GORE® EXCLUDER®
Conformable AAA Endoprosthesis
with ACTIVE CONTROL System

PRODUCT OVERVIEW
North America

Together, improving life

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GORE® EXCLUDER® Device Family

The GORE® EXCLUDER® Conformable AAA Endoprosthesis with ACTIVE CONTROL System

- A conformable stent graft and innovative delivery system, designed to maximize seal.
- The only EVAR device with angulation control.
- The only on-label EVAR solution in highly angulated aortic necks up to 90° and neck length of 10 mm.
- Expands the treatment range with a device for small (16-18 mm) aortic necks and highly angulated aortic necks.
- Innovation built on a legacy you can trust.

The GORE® ACTIVE CONTROL System

More control when you need it most

Adapts to challenging anatomy

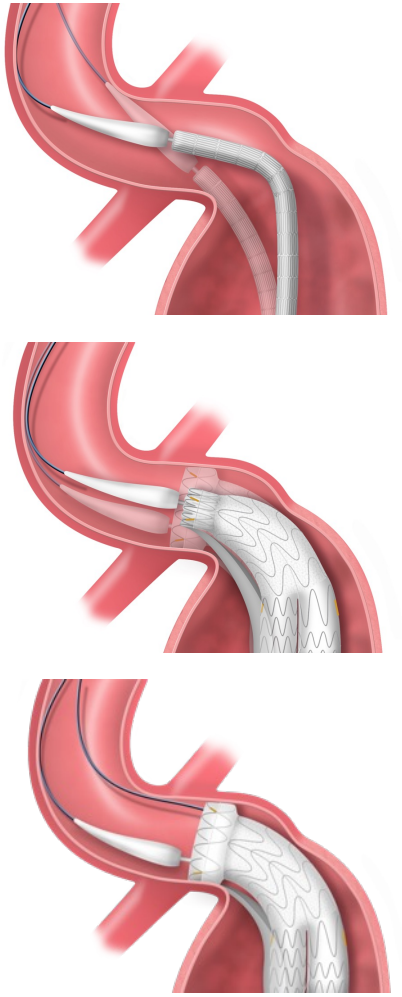
- Nesting stent rows help achieve optimal aortic wall apposition.
- Individual stent rings adapt closely to the anatomy to maximize seal.

Improves ease of repositioning

- Reconstrainable proximal anchors for refined positioning.
- Initial trunk deployment at ~70% diameter.

Aids orthogonal placement

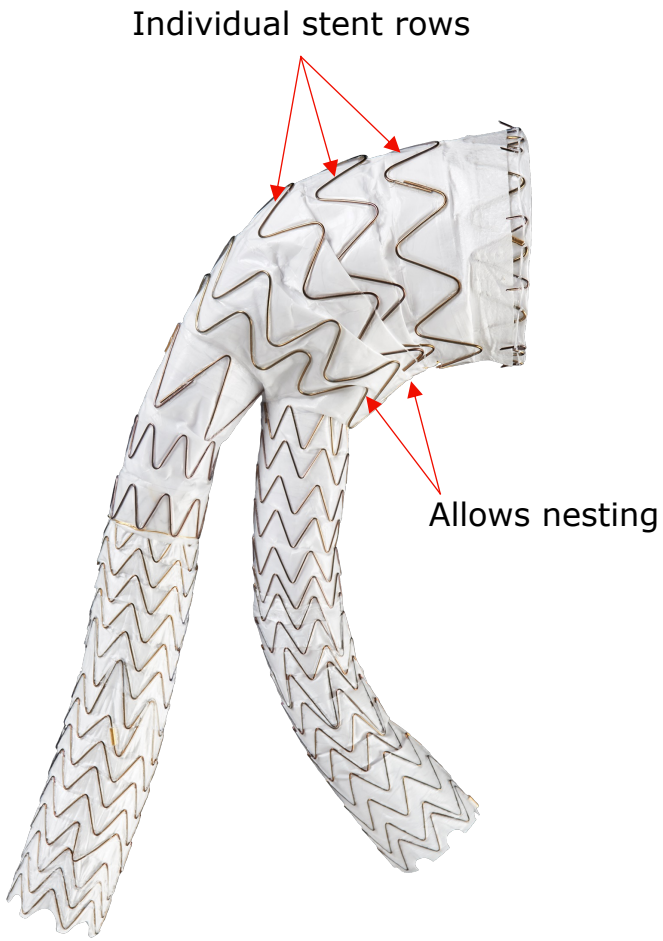
- Optional angulation control at 2 stages.
- Helps optimize seal in highly angulated necks.



Enhanced conformability

To achieve the conformability required for challenging aortic necks, the technology and proven results of the GORE® TAG® Conformable Thoracic Stent Graft platform were leveraged to inform the new EVAR stent graft design:

- Individual stent rows that allow for flexibility.
- ePTFE and FEP films that support both conformability and durability.



Enhanced device positioning

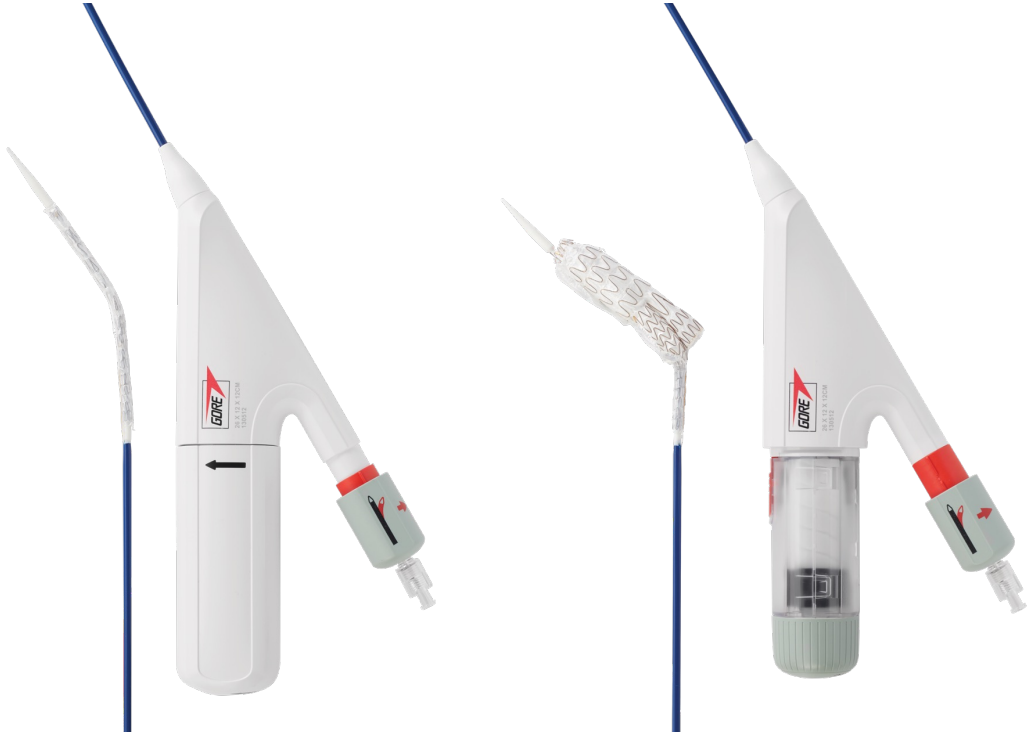
To provide more control and ease of repositioning in challenging anatomy, delivery system features include:

- Secondary sleeve, which constrains trunk body to ~70% diameter through the first stage of deployment
- Reconstrainable proximal anchors

Enhanced degree of control

Angulation control enables orthogonal delivery in challenging anatomy.

- Angulation wire within the delivery catheter is designed to provide control and precision in device positioning.
- Available when trunk is fully constrained or partially deployed.



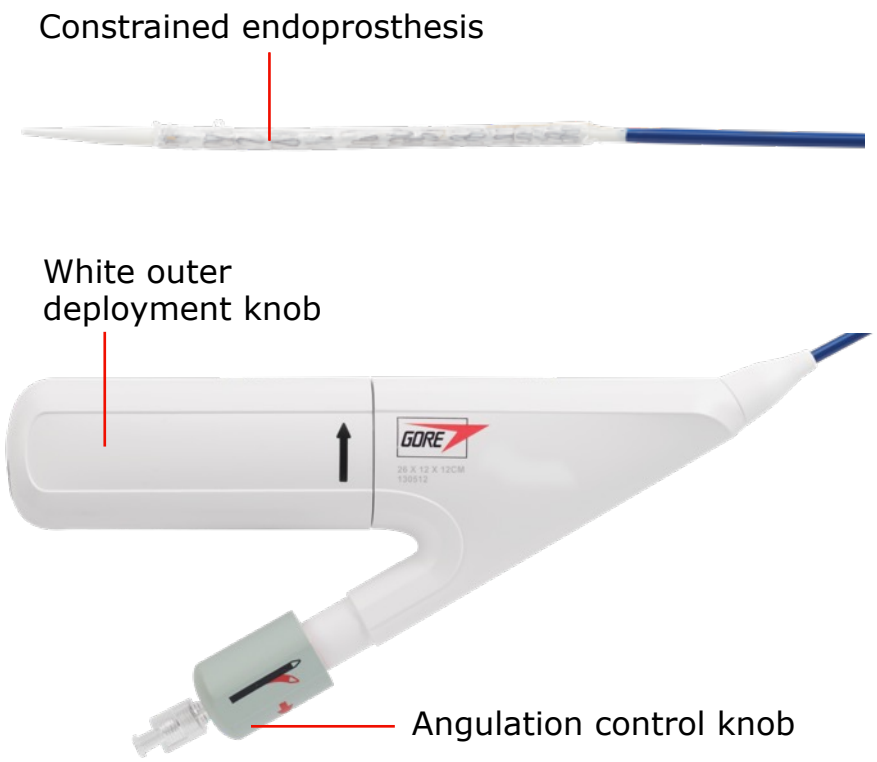
The degree of angulation shown is for demonstration only. The amount of device angle achieved in clinical use is dependent on several factors including: Guidewire, patient anatomy, device size, etc. The GORE® EXCLUDER® Conformable Device is indicated to treat patients with aortic neck angles up to 90°.

Product specifications – Trunk-Ipsilateral Leg component

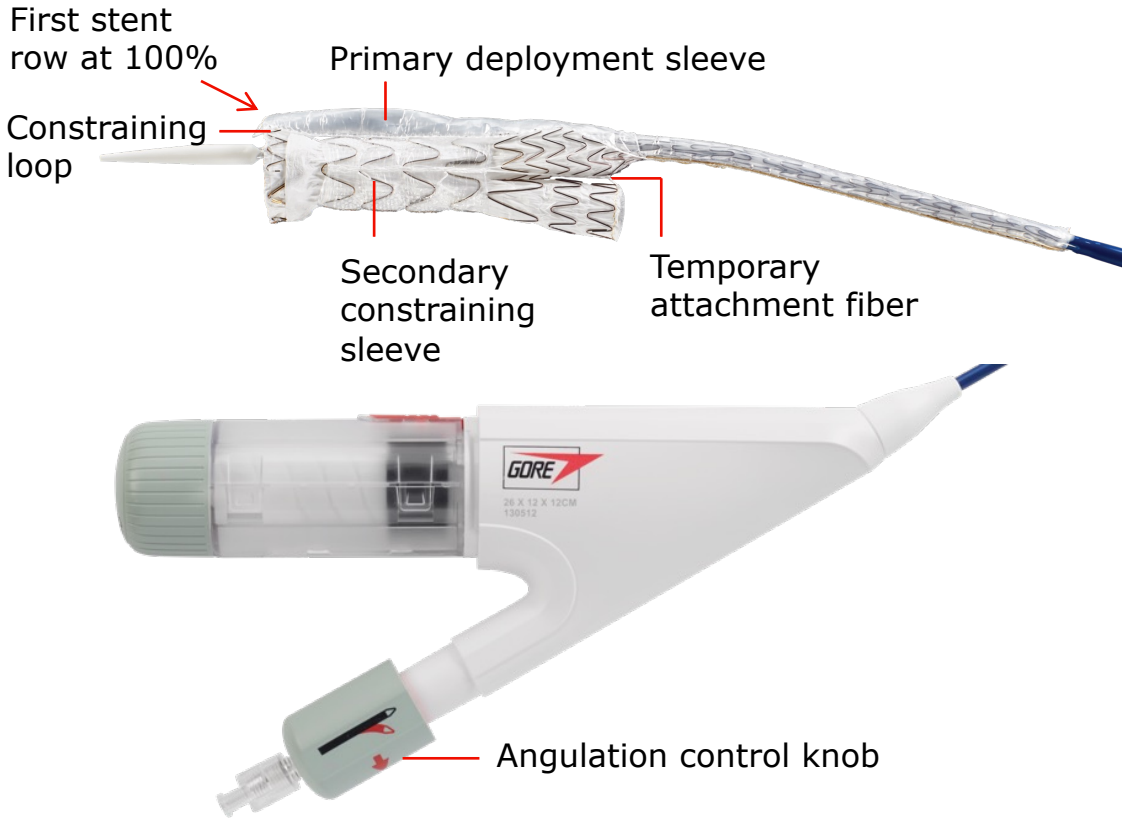
Catalogue number	Intended aortic vessel diameter (mm)	Aortic endoprosthesis diameter (mm)	Intended iliac vessel diameter (mm)	Iliac endoprosthesis diameter (mm)	Overall device length (cm)	Recommended introducer sheath (Fr)
CXT201212	16-18	20	10-11	12	12	15
CXT201412	16-18	20	12-13.5	14.5	12	15
CXT231412	19-21	23	12-13.5	14.5	12	15
CXT261412	22-23	26	12-13.5	14.5	12	16
CXT281412	24-26	28.5	12-13.5	14.5	12	16
CXT321414	27-29	32	12-13.5	14.5	14	18
CXT361414	30-32	36	12-13.5	14.5	14	18

Trunk-Ipsilateral Leg

Undeployed handle and device

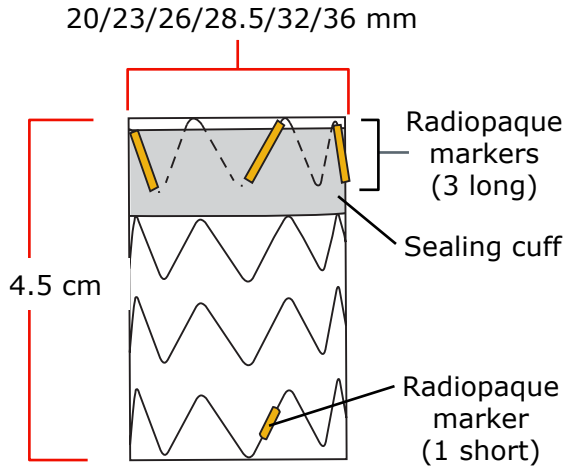


Exposed reconstraining mechanism, partially deployed endoprosthesis

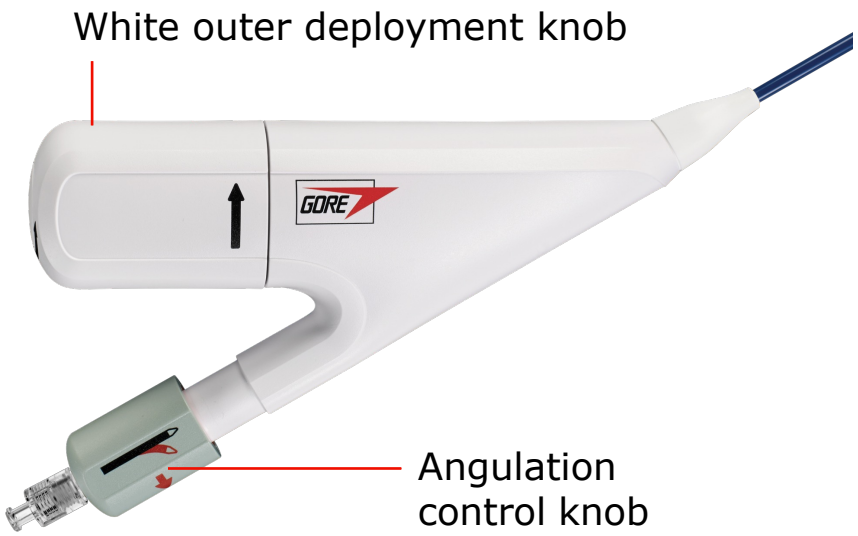


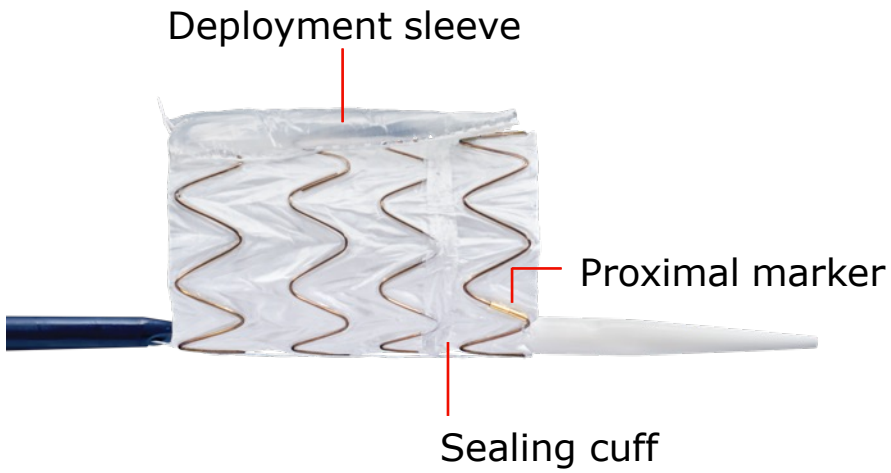
Product specifications – Aortic Extender

Catalogue number	Intended aortic diameter (mm)	Endoprosthesis diameter (mm)	Endoprosthesis length (cm)	Recommended sheath size (Fr)
CXA200005	16-18	20	4.5	15
CXA230005	19-21	23	4.5	15
CXA260005	22-23	26	4.5	15
CXA280005	24-26	28.5	4.5	16
CXA320005	27-29	32	4.5	18
CXA360005	30-32	36	4.5	18



Aortic Extender





GORE® ACTIVE CONTROL System – Angulation control on Aortic Extenders

Angulation wire not advanced

Angulation wire halfway advanced

Angulation wire 3/4 advanced

Angulation wire fully advanced

The degree of angulation shown is for demonstration only. The amount of device angle achieved in clinical use is dependent on several factors including: Guidewire, patient anatomy, device size, etc. The GORE® EXCLUDER® Conformable Device is indicated to treat patients with aortic neck angles up to 90°.

Multi-component design

GORE® EXCLUDER®
AAA Endoprosthesis
featuring C3® Delivery System

- Trunk-Ipsilateral Leg
- Aortic Extender

Contralateral Leg
Iliac Extender

GORE® EXCLUDER®
Conformable AAA Endoprosthesis
with ACTIVE CONTROL System

- Trunk-Ipsilateral Leg
- Aortic Extender

Product specifications – Trunk-Ipsilateral Leg comparison

GORE® EXCLUDER® AAA Endoprosthesis featuring C3® Delivery System

- Paired anchors
- Continuous sinusoidal design
- Connecting wire
- Aortic treatment range: 19-32 mm
- Indicated for neck angles ≤ 60° and ≥ 15 mm lengths
- 4/5/6 cm trunk body

Connecting wire at bifurcation

Temporary attachment fiber at contralateral gate

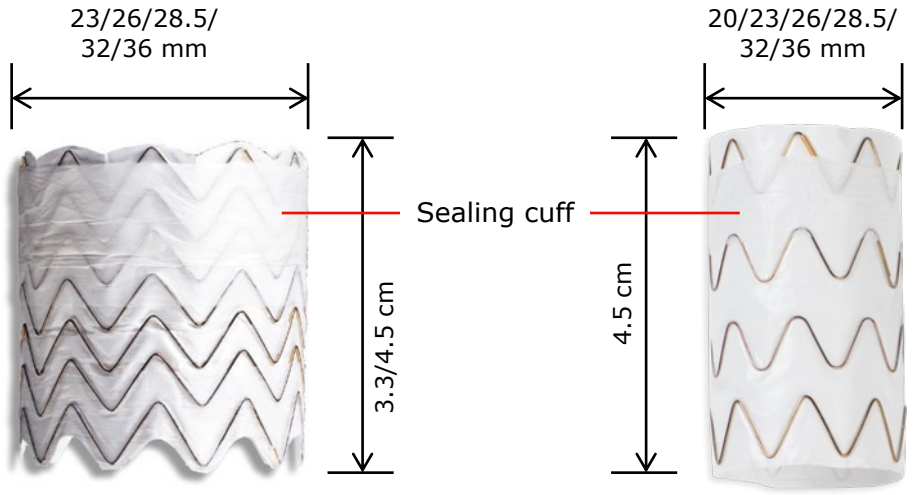
GORE® EXCLUDER® Conformable AAA Endoprosthesis with ACTIVE CONTROL System

- Individual anchors
- Individual stent rows
- Temporary attachment fiber
- Aortic treatment range: 16-32 mm
- Indicated for neck angles ≤ 90° and ≥ 10 mm lengths
- 5.5/6.5 cm trunk body

Aortic Extender comparison

GORE® EXCLUDER®
AAA Endoprosthesis
featuring C3® Delivery System

- Continuous sinusoidal design
- 3.3/4.5 cm

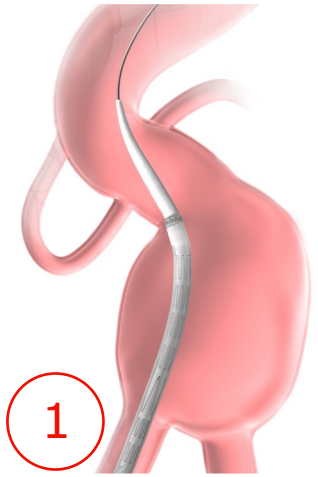


GORE® EXCLUDER®
Conformable AAA Endoprosthesis
with ACTIVE CONTROL System

- Individual stent rows
- 4.5 cm

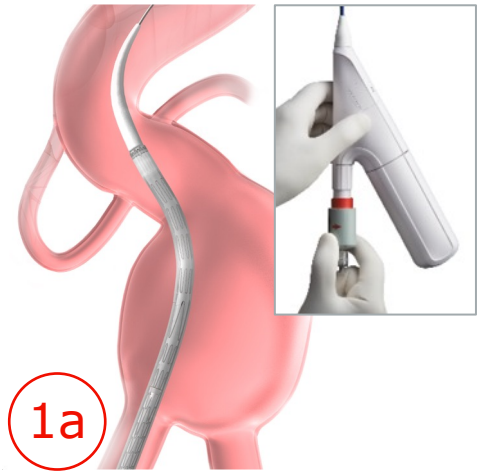
Deployment sequence

Trunk-Ipsilateral Leg Endoprosthesis



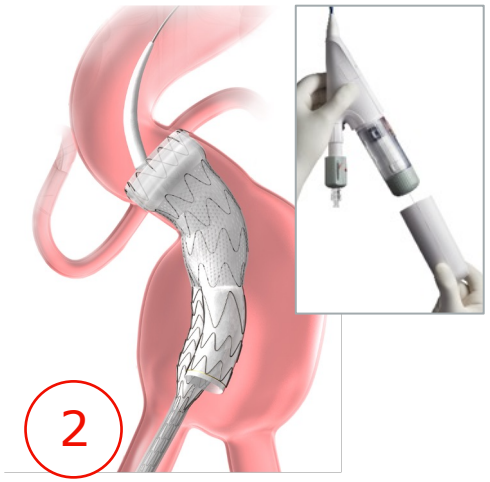
Constrained Trunk-Ipsilateral Leg endoprosthesis

Advance constrained Trunk-Ipsilateral Leg to desired location.



Optional step to optimize positioning: Angulation control prior to stage 1 Trunk-Ipsilateral Leg deployment.

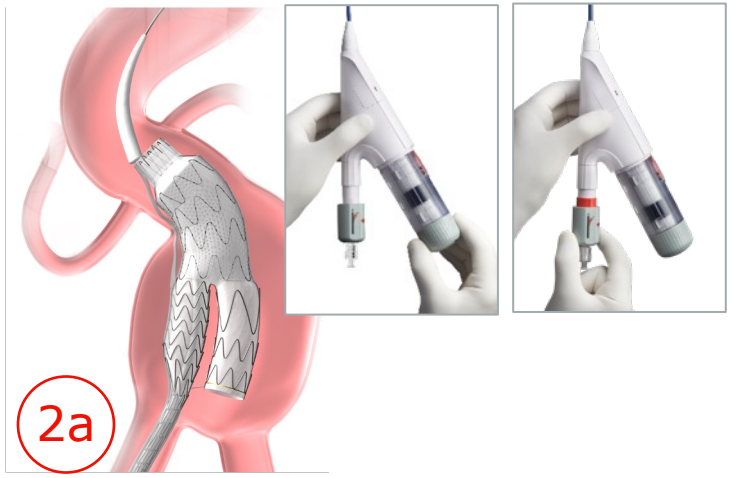
Rotate gray angulation control knob clockwise to advance angulation wire.



Partially deployed trunk

Deployment stage 1: Rotate and pull white outer deployment knob.

Result: Deployment of Trunk-Ipsilateral Leg to level of contralateral gate. Proximal stent row is full diameter. Trunk body is ~70% of full diameter. Ipsilateral Leg is fully constrained.



Repositioning and use of angulation control for optimizing position.

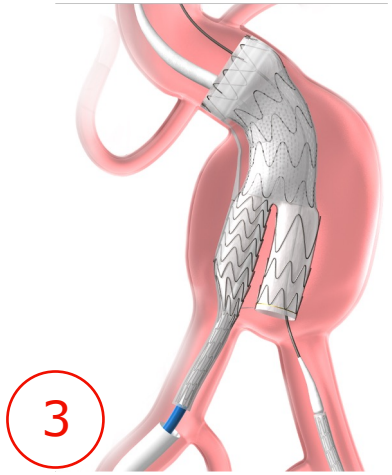
Repositioning only: Rotate gray constraining dial to constrain proximal end of trunk.

Use of angulation control: Rotate gray constraining dial to constrain proximal end of trunk. Rotate gray angulation control knob to advance angulation wire.

Warning: Do not rotate the trunk or Aortic Extender delivery catheter when the angulation wire is advanced. Device and/or catheter damage may occur.

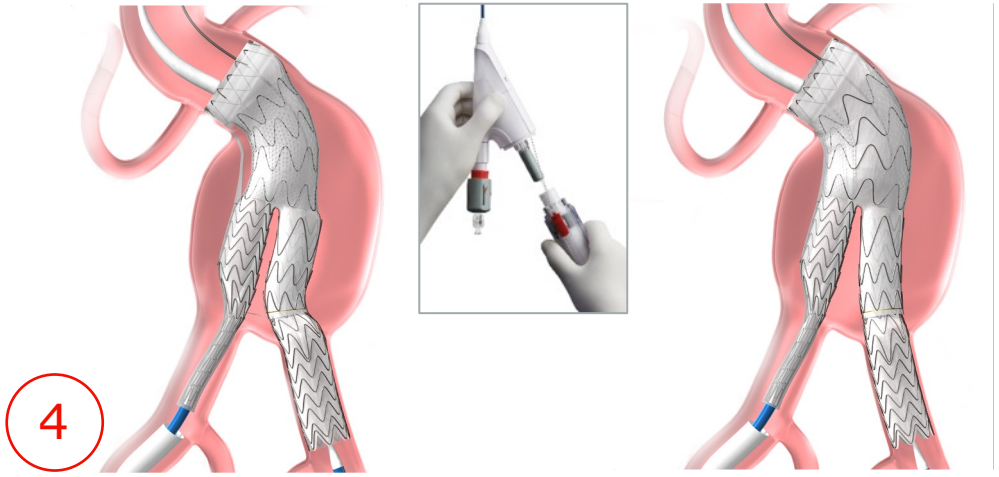
Deployment sequence (continued)

Trunk-Ipsilateral Leg Endoprosthesis



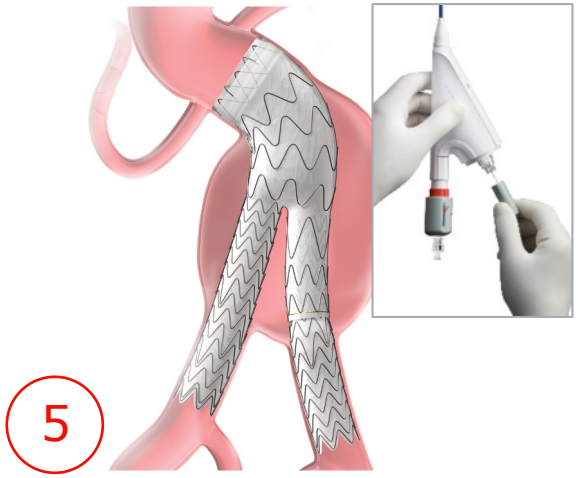
Partially deployed trunk: Contralateral Leg deployment

Cannulate contralateral gate, advance introducer sheath into gate, then advance and deploy Contralateral Leg into gate.



Constraining mechanism removal and secondary sleeve deployment

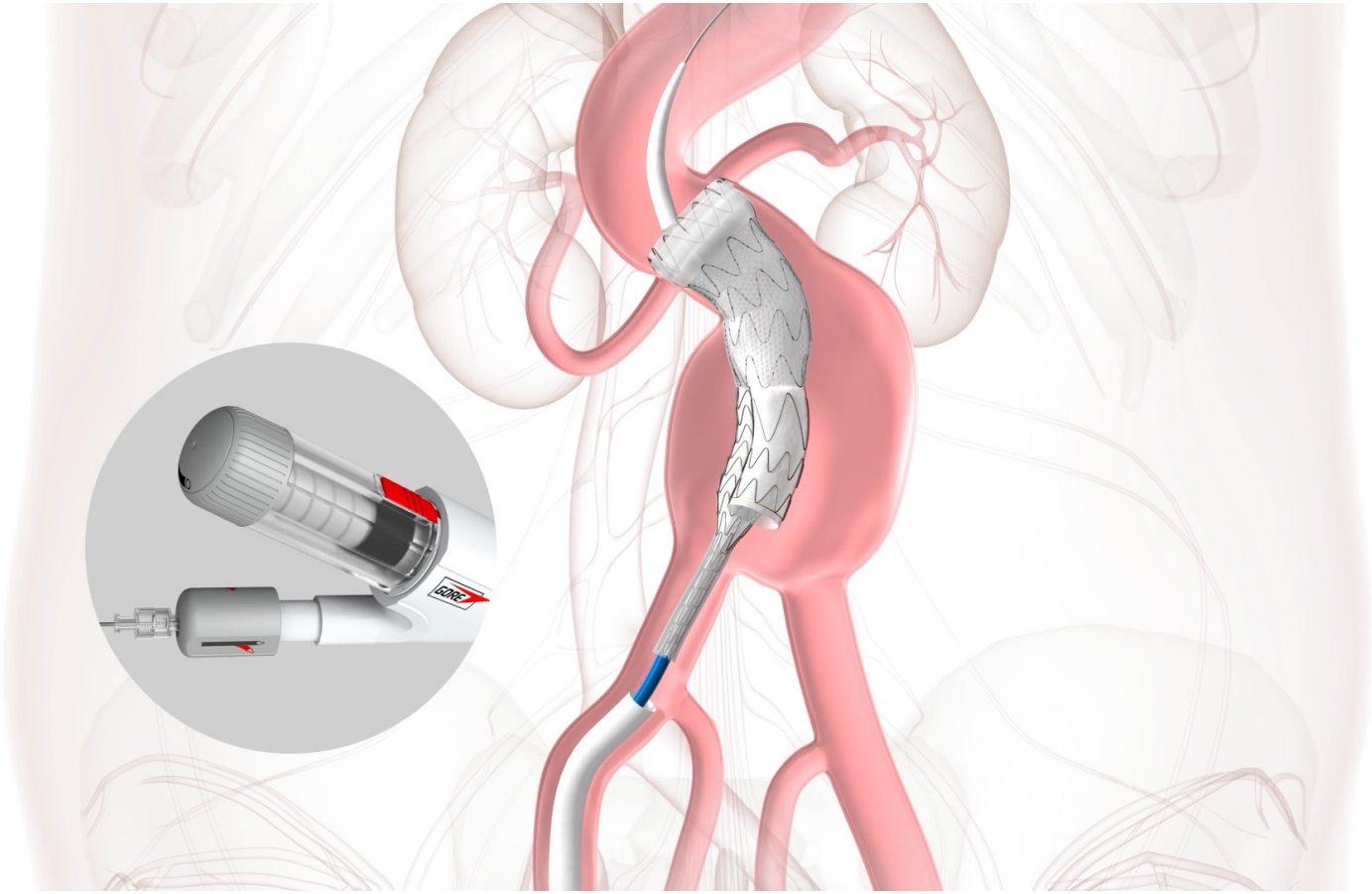
Transition stage: Pull back and hold red safety tab, rotate transparent knob and pull back in continuous motion.
Result:
– Constraining loop, lock pin and secondary sleeve deployment line removal
– Trunk body deploys to full diameter
– Contralateral gate detaches from Trunk-Ipsilateral Leg



Fully deployed trunk: Ipsilateral Leg deployment

Deployment stage 2: Rotate and pull gray deployment knob.
Result: Deployment of Ipsilateral Leg.

Animation



U.S. Pivotal Trial overview

Study design: Prospective, non-randomized study with 2 arms.

- Short neck sub-study:
  80 patients through 1-year follow-up.
  - 5-year follow-up is planned.
- High neck angulation sub-study:
  95 patients through 1-year follow-up.
  - 5-year follow-up is planned.
- National principal investigator:
  Robert Rhee, M.D., Maimonides Medical Center

Assessment of the GORE® EXCLUDER® Conformable AAA Endoprosthesis in the Treatment of Abdominal Aortic Aneurysms. NLM Identifier: NCT02489539. Published July 3, 2015. Updated January 26, 2023. Accessed March 26, 2024. https://clinicaltrials.gov/ct2/show/NCT02489539

Patients with neck angles ≤ 60° outcomes: 1-year follow-up*,†

100%

Technical success

Freedom from device-related serious adverse events

Patency

ZERO REPORTED

Type I and III endoleaks

Migrations

Ruptures

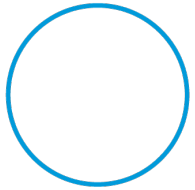
Conversions to open repair

Stent fractures

Limb occlusions

Change in AAA diameter at 1 year‡

27 (36.5%)
≥ 5 mm decrease



46 (62.2%)
NO CHANGE

1 (1.4%)
≥ 5 mm increase

* For these data points, 79 patients were eligible for 1-year outcome analysis.

† One patient with aneurysm increase was found to have Type II endoleak.

‡ Change in AAA diameter as identified from baseline imaging taken closest to post-operative day 30 and no later than post-operative day 90.

Patients with neck angles between 60° and 90° outcomes: 1-year follow-up*

97.9%
Technical success

98.9%
Freedom from device-related serious adverse events

ZERO REPORTED
- Type III endoleaks
- Migrations
- Ruptures
- Stent fractures

4
Type I endoleaks†

1
Conversion to open repair‡

1
Device occlusion§

Change in AAA diameter‖

↓ **26** (34.7%)
≥ 5 mm decrease

○ **48** (64.0%)
NO CHANGE

↑ **1** (1.3%)
≥ 5 mm increase

* For these data points, 91 patients were eligible for 1-year outcome analysis.
† Core Lab identified endoleaks. 3 patients with Type 1 endoleaks were resolved at 1-year follow-up, 1 patient died of unrelated causes before 1-year follow-up.
‡ Subject underwent open surgical repair without explant of the EXCLUDER® Conformable Device. It was determined the event was unrelated to the device or the procedure.
§ Same patient that had to convert to open repair.
‖ Change in AAA diameter as identified from baseline imaging taken closest to post-operative day 30 and no later than post-operative day 90.

The GORE® EXCLUDER® Device family

GORE® EXCLUDER® Conformable AAA Endoprosthesis with ACTIVE CONTROL System

- Innovation built on a legacy you can trust.
- The only EVAR device with angulation control.

GORE® EXCLUDER® AAA Endoprosthesis featuring C3® Delivery System

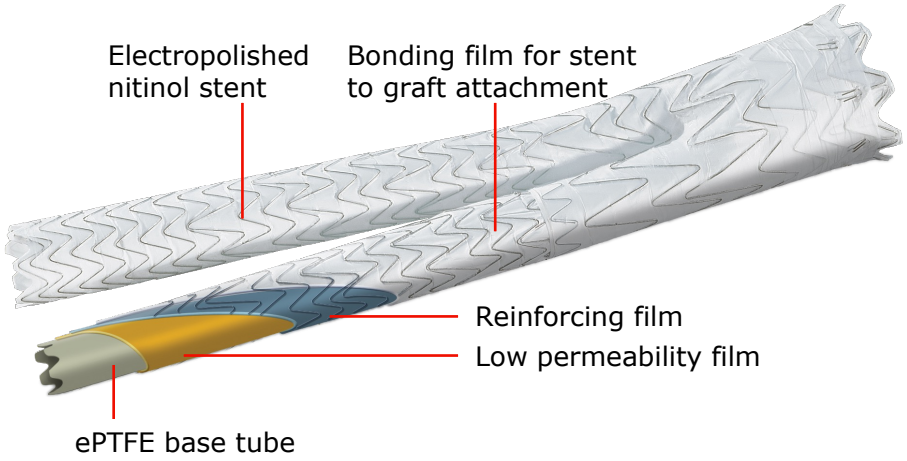
- An established choice for standard AAA treatment.
- Proven to be safe, effective and durable.

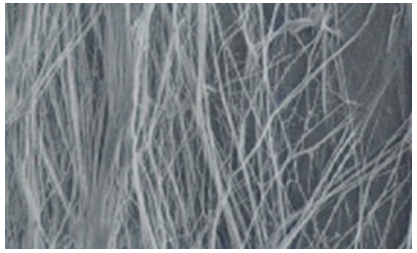
GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE)

- The first FDA-approved, off-the-shelf iliac branch solution.
- The broadest treatment range in iliac preservation.[1]

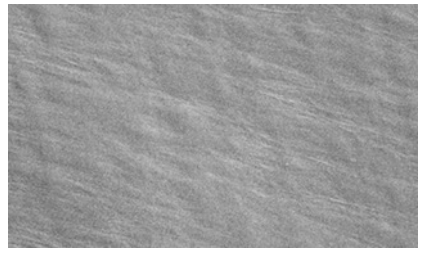
The GORE® EXCLUDER® Device family features Gore core technology and low permeability design

- Expanded polytetrafluoroethylene (ePTFE)
- Fluorinated ethylene propylene (FEP)
- Nitinol
  - Active fixation (nitinol anchors)
  - Self-expanding nitinol stent along entire exterior for full support
- Sutureless construction





SEM of reinforcing film
1000x magnification



SEM of low permeability film
1000x magnification

A legacy of innovation

The GORE® EXCLUDER® Device family of products are trusted by physicians to deliver durable patient outcomes.

1997 — The original GORE® EXCLUDER® AAA Endoprosthesis received CE Mark

2002 — FDA approved the GORE® EXCLUDER® AAA Endoprosthesis

2004 — Low permeability design introduced

2009 — New 31 mm trunk received FDA approval

2010 — New delivery system received CE Mark and FDA approval

2011 — New 23 and 27 mm contralateral limbs

2012 — New 35 mm trunk introduced and profile reduced on 31 mm trunk and large contralateral limbs

2013 — Iliac branch device received CE Mark

2014 — Profile reduced on 23 and 26 mm trunks and aortic extenders

2016 — Iliac branch device received FDA approval

2018 — Introduced the only EVAR device to feature angulation control in Europe

2020 — The only EVAR device to feature angulation control received FDA approval

2022 — 25 years is only the beginning

525,000
Patients treated worldwide*

FIRST
EVAR device with the option to reconstrain

FIRST
FDA-approved iliac branch device

ONLY
EVAR device to feature angulation control

MOST STUDIED
EVAR device†

* Based on the number of Trunk-Ipsilateral Legs distributed for GORE® EXCLUDER® Device family.
† Based on company-sponsored trials and registries shown on clinicaltrials.gov for currently available stent grafts.

References

1. Chaikof EL, Dalman RL, Eskandari MK, *et al.* The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm. *Journal of Vascular Surgery* 2018;67(1):2-77.e2.

Consult Instructions for Use
eifu.goremedical.com

GORE® EXCLUDER® AAA Endoprosthesis

INDICATIONS FOR USE: Trunk-Ipsilateral Leg and Contralateral Leg Endoprosthesis. The GORE® EXCLUDER® AAA Endoprosthesis is intended to exclude the aneurysm from the blood circulation in patients diagnosed with infrarenal abdominal aortic aneurysm (AAA) disease and who have appropriate anatomy as described below: Adequate iliac/femoral access; Infrarenal aortic neck treatment diameter range of 19–32 mm and a minimum aortic neck length of 15 mm; Proximal aortic neck angulation ≤ 60°; Iliac artery treatment diameter range of 8–25 mm and iliac distal vessel seal zone length of at least 10 mm. **Aortic Extender and Iliac Extender Endoprosthesis.** The Aortic and Iliac Extender Endoprostheses are intended to be used after deployment of the GORE® EXCLUDER® AAA Endoprosthesis. These extensions are intended to be used when additional length and/or sealing for aneurysmal exclusion is desired. **CONTRAINDICATIONS:** The GORE® EXCLUDER® AAA Endoprosthesis is contraindicated in: 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. ℞ Only

GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE)

INDICATIONS FOR USE IN THE U.S.: Iliac Branch and Internal Iliac Components. The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) is intended to be used with the GORE® EXCLUDER®AAA Endoprosthesis or the GORE® EXCLUDER® Conformable Endoprosthesis to isolate the common iliac artery from systemic blood flow and preserve blood flow in the external iliac and internal iliac arteries in patients with a common iliac or aortoiliac aneurysm, who have appropriate anatomy, including: Adequate iliac/femoral access; Minimum common iliac diameter of 17 mm at the proximal implantation zone of the IBE; External Iliac artery treatment diameter range of 6.5–25 mm and seal zone length of at least 10 mm; Internal iliac artery treatment diameter range of 6.5–13.5 mm and seal zone length of at least 10 mm; Adequate length from the lowest major renal artery to the internal iliac artery to accommodate the total endoprosthesis length, calculated by adding the minimum lengths of required components, taking into account appropriate overlaps between components. **GORE® EXCLUDER® Components used in conjunction with GORE® EXCLUDER® Iliac Branch Endoprosthesis: Trunk-Ipsilateral Leg Component.** The Trunk-Ipsilateral Leg is intended to provide proximal seal and fixation for the endovascular repair of the aneurysm. For more information on the Trunk-Ipsilateral Leg Component indications for use and deployment, see the GORE® EXCLUDER® AAA Endoprosthesis or the GORE® EXCLUDER® Conformable Endoprosthesis *Instructions for Use*. **Contralateral Leg Endoprosthesis Component.** The Contralateral Leg Endoprosthesis is intended to bridge the GORE® EXCLUDER® Device Trunk-Ipsilateral Component to the GORE® EXCLUDER® Iliac Branch Endoprosthesis following deployment of the GORE® EXCLUDER® Iliac Branch Endoprosthesis. Additionally, the Contralateral Leg Endoprosthesis is intended to be used for distal extension of the Iliac Branch Component in the external iliac artery. The Iliac Branch Component can treat external iliac artery diameters up to 13.5 mm. This ability to extend the Iliac Branch Component distally with any Contralateral Leg Endoprosthesis expands the external iliac artery treatment range up to 25 mm. For more information on the Trunk-Ipsilateral Leg and Contralateral Leg Endoprosthesis Component indications for use and deployment, see the GORE® EXCLUDER® AAA Endoprosthesis *Instructions for Use*. **Aortic Extender and Iliac Extender Components.** The Aortic and Iliac Extender Components can be used after deployment of the GORE® EXCLUDER® Iliac Branch and GORE® EXCLUDER® AAA Endoprostheses or the GORE® EXCLUDER® Conformable Endoprosthesis. These extensions are used when additional length and/or sealing for aneurysmal exclusion is desired. For more information on Aortic Extender and Iliac Extender indications for use and deployment, see the GORE® EXCLUDER® AAA Endoprosthesis or the GORE® EXCLUDER® Conformable Endoprosthesis *Instructions for Use*.
CONTRAINDICATIONS: The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) is contraindicated in: patients with known sensitivities or allergies to the device materials. All components of the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE), the GORE® EXCLUDER® AAA Endoprosthesis and GORE® EXCLUDER® Conformable Endoprosthesis contain ePTFE, FEP, nitinol (nickel-titanium alloy) and gold. 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. ℞ Only

INDICATIONS FOR USE IN CANADA: The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) is intended to isolate the common iliac artery from systemic blood flow and preserve blood flow in the external iliac and internal iliac arteries in patients with a common iliac or aortoiliac aneurysm, who have appropriate anatomy, including: Adequate iliac/femoral access, Minimum common iliac diameter of 17 mm at the proximal implantation zone of the IBE, External Iliac artery treatment diameter range of 6.5 – 25 mm and seal zone length of at least 10 mm, Internal iliac artery treatment diameter range of 6.5 – 13.5 mm and seal zone length of at least 10 mm. Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

Together, improving life

Consult Instructions for Use
eifu.goremedical.com

GORE® EXCLUDER® Conformable AAA Endoprosthesis

INDICATIONS FOR USE: The GORE® EXCLUDER® Conformable AAA Endoprosthesis is intended to exclude the aneurysm from the blood circulation in patients diagnosed with infrarenal abdominal aortic aneurysm (AAA) disease and who have appropriate anatomy as described below: Adequate iliac/femoral access; Infrarenal aortic neck treatment diameter range of 16-32 mm and a minimum aortic neck length of 10 mm; Proximal aortic neck angulation ≤ 90°; Iliac artery treatment diameter range of 8-25 mm and iliac distal vessel seal zone length of at least 10 mm. **Aortic Extender Endoprosthesis and Iliac Extender Endoprosthesis Components** are intended to be used after deployment of the GORE® EXCLUDER® Conformable AAA Endoprosthesis. These extensions are intended to be used when additional length and/or sealing for aneurysmal exclusion is desired. **CONTRAINDICATIONS**: The GORE® EXCLUDER® Conformable AAA Endoprosthesis is contraindicated in: patients with known sensitivities or allergies to the device materials. All components of the GORE® EXCLUDER® Conformable Endoprosthesis contain expanded polytetrafluoroethylene (ePTFE), fluorinated ethylene propylene (FEP), nitinol (nickel-titanium alloy) and gold. Patients with 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. ℞ Only

GORE® TAG® Conformable Thoracic Stent Graft

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:** Patients with known sensitivities or allergies to the device materials; patients who have a condition that threatens to infect the graft. Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

INDICATIONS FOR USE UNDER CE MARK: The GORE® TAG® Conformable Thoracic Stent Graft is indicated for endovascular repair of all lesions of the descending thoracic aorta, including isolated lesions, such as aneurysm and traumatic transection, and Type B dissections. **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. ℞ Only

Products listed may not be available in all markets.

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