#### **GORE® TAG®** Conformable Thoracic Stent Graft

# U.S. IDE Clinical Trials

Five-year data across etiologies

GET STARTED



Together, improving life

## Longterm results you can trust

U.S. IDE Clinical Trials: Five year data across ALL etiologies

ZERO

Migrations<sup>\*</sup> Fractures Compressions

Type III endoleaks Frosions

100% Procedural survival

Low rates of

Endoleaks requiring reintervention **Device-related** reinterventions



#### View trials







Thoracic Aortic Aneurysm »

\* Migrations are reported as those requiring reintervention.

Acute Complicated Type B Dissection »

## Acute Complicated Type B Dissection

Long-term outcomes in a prospective multicenter trial



U.S. IDE Clinical Trial



### 5-year data

**91**%

of patients exhibited an increase in true lumen diameter<sup>\*</sup>



complete thrombosis observed

# 96%

of patients did not experience late deaths attributable to aortic pathology after 30 days<sup>†</sup>

ZERO

Migrations<sup>‡</sup> Type III endoleaks Erosions Compressions

#### Fractures

Conversions to open surgical repair

View trials







Thoracic Aortic Aneurysm »

\* At five years.

+ 8% 30-day mortality rate.

 Migrations are reported as those requiring reintervention. Acute Complicated Type B Dissection »

## **Traumatic Aortic Transection**

Long-term outcomes in a prospective multicenter trial







#### 5-year data

100%

Freedom from aortic-related mortality

ZERO

99%

did not experience a device/procedurerelated stroke<sup>\*</sup> 95%

Freedom from all-cause mortality at 30 days 89%

Freedom from all-cause mortality at 5 years

Reinterventions Endoleaks<sup>†</sup> Ruptures<sup>†</sup> Fractures Lumen obstructions Thrombus related events Conversions to open surgical repair

Compressions Migrations<sup>§</sup> Erosions

View trials







Thoracic Aortic Aneurysm »



As published in: The Annals of Thoracic Surgery (2021).

\* n = 1 post procedural, ischemic, stroke.

+ No serious endoleaks reported. Two minor endoleaks were reported which resolved without reintervention.

‡ Post procedure.

§ Requiring reinterventions.

Acute Complicated Type B Dissection »

## Thoracic Aortic Aneurysm

Long-term outcomes in a prospective multicenter trial





### 5-year data

88%

Freedom from device-related reinterventions

ZERO

82%

Stable aneurysm sac diameters

Fractures

Compressions

Type III endoleaks

Migrations\*

93%

Freedom from aneurysm-related mortality

Conversions to open surgical repair Erosions

Low rates of

Reintervention<sup>+</sup> Proximal leaks<sup>‡</sup> Rupture<sup>§</sup>



As published in: Journal of Vascular Surgery (2021).

- \* With clinical sequelae resulting in reinterventions through five-years.
- † Device related reinterventions: 7.6% (n=5) four of the five were treatments for endoleaks and one for a distal thoracic pseudoaneurysm.
- $\ddagger$  Type la was rare n = 1.

§ 1.5% n = 1.





Acute Complicated Type B Dissection »

View trials

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Thoracic Aortic Aneurysm »



## Contact a Gore representative to learn more. tevar.tv

#### References

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Consult Instructions for Use eifu.goremedical.com

**INDICATIONS FOR USE IN THE U.S.:** The GORE<sup>®</sup> TAG<sup>®</sup> 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;  $\ge$  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;  $\ge$  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<sup>®</sup> TAG<sup>®</sup> Conformable Thoracic Stent Graft is contraindicated in: Patients with known sensitivities or allergies to the device materials (Table 1); 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.  $R_{X \text{ only}}$ 

**INDICATIONS FOR USE UNDER CE MARK:** The GORE® TAG® Conformable Thoracic Stent Graft is indicated for endovascular repair of the descending thoracic aorta. **CONTRAINDICATIONS:** Patients with known sensitivities or allergies to the device materials; patients with a systemic infection who may be at increased risk of endovascular graft infection. 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. R<sub>X Only</sub>

Products listed may not be available in all markets.

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