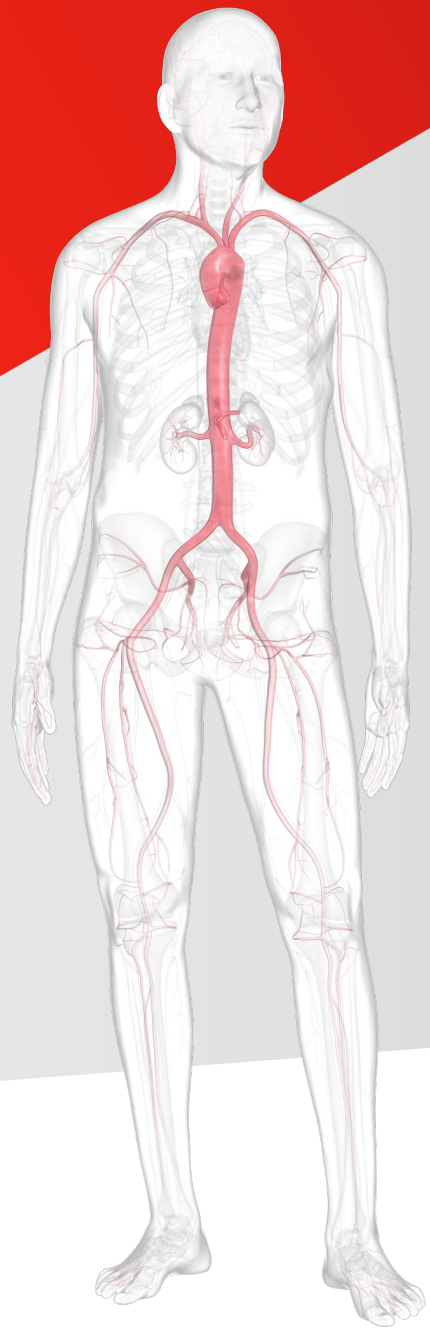
AORTIC CONDITIONS

treated with Gore portfolio of devices

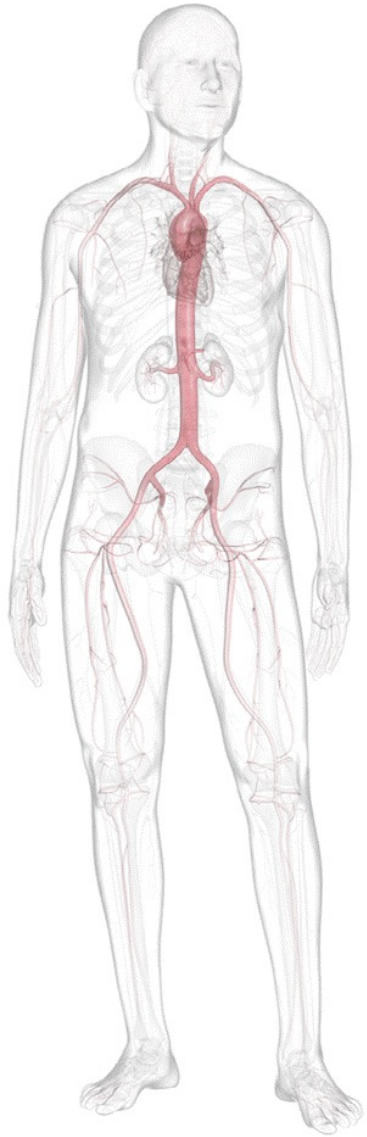
A Health Care Resource



Let’s get started >

Together, improving life

This educational information is intended to be general guidance based on current medical information and standards of care in the field. The information here may not be complete, and is not intended to be a replacement for the *Instructions for Use* (IFU), nor for the education, training and professional judgment of health care providers (HCPs). Gore Associates or authorized agents do not practice medicine. HCPs remain responsible for making decisions about patient care and the use of medical technologies.



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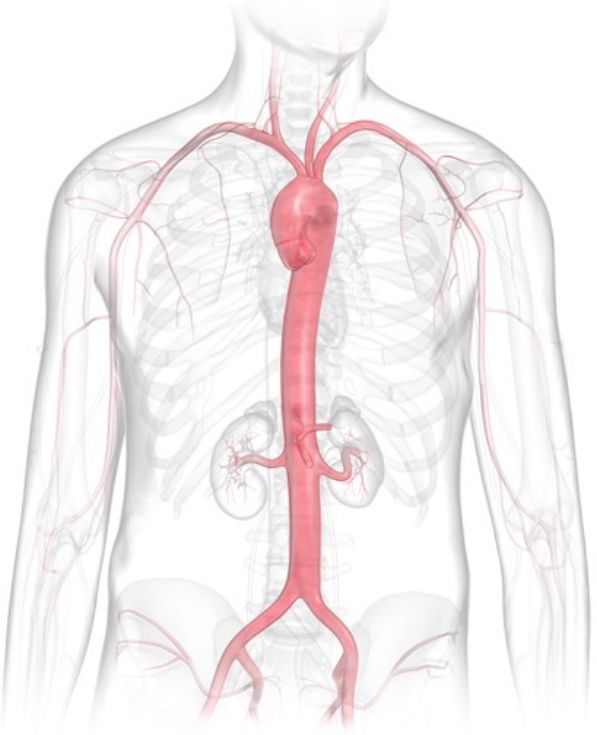
The aorta

The aorta is the main artery that carries oxygen-filled blood from the heart to all parts of the body through smaller branched arteries.

In the thorax (chest), blood travels from the heart through the ascending aorta into the aortic arch and branches into the innominate, left common carotid and left subclavian arteries.

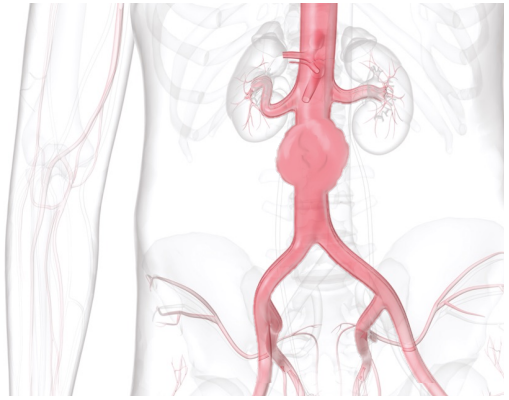
These branch vessels carry blood to the heart muscle, arms, shoulders, chest, neck, face and head (including the brain). Once past the aortic arch, the aorta turns downward becoming the descending aorta and abdominal aorta which carries blood to the spine, organs and lower areas of the body.



Aortic conditions

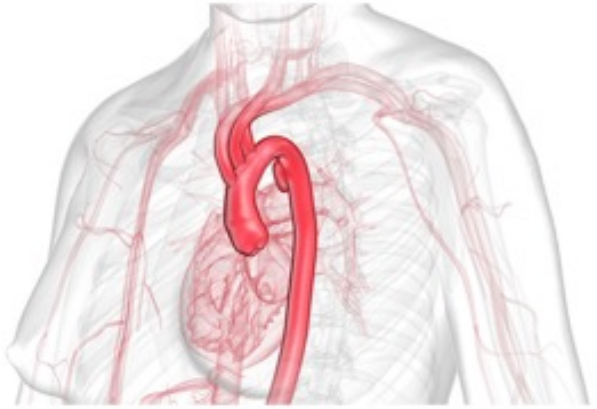
In this module, we will focus on 3 common diseases that affect the aorta:

Aneurysm



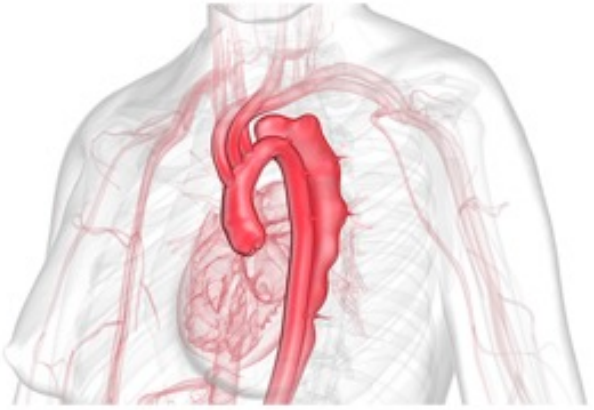
- Aneurysm — vessel wall dilation and ballooning outwards

Transection



- Transection — tear through some or all layers of the aorta, usually caused by trauma

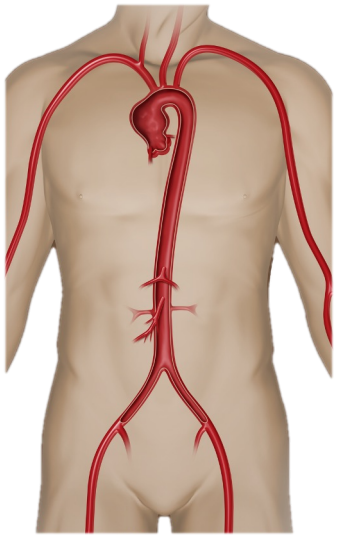
Dissection



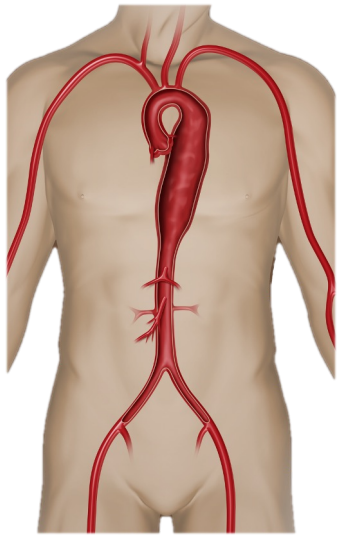
- Dissection — blood flow in between layers of the aorta, may lead to aneurysm or malperfusion

Locations and classifications of aortic aneurysms

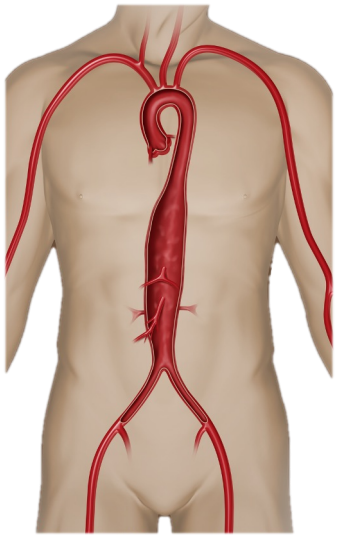
Aortic aneurysms are classified by where they occur. As you can see, aneurysms can affect any part of the aorta.



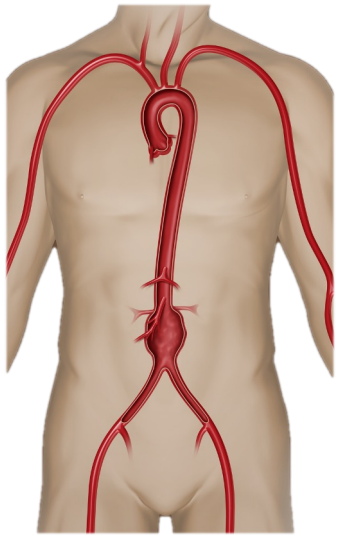
Ascending aorta and aortic arch



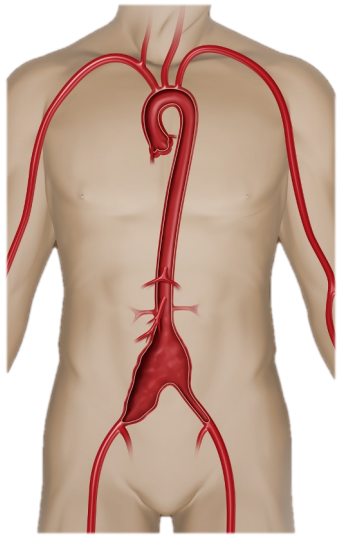
Descending thoracic aorta



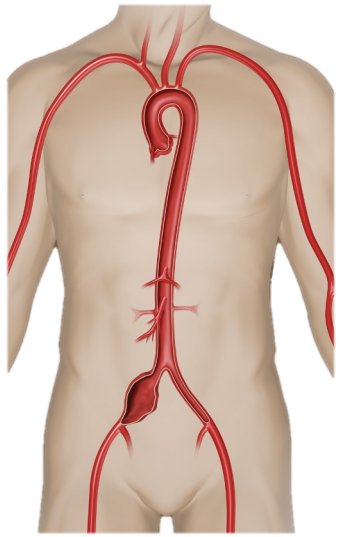
Thoracoabdominal aorta



Abdominal aorta



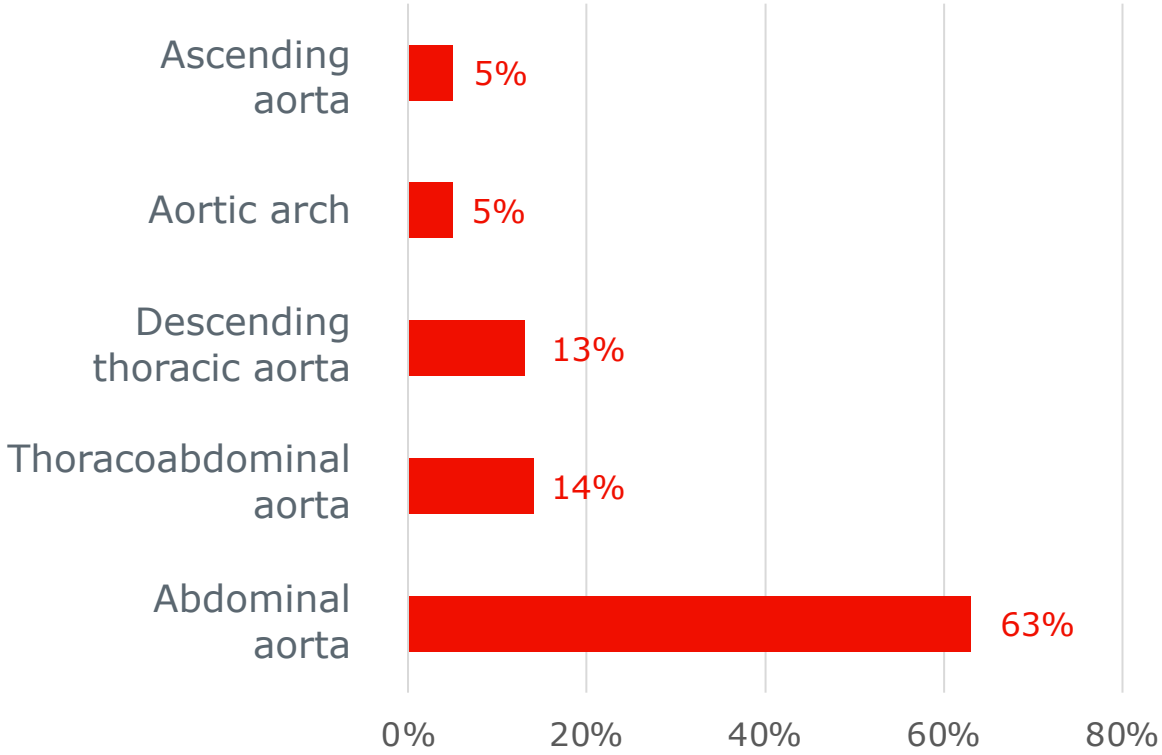
Aortoiliac

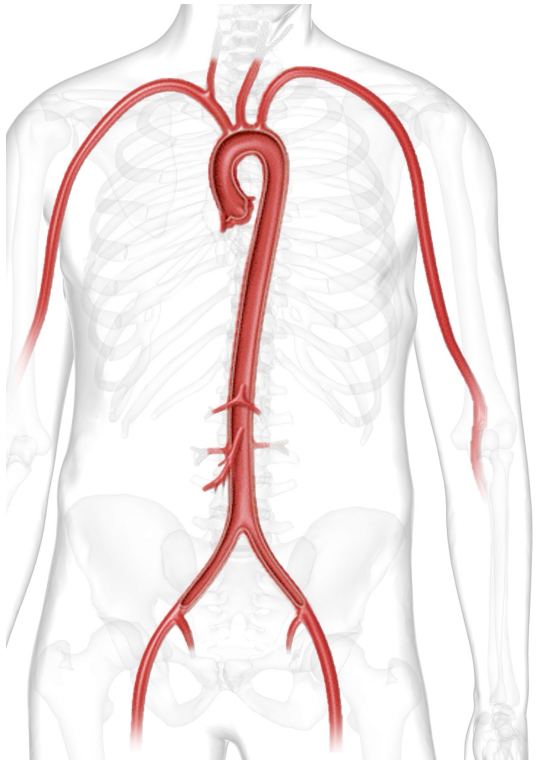


Isolated iliac

Locations and incident trends[1]

Aneurysms can form at any location along the aorta, although they most commonly form in the abdominal segment.





Normal aorta

Treatment options — open surgery

Open surgical repair is an operation to remove the diseased or injured portion of the aorta when it is considered dangerous and at risk for rupture.

During this type of operation, the doctor makes an incision (cut) and repairs the aorta by replacing the diseased or injured section with a synthetic graft (tube) that is sewn into place with sutures.

This procedure requires stopping the flow of blood through the aorta while the graft is being put into place. Open surgical repair is typically performed under general anesthesia and takes about 2-4 hours to complete.

Patients can expect to spend several days in the hospital with some time in the intensive care unit (ICU) immediately following surgery. Depending on how quickly the body heals and any other associated health conditions, **recovery time may take about 3-6 months.**

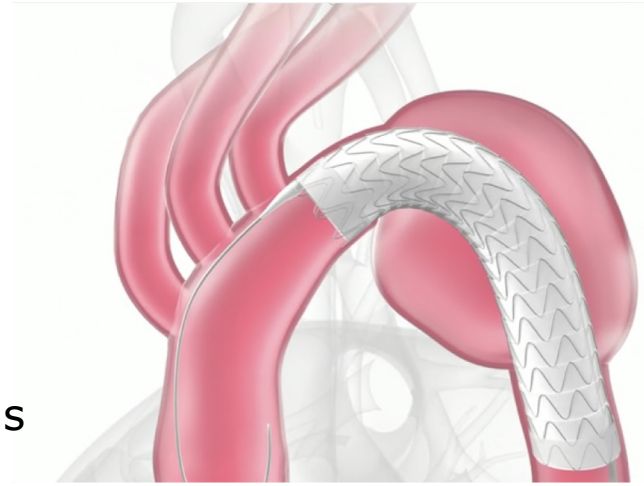
Treatment options — endovascular surgery

Endovascular repair is a procedure for the treatment of diseases or injuries of the aorta**. Less invasive than open surgery, it involves excluding (sealing off) the diseased segment by placing an endovascular graft inside of the diseased aorta, relining and making a new path for blood flow**.

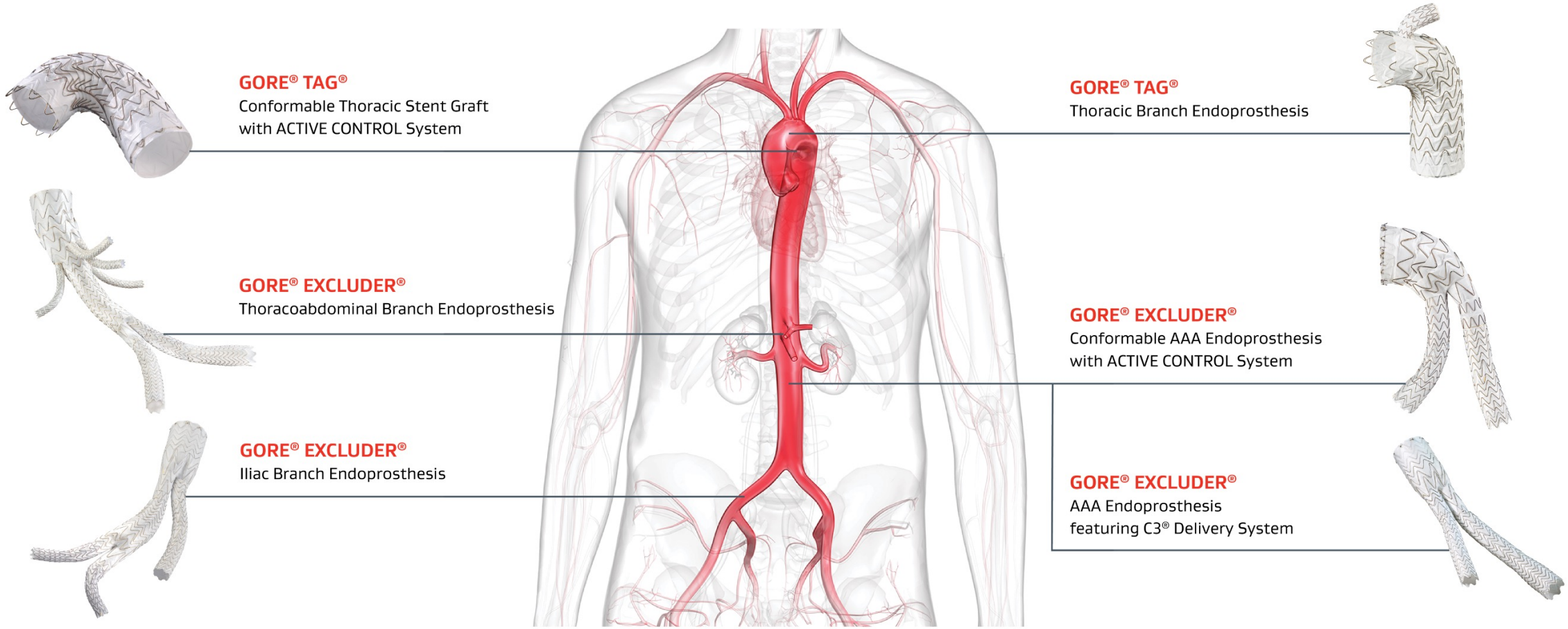
The endovascular graft remains inside the aorta permanently through the use of a metal stent creating a tight fit and seal against the wall of the aorta.

Endovascular repair may be performed under general, regional or local anesthesia. The procedure typically takes 1–3 hours to complete. Patients may have a hospital stay of a few days and **return to normal activity within 2–6 weeks after the procedure**, depending on any other health conditions.

Endovascular aortic repair may not be suitable for all anatomies. Considerations such as vessel access may prohibit endovascular treatment.



Gore is committed to providing patients and physicians with the most complete portfolio of durable treatment options for aortic disease



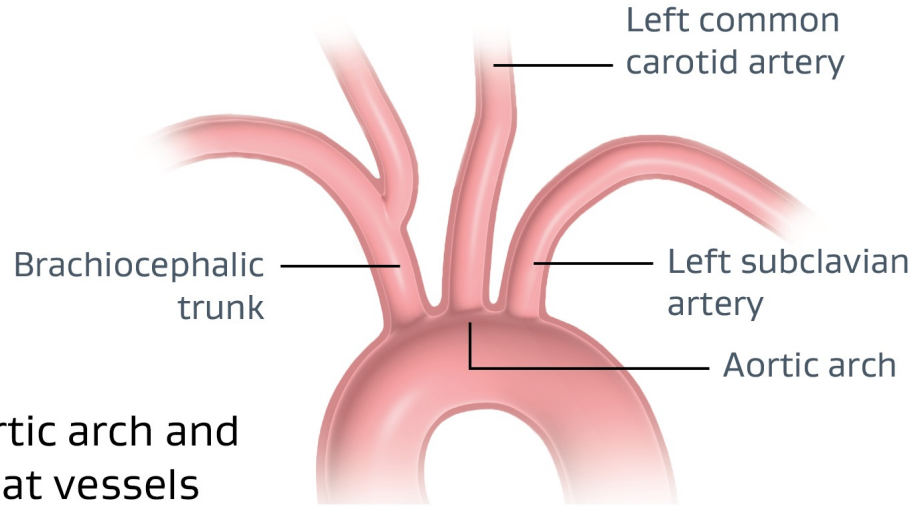
Aortic arch

Vessels of the aorta (the great vessels)

The ascending aorta transitions to the aortic arch where blood is fed to the 3 great vessels which supply blood to the head, neck and arms

The 3 vessels include:

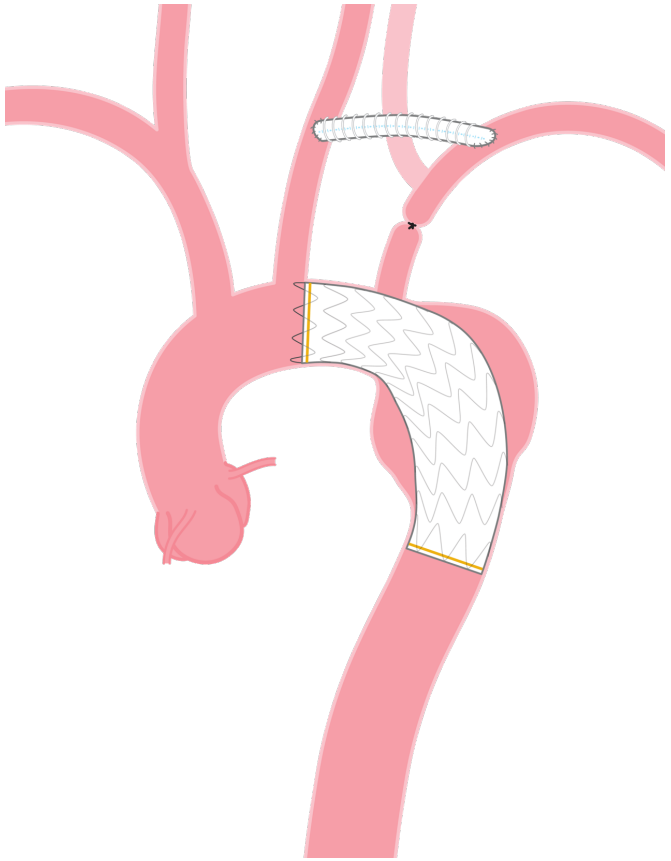
- Brachiocephalic trunk
- Left common carotid artery
- Left subclavian artery



The aortic arch and the great vessels

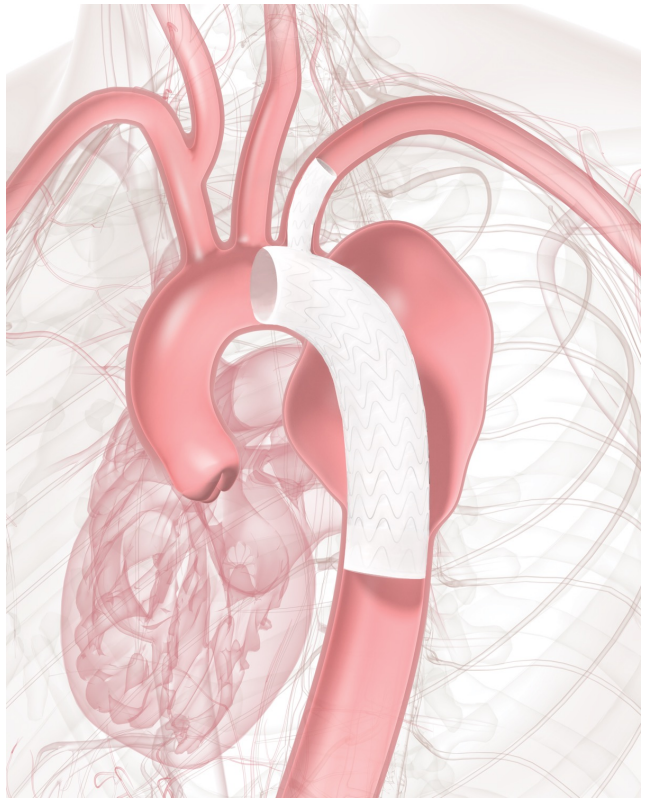
Open debranching of great vessels

- If the aortic disease extends too close to the great vessel(s), treatment may also need to include the branch vessel(s).
- For open debranching, this includes accessing the branch vessel(s) surgically to redirect blood flow.
- The location of the vessel(s) dictates how it may be accessed and where it may be connected.



Endovascular repair

- Blood flow to the branch vessel can also be maintained endovascularly by using a stent graft to connect the aorta to the great vessel.
- At the discretion of the physician, several different techniques may be employed which may include off-label use of products approved for other locations.

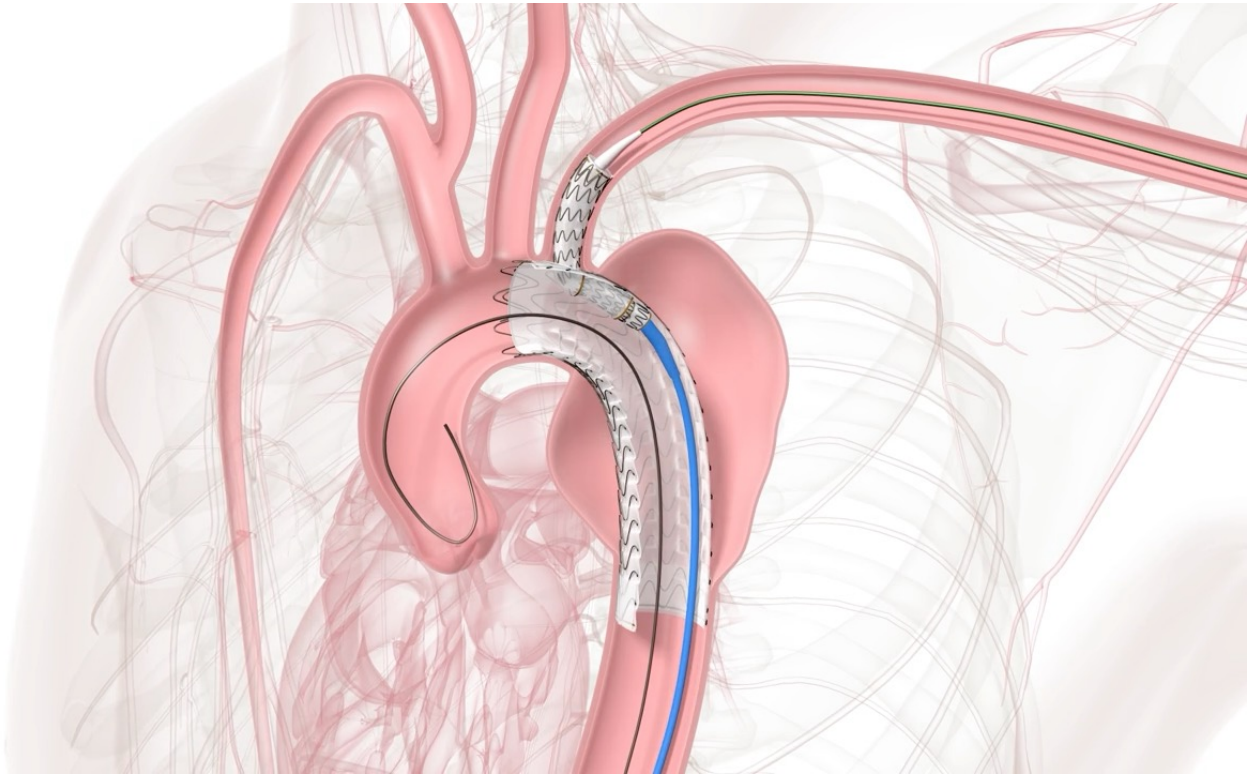


GORE® TAG® Thoracic Branch Endoprosthesis

- The GORE® TAG® Thoracic Branch Endoprosthesis (TBE) is intended for endovascular repair of pathologies of the descending thoracic aorta (DTA) including the left subclavian artery.
- The components of TBE include the main body which is inserted in the thoracic aorta. A Side Branch Component is then inserted inside the main body and branches between the aorta and the left subclavian artery. An optional Aortic Extender is available to extend the proximal portion of the main body if needed.
- TBE, either alone or in combination with the GORE® TAG® Conformable Thoracic Stent Graft, is placed across the diseased portion of the aorta.

GORE® TAG® Thoracic Branch Endoprosthesis (continued)

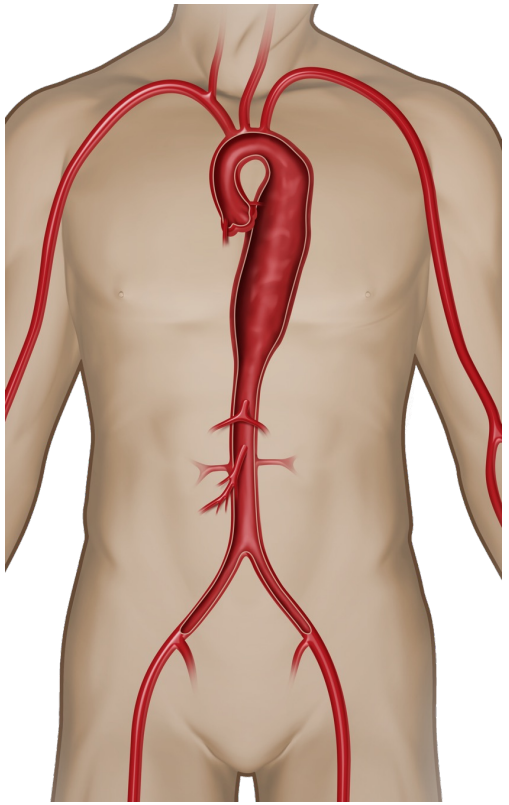
Deployment animation



Descending thoracic aorta

As the aorta descends from the great vessels, it follows the spine and extends downwards towards the diaphragm.

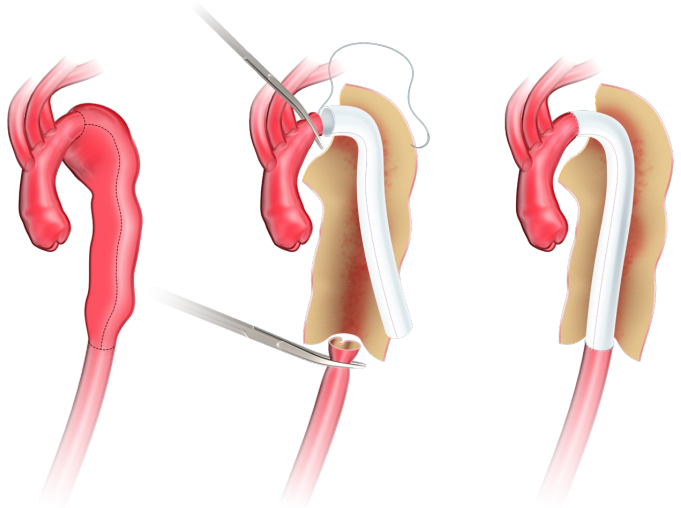
Aneurysms, dissections and transections can occur in the descending thoracic aorta. Transections most commonly occur adjacent to the left subclavian artery and are a result of trauma (e.g., car accident).



Open surgery

The type of surgical repair of the thoracic aorta will depend on several factors: the type of disease, location and extent of disease and the patient's tolerance for the procedure.

For open repair of the descending thoracic aorta, a large incision may extend from the back under the shoulder blade around the side of the rib cage to just under the breast (thoracotomy). These approaches allow the surgeon to visualize the aorta directly to perform the open repair.

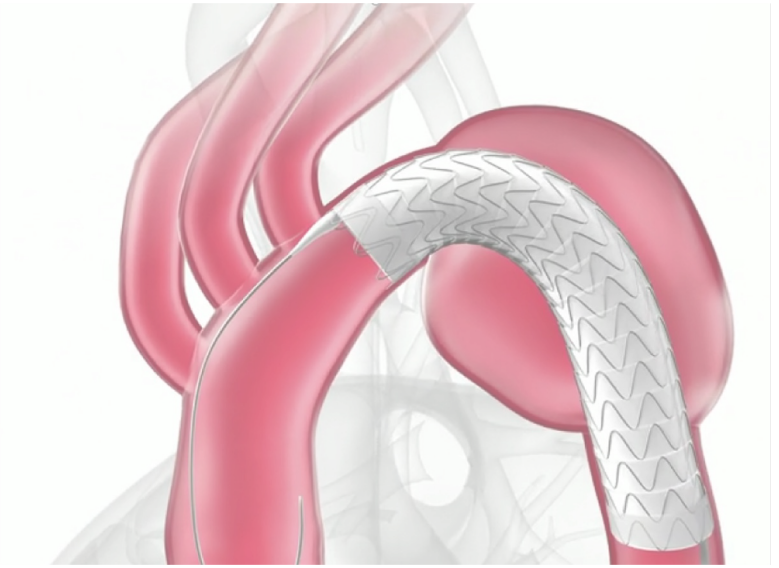


Thoracic endovascular aortic repair (TEVAR)

TEVAR is a less invasive treatment option which generally carries fewer procedural complications.[2,3] In performing TEVAR, 1 or more stent grafts may be placed in the aorta to exclude the diseased portion and maintain blood flow.

The endovascular graft remains inside the aorta permanently through the use of a stent creating a tight fit and seal against the wall of the aorta.

Endovascular repair may be performed under general, regional or local anesthesia. The procedure typically takes 1–3 hours to complete. Patients may have a hospital stay of a few days and return to normal activity within 2–6 weeks after the procedure, depending on any other health conditions.

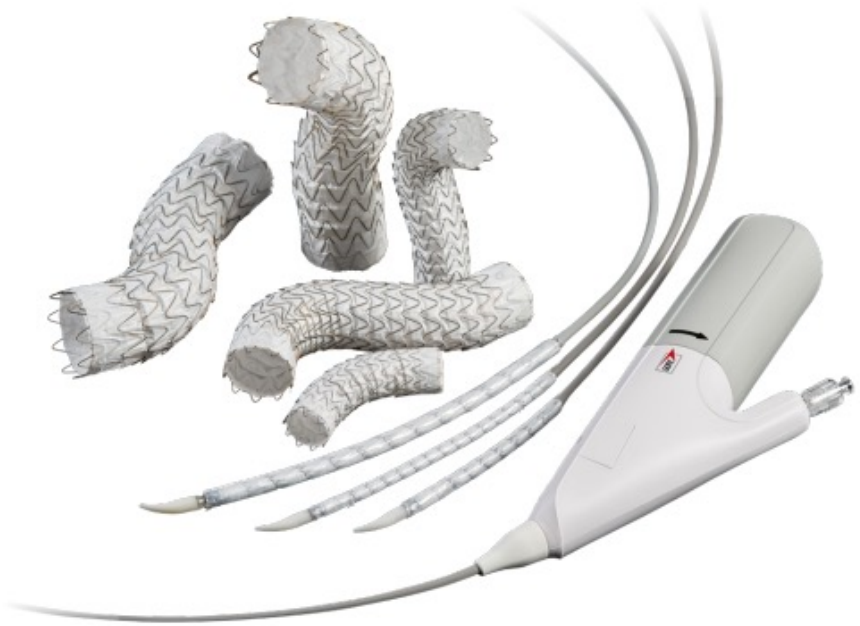


GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System

The GORE® TAG® Conformable Thoracic Stent Graft is intended for **endovascular repair of the descending thoracic aorta** (DTA), and it's approved to treat all lesions of the descending thoracic aorta, in patients who have appropriate anatomy.

The endovascular graft is a one-piece, tube-shaped device that re-lines the aorta and extends from as high as the aortic arch below left common carotid artery, to as low as the abdomen above the celiac artery. The GORE® TAG® Conformable Thoracic Stent Graft is made of ePTFE, a material similar to plastic, with an outer metallic support structure known as a stent.

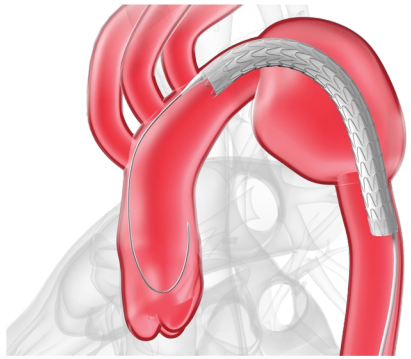
One or more GORE® TAG® Conformable Thoracic Stent Grafts may be placed in the descending thoracic aorta.

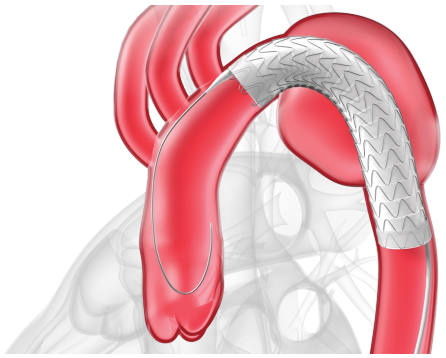


Where *conformability* meets control

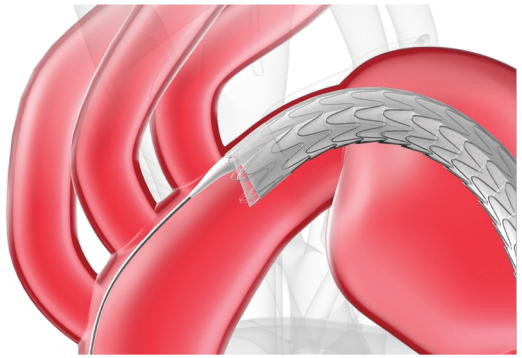
GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL

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





Staged deployment

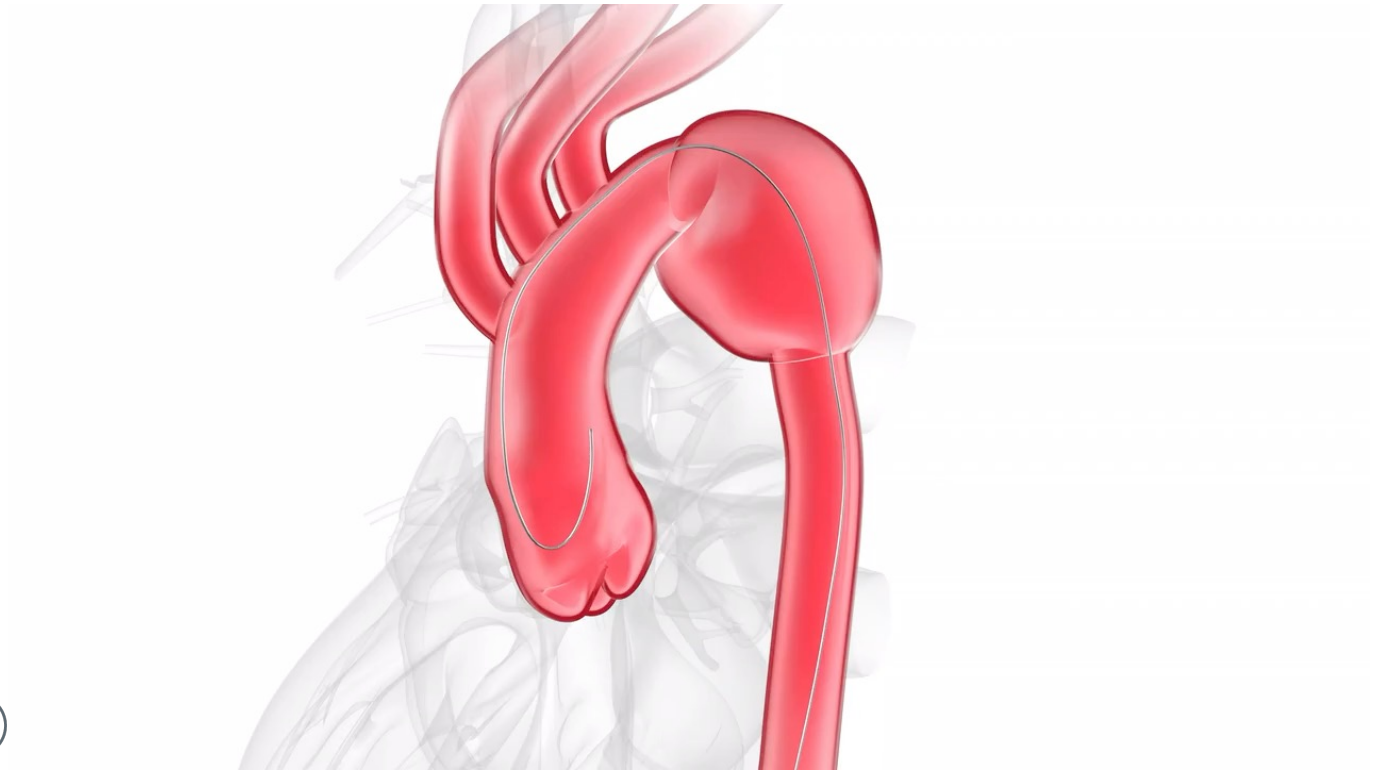


Angulation control at intermediate diameter

Angulation control at full diameter

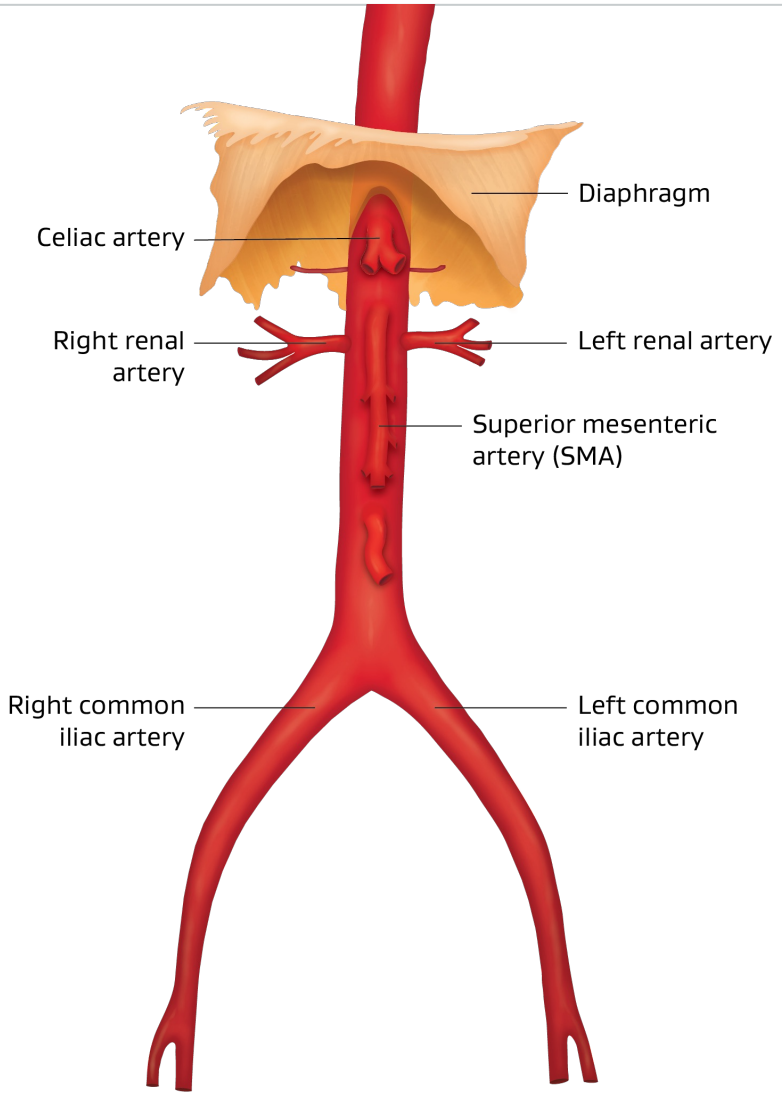
GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System

Deployment animation



Thoracoabdominal aorta anatomy

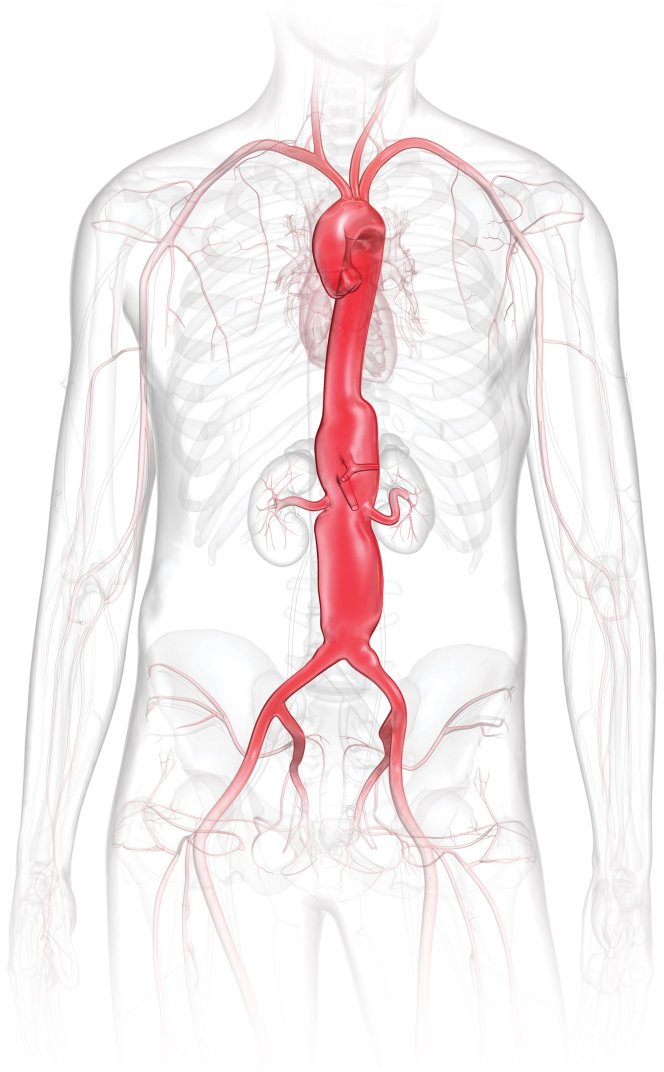
As the aorta descends to the level of the diaphragm, it branches again to 4 different vessels called the visceral branch arteries which include the celiac artery, superior mesenteric artery (SMA), the left renal artery and the right renal artery. These arteries deliver blood to the gut and kidneys.



Diseases of the thoracoabdominal aorta

Both aneurysms and dissections can extend into the descending thoracic aorta where vessels branch out to provide blood to the organs.

The diseased portion can include any number of branches within the thoracoabdominal aorta.

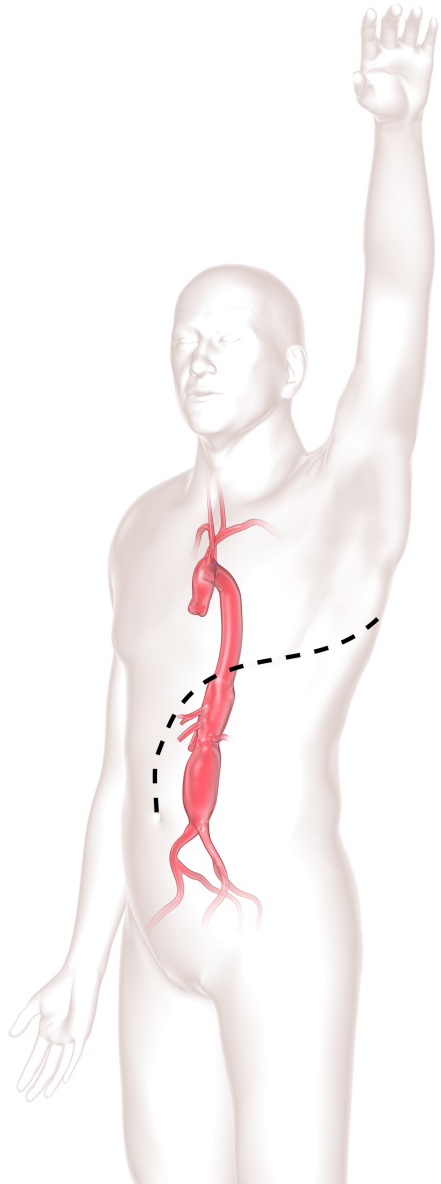


Open surgery

Open surgery of the thoracoabdominal aorta involves a lengthy incision and potential removal of ribs to access the aorta.

Depending on location and extent of disease, the aorta or other vessels may need to be clamped to prevent blood flow while a surgical graft is sewn into place.

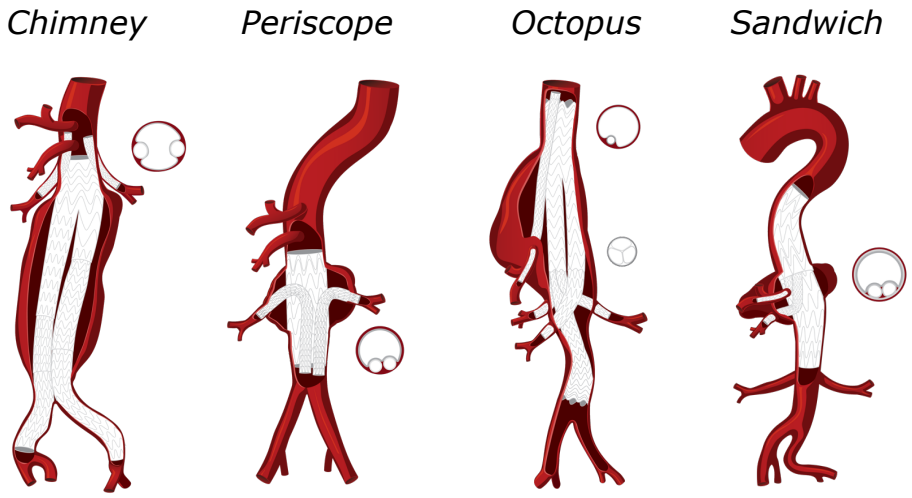
Patients typically stay in the hospital for 5–10 days with an additional 4–6 week recovery period at home or in an extended care facility.



Endovascular repair

Endovascular repair can be achieved by excluding blood flow to the aneurysm by placing stent graft(s). Historically, the only endovascular options available include:

- Off-label techniques using grafts approved for use in other parts of the body.
- Custom grafts which may take weeks to be constructed and do not include branch components.



Off-label techniques

GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE)

TAMBE is intended for endovascular repair of thoracoabdominal aortic aneurysms and high-surgical risk pararenal abdominal aortic aneurysms in patients who have appropriate anatomy. It is a modular system that incorporates multiple Gore products to treat a wide range of anatomies.

Aortic Component (AC)

Branch Components

GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis (VBX Stent Graft)

Distal Bifurcated Component (DBC)

GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) – Iliac Branch Component

Contralateral Leg Component

GORE® EXCLUDER® AAA Endoprosthesis – Contralateral Leg Endoprosthesis and/or Iliac Endoprosthesis

DBC Extender Component

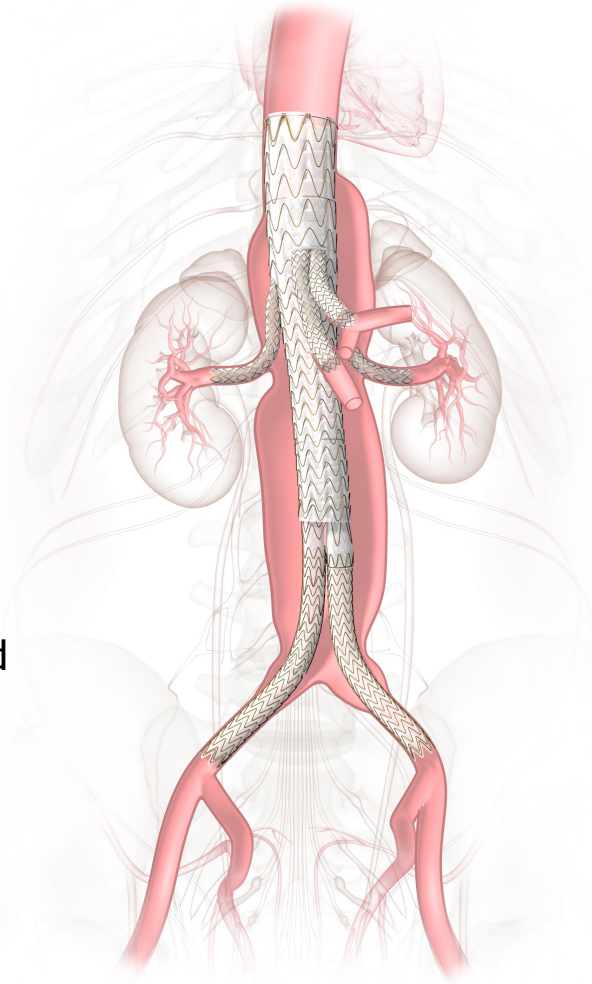
GORE® EXCLUDER® AAA Endoprosthesis – Aortic Extender

TAMBE (continued)

TAMBE leverages proven performance and durability of the **GORE® EXCLUDER® Device** family and the **GORE® VIABAHN® VBX Device** family and is implanted with Gore products that have been clinically and non-clinically tested together to treat thoracoabdominal aortic aneurysms (TAAAs) and pararenal abdominal aortic aneurysms (PAAAs).

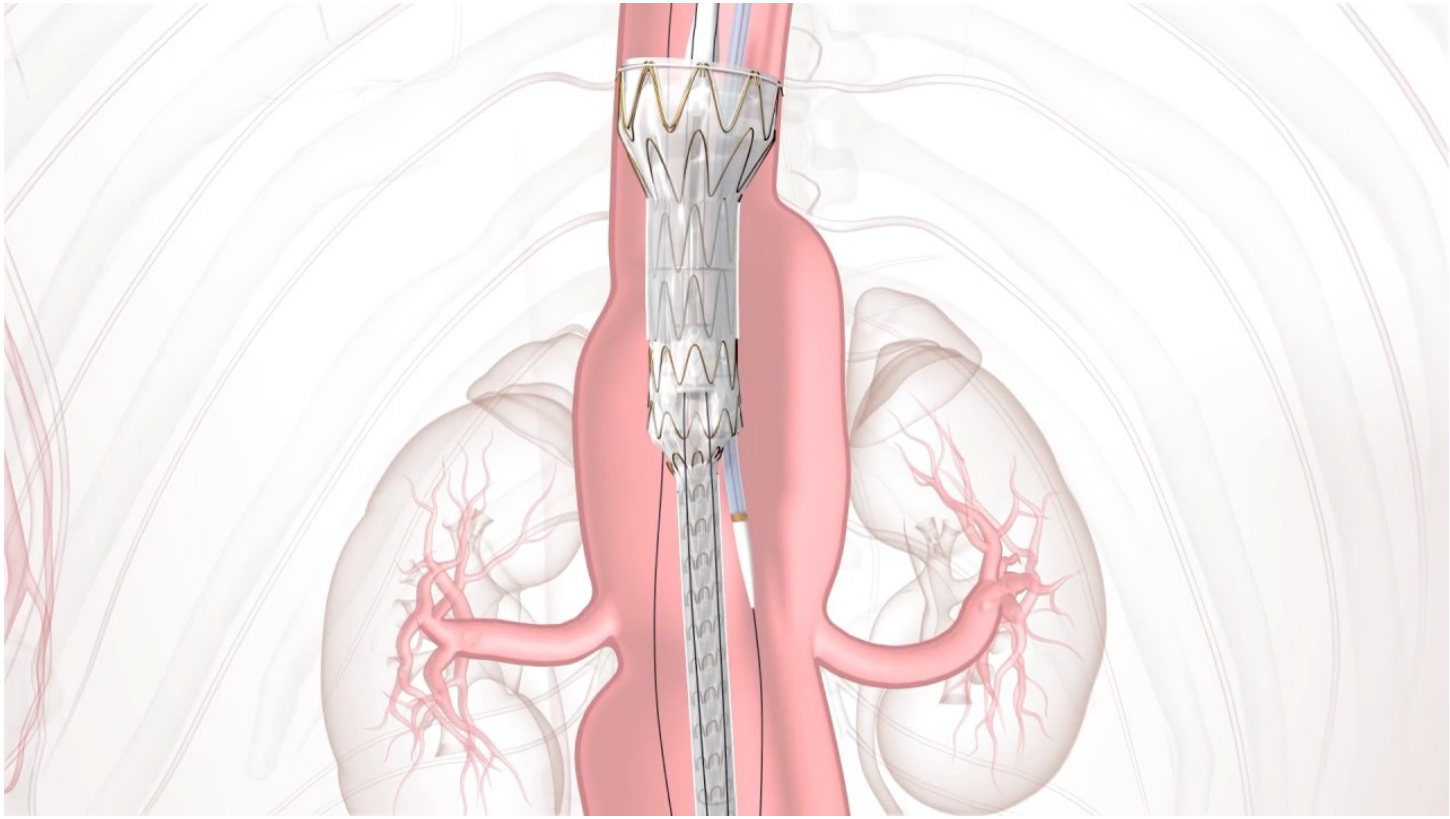
All components are off-the-shelf, designed and tested together, without the need for modification, alteration or custom design:

- This supports timely patient treatment.[4,5]
- Reduces procedure complexity and may reduce overall procedure time when compared to other endovascular treatment options.[4,5]
- The TAMBE pre-cannulated design facilitates the placement of the Branch Components to the visceral branch arteries. Patency of the visceral branch arteries is important to maintain perfusion to the abdominal organs (kidneys, liver, stomach, spleen and intestines) and spinal cord. Interruption to blood flow may lead to adverse events and complications which are costly to treat and have a negative impact on the patient.[6]



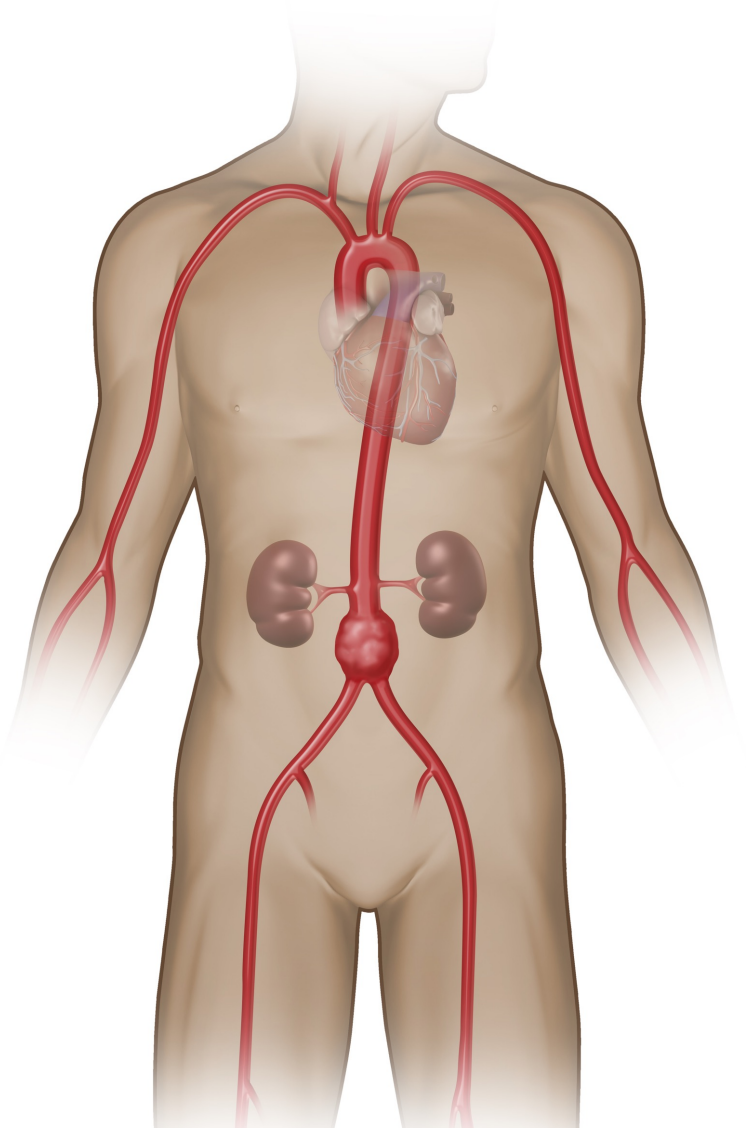
TAMBE (continued)

Deployment animation



Abdominal aorta

- As the aorta extends below the renal arteries it becomes the infrarenal abdominal aorta and is located approximately behind your belly button.
- This is the most common location for aneurysms due to anatomical changes in the aorta at this level.

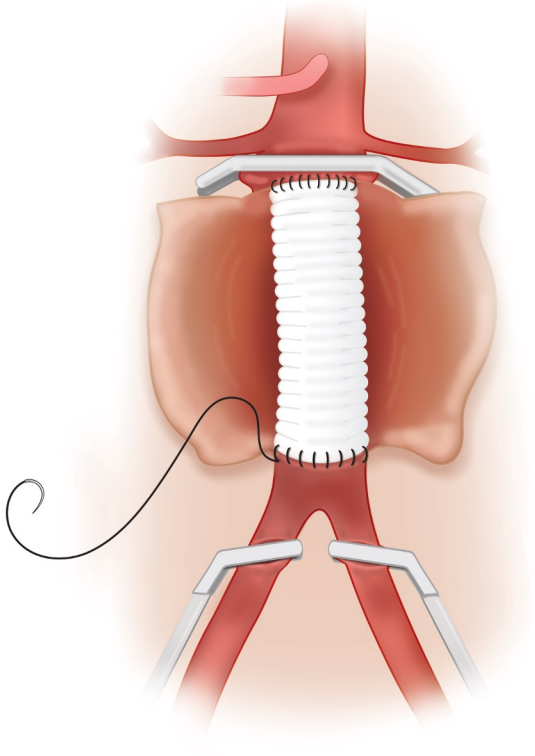


Open surgery

This surgical procedure involves cutting open the abdomen to replace the aneurysm with a synthetic graft that is sewn into place with suture. This is a major operation and carries some risk.[7,8]

However, it is successful in most cases and the long-term outlook is good. The graft is intended to function for the remainder of the patient's life.

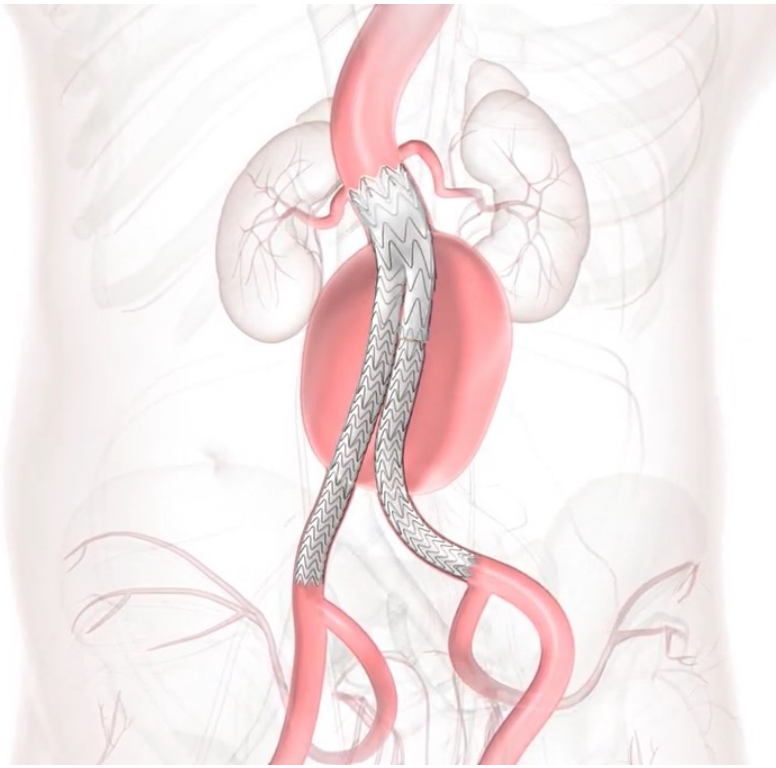
Open surgical repair is typically performed under general anesthesia and takes about 2–4 hours to complete. Patients usually stay overnight in the intensive care unit and another 8–11 days in the hospital.[9,10] Depending on how quickly your body heals, hospitalization and recovery time may take about 3 months.



Endovascular aortic repair (EVAR)

Although open repair has good results, not all patients can tolerate this major operation. EVAR has become standard practice for the treatment of abdominal aortic aneurysms.

EVAR requires preserving blood supply where the aorta branches off into iliac arteries. This requires gaining access from both sides and involves 2 or more components.

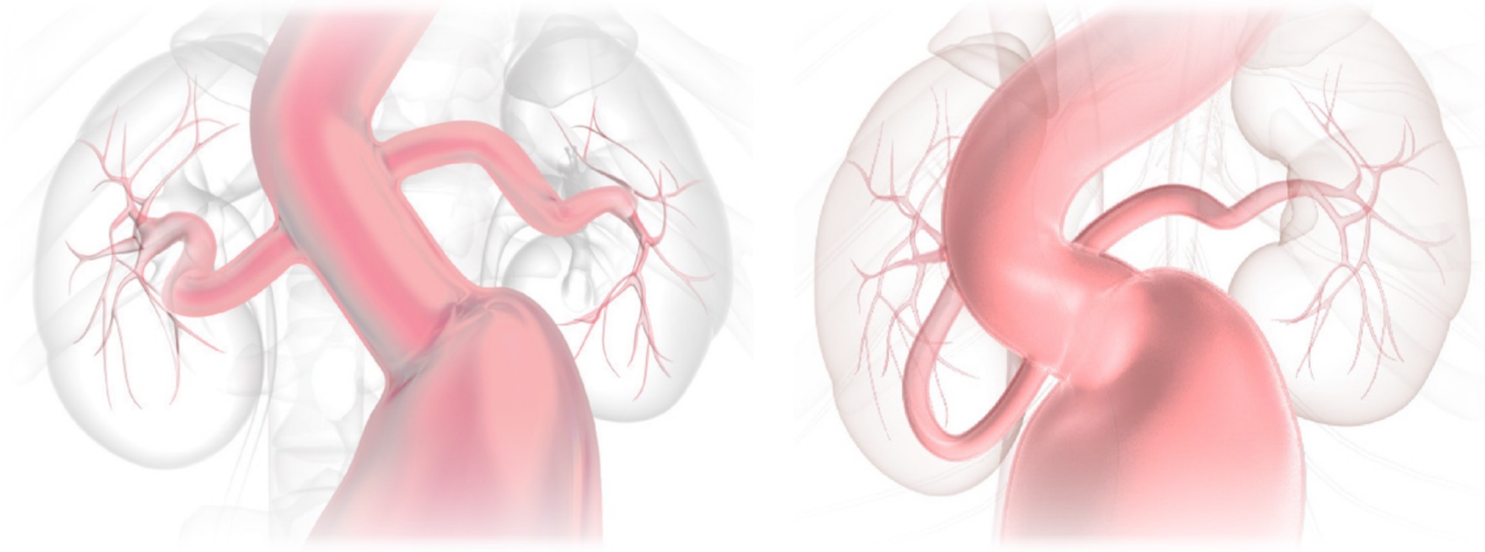


Consideration for endovascular abdominal aortic aneurysm treatments

A CT scan is used in order to plan treatment for the aneurysm.

Measurements required include but are not limited to:

- Length and diameter of the abdominal aorta
- Aortic neck length and angulation
- Position of renal arteries
- Length and diameter of the iliac arteries



GORE® EXCLUDER® Device family

The GORE® EXCLUDER® Device family is a series of devices intended for endovascular repair of an abdominal aortic aneurysms (AAA).

GORE® EXCLUDER® AAA Endoprosthesis

- Trunk-Ipsilateral Leg
- Aortic Extender

GORE® EXCLUDER® AAA Endoprosthesis

- Contralateral Legs
- Iliac Extenders

GORE® EXCLUDER® Conformable AAA Endoprosthesis with ACTIVE CONTROL System

- Trunk-Ipsilateral Leg
- Aortic Extender

See respective *Instructions for Use (IFU)* for complete information.

GORE® EXCLUDER® Device family (continued)

The GORE® EXCLUDER® Device family offers advantages of minimally invasive repair to patients that may have been previously excluded or treated surgically.

GORE® EXCLUDER® AAA Endoprosthesis featuring C3® Delivery System

Treats majority of a patient's AAA needs.

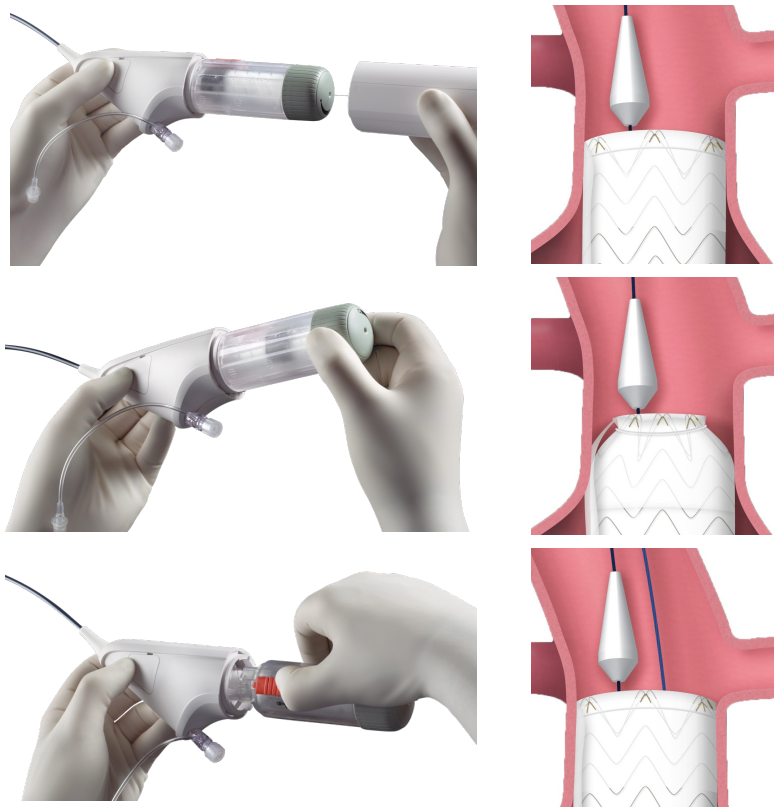
GORE® EXCLUDER® Conformable AAA Endoprosthesis with ACTIVE CONTROL System

Expands EVAR to challenging anatomies, including short, small or angulated necks up to 90°.

See respective *Instructions for Use (IFU)* for complete information.

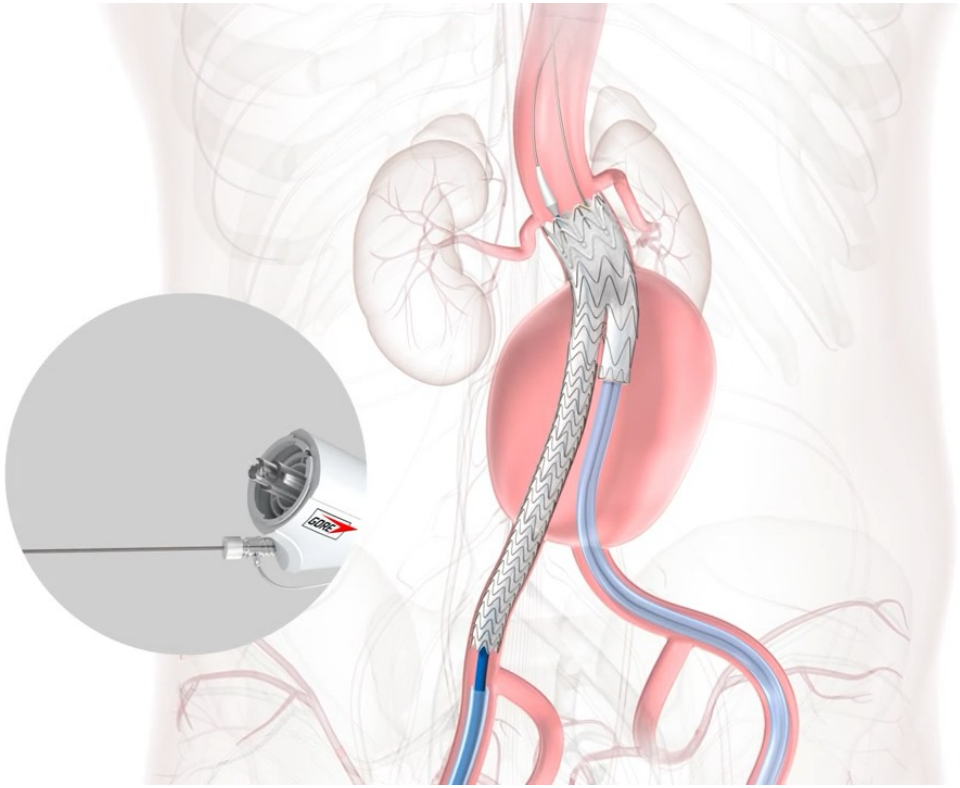
GORE® C3 Delivery System

- Repositionable to obtain optimal seal
  - A unique delivery system provides the ability to reconstrain the proximal end of the device and reposition for ideal placement.
  - More opportunities to maximize infrarenal seal.



GORE® EXCLUDER® AAA Endoprosthesis

Deployment animation



GORE® EXCLUDER® Conformable AAA Endoprosthesis with ACTIVE CONTROL System

What is the GORE® ACTIVE CONTROL System?

Conformable stent graft

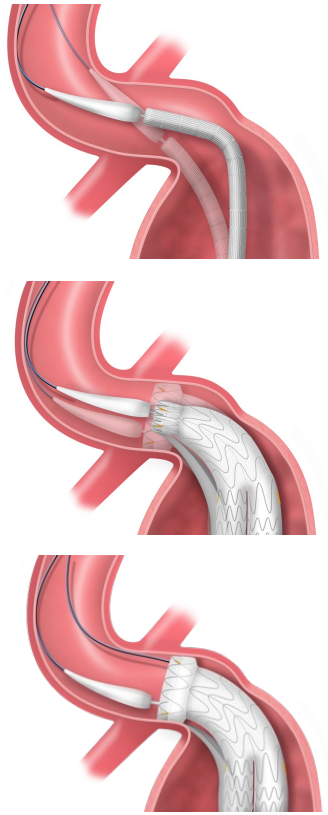
- Helps achieve optimal aortic wall apposition.
- Adapts closely to the anatomy to maximize seal.

Enhanced device positioning

- Ability to reconstrain proximal end for refined positioning.
- Initial trunk deployment at ~70% diameter to improve ease of repositioning in challenging anatomy.

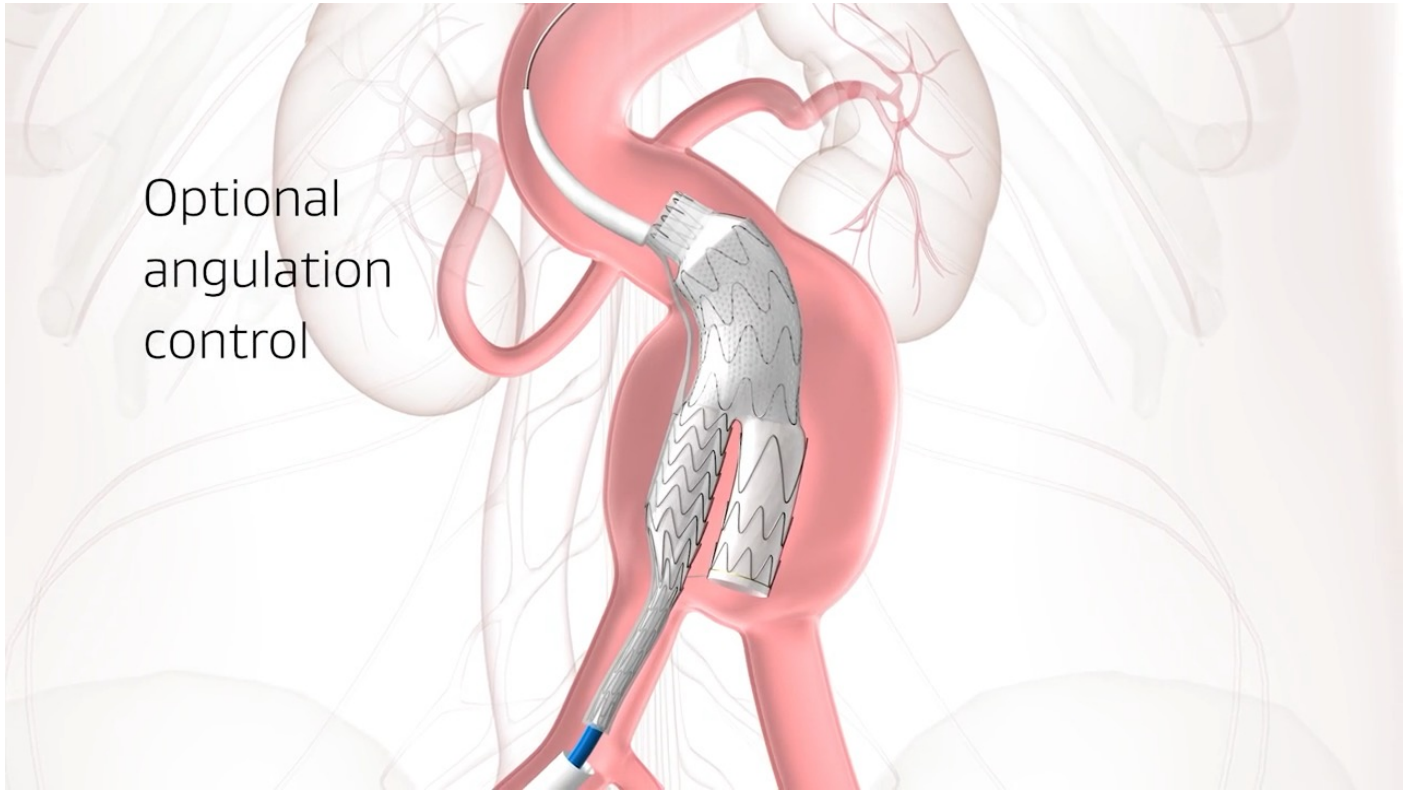
Optional angulation control

- Aids in orthogonal placement to optimize seal within flow lumen.
- Controlled delivery allows for refinement of angulation at 2 stages.



GORE® EXCLUDER® Conformable AAA Endoprosthesis with ACTIVE CONTROL System (continued)

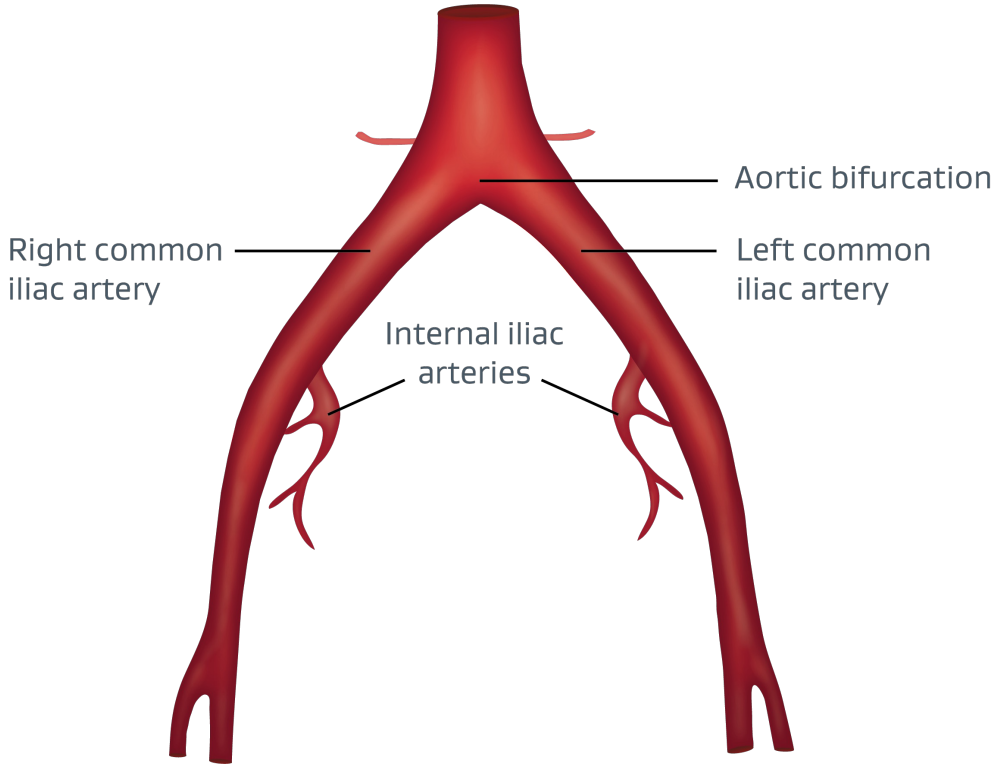
Deployment animation



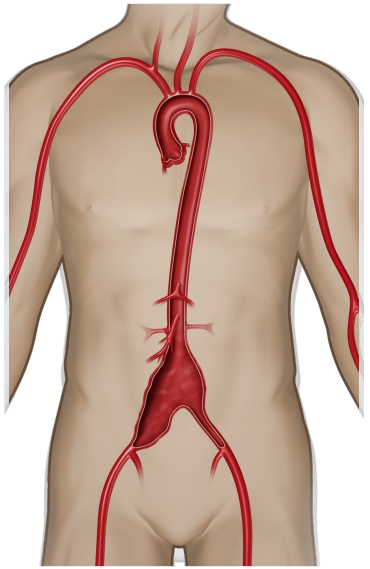
Iliac bifurcation

The abdominal aorta bifurcates into the right and left iliac arteries. These arteries have mirrored pathways and distributions.

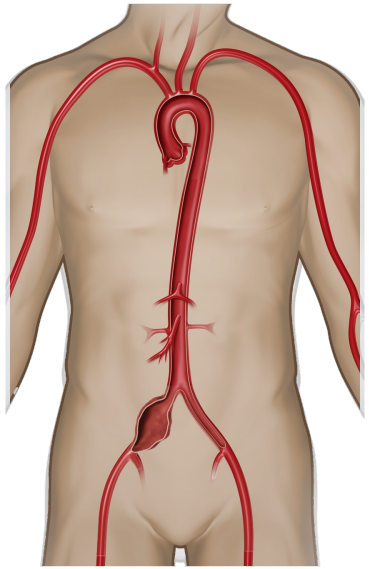
The iliac arteries and their branches supply blood to the pelvic organs and muscles, abdominal wall, colon, rectum, spinal cord and gluteal muscles.



Aortoiliac aneurysm



In approximately **25 percent**[11] of patients with an abdominal aortic aneurysm (AAA), the aneurysm extends into at least 1 of the common iliac arteries. These are referred to as aortoiliac aneurysms.

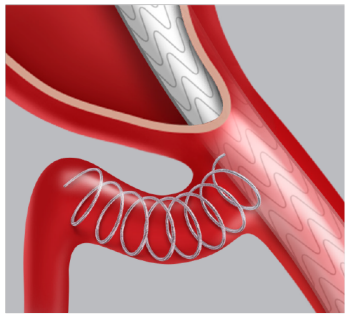


Additionally, the aneurysm may be isolated to the common iliac artery, which are referred to as common iliac artery aneurysms.

Complications from covering the internal iliac branch artery (hypogastric)

Clinical implications[12-15]

- Treatment of iliac artery aneurysms can sometimes involve occluding the hypogastric which can create complications for the patients.



Up to 55%
Significant hip and/or buttock claudication

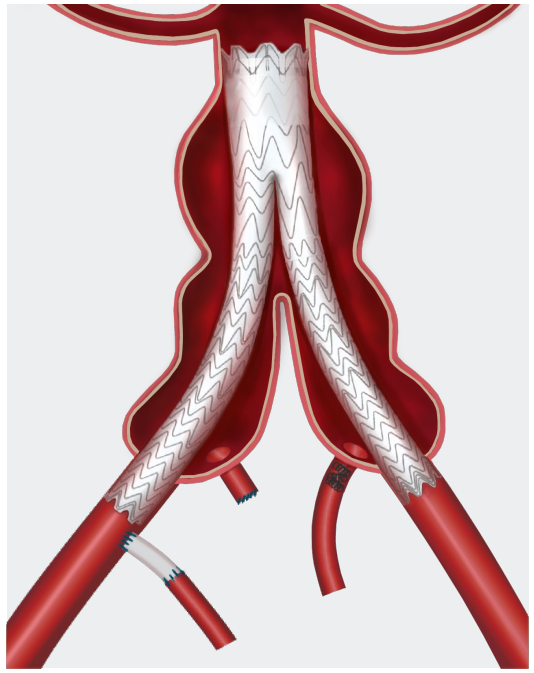
Up to 45%
Erectile dysfunction

2-3%
Colonic ischemia

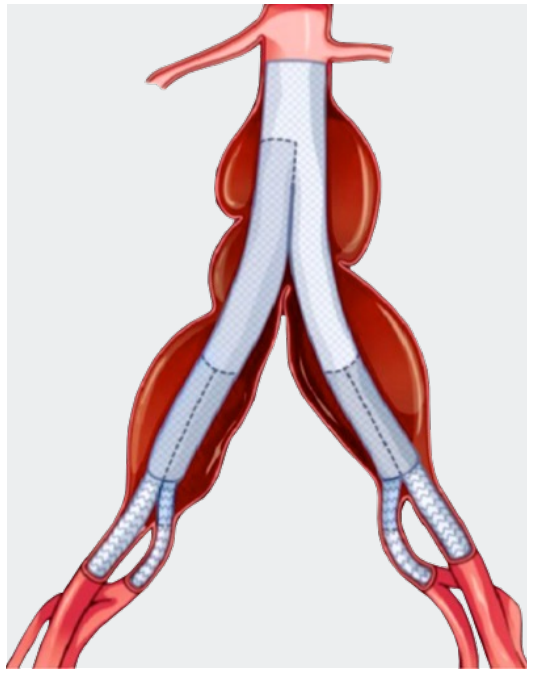
Rare
Spinal chord ischemia

"The question of whether to preserve or sacrifice the hypogastric artery is fundamental with regard to a possible decrease of complications."[14]

Treatment practices for hypogastric preservation

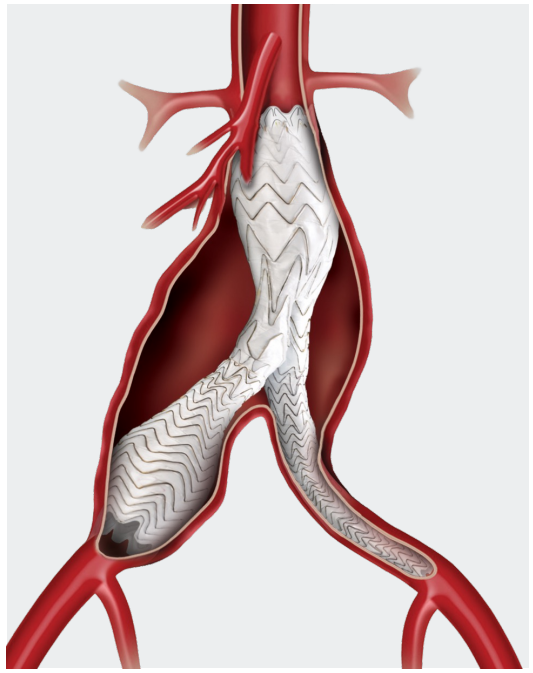


Open/hybrid repair

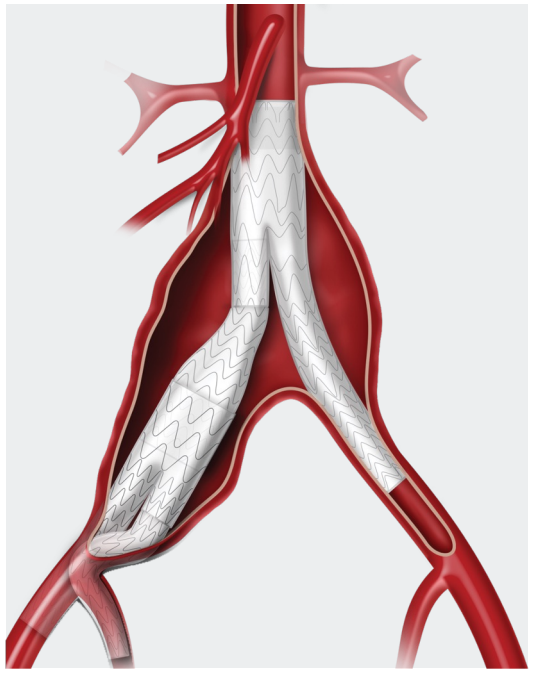


Complex endovascular techniques

Not within *Instructions for Use* (IFU) for Gore devices



Flared limbs



Dedicated iliac branch devices

Note that the parallel stenting procedure is not within the scope of the IFU. Gore does not promote the off-label use of its devices.
The GORE® EXCLUDER® Iliac Branch Endoprosthesis presents potential advantages for patients and hospitals when compared with these options.

GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE)

IBE is the first complete system fully designed for the iliac branch, built from the GORE® EXCLUDER® Device platform.

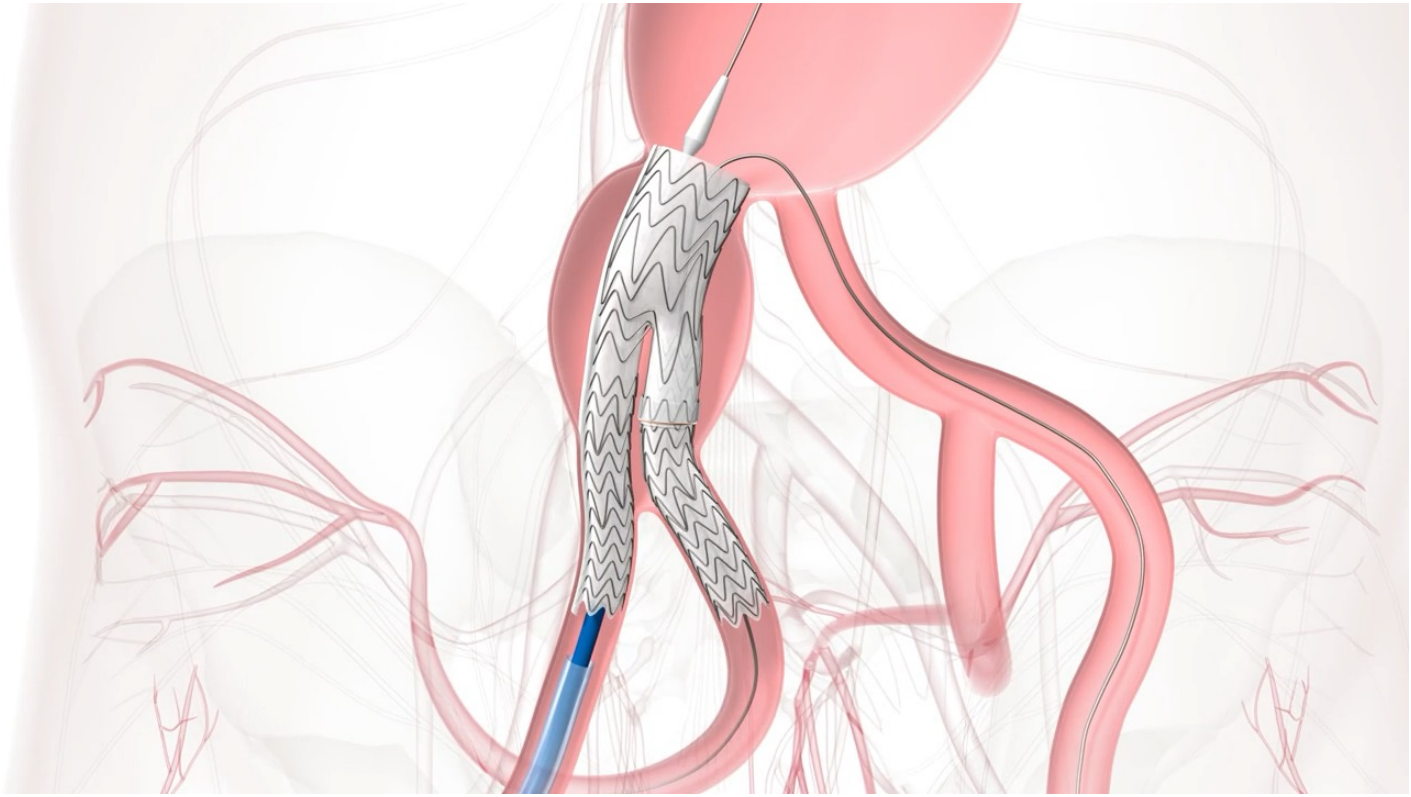
GORE® EXCLUDER®
Iliac Branch Endoprosthesis

Excludes aneurysm while preserving flow to the iliac arteries.

See respective *Instructions for Use (IFU)* for complete information.

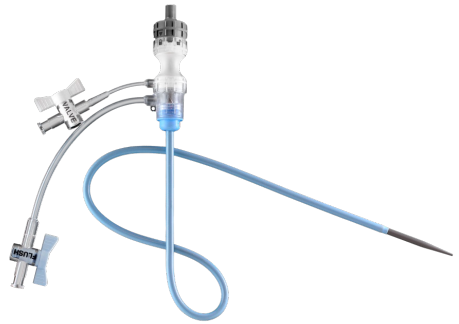
IBE (continued)

Deployment animation



Aortic accessories

Each accessory plays a key role in supporting our best-in-class EVAR and TEVAR devices, promoting positive outcomes.

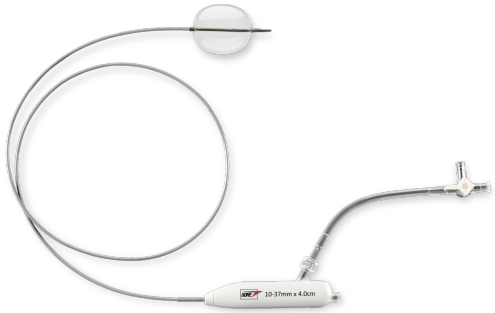


GORE® DRYSEAL Flex Introducer Sheath

supports access to challenging anatomies.

GORE® Tri-Lobe Balloon Catheter

provides surgeons with greater stability and control in positioning endovascular grafts.



GORE® Molding & Occlusion Balloon

addresses the challenge of consistently achieving the best possible EVAR stent graft seal and temporary vessel occlusion.

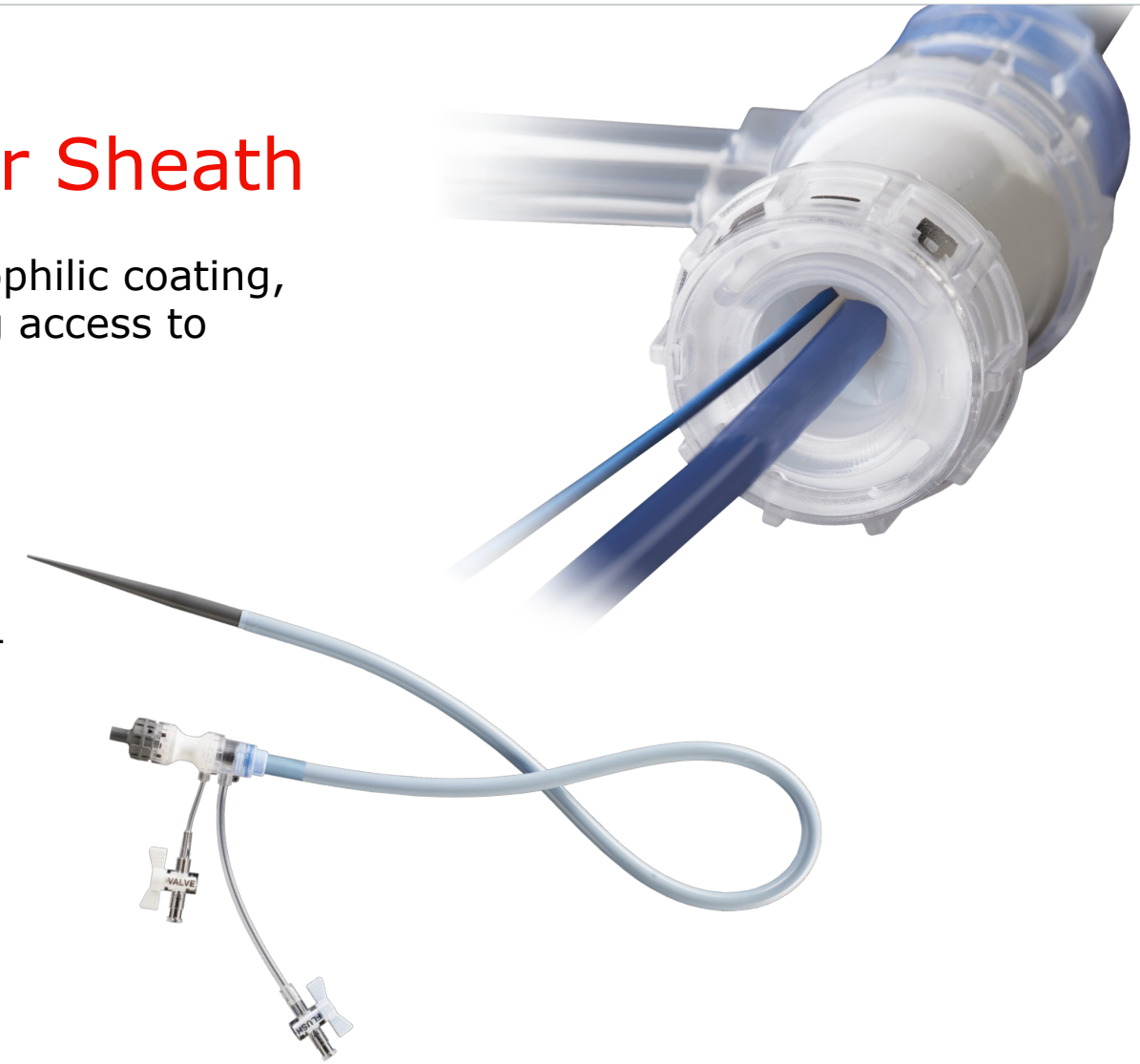
GORE® Tri-Lumen Catheter

facilitates guidewire placement in procedures requiring multiple guidewires.

GORE® DRYSEAL Flex Introducer Sheath

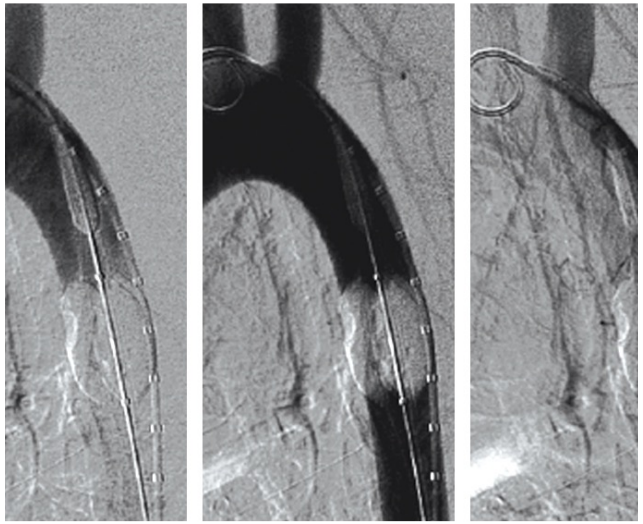
The GORE® DRYSEAL Flex Introducer Sheath with hydrophilic coating, offers enhanced flexibility and kink resistance, providing access to challenging anatomies during endovascular repair.

- **Deliver with ease:** Hydrophilic coating and enhanced flexibility provide exceptional access to challenging anatomies and branch vessels.
- **Minimize blood loss:** The exclusive GORE® DRYSEAL Flex Introducer Sheath valve enables introduction of multiple devices with proven hemostasis control.
- **Care for more patients:** Optimized profile and new configurations provide tailored delivery options for a broader range of patient anatomy.
- **Complete confidence:** Engineered for use with our endovascular portfolio.



GORE® Tri-Lobe Balloon Catheter

- Used to facilitate endovascular repair of the thoracic or abdominal aorta.
- The unique lobed design allows inflation without complete blockage of the aortic blood flow.
- The non-occlusive nature of the balloon is designed to prevent migration of the stent graft in the high-pressure area near the heart during ballooning.

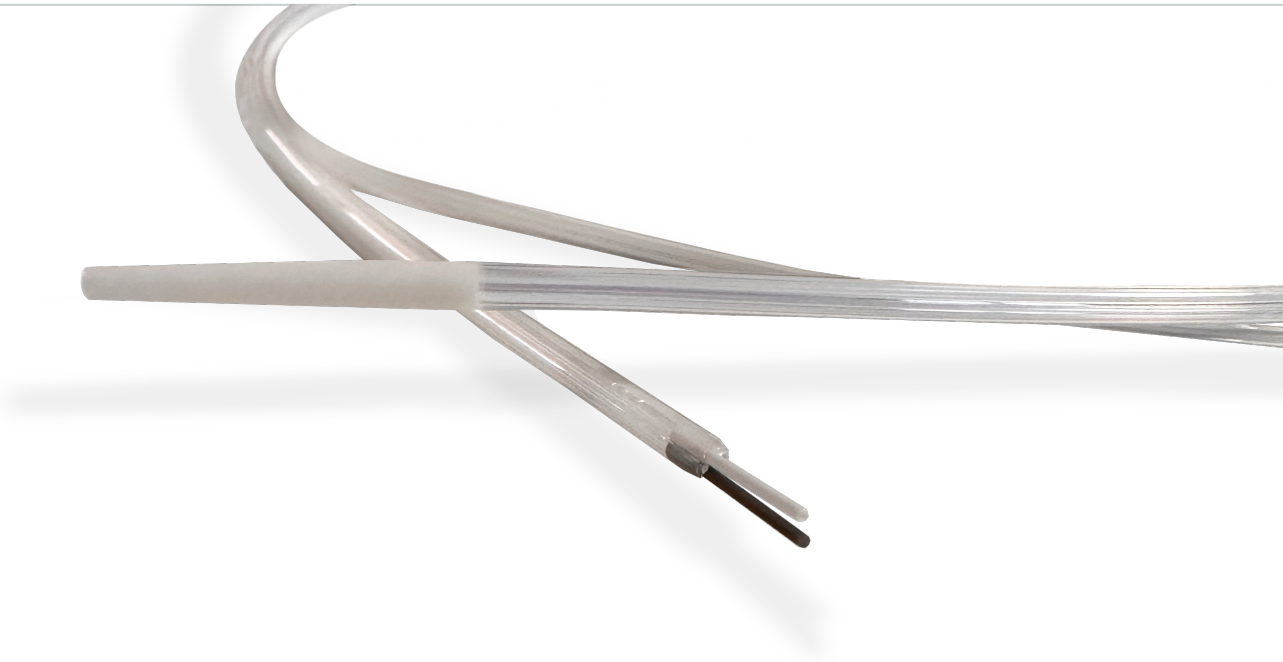


GORE® Molding & Occlusion Balloon (MOB)

- MOB is used to assist the expansion of self-expanding stent grafts to improve molding and fixation to the vessel wall.
- MOB, identified by a single part number, has been validated to function across all available EVAR sizes within the 10-37 mm range. Designed with a low profile, the MOB balloon offers excellent pushability and trackability, effectively minimizing procedural risks.

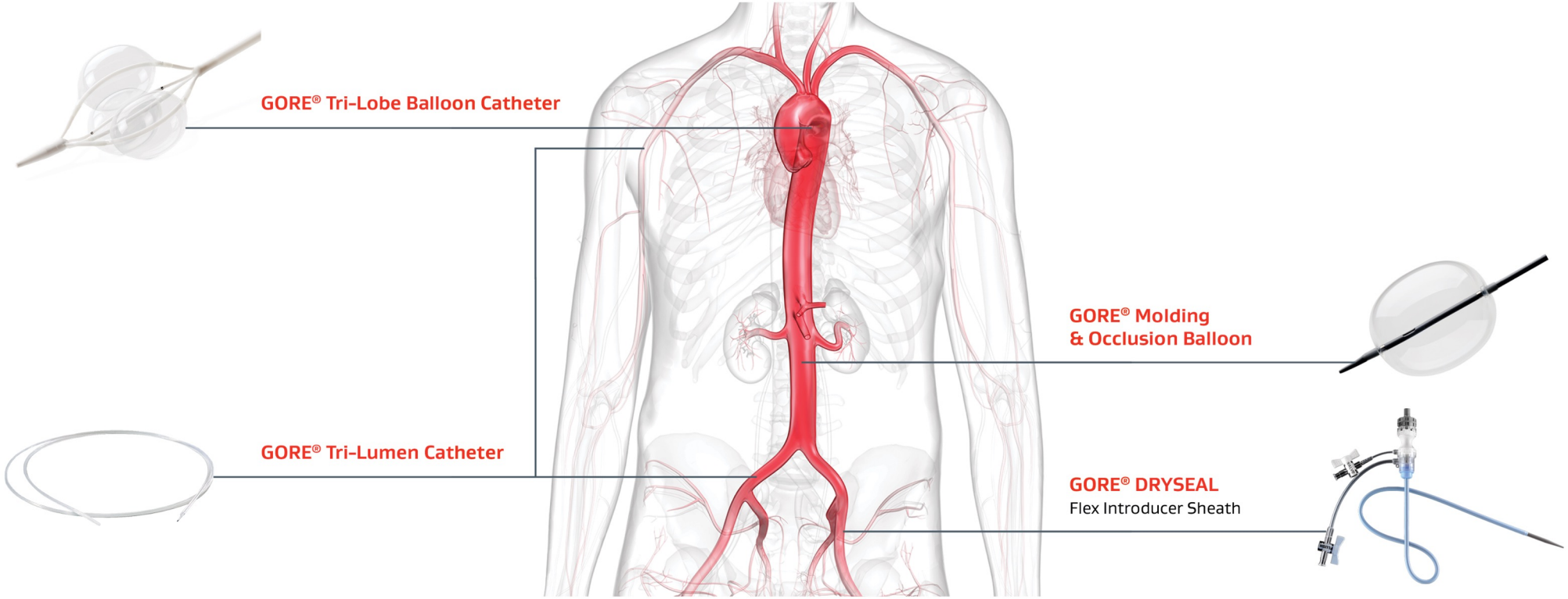
GORE® Tri-Lumen Catheter

The GORE® Tri-Lumen Catheter can be used during procedures to gain through-and-through access, facilitate the placement of guidewires and minimize the risk of tangled guidewires at the time of access.



The next generation in aortic accessories

Each accessory plays a key role in supporting our best-in-class EVAR and TEVAR devices, promoting positive outcomes.



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Consult Instructions for Use
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 for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

GORE® EXCLUDER® AAA Endoprosthesis
INDICATIONS FOR USE IN THE U.S.: 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® Conformable AAA Endoprosthesis
INDICATIONS FOR USE IN THE U.S.: 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® 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 Extende 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 is contraindicated in: patients with known sensitivities or allergies to the device materials. All components of the GORE® EXCLUDER® Iliac Branch Endoprosthesis, 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

Consult Instructions for Use
eifu.goremedical.com

GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE)
INDICATIONS FOR USE IN THE U.S.: The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is indicated for endovascular repair in patients with thoracoabdominal aortic aneurysms and high-surgical risk patients with pararenal aortic aneurysms who have appropriate anatomy as described below: Adequate iliac/femoral access and brachial/axillary access; proximal (supraceliac) aortic neck treatment diameter range over 2 cm seal zone of 22-34 mm for aneurysms extending up to 6.5 cm or less above the origin of the most proximal branch vessel; aortic neck angle ≤ 60° at the Aortic Component proximal seal zone; iliac artery treatment diameter range of 8-25 mm and iliac artery seal zone length of at least 10 mm; renal artery seal zone diameters between 4.0-10.0 mm; celiac and superior mesenteric artery seal zone diameters between 5.0-12.0 mm; ≥ 15 mm seal zone length in renal arteries, superior mesenteric artery and celiac artery; and visceral segment of aorta (3 cm proximal through 9.5 cm distal to the most proximal visceral artery) must be ≥ 20 mm in diameter. **CONTRAINDICATIONS:** The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is contraindicated in: Patients with known sensitivities or allergies to the TAMBE materials including ePTFE, FEP, nickel titanium alloy (Nitinol), stainless steel and gold. Patients who have a condition that threatens to infect the graft. Patients with known hypersensitivity to heparin, including patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II and cannot receive the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis. 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® Molding & Occlusion Balloon Catheter (MOB)
INDICATIONS FOR USE IN THE U.S.: The GORE® Molding and Occlusion Balloon Catheter is intended for temporary occlusion of large diameter vessels or to assist the expansion of self-expanding endovascular prostheses (stent grafts). **CONTRAINDICATIONS:** The GORE® Molding and Occlusion Balloon Catheter is contraindicated in patients who: are contraindicated to contrast media or anticoagulants; have an arterial entry site that cannot accommodate a 10 Fr introducer sheath; are minors; are pregnant. 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. 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 IN THE U.S.: The GORE® TAG® Conformable Thoracic Stent Graft is intended for endovascular repair of all lesions of the descending thoracic aorta, including: isolated lesions in patients who have appropriate anatomy, including: adequate iliac/femoral access, aortic inner diameter in the range of 16-42 mm, ≥ 20 mm non-aneurysmal aorta proximal and distal to the lesion; Type B dissections in patients who have appropriate anatomy, including: adequate iliac/femoral access, ≥ 20 mm landing zone proximal to the primary entry tear; proximal extent of the landing zone must not be dissected, diameter at proximal extent of proximal landing zone in the range of 16-42 mm. **CONTRAINDICATIONS:** Patients with known sensitivities or allergies to the device materials; patients who have a condition that threatens to infect the graft. Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ 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 ≥ 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 for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

GORE® Tri-Lobe Balloon Catheter
INDICATIONS FOR USE IN THE U.S.: The GORE® Tri-Lobe Balloon Catheter is indicated to facilitate in the endovascular repair of the thoracic or abdominal aorta due to lesions including aneurysms, dissections, trauma, and penetrating aortic ulcers. **CONTRAINDICATIONS:** There are no known contraindications. 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

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Together, improving life

GORE® Tri-Lumen Catheter
INDICATIONS FOR USE IN THE U.S.: The GORE® Tri-Lumen Catheter is a multi-lumen catheter indicated for use in endovascular procedures requiring multiple guidewires and through-and-through access, in which the catheter leading tip exits the patient, for the implantation of branched stent grafts. Standard techniques for placement of vascular access sheaths, catheters and wires should be employed. **CONTRAINDICATIONS:** No known contraindications. 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® VIABAHN® VBX Balloon Expandable Endoprosthesis
INDICATIONS FOR USE IN THE U.S.: The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is indicated for the treatment of de novo or restenotic lesions found in iliac arteries with reference vessel diameters ranging from 5 mm-13 mm and lesion lengths up to 110 mm, including lesions at the aortic bifurcation. The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is also indicated for use with thoracoabdominal and pararenal branched devices indicated with the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis as a branch component. **CONTRAINDICATIONS:** Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in 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 for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

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Products listed may not be available in all markets.

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