02, to evaluate the use of the 45 mm GORE® TAG® Device for the repair of aneurysms of the DTA in subjects with aortas ranging from 37-42 mm. Data from this study follows the TAG 04-01 study data. Gore modified the GORE® TAG® Thoracic Endoprosthesis and conducted an additional study to evaluate a modified version of the device, commercially released as the Conformable GORE® TAG® Thoracic Endoprosthesis. This fifth study, TAG 08-03, evaluated the Conformable GORE® TAG® Thoracic Endoprosthesis for the treatment of aneurysms of the DTA with aortas ranging from 16-42 mm in diameter. Data from this study follows the TAG 06-02 study data. In order to expand the indications for use from aneurysms to isolated lesions of the DTA, excluding dissection, a sixth study, TAG 08-02, was conducted to evaluate the Conformable GORE® TAG® Thoracic Endoprosthesis for the treatment of traumatic aortic transections of the DTA with aortas ranging from 16-42 mm in diameter. Data from this study follows the TAG 08-03 study data. To further expand the indications for use from isolated lesions to all lesions in the DTA including Type B dissections, a seventh study, TAG 08-01, was conducted to evaluate the Conformable GORE® TAG® Thoracic Endoprosthesis for the treatment of acute complicated Type B dissections with proximal aortic diameters ranging from 16-42mm. Data from this study follows the TAG 08-02 study data. The GORE® TAG® Conformable Thoracic Stent Graft maintains the same stent graft as the modified device, commercially known as the Conformable GORE® TAG® Thoracic Endoprosthesis, which was evaluated in the TAG 08-03, TAG 08-02, and TAG 08-01 studies for the treatment of aneurysms, isolated lesions, and Type B dissections of the DTA. Therefore, this Instructions for Use contains the results of these US clinical studies.

Materials management information

Handling

- Devices have a 3-year shelf life. Devices may be stored at ambient temperature and the boxes can be hung or stacked on a shelf.
- The device is packaged in a sterile tray within a box. Unit = box of 1.
- The device is MRI Conditional. It can be scanned safely under the following conditions:
  - Static magnetic field of 1.5 or 3.0 Tesla only
  - Maximum spatial gradient magnetic field of ≤ 3000 Gauss / cm
  - Maximum scanner displayed whole-body-averaged specific absorption rate (SAR) of 3.0@ / kg for 15 minutes of scanning
  - The device is visible on X-RAY and exposed to ultrasound

Product replacement

The GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System may replace any of the following products:

- MEDTRONIC VALIANT® Thoracic Stent Graft with CAPTIVIA® Delivery System (August 14, 2019)
  - https://www.medtronic.com/us-en/healthcare-professionals/products/cardiovascular/aortic-stent-grafts/valiant-thoracic-stent-graft-with-captivia-delivery-system.html
- MEDTRONIC VALIANT® NAVION Thoracic Stent Graft System (August 14, 2019)
  - https://www.medtronic.com/us-en/healthcare-professionals/products/cardiovascular/aortic-stent-grafts/valiant-navion-thoracic-stent-graft-system.html
- COOK® ZENITH® ALPHA Thoracic Stent Graft System (August 14, 2019)
  - https://aortic.cookmedical.com/thoracic/
- BOLTON® RELAY® Plus Thoracic Stent Graft System (August 14, 2019)
  - https://www.boltonmedical.com/products/relayplus/

While GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System can replace all of the above listed products, those products may not all be able to replace the GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System due to size variation, size limitations or diameter performance issues.

This device will also be replacing the Conformable GORE® TAG® Thoracic Endoprosthesis which is planned to be fully phased out in the fall of 2020.

References

Value analysis handbook

Lane RL, Miller S, Ramshaw B, Seigfried RJ, Root K, DeMarinis M; W. L. Gore & Associates, Inc. The Future of Value Analysis. A Handbook for Health Care Professionals. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2018. [Booklet]. AX1291-EN3.

Studies and registries

GREAT registry

GREAT Registry: Tjaden BL, Sandhu H, Miller C, et al. Outcomes from the Gore Global Registry for Endovascular Aortic treatment in patients undergoing thoracic endovascular aortic repair for type B dissection. *Journal of Vascular Surgery*. 2018;68(5):1314-1323

SURPASS study

Data within references the SURPASS DATA: W. L. Gore & Associates. Observational Registry Characterizing the Performance and Feature Use of the GORE® TAG® Conformable Thoracic Stent Graft Featuring ACTIVE CONTROL System. Bethesda, MD: National Library of Medicine; 2010. Available from: https://clinicaltrials.gov/ct2/show/NCT03286400. NLM Identifier: NCT03286400. Published September 18, 2017. Updated January 7, 2019. Accessed May 13, 2019. Results of 30-day follow-up data as reported by sites.

SURPASS flyer

AY0121-EN1 May 2019

GREAT flyer

AY0555-EN1 June 2019

References

FDA clearance

U.S. FOOD & DRUG ADMINISTRATION

May 14, 2019

W. L. Gore & Associates, Inc.
John Malone
Regulatory Affairs
3450 W. Kiltie Lane
Flagstaff, Arizona 86005

Re: P040043/S106
Trade/Device Name: GORE TAG Conformable Thoracic Stent Graft with ACTIVE CONTROL System
Product Code: MIH
Filed: November 15, 2018

Dear John Malone:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) 180-day supplement, which requested approval for the following:

- Modifications to the delivery system;
- Implementation of six additional implant lengths;
- Reduction in profile for a subset of device sizes; and
- Updates to the Instructions for Use to reflect the changes in device design and directions for use.

The device, as modified, will be marketed under the trade name GORE TAG Conformable Thoracic Stent Graft with ACTIVE CONTROL System and is indicated for the endovascular repair of all lesions of the descending thoracic aorta in patients who have appropriate anatomy. Based upon the information submitted, the PMA supplement is approved. You may begin commercial distribution of the device as modified by your PMA supplement in accordance with the conditions described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

References

FDA clearance

sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 3 years. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. This report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI website, http://www.fda.gov/udi.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52 for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

References

FDA clearance

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1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm and on combination product postmarketing safety reporting is available at (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm).

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the postmarketing safety reporting requirements (21 CFR 4, Subpart B) for combination products, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with a copy of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

References

FDA clearance

P040043/S106 - John Malone Page 4

If you have any questions concerning this approval order, please contact Rohini Retarekar at 240-402-3750 or Rohini.Retarekar@fda.hhs.gov.

Sincerely,

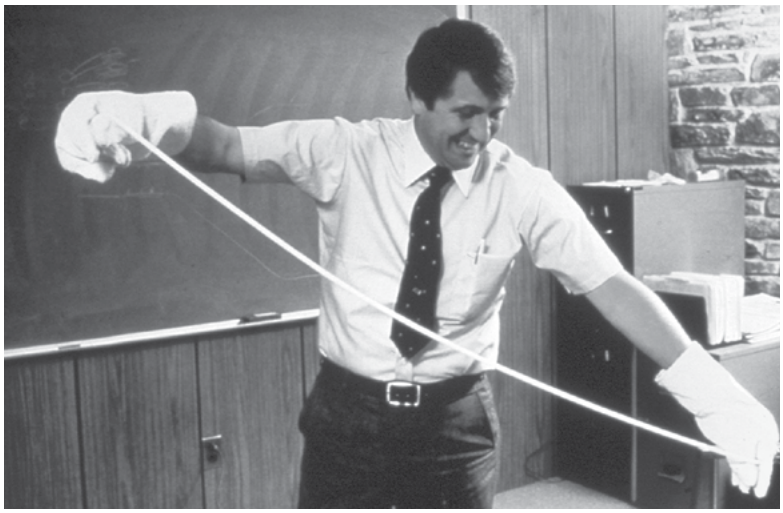
Nicole G. Ibrahim -S

for Bram Zuckerman, M.D.
Director
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

About Gore

W. L. Gore & Associates, Inc.

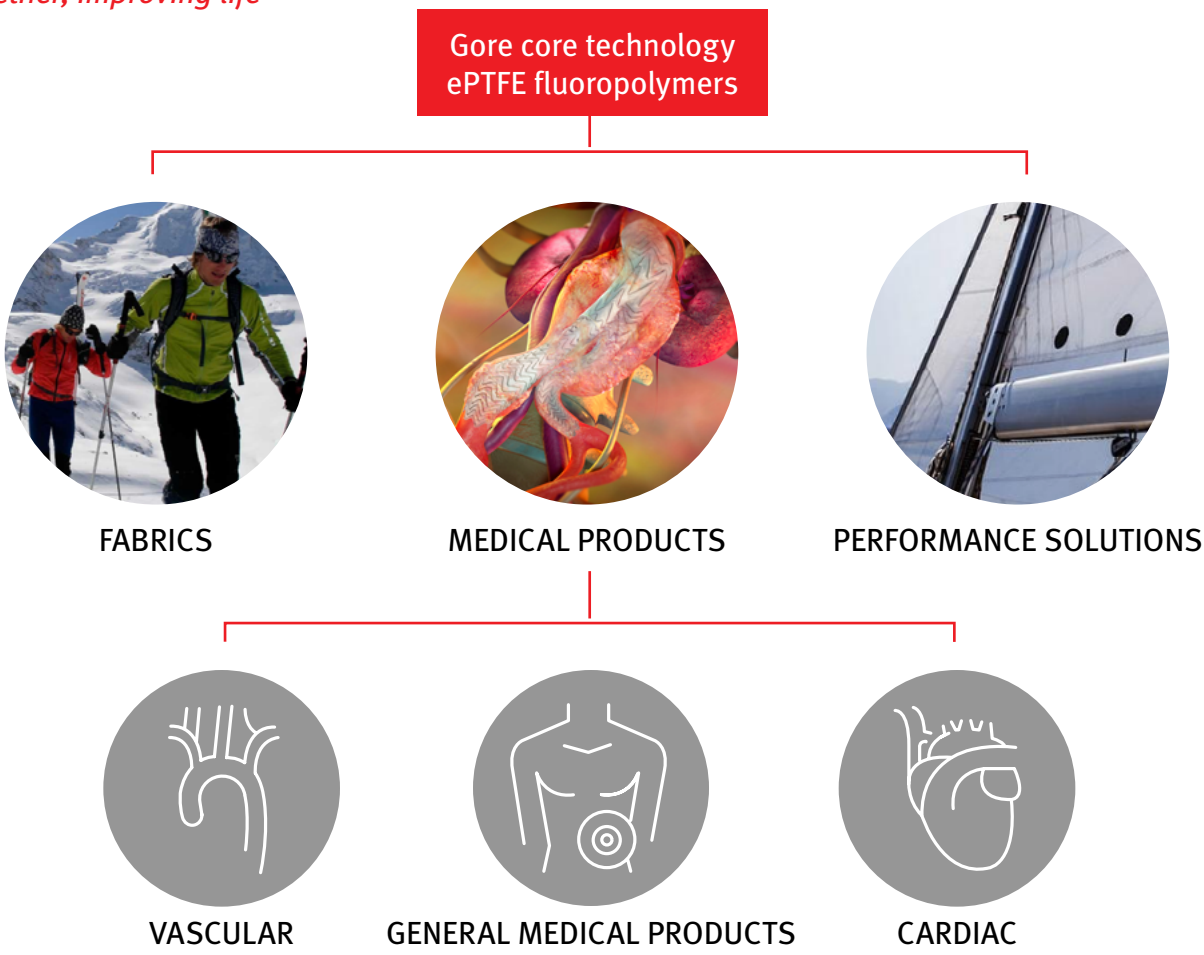
Inspired by challenges, committed to performance.



- Founded January 1, 1958
- Privately held
- Over $3.2 billion in annual sales
  - Associates held to a high standard
  - You, the customer and your needs are our focus

Gore Medical Products Division

Together, improving life



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goremedical.com

Consult Instructions for Use

Refer to *Instructions for Use* at goremedical.com for a complete description of all warnings, precautions and contraindications. ℞ Only

Products listed may not be available in all markets.