

**GORE® DRYSEAL**

Flex Introducer Sheath

**GORE® TAG®**

Conformable Thoracic Stent Graft

**GORE® TAG®**

Thoracic Branch Endoprosthesis



# ADVANCING CARE, MINIMIZING AIR

Making a measurable difference  
through recommended use.

GET STARTED



*Together, improving life*



# You always seek the best options for patients

When you choose Gore, you choose a time-tested TEVAR legacy of safety and effectiveness.

10 clinical studies

more than

20 years

of clinical experience

more than

250,000\*

TAG® Devices distributed worldwide

GREAT Global Registry for Endovascular Aortic Treatment

## We always seek ways to support you

As your Aortic Ally, we listen carefully when we hear conversations around patient outcomes.

In recent literature, questions have been raised around the volume of air released by TEVAR endografts. Estimates ranged from 0.10 - 1.02 mL (average: 0.59 mL) based on limited testing using various flushing techniques not included in respective device *Instructions for Use*.<sup>1,2</sup>



## We're here to clear the air

When used as recommended,<sup>3-5</sup> Gore TEVAR solutions facilitate a means for minimizing air.†

### Distinctive designs enable effective techniques

- **Constraining sleeve:** Enables use with the exclusive GORE® DRYSEAL Valve.
- **Pressurized valve:** Creates a squeegee effect, removing air from the constrained device during insertion.
- **Back-bleeding:** Pausing insertion allows blood to flow back out of the exposed end of the device, releasing additional air.

\* Data on file 2022; W. L. Gore & Associates, Inc; Flagstaff, AZ.

† Data on file 2023; W. L. Gore & Associates, Inc; Flagstaff, AZ.

# An integrated approach in action

To evaluate air volume, we developed a clinically relevant test method that simulated recommended use<sup>3-5</sup> and physiological conditions.\*



1. GORE® DRYSEAL Valve inflated with 2.5 mL saline.<sup>3</sup>
2. Back-bleeding technique.<sup>4-5</sup>
3. Devices deployed in blood mimic with mean arterial pressure (67 mmHg).

## GORE® DRYSEAL

Flex Introducer Sheath  
technology alone

.016 mL

## GORE® DRYSEAL

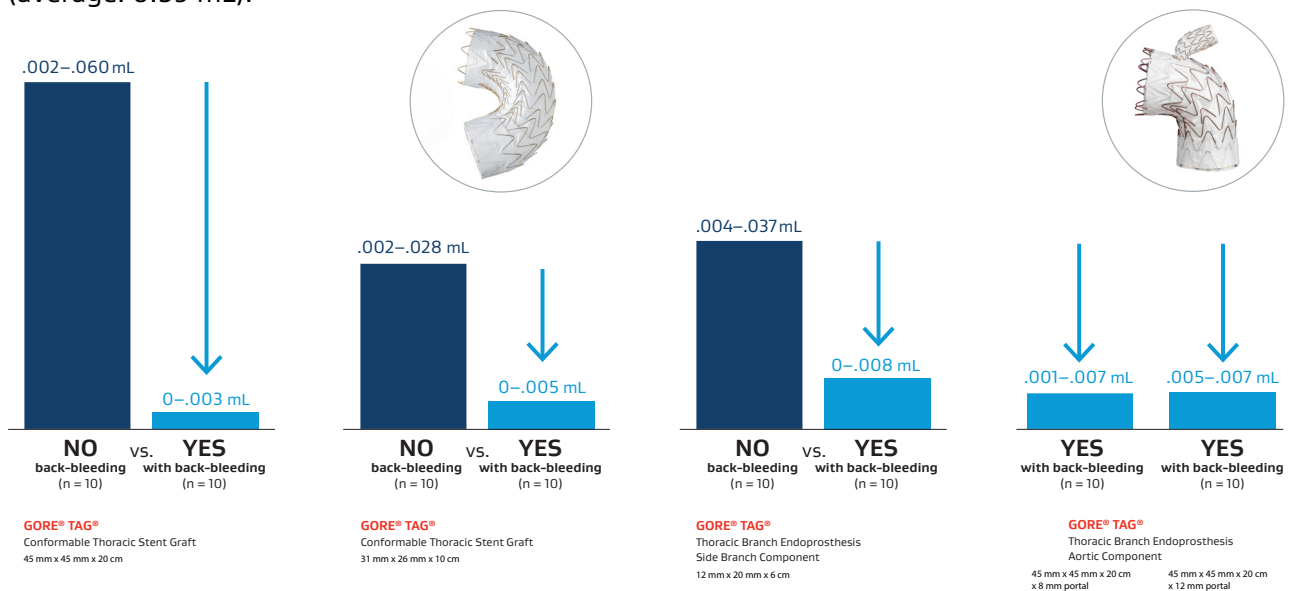
Flex Introducer Sheath  
+ back-bleeding technique

.002 mL

Across all devices and configurations, recommended use reduced average air volume to minimal levels in testing.

In literature, estimates ranged from 0.10 - 1.02 mL (average: 0.59 mL).<sup>1,2</sup>

## Volume of air released



\* Data on file 2023; W. L. Gore & Associates, Inc; Flagstaff, AZ.

Bench-top evaluations are intended to demonstrate relative physical characteristics and may not correlate to clinical results. The test method here was designed to simulate physiological conditions as closely as possible, with the intent to capture relevant data that would demonstrate likely clinical results.

See the evidence in this step-by-step overview.



## Setting the bar in TEVAR

With air volume in question, we're committed to providing answers. When introduced as intended, Gore thoracic stent grafts release minimal levels of air.

Through distinctive designs we can make a measurable difference—advancing TEVAR care by minimizing air.



## References

1. Rohlfes F, Tsilimparis N, Saleptsis V, Diener H, Debus ES, Kölbel T. Air embolism during TEVAR: carbon dioxide flushing decreases the amount of gas released from thoracic stent-grafts during deployment. *Journal of Endovascular Therapy* 2017;24(1):84-88.
2. Inci K, Koutouzi G, Chernoray V, Jeppsson A, Nilsson H, Falkenberg M. Air bubbles are released by thoracic endograft deployment: an in vitro experimental study. *SAGE Open Medicine*. In press.
3. GORE® DRYSEAL Flex Introducer Sheath [Instructions for Use]. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2021. MD179444.
4. GORE® TAG® Conformable Thoracic Stent Graft [Instructions for Use]. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2021. MD164940.
5. GORE® TAG® Thoracic Branch Endoprosthesis (TBE) [Instructions for Use]. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2022. MD184153.

 Consult Instructions  
for Use  
[eifu.goremedical.com](http://eifu.goremedical.com)

**GORE® DRYSEAL Flex Introducer Sheath. INDICATIONS FOR USE IN THE U.S.:** The GORE® DrySeal Flex Introducer Sheath is intended to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions.

**CONTRAINDICATIONS:** There are no known contraindications for this device. Refer to *Instructions for Use* at [eifu.goremedical.com](http://eifu.goremedical.com) for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. Rx Only

**GORE® TAG® Conformable Thoracic Stent Graft. 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,  $\geq 20$  mm non-aneurysmal aorta proximal and distal to the lesion; Type B dissections in patients who have appropriate anatomy, including: adequate iliac/femoral access,  $\geq 20$  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](http://eifu.goremedical.com) for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. Rx Only

**GORE® TAG® Thoracic Branch Endoprosthesis (TBE). INDICATIONS FOR USE IN THE U.S.:** The GORE® TAG® Thoracic Branch Endoprosthesis is indicated for endovascular repair of lesions of the descending thoracic aorta, while maintaining flow into the left subclavian artery, in patients who have: Adequate iliac/femoral access; Proximal Aortic Landing Zones: For Isolated Lesion Patients: Proximal landing zone cannot be aneurysmal, dissected, heavily calcified or heavily thrombosed; For Dissection Patients: Primary entry tear must be distal to the left subclavian artery and the proximal extent of the landing zone must not be dissected; Aortic inner diameter range 16-42 mm; Proximal segment length (length from distal edge of left subclavian artery to mid left common carotid ostium) of at least 2.0-4.0 cm, depending on Aortic Component selection; Proximal covered length (measured from distal edge of left subclavian artery to distal edge of left common carotid artery ostium) of at least 15-36 mm, depending on Aortic Component selection; For patients with prior ascending aorta or aortic arch repair with surgical graft: at least 2 cm landing zone proximal to the distal anastomosis; Left Subclavian Landing Zone: Landing zone cannot be aneurysmal, dissected, heavily thrombosed and severely tortuous (180 degree turn within the treated length); Left subclavian artery inner diameter of 6-18 mm, depending on Side Branch Portal diameter selected; Left subclavian artery minimum length of 2.5-3.0 cm, depending on Side Branch Portal diameter selected. Distal Landing Zone (Isolated Lesion Patients only): Outer curve length must be  $\geq 2$  cm proximal to celiac artery; Aortic inner diameter range 16-42 mm; Non aneurysmal, dissected, heavily calcified or heavily thrombosed landing zone; Native Aorta or previously placed GORE® TAG® Conformable Thoracic Stent Graft. **CONTRAINDICATIONS:** The GORE® TAG® Thoracic Branch Endoprosthesis is contraindicated in: Patients with known sensitivities or allergies to the device materials [ePTFE (polytetrafluoroethylene), FEP (fluoroethylpropylene), Nitinol (nickel, titanium), Gold, SB Component only - Heparin (CBAS® Heparin Surface)]; Patients who have a condition that threatens to infect the graft; Patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II. Refer to *Instructions for Use* at [eifu.goremedical.com](http://eifu.goremedical.com) for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. Rx Only

Products listed may not be available in all markets.

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