INSTRUCTIONS FOR USE FOR:

CONFORMABLE
AAA ENDOPROSTHESIS

en

English

Low Permeability Design

1A • 1B • 1C

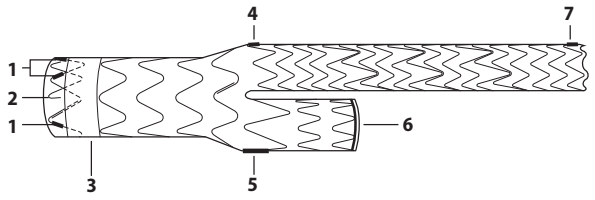

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Figure 1A: Trunk-Ipsilateral Leg Endoprosthesis (Aortic Diameter of 20 mm)

Trunk-Ipsilateral Leg Endoprosthesis Radiopaque Markers:

- Three (3) short markers at the proximal aortic end.
- One (1) long and one (1) short marker at the endoposthesis bifurcation level. The long marker denotes the contralateral leg side location and orientation.
- One (1) marker ring at the opening of the contralateral leg hole.
- One (1) short marker at the iliac end of the ipsilateral leg.

1. Proximal Radiopaque Markers (3)
2. Anchors
3. Sealing Cuff
4. Ipsilateral (Short) Radiopaque Marker
5. Contralateral (Long) Radiopaque Marker
6. Radiopaque Marker Ring
7. Distal Radiopaque Marker (1)

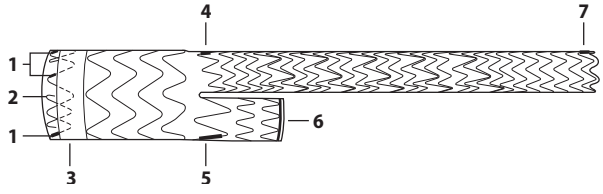

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Figure 1B: Trunk-Ipsilateral Leg Endoprosthesis (Aortic Diameters of 23, 26, or 28.5 mm)

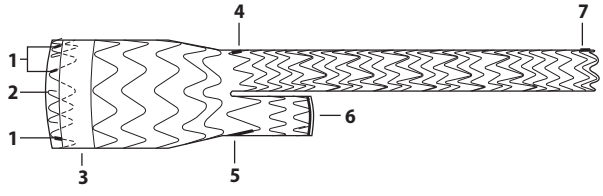

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Figure 1C: Trunk-Ipsilateral Leg Endoprosthesis (Aortic Diameters of 32 or 36 mm)

2A

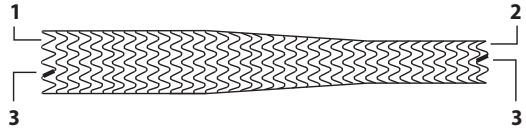

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Figure 2A: Contralateral Leg Endoprosthesis (Distal Iliac Diameters of 12 and 14.5 mm)

Contralateral Leg Endoprosthesis Radiopaque Markers:

- One (1) marker at each end

1. Leading End
2. Trailing End
3. Radiopaque Marker

2B

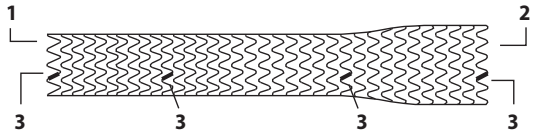

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Figure 2B: Contralateral Leg Endoprosthesis (Distal Iliac Diameters of 16, 18, 20, 23, and 27 mm)

Contralateral Leg Endoprosthesis Radiopaque Markers:

- One (1) marker at each end
- One (1) marker located 3 cm below the proximal end
- One (1) marker located 4 cm above the distal end (16, 18, and 20 mm Contralateral Leg devices only)
- One (1) marker located 5 cm above the distal end (23 mm Contralateral Leg device only)
- One (1) marker located 6 cm above the distal end (27 mm Contralateral Leg device only) *

1. Leading End
2. Trailing End
3. Radiopaque Marker

* Note: The 27 mm x 10 cm does not have a radiopaque marker 6 cm above the distal end.

3A

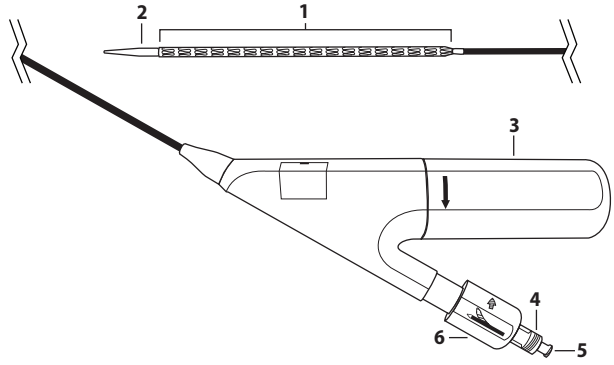

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Figure 3A: GORE® EXCLUDER® Conformable AAA Endoprosthesis Trunk-Ipsilateral Leg Component on Delivery Catheter

1. Constrained Endoprosthesis
2. Radiopaque Leading Tip
3. White Outer Deployment Knob
4. Tuohy-Borst Valve
5. Guidewire Lumen and Flushing Port
6. Angulation Control Knob

3B

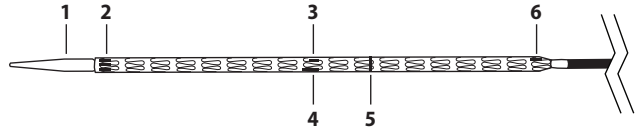

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Figure 3B: Constrained GORE® EXCLUDER® Conformable Trunk-Ipsilateral Leg Component on Delivery Catheter with Radiopaque Markers

1. Radiopaque Leading Tip
2. Proximal Radiopaque Markers (3)
3. Ipsilateral (Short) Radiopaque Marker
4. Contralateral (Long) Radiopaque Marker
5. Radiopaque Marker Ring on Contralateral Gate
6. Distal Radiopaque Marker (1)

3C

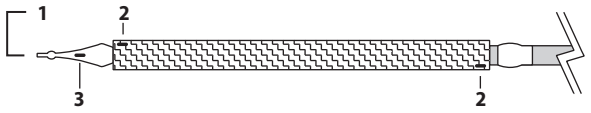

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Figure 3C: Constrained GORE® EXCLUDER® Contralateral Leg Endoprosthesis (Distal Diameters of 12 and 14.5 mm) on Delivery Catheter with Radiopaque Markers

1. Leading End
2. Radiopaque Marker
3. Radiopaque Marker on Delivery Catheter

3D

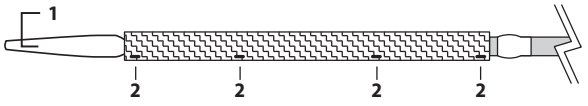

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Figure 3D: Constrained GORE® EXCLUDER® Contralateral Leg Endoprosthesis (Distal Iliac Diameters of 16, 18, 20, 23, and 27 mm) on Delivery Catheter with Radiopaque Markers

1. Radiopaque Leading Tip
2. Radiopaque Marker
   * Note: the 27 mm x 10 cm Contralateral Leg Endoprosthesis has three (3) radiopaque markers; One (1) at each end and one (1) located 3 cm below the proximal end.

3E

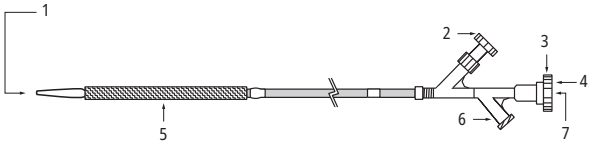

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Figure 3E: Delivery Catheter of Contralateral Leg and Iliac Extender Endoprosthesis

1. Leading End
2. Deployment Knob
3. Tuohy-Borst Valve
4. Trailing End
5. Constrained Endoprosthesis
6. Flushing Port
7. Guidewire Lumen

4

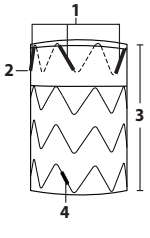

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Figure 4: GORE® EXCLUDER® Conformable Aortic Extender Endoprosthesis Aortic Extender Radiopaque Markers (4 total):

- Three (3) long markers at the proximal end
- One (1) short marker at the distal end

1. Proximal Radiopaque Markers (3 Long)
2. Sealing Cuff
3. 4.5 cm*
4. Distal Radiopaque Marker (1 Short)

*Note: All dimensions are nominal.

5A

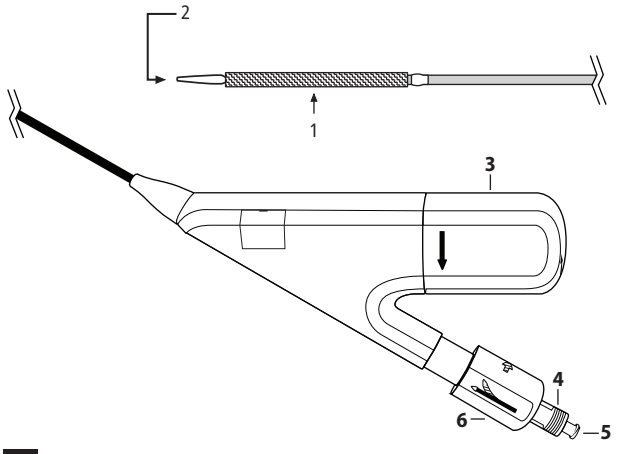

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Figure 5A: GORE® EXCLUDER® Conformable Aortic Extender Endoprosthesis on Delivery Catheter

1. Constrained Endoprosthesis
2. Radiopaque Leading Tip
3. White Outer Deployment Knob
4. Tuohy-Borst Valve
5. Guidewire Lumen and Flushing Port
6. Angulation Control Knob

5B

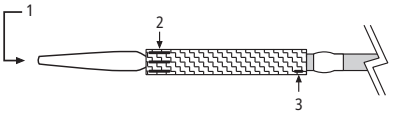

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Figure 5B: Constrained GORE® EXCLUDER® Conformable Aortic Extender Endoprosthesis on Delivery Catheter with Radiopaque Markers

1. Radiopaque Leading Tip
2. Proximal Radiopaque Markers (3 Long)
3. Distal Radiopaque Marker (1 Short)

6A

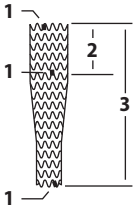

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Figure 6A: Iliac Extender Endoprosthesis *
Iliac Extender Radiopaque Markers (3 total):

- Two (2) end markers: one (1) at each end
- One (1) marker located 3 cm below the proximal end

* Note: All dimensions are nominal.

1. Radiopaque Marker (1)
2. 3 cm
3. 7 cm

6B

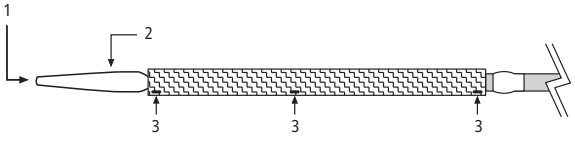

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Figure 6B: Constrained Iliac Extender Endoprosthesis (Distal Iliac Diameters of 10, 12, and 14.5 mm)

1. Leading End
2. Radiopaque Marker on Delivery Catheter
3. Radiopaque Marker

7A • 7B • 7C

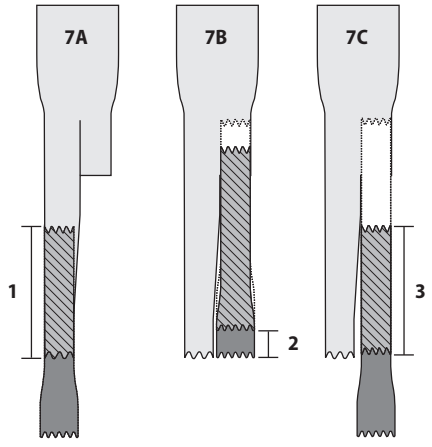

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Figure 7: Contralateral Leg Endoprosthesis as an Iliac Extender (Distal Iliac Diameters of 16, 18, 20, 23, and 27 mm)

1. A minimum overlap of 3 cm with the Ipsilateral Leg is required.
2. If the Contralateral Leg and Iliac Extender diameters are identical, the taper zone can be deployed inside the previously deployed Contralateral Leg.
3. A minimum overlap of 3 cm with the Contralateral Leg is required. This overlap should be achieved prior to the beginning of the distal taper zone of the 18, 20, 23, and 27 mm Contralateral Leg.

8

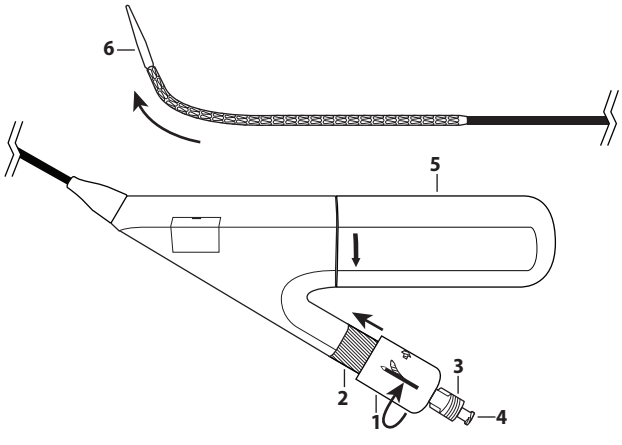

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Figure 8: GORE® EXCLUDER® Conformable AAA Endoprosthesis Delivery System – OPTIONAL: Angulation of Constrained Trunk-Ipsilateral Leg Component*

* Note: Device angulation in figure is representative of a 20 mm Trunk. The amount of angulation will vary depending on Trunk diameter and patient anatomy.

1. Angulation Control Knob
2. Angulation Control Red Indicator : Angulation Wire is Advanced
3. Touhy-Borst Valve
4. Guidewire Lumen and Flushing Port
5. White Outer Deployment Knob
6. Radiopaque Leading Tip

9A

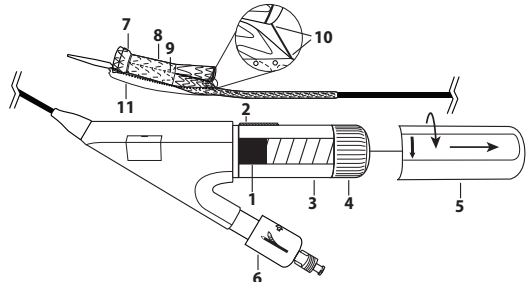

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Figure 9A: GORE® EXCLUDER® Conformable AAA Endoprosthesis Delivery System – Deployment of the Proximal Trunk – White Outer Deployment Knob Removal

1. Black Nut
2. Red Safety Lock
3. Transparent Knob
4. Gray Constraining Dial
5. White Outer Deployment Knob
6. Angulation Control Knob
7. Sealing Cuff
8. Secondary Sleeve
9. Secondary Sleeve Deployment Line Stitch
10. Temporary Attachment Fiber (of Secondary Sleeve Deployment Line)
11. Primary Constraining Sleeve

9B

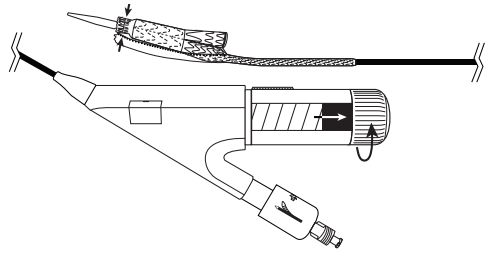

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Figure 9B: GORE® EXCLUDER® Conformable AAA Endoprosthesis Delivery System – OPTIONAL: Constraining of Anchor Seal Row on Proximal Trunk

9C

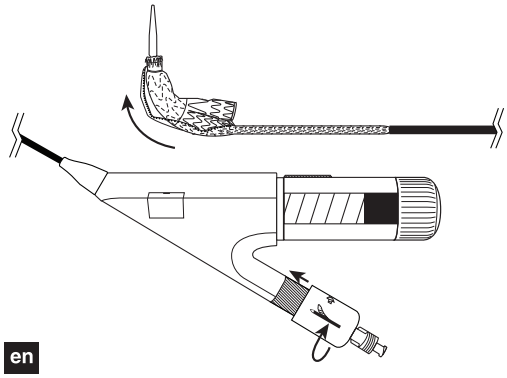

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Figure 9C: GORE® EXCLUDER® Conformable AAA Endoprosthesis Delivery System – OPTIONAL: Angulation of Constrained Proximal Trunk*

* Note: Device angulation in figure is representative of a 20 mm Trunk. The amount of device angulation will vary depending on Trunk diameter and patient anatomy.

9D

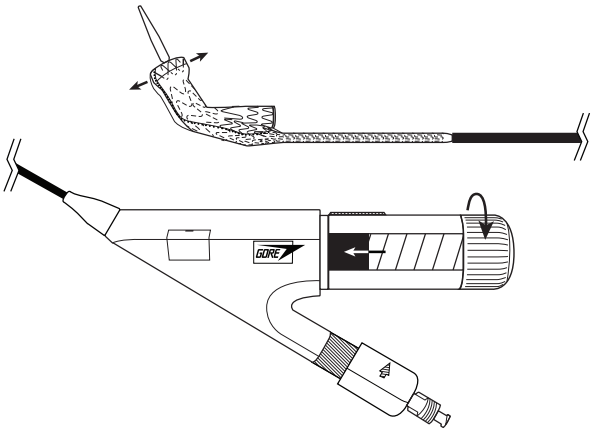

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Figure 9D: GORE® EXCLUDER® Conformable AAA Endoprosthesis Delivery System – OPTIONAL: Unconstraining (Reopening) of Anchor Seal Row on Angulated Proximal Trunk*

* Note: Device angulation in figure is representative of a 20 mm Trunk. The amount of device angulation will vary depending on Trunk diameter and patient anatomy.

9E

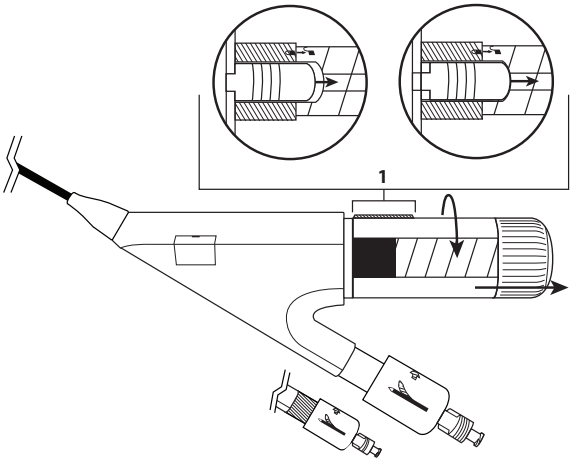

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Figure 9E: GORE® EXCLUDER® Conformable AAA Endoprosthesis Delivery System – Disengaging the Constraining Mechanism

1. Red Safety Lock

9F

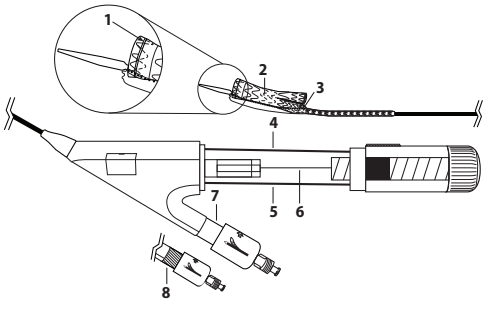

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Figure 9F: GORE® EXCLUDER® Conformable AAA Endoprosthesis Delivery System – Removal of the Constraining Mechanism and Deployment of Secondary Sleeve

1. Constraining Loop
2. Secondary Sleeve Stitch Line Deploying
3. Secondary Sleeve Deployment Line (Temporary Attachment Fiber)
4. Constraining Loop
5. Lock Pin
6. Secondary Sleeve Deployment Line
7. Angulation Wire is Retracted (No Red Indicator)
8. Angulation Control Red Indicator: Angulation Wire is Advanced

9G

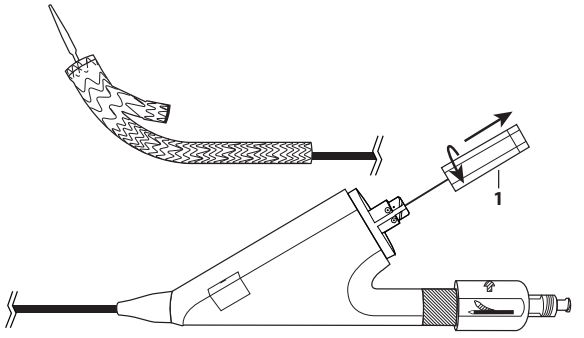

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Figure 9G: GORE® EXCLUDER® Conformable AAA Endoprosthesis Delivery System – Deployment of Ipsilateral Leg of the Trunk-Ipsilateral Leg Component

1. Gray Deployment Knob

10A

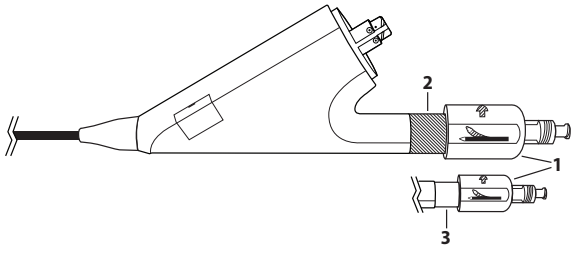

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Figure 10A: GORE® EXCLUDER® Conformable AAA Endoprosthesis Delivery System – Retraction of Angulation Wire

1. Angulation Control Knob
2. Angulation Control Red Indicator: Angulation Wire is Advanced
3. Angulation Wire is Retracted (No Red Indicator)

10B

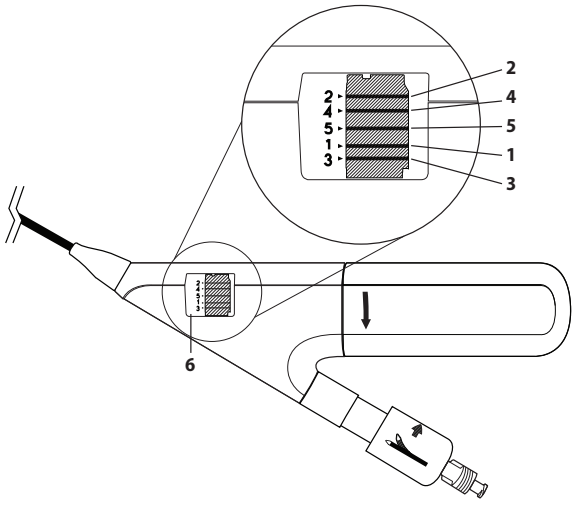

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Figure 10B: GORE® EXCLUDER® Conformable AAA Endoprosthesis Delivery System – Trunk-Ipsilateral Leg – Deployment Line Access Hatch

1. First Deployment Line of Primary Sleeve
2. Lock Pin
3. Constraining Loop
4. Secondary Sleeve Deployment Line
5. Second Deployment Line of Primary Sleeve (Ipsilateral Leg)
6. Deployment Line Access Hatch

11A

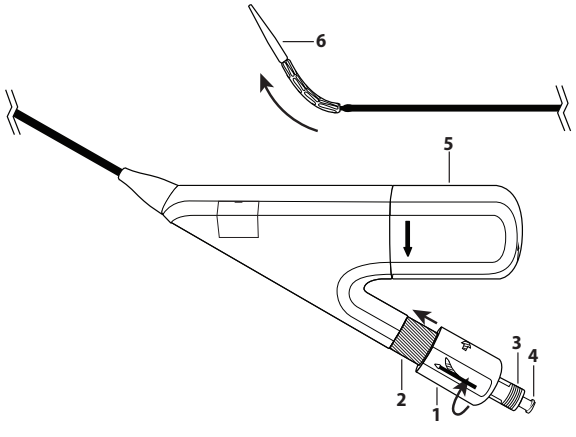

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Figure 11A: GORE® EXCLUDER® Conformable Aortic Extender Delivery System – OPTIONAL: Angulation of Constrained Aortic Extender

1. Angulation Control Knob
2. Angulation Control Red Indicator: Angulation Wire is Advanced
3. Touhy-Borst Valve
4. Guidewire Lumen and Flushing Port
5. White Outer Deployment Knob
6. Radiopaque Leading Tip

11B

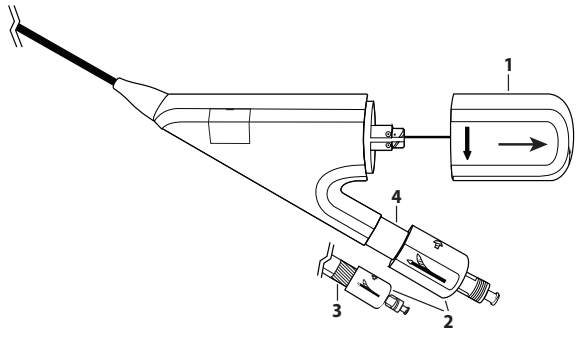

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Figure 11B: GORE® EXCLUDER® Conformable Aortic Extender Delivery System – Deployment of Aortic Extender – White Outer Deployment Knob Removal

1. White Outer Deployment Knob
2. Angulation Control Knob
3. Angulation Control Red Indicator: Angulation Wire is Advanced
4. Angulation Wire is Retracted (No Red Indicator)

11C

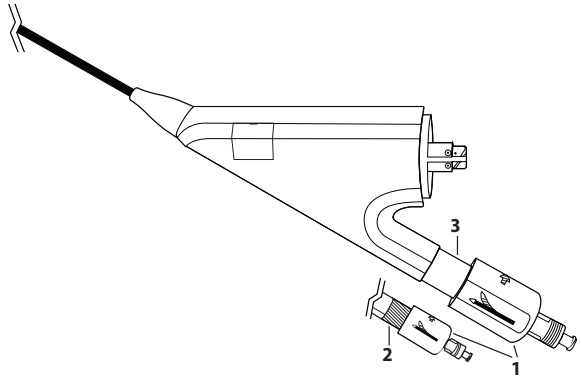

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Figure 11C: GORE® EXCLUDER® Conformable Aortic Extender Delivery System – Retraction of Angulation Wire

1. Angulation Control Knob
2. Angulation Control Red Indicator: Angulation Wire is Advanced
3. Angulation Wire is Retracted (No Red Indicator)

11D

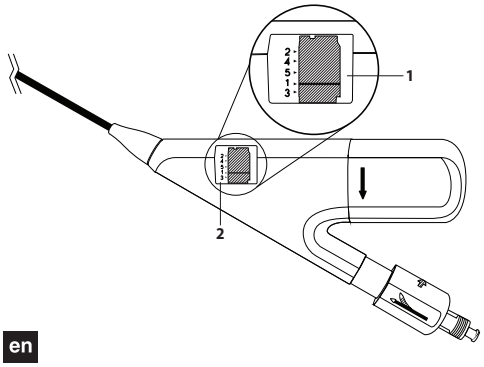

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Figure 11D: GORE® EXCLUDER® Conformable Aortic Extender Delivery System – Aortic Extender – Deployment Line Access Hatch

1. Aortic Extender Deployment Line
2. Deployment Line Access Hatch

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- **Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious surgical consequences or injury to the patient.**

INSTRUCTIONS FOR USE
***GORE® EXCLUDER®* CONFORMABLE AAA ENDOPROSTHESIS**

DESCRIPTION

GORE® EXCLUDER® Conformable AAA Endoprosthesis

The GORE® EXCLUDER® Conformable AAA Endoprosthesis (EXCC) provides endovascular treatment of infrarenal abdominal aortic aneurysms (AAA). The GORE® EXCLUDER® Conformable AAA Endoprosthesis is a multi-component system consisting of a Trunk-Ipsilateral Leg Endoprosthesis, a Contralateral Leg Endoprosthesis, an Aortic Extender Endoprosthesis for proximal extension, and an Iliac Extender Endoprosthesis for distal extension. The graft material for each component is expanded polytetrafluoroethylene (ePTFE) and fluorinated ethylene propylene (FEP) that is supported by nitinol (nickel titanium alloy) wire along its external surface. Nitinol anchors and an ePTFE / FEP sealing cuff are located at the leading (proximal) end of the trunk (Figures 1A, 1B, and 1C) and a sealing cuff is located at the leading (proximal) end of the Aortic Extender (Figure 4). All components have gold radiopaque markers for visualization (Figures 1, 2, 4, and 6A). An ePTFE / FEP sleeve is used to constrain the endoprostheses on the delivery catheter (Figures 3A, 3B, 3C, 3D, and 5A). All components of the GORE® EXCLUDER® Conformable AAA Endoprosthesis are of the low permeability design, which is the only design available. Each component of the GORE® EXCLUDER® Conformable AAA Endoprosthesis is described below.

GORE® EXCLUDER® Conformable Trunk-Ipsilateral Leg Endoprosthesis

The GORE® EXCLUDER® Conformable Trunk-Ipsilateral Leg Endoprosthesis (Trunk) (Figures 1A, 1B, and 1C) is compatible and is intended to be used in conjunction with the GORE® EXCLUDER® Contralateral Leg Endoprosthesis (Figures 2A and 2B). The GORE® EXCLUDER® Conformable Trunk-Ipsilateral Leg Endoprosthesis includes an ePTFE / FEP secondary constraining sleeve which constrains the Trunk body and is seen when the Trunk is partially deployed to the contralateral gate (Figures 9A, 9B, 9C, and 9D). The Gore ® EXCLUDER® Conformable Trunk-Ipsilateral Leg Endoprosthesis delivery system includes an angulation control knob that enables the user to angle the proximal end of the device to promote orthogonal placement in the patient's aorta (Figure 3A, 9, 10). The GORE® EXCLUDER® Conformable Trunk-Ipsilateral Leg Endoprosthesis is intended to be used with the GORE® EXCLUDER® Conformable Aortic Extender Endoprosthesis (Figures 4, 5A, and 5B) for proximal extension and the GORE® EXCLUDER® Contralateral Leg Endoprosthesis (Figures 2A, 2B, 3C, and 3D) and GORE® EXCLUDER® Iliac Extender Endoprosthesis (Figures 6A and 6B) for distal extension. Following deployment, the ePTFE / FEP primary and secondary constraining sleeves remain *in situ* between the endoprosthesis and the vessel wall.

GORE® EXCLUDER® Conformable Aortic Extender Endoprosthesis

The GORE® EXCLUDER® Conformable Aortic Extender Endoprosthesis (Aortic Extender) (Figures 4, 5A, and 5B) provides proximal extension of approximately 2.2 cm of the leading (proximal) end of the Trunk. The Aortic Extender can be placed at variable extension lengths from 0 cm to 2.2 cm of the leading (proximal) end of the Trunk, allowing customization of extender treatment length based on patient anatomy and physician preference. This extension requires a minimum of approximately 2.2 cm overlap with the Trunk. Deployment of the Aortic Extender initiates from the trailing (distal) end and proceeds towards the leading (proximal) end of the endoprosthesis and delivery catheter. The Gore ® EXCLUDER® Conformable Aortic Extender Endoprosthesis delivery system includes an angulation control knob that enables the user to angle the proximal end of the device to promote orthogonal placement in the patient's aorta (Figure 5A, 10, 11). Following deployment, the ePTFE / FEP sleeve remains *in situ* between the endoprosthesis and the vessel wall.

GORE® EXCLUDER® Contralateral Leg Endoprosthesis

The GORE® EXCLUDER® Contralateral Leg Endoprosthesis (Contralateral Leg) (Figures 2A and 2B) is intended to be used with the GORE® EXCLUDER® Conformable Trunk-Ipsilateral Leg Endoprosthesis. Deployment of the Contralateral Leg initiates from the leading (proximal) end and proceeds toward the trailing (distal) end of the delivery catheter (Figures 3C, 3D, and 3E). The ePTFE / FEP constraining sleeve remains *in situ* between the endoprosthesis and the vessel wall.

GORE® EXCLUDER® Contralateral Leg Endoprosthesis Used as Iliac Extender Endoprosthesis (Distal Iliac Diameters of 16, 18, 20, 23, and 27 mm)

Only Contralateral Leg Endoprostheses described in Figure 2B may also be utilized as Iliac Extenders as depicted in Figure 7. A minimum overlap of 3 cm between the previously deployed Ipsilateral Leg (Figure 7A) or Contralateral Leg (Figures 7B and 7C) is required. A radiopaque marker located 3 cm below the proximal end is provided to confirm this overlap. This overlap should be achieved prior to the beginning of the distal taper zone of the 18, 20, 23, and 27 mm Contralateral Leg. Further, the distal end including the taper zone should not be deployed inside the previously deployed Ipsilateral Leg or Contralateral Leg of the GORE® EXCLUDER® Conformable AAA Endoprosthesis if the distal end diameters are 12 or 14.5 mm.

The 16, 18, and 20 mm Contralateral Legs have a radiopaque marker located 4 cm above the distal end which defines the recommended minimal extension required of the Contralateral Leg as an Iliac Extender. The 23 and 27 mm Contralateral Legs have a radiopaque marker located 5 cm and 6 cm, respectively, above the distal end which defines the recommended minimal extension required of the Contralateral Leg as an Iliac Extender*. However, when the Contralateral Leg and Iliac Extender diameters are identical, the taper zone can be deployed inside the previously deployed Contralateral Leg (Figure 7B).

*** NOTE: The 27 mm x 10 cm Contralateral Leg Endoprosthesis has only three (3) radiopaque markers; One (1) located at each end and one (1) located 3 cm below the proximal end.**

GORE® EXCLUDER® Iliac Extender Endoprosthesis (Distal Iliac Diameters of 10, 12, and 14.5 mm)

The Iliac Extender Endoprosthesis (Iliac Extender) provides an extension of up to 4 cm of either the ipsilateral or contralateral leg. The extender component can be placed at variable extension lengths from 0 cm to 4 cm allowing customization of extender treatment length based on patient anatomy and physician preference. A radiopaque marker is located 3 cm from the leading (proximal) end (Figures 6A and 6B). This marker denotes the recommended minimum overlap with the ipsilateral or contralateral leg of the GORE® EXCLUDER® Conformable AAA Endoprosthesis. Deployment of the Iliac Extender initiates from the leading (proximal) end and proceeds toward the trailing (distal) end of the delivery catheter (Figure 3E). Following deployment, the ePTFE / FEP sleeve remains *in situ* between the endoprosthesis and the vessel wall.

INDICATIONS FOR USE

Trunk-Ipsilateral Leg Endoprosthesis and Contralateral Leg Endoprosthesis Components

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 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 Endoprosthesis and Iliac Extender Endoprosthesis Components

The Aortic and Iliac Extender Endoprostheses 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
- Patients with a systemic infection who may be at increased risk of endovascular graft infection.

WARNINGS AND PRECAUTIONS

General

- Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious surgical consequences or injury to the patient.
- The GORE® Medical Device is designed for single use only; do not reuse device. Gore does not have data regarding reuse of this device. Reuse may cause device failure or procedural complications including device damage, compromised device biocompatibility, and device contamination. Reuse may result in infection, serious injury, or patient death.
- Any modifications made to the device may cause serious surgical consequences or injury to the patient.
- **The long-term performance of stent-grafts has not been established.** All patients should be advised this treatment modality requires long-term, regular follow-up to assess patients' health status and stent-graft performance. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms) should receive enhanced follow-up (See IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP).
- The GORE® EXCLUDER® Conformable AAA Endoprosthesis should only be used by physicians experienced in vascular interventional techniques, and who have successfully completed the appropriate physician training program.
- The GORE® EXCLUDER® Conformable AAA Endoprosthesis is not recommended in patients unable to undergo, or who will not be compliant with the necessary pre- and post-operative imaging and follow-up described in IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP.
- Intervention or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aneurysms and / or persistent endoleak. An increase in aneurysm size and / or persistent endoleak may lead to aneurysm rupture.
- Always have a vascular surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

Patient Selection, Treatment, and Follow-Up

- The safety and effectiveness of the GORE® EXCLUDER® Conformable AAA Endoprosthesis have not been evaluated in the following patient populations:
  - traumatic aortic injury
  - leaking: pending rupture or ruptured aneurysms
  - mycotic aneurysms
  - pseudoaneurysms resulting from previous graft placement
  - revision of previously placed stent grafts
  - genetic connective tissue disease (e.g., Marfans or Ehlers-Danlos Syndromes)
  - concomitant thoracic aortic or thoracoabdominal aneurysms
  - inflammatory aneurysms
  - patients with active systemic infections
  - pregnant or nursing females
  - morbidly obese patients
  - patients less than 21 years old
  - patients with less than 15 mm in length or > 60° angulation of the proximal aortic neck
  - patients with creatinine levels > 2.5 mg/dl
- Ilio-femoral access vessel size and morphology (minimal thrombus, calcium and / or tortuosity) should be compatible with vascular access techniques and accessories of the delivery profile of a 12 Fr - 18 Fr vascular introducer sheath.
- Key anatomic elements that may affect successful exclusion of the aneurysm include severe proximal neck angulation (> 60˚), short proximal aortic neck (<15 mm), and significant thrombus and / or calcium at the arterial implantation sites, specifically the proximal aortic neck and distal iliac artery interface. Significant thrombus may be quantified as thrombus ≥ 2 mm in thickness and / or ≥ 25% of the vessel circumference in the intended seal zone of the aortic neck. Irregular calcium and / or plaque may compromise the fixation and sealing of the implantation sites.
- The GORE® EXCLUDER® Conformable AAA Endoprosthesis is not recommended in patients who cannot tolerate contrast agents necessary for intraoperative and post-operative follow-up imaging.
- The GORE® EXCLUDER® Conformable AAA Endoprosthesis is not recommended in patients exceeding weight and / or size limits which compromise or prevent the necessary imaging requirements.
- The GORE® EXCLUDER® Conformable AAA Endoprosthesis is not recommended in patients with known sensitivities or allergies to ePTFE, FEP, gold, nickel, or titanium.

Implant Procedure

- Systemic anticoagulation should be used during the implantation procedure based on hospital and physician preferred protocol. If heparin is contraindicated, an alternative anticoagulant should be considered.
- Minimize handling of the constrained endoprosthesis during preparation and insertion to decrease the risk of endoprosthesis contamination and infection.
- Do not advance the device outside of the sheath while tracking it into position. Catheter breakage or premature deployment have occurred with the Contralateral Leg and Iliac Extender components and may result in potential patient harms, see ADVERSE EVENTS.
- Do not attempt to advance the Aortic Extender through the 12 Fr introducer sheath. The Aortic Extender is designed for a 15 Fr, 16 Fr, or 18 Fr introducer sheath.
- Do not rotate the Trunk Contralateral Leg, Iliac Extender, or Aortic Extender delivery catheter while the endoprosthesis is inside the introducer sheath. Catheter breakage or premature deployment have occurred with the Contralateral Leg and Iliac Extender components and may result in potential patient harms, see ADVERSE EVENTS.
- Do not rotate the Trunk or Aortic Extender delivery catheter beyond 360° to avoid delivery system damage and / or premature deployment.
- Do not rotate the Contralateral Leg, or Iliac Extender delivery catheter during delivery, positioning or deployment. Catheter breakage or separation or premature deployment have occurred and may result in potential patient harms, see ADVERSE EVENTS.
- Do not rotate the Trunk or Aortic Extender delivery catheter when the Angulation Wire is advanced. Device and / or catheter damage may occur.
- Excessive torsion of the device may result in catheter damage.
- Do not rotate the Trunk delivery catheter beyond 90˚ when the Trunk is partially deployed to avoid delivery system damage and / or twisting / kinking of endoprosthesis.
- Do not rotate the Contralateral Leg and Iliac Extender delivery catheter during delivery, positioning or deployment. Catheter breakage or premature deployment may occur.
- Deployment of the Trunk over a floppy (soft) section of a guidewire with the Angulation Wire in its most advanced position may cause the delivery catheter to bend excessively leading to distal movement of the Trunk during deployment.
- Do not attempt to remove a partially deployed Trunk component.
- Do not attempt to withdraw any undeployed endoprosthesis through the introducer sheath. The sheath and catheter must be removed together. Catheter breakage or separation or premature deployment have occurred with the Contralateral Leg and Iliac Extender components and may result in potential patient harms, see ADVERSE EVENTS.
- **Do not attempt to reposition the endoprosthesis after complete deployment of the device. Vessel damage or device misplacement may result.**
- Do not continue advancing any portion of the delivery system if resistance is felt during advancement of the guidewire, sheath, or catheter. Stop and assess the cause of resistance. Vessel or catheter damage or premature deployment have occurred with the Contralateral Leg and Iliac Extender components and may result in potential patient harms, see ADVERSE EVENTS.
- Excessive rotational and / or longitudinal repositioning of the device in highly angulated anatomy may cause the primary constraining sleeve to be positioned proximal to device. Coverage of branch artery may occur.
- Do not advance Angulation Wire after Transparent Knob and Constraining Mechanism Removal. Catheter damage and / or device misplacement may occur.
- Do not deploy the Aortic Extender Component over a floppy section of a guidewire. Distal movement of the device may occur during deployment.
- **Do not continue to withdraw the delivery catheter if resistance is felt during removal through the introducer sheath. Forcibly withdrawing the delivery catheter through the introducer sheath when resistance is encountered has resulted in adverse events with the Contralateral Leg and Iliac Extender components including catheter breakage or separation resulting in potential patients harms, see ADVERSE EVENTS.**

- **Do not withdraw the delivery catheter when the Angulation Wire is advanced. Failure to fully retract the Angulation Wire prior to delivery catheter withdrawal may cause patient injury, device misplacement, device damage, and / or vessel damage to occur.**
- Incorrect deployment or migration of the endoprosthesis may require surgical intervention.
- Catheter leading end separation or breakage and related potential patient harms have occurred with Contralateral Leg and Iliac Extender devices. See ADVERSE EVENTS. If catheter separation occurs, use best medical judgment to determine the appropriate course of action for the patient.
  Effective removal of the catheter component has been reported through both surgical (e.g. cut down) and endovascular techniques (e.g. snaring, sheath removal).
- Do not cover significant renal or mesenteric arteries with the endoprosthesis. Vessel occlusion may occur. During the US clinical studies, this device was not studied in patients with two occluded internal iliac arteries.
- While using 16, 18, 20, 23, or 27 mm Contralateral Legs as an Iliac Extender, ensure that the distal end including the taper zone will not be deployed inside the previously deployed Ipsilateral Leg or Contralateral Leg of the GORE® EXCLUDER® Conformable AAA Endoprosthesis. However, when the Contralateral Leg and Iliac Extender diameters are identical, the taper zone can be deployed inside the previously deployed Contralateral Leg (Figure 7B).
- While using 16, 18, 20, 23, or 27 mm Contralateral Legs as an Iliac Extender, the 3 cm mandatory overlap must be achieved prior to the beginning of the distal taper zone of the 18, 20, 23, and 27 mm Contralateral Leg. Inadequate sealing may lead to endoleak.

MRI Safety Information

Non-clinical testing demonstrated that the GORE® EXCLUDER® Conformable AAA Endoprosthesis is MR Conditional. A patient with this device can be safely scanned, immediately after device placement, in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla only
- Maximum spatial gradient magnetic field of 3,000-Gauss/cm (30 Tesla/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg (Normal Operating Mode)

Under the scan conditions defined above, the GORE® EXCLUDER® Conformable AAA Endoprosthesis is expected to produce a maximum temperature rise of 2.0˚C after 15 minutes of continuous scanning.
In non-clinical testing, the image artifact caused by the device extends approximately 8 mm from the GORE® EXCLUDER® Conformable AAA Endoprosthesis when imaged with a gradient echo pulse sequence and a 3-Tesla MRI system. The artifact does not obscure the device lumen.

POTENTIAL DEVICE OR PROCEDURE RELATED ADVERSE EVENTS

Adverse events that may occur and / or require intervention or additional intraoperative procedure time include, but are not limited to:

- allergic reaction and / or anaphylactoid response to x-ray contrast dye, anti-platelet therapy, device materials
- amputation
- anesthetic complications
- aneurysm enlargement
- aneurysm rupture and death
- arterial or venous thrombosis and / or pseudoaneurysm
- arteriovenous fistula
- bleeding, hematoma, or coagulopathy
- bowel (e.g., ileus, gastrointestinal bleeding, fistula, transient ischemia, infarction, necrosis)
- cardiac (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension or hypertension)
- claudication (e.g., buttock, lower limb)
- delivery catheter: damage, failure, difficulty / unable to remove
- death
- dissection, perforation, or ruptures of the aortic vessel and surrounding vasculature
- edema
- embolization (micro and macro) with transient or permanent ischemia
- endoleak
- endoprosthesis or delivery system: improper component placement; incomplete component deployment; unintentional / premature component deployment; leading end catheter component retention; component migration; separation of graft material from stent; occlusion; infection; stent fracture; graft material failure, dilatation, erosion, puncture, perigraft flow
- fever and localized inflammation
- fistula
- genitourinary (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection)
- hepatic failure
- impotence
- infection (e.g., aneurysm, device or access sites)
- multi-system organ failure
- neurologic damage, local or systemic (e.g., stroke, paraplegia, paraparesis)
- occlusion / stenosis of device or native vessel
- post-implant syndrome
- pulmonary complications (e.g., pneumonia, respiratory failure)
- radiation injury, late malignancy
- renal (e.g., artery occlusion, contrast toxicity, insufficiency, failure)
- surgical cut down, bypass, or conversion
- tissue necrosis
- wound (e.g., infection, dehiscence)
- vascular spasm or vascular trauma (e.g., aorta dissection, aorta damage, ilio-femoral vessel dissection, bleeding, rupture, death)

Device Related Adverse Event Reporting

Any adverse event involving the GORE® EXCLUDER® Conformable AAA Endoprosthesis should be reported to W. L. Gore & Associates immediately. To report an event in the US, call 800.437.8181. Outside the US, contact your local technical representative.

CLINICAL STUDY OUTCOMES (AAA 13-03)

The AAA 13-03 clinical study was conducted to assess the safety and effectiveness of the GORE® EXCLUDER® Conformable AAA Endoprosthesis (EXCC device) in the treatment of infrarenal abdominal aortic aneurysms (AAAs). This cohort included patients with proximal aortic neck length ≥ 10mm and aortic neck angles ≤ 60°. The study completed enrollment in February 2019 with a total of 80 subjects enrolled.

Inclusion / Exclusion Criteria

Inclusion Criteria

1. AAA meeting any of the following criteria:
   - Maximum diameter ≥ 50 mm
   - Rapid growth (> 5 mm in a 6 month period)
   - Non-ruptured AAA presenting with clinical symptoms

2. Adequate anatomy to receive the EXCC Device, including:
   - Adequate iliac / femoral access
   - Infrarenal aortic neck diameter 16-32 mm
   - Infrarenal aortic neck length ≥ 10 mm
   - Aortic neck angle ≤ 60˚
   - Distal iliac artery seal zone ≥ 10 mm
   - Iliac artery diameter 8-25 mm
3. An Informed Consent Form (ICF) signed by subject
4. Male or infertile female*
5. Able to comply with Protocol requirements including following-up
6. Life expectancy > 2 years
7. Age ≥ 21 years

* Infertile female – condition which prevents pregnancy, e.g., hysterectomy, tubal ligation or post-menopausal for greater than 1 year. Subjects will be allocated to the appropriate substudy based on the aortic neck angle measurement recorded during screening.

Exclusion Criteria

1. Mycotic or ruptured aneurysm
2. Known concomitant thoracic aortic aneurysm which requires surgical intervention
3. Renal insufficiency defined as creatinine > 2.5 mg / dL or patient undergoing dialysis
4. New York Heart Association (NYHA) class IV
5. Aneurysmal, dissected, heavily calcified, or heavily thrombosed landing zone(s)
6. Severely tortuous or stenotic iliac and / or femoral arteries
7. Patient has body habitus or other medical condition which prevents adequate delineation of the aorta
8. Participating in another investigational device or drug study within 1 year of treatment
9. Systemic infection which may increase the risk of endovascular graft infection
10. Known degenerative connective tissue disease, e.g., Marfan or Ehler-Danlos Syndrome
11. Planned concomitant surgical procedure or major surgery within 30 days of treatment date
12. Known history of drug abuse
13. Known sensitivities or allergies to the device materials

Baseline Characteristics

The majority of enrolled subjects are male (88.8%) and white (93.8%). Enrolled subjects have a mean age of 73.5 years and a mean BMI of 29.5 kg/m2. The majority subjects have a history of hypercholesterolemia (87.5%), hypertension (73.8%), and tobacco use (66.3%). All subjects are classified as ASA IV or lower. All subjects are classified as NYHA III or lower. The mean Society of Vascular Surgeon's (SVS) risk score was 5.8. Subjects had a median maximum aortic diameter of 54.0 mm.

Table 1. Subject Demographics

	AAA 13-03
Number of Enrolled Subjects	80
Sex at Birth	
Male	71(88.8%)
Female	9(11.3%)
Ethnicity	
Not Hispanic or Latino	75(93.8%)
Hispanic or Latino	1(1.3%)
Unknown	4(5.0%)
Race	
White	75(93.8%)
Black	3(3.8%)
Asian	1(1.3%)
American Indian or Alaska Native	0
Hawaiian or Pacific Islander	0
Other	2(2.5%)
Age (yrs)	
n	80
Mean (Std Dev)	73.5(8.14)
Median	73.5
Range	(56.0,96.0)
Weight (kg)	
n	80
Mean (Std Dev)	89.5(17.82)
Median	87.5
Range	(53.2,132.9)
Height (cm)	
n	80
Mean (Std Dev)	173.9(9.68)
Median	173.4
Range	(144.4,199.4)
BMI (kg/m^2)	
n	80
Mean (Std Dev)	29.5(5.05)
Median	28.5
Range	(21.6,46.1)

Table 2. Subject Medical History

	AAA 13-03
Hypercholesterolemia	70(87.5%)
Hypertension	59(73.8%)
Tobacco Use	53(66.3%)
Cancer	24(30.0%)
Chronic Obstructive Pulmonary Disease	20(25.0%)
Diabetes Mellitus	17(21.3%)
Cardiac Arrhythmia	14(17.5%)
Myocardial Infarction	14(17.5%)
Peripheral Vascular Disease	12(15.0%)
Renal Insufficiency	11(13.8%)
Cerebrovascular disease	10(12.5%)
Congestive Heart Failure	9(11.3%)
Coronary Artery Bypass Graft	9(11.3%)
Other Concomitant Aneurysm	5(6.3%)
Paraplegia	3(3.8%)
Thromboembolic Event	3(3.8%)

Table 3. Subject Risk Factors

	AAA 13-03
Number of Enrolled Subjects	80
ASA Classification	
I	7(8.8%)
II	31(38.8%)
III	39(48.8%)
IV	3(3.8%)
V	0(0%)
NYHA Classification	
I	31(38.8%)
II	11(13.8%)
III	1(1.3%)
IV	0(0%)
No Cardiac Disease	37(46.3%)
SVS Risk Score	
Diabetes	
0	63(78.8%)
1	10(12.5%)
2	7(8.8%)
3	0(0%)
Tobacco Use	
0	44(55.0%)
1	16(20.0%)
2	17(21.3%)
3	3(3.8%)
Hypertension	
0	21(26.3%)
1	26(32.5%)
2	24(30.0%)
3	9(11.3%)
Hyperlipidemia	
0	13(16.3%)
1	10(12.5%)
2	3(3.8%)
3	54(67.5%)
Cardiac Status	
0	53(66.3%)
1	12(15.0%)
2	14(17.5%)
3	1(1.3%)
Carotid Disease	
0	72(90.0%)
1	7(8.8%)
2	1(1.3%)
3	0(0%)

Renal Status	
0	69(86.3%)
1	11(13.8%)
2	0(0%)
3	0(0%)
Pulmonary Status	
0	57(71.3%)
1	9(11.3%)
2	13(16.3%)
3	1(1.3%)
Summary SVS Risk Score	
n	80
Mean (Std Dev)	5.8(3.2)
Median	6.0
Range	(0,14)

Table 4. Anatomical Aortic Measurements

	Site	Gore Imaging Sciences (GIS)[1]
Proximal Aortic Neck Length (mm)		
n	80	80
Mean (Std Dev)	26.1(13.01)	23.9(13.07)
Median	24.5	21.7
Range	(10.0,90.0)	(10.0,95.0)
Maximum Aortic Diameter (mm)		
n	80	-
Mean (Std Dev)	55 .8(6 .07)	-
Median	54 .0	-
Range	(43 .0,78 .0)	-

[1]Gore Imaging Sciences is comprised of film reading experts who reviewed pre-treatment images as a part of the screening process in support of the investigational trial.

Figure 12. Proximal Aortic Neck Length Distribution per Site Assessment

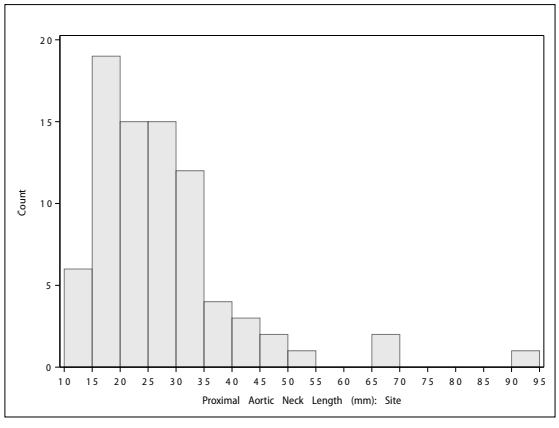


Figure 13. Proximal Aortic Neck Length Distribution per Gore Imaging Sciences (GIS) Assessment

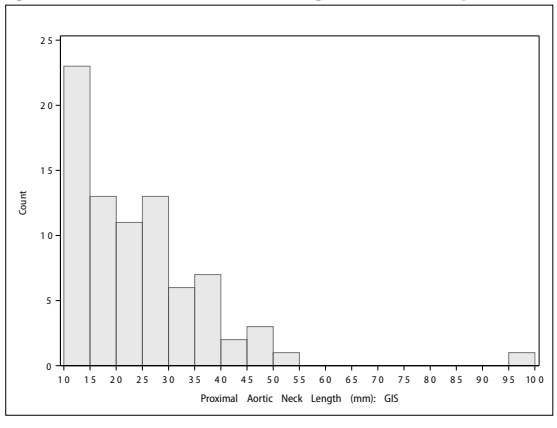
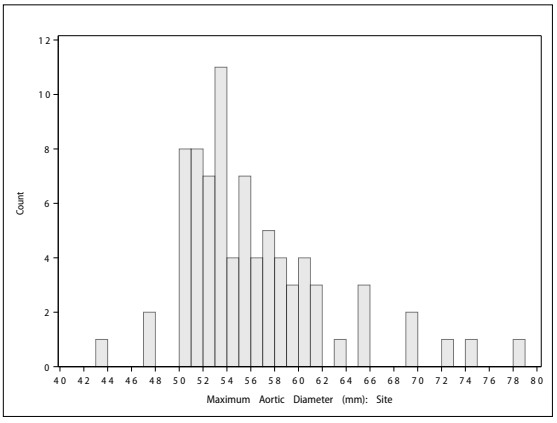


Figure 14. Maximum Aortic Diameter Distribution per Site Assessment



Subject Compliance and Disposition

Subjects enrolled in the study are required to return for follow-up visits at 1, 6, 12, 24, 36, 48, and 60 months post-treatment. Eighty (80) enrolled subjects were eligible for a 1-month follow-up visit, and 79 subjects had a 1-month follow-up visit. Seventy-five (75) subjects returned for a 12-month follow-up visit, no subjects were lost to follow-up or discontinued. Six (6) subject deaths were reported in the study. Subject follow-up remains ongoing.

Table 5. Subject Disposition and Compliance by Study Period

		Follow-up Compliance[1]					Events Prior to Next Interval[1]			
Study Period	Eligible for Follow-Up	Subjects with Visit in Window[2]	Physical Exam Performed	Any CT Scan Performed	Contrast CT Performed	Within Window No CT Yet[3]	Death	Conversion	Discontinued	Not Due for Next Window
Procedure	80	-	-	-	-	-	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Post-Procedure	80	-	-	-	-	-	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1 Month	80	79 (98.8%)	77 (96.3%)	79 (98.8%)	77 (96.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
6 Months	80	77 (96.3%)	72 (90.0%)	75 (93.8%)	71 (88.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12 Months	80	75 (93.8%)	72 (90.0%)	74 (92.5%)	69 (86.3%)	0 (0%)	4 (5.0%)	0 (0%)	0 (0%)	3 (3.8%)
24 Months	73	13 (17.8%)	10 (13.7%)	13 (17.8%)	10 (13.7%)	58 (79.5%)	2 (2.7%)	0 (0%)	0 (0%)	71 (97.3%)

Study period definitions: Procedure (0 days) Post-Procedure (1-14 days) 1 Month (15-59 days) 6 Months (60-242 days) 12 Months (243-546 days) 24 Months (547-911 days)
[1] Percentages are based on number of subjects eligible for follow-up in study period.
[2] Any visit consisting of physical exam or CT scan.
[3] Subjects still within the study window out of those who have not yet had a CT scan.

Table 6 summarizes the evaluated Core Lab parameters over prescribed follow-up time windows for subjects in the study. Core Lab evaluations of endoleaks, patency, AAA rupture, migration, wire fracture, extrusion, lumen obstructions, device compression, and diameter change were dependent on the availability of a contrast-enhanced CT scan. At 12-month follow-up, 74 subjects had a CT performed. Of those 69 subjects had a contrast enhanced CT performed and five (5) subjects had only a non-contrast enhanced CT performed. Of the 74 CTs that were performed at the 12-month follow-up visit, the Core Lab was not able to evaluate all parameters for each CT that was submitted. At the 12 month follow-up visit interval the Core Lab was able to evaluate 67 subjects for endoleaks, 68 subjects for component patency, 69 subjects for AAA rupture, 73 subjects for migration, 71 subjects for extrusion/erosion, 68 subjects for lumen obstruction, 73 subjects for device compression and 73 subjects for diameter change. Five (5) subjects had a non- contrast CT performed at the 12-month follow-up visit in lieu of a contrast enhanced CT due to reasons including decline in subject renal function or incorrect CT performed by site radiology department in error. Three (3) subjects did not have any CT performed due to reasons including CT cost or site's inability to contact the subject. Three (3) subjects did not have a 12-month CT performed due to subject death.

Table 6. Evaluability of Core Lab Parameters

Study Period	Eligible for Follow-Up	Endoleak Evaluable (All Types)	Component Patency Evaluable	AAA Rupture Evaluable	Migration Evaluable	Wire Fracture Evaluable[1]	Extrusion / Erosion Evaluable	Lumen Obstruction Evaluable	Device Compression Evaluable	Diameter Change Evaluable[2]
1 Month	80	75(93.8%)	76(95.0%)	77(96.3%)	79(98.8%)	73(91.3%)	79(98.8%)	77(96.3%)	79(98.8%)	-
6 Months	80	70(87.5%)	72(90.0%)	72(90.0%)	75(93.8%)	69(86.3%)	75(93.8%)	72(90.0%)	75(93.8%)	74(92.5%)
12 Months	80	67(83.8%)	68(85.0%)	69(86.3%)	73(91.3%)	71(88.8%)	73(91.3%)	68(85.0%)	73(91.3%)	73(91.3%)
24 Months	73	10(13.7%)	10(13.7%)	10(13.7%)	11(15.1%)	11(15.1%)	11(15.1%)	10(13.7%)	11(15.1%)	11(15.1%)

Study period definitions: 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days)
[1] Wire fracture was considered evaluable if any fracture was present or at a minimum the non-overlap areas of investigational device could be assessed.
[2] Diameter change was considered evaluable if baseline (1 Month) and follow-up measurement were both available.

Procedure and Recovery

All enrolled subjects had procedural technical success. The median procedural time was 84 minutes, and median procedural blood loss was 50 mL. The median number of devices used in the index procedure was 2.0 devices.

Table 7. Summary of Device Usage Data at Initial Treatment

	AAA 13-03
Number of Subjects Enrolled	80
Number of Subjects with Devices Implanted at Initial Treatment	80
GORE® EXCLUDER® Device Components	
Subjects with Trunks Implanted	80(100.0%)
Subjects with Contralateral Legs Implanted	79(98.8%)

Subjects with Aortic Extenders Implanted	6(7.5%)
Subjects with Iliac Extenders Implanted	8(10.0%)
Number of Devices Implanted	
2	41(51.3%)
3	37(46.3%)
4	2(2.5%)
Number of Devices Per Subject	
n devices	201
Mean (Std Dev)	2.5(0.6)
Median	2.0
Range	(2,4)
Subjects with Additional Devices Implanted at Procedure[1]	3(3.8%)
External iliac artery stent	1(1.3%)
Renal artery stent graft	2(2.5%)

[1] Additional devices in the treated area or connected to study device components.

A listing of EXCC Trunk device sizes used in the study are found in Table 8. A listing of EXCC AE device sizes used in the study are found in Table 9.

Table 8. Distribution of Dimensions of EXCLUDER Trunks – Ipsilateral Legs Implanted at Initial Procedure

Proximal Diameter (mm)	Distal Diameter (mm)	Length (cm)	Devices (N=80)
20	12	12	-
20	12	14	-
20	12	16	-
20	14.5	14	2(2.5%)
20	14.5	16	1(1.3%)
23	12	12	-
23	12	14	1(1.3%)
23	12	16	3(3.8%)
23	12	18	2(2.5%)
23	14.5	12	3(3.8%)
23	14.5	14	1(1.3%)
23	14.5	16	10(12.5%)
23	14.5	18	5(6.3%)
26	12	12	1(1.3%)
26	12	14	-
26	12	16	2(2.5%)
26	12	18	2(2.5%)
26	14.5	12	4(5.0%)
26	14.5	14	6(7.5%)
26	14.5	16	10(12.5%)
26	14.5	18	7(8.8%)
28.5	12	12	-
28.5	12	14	-
28.5	12	16	2(2.5%)
28.5	12	18	1(1.3%)
28.5	14.5	12	6(7.5%)
28.5	14.5	14	3(3.8%)
28.5	14.5	16	2(2.5%)
28.5	14.5	18	1(1.3%)
32	14.5	14	3(3.8%)
32	14.5	16	1(1.3%)
32	14.5	18	-
36	14.5	14	-
36	14.5	16	1(1.3%)
36	14.5	18	-

Table 9. Distribution of Dimensions of EXCLUDER Aortic Extenders Implanted at Initial Procedure

Diameter (mm)	Length (cm)	Devices (N=6)
20	4.5	-
23	4.5	2(33.3%)
26	4.5	1(16.7%)
28.5	4.5	3(50.0%)
32	4.5	-
36	4.5	-

Table 10. Summary of Procedure Data

	AAA 13-03
Subjects Initiating Procedure	80
Endovascular Access Method on Left Side	
Percutaneous	70(87.5%)
Cut-down	10(12.5%)
Cut-down and Conduit	0(0.0%)
Endovascular Access Method on Right Side	
Percutaneous	72(90.0%)
Cut-down	8(10.0%)
Cut-down and Conduit	0(0.0%)
Anesthesia Method[1]	
General	72(90.0%)
Regional	4(5.0%)
Local	3(3.8%)
Procedure Time (minutes)	
n	80
Mean (Std Dev)	89.1(37.9)
Median	84.0
Range	(33,251)
Blood Loss (mL)	
n	80
Mean (Std Dev)	75.6(121.7)
Median	50.0
Range	(0,1000)
Total Fluoro Time (minutes)	
n	79
Mean (Std Dev)	16.4(7.4)
Median	14.0
Range	(8,42)
Contrast Used During Procedure (mL)	
n	79
Mean (Std Dev)	82.2(32.7)
Median	75.0
Range	(14,200)
Transfusion	1(1.3%)
Heparin Administered	79(98.8%)
Procedure Survival	80(100.0%)
Open Surgical Conversion	0(0.0%)
Additional Procedures at Treatment	7(8.8%)
PTA	0(0.0%)
Stent	5(6.3%)
Thrombectomy	0(0.0%)
Embolization	1(1.3%)
Endostaples	0(0.0%)
Other	1(1.3%)

[1] One subject's anesthesia method was monitored anesthesia care (MAC), which is not accounted for in the table.

Table 11. Summary of Hospitalization Data

	AAA 13-03
Subjects Initiating Procedure	80
Intubation Duration (hours)	
n	61
Mean (Std Dev)	2.2(1.0)
Median	2.0
Range	(0,5)
Ventilator Duration (hours)	
n	62
Mean (Std Dev)	2.2(1.0)
Median	2.0
Range	(0,5)
ICU Stay	9(11.3%)
ICU Duration (hours)	
n	17
Mean (Std Dev)	14.1(15.3)
Median	19.0
Range	(0,51)
Hospital Survival	80(100.0%)
Hospitalization Duration (days)	
n	80
Mean (Std Dev)	1.2(0.6)
Median	1.0
Range	(1,4)
Return to Normal Activities (days)	
n	80
Mean (Std Dev)	23.7(27.1)
Median	20.0
Range	(0,174)

Table 12. Summary of Technical Success Results

	AAA 13-03
Number of Enrolled Subjects	80
Technical Success	80(100%)
Femoral artery access obtained	80(100%)
EXCC Device successfully deployed within the proximal neck seal zone	80(100%)
Delivery catheters successfully removed	80(100%)
EXCC Device patent and free from significant twist, kinks, or obstruction (> 30% luminal stenosis) upon final deployment	80(100%)
Absence of type I or type III endoleak on completion angiography	80(100%)
Access site closure successful (either surgical or percutaneous)	80(100%)

Safety Outcomes

Primary Safety Endpoint

The primary safety endpoint was a composite of the following within 30 days of the initial procedure: death, stroke, myocardial infarction, bowel ischemia, paraplegia, respiratory failure, renal failure, procedural blood loss > 1000 mL, and thromboembolic events including limb occlusion and distal embolic events. The primary safety endpoint was analyzed for eligible subjects. Of the 80 enrolled subjects, 79 subjects completed the required assessments to be evaluated for the primary safety endpoint. The percentage of subjects free from a primary safety endpoint event was 100.0%. The lower confidence limit for freedom from primary safety endpoint events was 96.3%, which exceeded the performance goal of 79%. The results of the primary safety endpoint analysis are provided in Table 13.

Table 13. Primary Safety Endpoint Result

	AAA 13-03	95% LCL
Subjects Eligible for Primary Safety Endpoint Analysis	79	
Freedom from Primary Safety Endpoint Event	79/79(100.0%)	96.3%
Freedom from Death	79/79(100.0%)	
Freedom from Stroke	79/79(100.0%)	
Freedom from Myocardial Infarction	79/79(100.0%)	
Freedom from Bowel Ischemia	79/79(100.0%)	

Freedom from Paraplegia	79/79(100.0%)	
Freedom from Respiratory Failure	79/79(100.0%)	
Freedom from Renal Failure	79/79(100.0%)	
Freedom from Procedural Blood Loss >1000 mL	79/79(100.0%)	
Freedom from Thromboembolic Events	79/79(100.0%)	

95% LCL represents one-sided 95% Lower Confidence Limit by exact Clopper-Pearson method

Worst Case Sensivity Analysis

There was one (1) subject ineligible for Primary Safety analysis. In the worst case sensitivity analysis for the safety outcome, this subject was considered to have experienced an endpoint event. The resulting ratio was 79/80 subjects with freedom from a primary safety endpoint event, and the corresponding 95% lower confidence limit was 94.2% which exceeded the performance goal of 79%.

Major Adverse Events (MAE) were defined as any adverse event meeting a primary safety endpoint definition extended through 1 year. A summary of MAEs is found in Table 14. Three (3) subjects died in the 12 month interval. One (1) subject's cause of death was pneumonia, which also met the definition for respiratory failure.

Table 14. Summary of Major Adverse Events

	Follow-Up Period				
	Procedure	**1 Month**	**6 Months**	**12 Months**	**Total**
Number of Enrolled Subjects	80	80	80	79	80
Any Major Adverse Event	0(0%)	0(0%)	0(0%)	3(3.8%)	3(3.8%)
Death	0(0%)	0(0%)	0(0%)	3(3.8%)	3(3.8%)
Stroke	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
Myocardial Infarction	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
Bowel Ischemia	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
Paraplegia	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
Respiratory Failure	0(0%)	0(0%)	0(0%)	1(1.3%)	1(1.3%)
Renal Failure	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
Procedural Blood Loss >1000 ml	0(0%)	-	-	-	0(0%)
Thromboembolic Event	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)

Note: Column header counts and denominators are the number of subjects at risk at the start of each interval.
Study period definitions: Procedure (0 days), 1 Month (1-30 days), 6 Months (31-183 days), 12 Months (184-365 days), Total (0-365 days).
MedDRA Version: 23.0

Adverse events were classified as serious and non-serious. Serious Adverse Events (SAEs) were defined as any event that: led to death; led to serious deterioration in the health of a subject that: resulted in a life threatening illness or injury, resulted in a permanent impairment of a body structure or a body function, required inpatient hospitalization or prolongation of existing hospitalization, resulted in medical or surgical intervention to prevent permanent impairment to a body structure or a body function; or led to fetal distress, fetal death, or a congenital abnormality or birth defect. The estimate of proportion of subjects free from a SAE at 30-day follow-up was 95.0%. The estimate of proportion of subjects free from a SAE at one year follow-up was 79.8%. There were zero device-related SAEs and three procedure-related SAEs (incision site ecchymosis, type II endoleak, and femoral artery pseudoaneurysm) as determined by site investigators.
A summary of procedure related SAEs in the study is found in Table 15. At the time of data export, there were three site reported procedure-related SAEs in the study. One subject experienced an "incision site ecchymosis" on Post-operative Day (POD) 3, which resolved without treatment and sequelae on POD 14. Another subject experienced a right femoral artery pseudoaneurysm during the index procedure which was treated with surgical repair during the index procedure, and resolved without sequela on the same day. A third subject experienced a Type II endoleak on POD 749 which was treated with glue embolization; the endoleak remains ongoing. There are no device-related SAEs in the study.

Table 15. Procedure-Related SAEs by Study Period

	Post-Treatment Follow-up Period						
	Procedure	**1 Month**	**6 Months**	**12 Months**	**24 Months**	**36 Months**	**Total**
Number of Subjects	80	80	80	79	61	7	80
Any Serious Adverse Event	1 (1.3%)	1 (1.3%)	0 (0%)	0 (0%)	0 (0%)	1 (14.3%)	3 (3.8%)
General disorders and administration site conditions	0 (0%)	0 (0%)	-	-	-	1 (14.3%)	1 (1.3%)
Vascular complications associated with device	-	-	-	-	-	1 (14.3%)	1 (1.3%)
Stent-graft endoleak	-	-	-	-	-	1 (14.3%)	1 (1.3%)
Injury, poisoning and procedural complications	1 (1.3%)	1 (1.3%)	-	-	-	0 (0%)	2 (2.5%)
Cardiac and vascular procedural complications	1 (1.3%)	0 (0%)	-	-	-	-	1 (1.3%)
Vascular pseudoaneurysm	1 (1.3%)	-	-	-	-	-	1 (1.3%)
Non-site specific procedural complications	0 (0%)	1 (1.3%)	-	-	-	-	1 (1.3%)
Incision site haemorrhage	-	1 (1.3%)	-	-	-	-	1 (1.3%)

Note: Column header counts and denominators are the number of subjects at risk at the start of each interval. Entries Represent MedDRA SOC, HLT and PT and are identified by increasing level of indentation. Dashes are used below headings with zero values.
Study period definitions: Procedure (0 days), 1 Month (1-30 days), 6 Months (31-183 days), 12 Months (184-365 days), 24 Months (366-731 days), 36 Months (732-1096 days), Total (0-1096 days)
MedDRA Version: 23.0

Mortality

Freedom from aneurysm-related death was 100% at one-year follow-up. The survival estimate is 96.2% at one year follow-up.

Table 16. Listing of All Deaths

Study Day	Cause of Death (Lowest Level Term)
269	Ascites
270	Pneumonia
315	Cardiomyopathy
500	Septic shock
548	Sepsis
568	Cardiopulmonary failure

Device Effectiveness Outcomes

The formal effectiveness assessment for the study was based on the primary endpoint of treatment success. This was defined as a composite of technical success (successful access and deployment of all required EXCC device components) and freedom from:

- Type I endoleak in the 12 month window
- Type III endoleak in the 12 month window
- Migration (10 mm or more) between the one month and at the 12 month window
- AAA enlargement ≥ 5 mm with or without intervention between the one month and the 12 month window
- AAA rupture through the 12 month window
- Conversion to open repair through the 12 month window

The primary effectiveness endpoint was analyzed for eligible subjects. Of the 80 enrolled subjects, 66 subjects were eligible for primary effectiveness endpoint analysis. The percentage of subjects free from a primary effectiveness endpoint event was 98.5%. The lower confidence limit for freedom from primary effectiveness endpoint event was 93.0%, which exceeded the primary effectiveness endpoint performance goal of 80%. The results of the primary effectiveness endpoint analysis are provided in Table 17.

Table 17. Primary Effectiveness Endpoint Results

	AAA 13-03	95% LCL
Subjects Eligible for Primary Effectiveness Endpoint Analysis	66	
Primary Effectiveness Endpoint Success	65(98.5%)	93.0%
Technical Success	66(100.0%)	
Successful Access	66(100.0%)	
Successful Deployment of Devices in the Intended Location	66(100.0%)	
Patent Device Components	66(100.0%)	
Absence of Type I and Type III Endoleak	66(100.0%)	
Successful Access Closure	66(100.0%)	
Freedom from Type I Endoleak in the 12 Month Window	66(100.0%)	
Freedom from Type III Endoleak in the 12 Month Window	66(100.0%)	
Freedom from Migration ≥ 10 mm between 1 Month and 12 Month Window	66(100.0%)	
Freedom from AAA Enlargement ≥ 5 mm	65(98.5%)	
Freedom from AAA Rupture	66(100.0%)	
Freedom from Conversion to Open Repair	66(100.0%)	

95% LCL represents one-sided 95% Lower Confidence Limit by exact Clopper-Pearson method

Worst Case Sensitivity Analysis

Fourteen (14) subjects were not eligible for primary effectiveness endpoint analysis due to missed follow-up or discontinuation. In the worst case sensitivity analysis, these subjects were considered to have experienced an endpoint event resulting in an overall success rate of 65/80 subjects (81.3%). The 95% lower confidence limit was 72.6% which did not exceed the performance goal, thus necessitating a tipping point analysis.

Tipping Point Analysis

Of the fourteen (14) subjects ineligible for analysis, three of those subjects did not have a contrast enhanced CT performed at their 1-month follow-up visit, eight subjects did not have a contrast enhanced CT at their 12-month follow-up visit (five of those subjects received non-contrast CT scans in lieu of a contrast enhanced CT) and three subjects died in the 12 month analysis window. The primary effectiveness performance goal of 80% would tolerate a maximum of 8/14 subjects with endpoint events among the group of subjects who were ineligible for effectiveness analysis; whereas, the observed freedom from effectiveness endpoint events in the primary analysis was 65/66 (98.5%). In consideration of the observed rate of primary effectiveness events of 1/66 (1.5%), it is unlikely the tipping point threshold of 8/14 (57.1%) was reached among the subjects not evaluated.

Change in Maximum Abdominal Aortic Diameter

Changes in maximum aneurysm diameter from baseline as measured by the Core Lab are summarized in Table 18. Per Core Lab-reported data, twenty-six (26) subjects in the 6 month visit window and twenty-seven (27) subjects in the 12 month visit window had an AAA decrease of ≥ 5 mm. There was one subject in both the 6 month visit window and 12 month visit window that had a Core Lab-reported AAA increase of ≥ 5 mm. No re-interventions were planned on the subject with the Core Lab-reported AAA increase of ≥ 5 mm and subject follow up is continuing.

Table 18. Change in Maximum Abdominal Aortic Diameter From Baseline

	6 Months	12 Months	24 Months
Number of Subjects with Available Data[1]	74	73	11
Change in Maximum Abdominal Aortic Diameter from Baseline (Core Lab)			
≥ 5 mm Decrease	26(35.1%)	27(37.0%)	6(54.5%)
No Change	47(63.5%)	45(61.6%)	4(36.4%)
≥ 5 mm Increase	1(1.4%)	1(1.4%)	1(9.1%)

Study period definitions: 6 Months (60-242 days) 12 Months (243-546 days) 24 Months (547-911 days)
If multiple observations are contained within a single study window, the observation closest to the target study window date is used.
[1] Subjects must have a baseline (1 month) and a post-baseline measurement to be available for evaluation .

Table 19. Summary of Reinterventions Adjudicated by CEC by Time Window

	Post Treatment Follow-up Period									
	Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total
Number of Subjects	80	80	80	79	79	19	0	0	0	80
Subjects with Any Reintervention Adjudicated by CEC	0(0%)	0(0%)	1(1.3%)	1(1.3%)	1(1.3%)	0(0%)	0(0%)	0(0%)	0(0%)	2(2.5%)
Conversion to open repair	-	-	0(0%)	0(0%)	0(0%)	-	-	-	-	0(0%)
Open Surgical Repair without EXCC Device Explant	-	-	0(0%)	0(0%)	0(0%)	-	-	-	-	0(0%)
Glue (fibrin, polymer, etc.)	-	-	0(0%)	0(0%)	0(0%)	-	-	-	-	0(0%)
PTA	-	-	0(0%)	0(0%)	0(0%)	-	-	-	-	0(0%)
Stent	-	-	1(1.3%)	0(0%)	0(0%)	-	-	-	-	1(1.3%)
Thrombectomy	-	-	0(0%)	0(0%)	0(0%)	-	-	-	-	0(0%)
Endostaples	-	-	0(0%)	0(0%)	0(0%)	-	-	-	-	0(0%)
Stent Graft – Thoracic	-	-	0(0%)	0(0%)	0(0%)	-	-	-	-	0(0%)
Stent Graft – Abdominal, Proximal Extension	-	-	0(0%)	0(0%)	0(0%)	-	-	-	-	0(0%)
Stent Graft – Abdominal, Interdevice Junction Coverage	-	-	0(0%)	0(0%)	0(0%)	-	-	-	-	0(0%)
Stent Graft – Abdominal, Distal Extension	-	-	0(0%)	0(0%)	0(0%)	-	-	-	-	0(0%)
Stent Graft – Peripheral	-	-	0(0%)	0(0%)	0(0%)	-	-	-	-	0(0%)
Embolization	-	-	0(0%)	1(1.3%)	1(1.3%)	-	-	-	-	1(1.3%)
Other surgery, treatment, or procedure	-	-	0(0%)	0(0%)	1(1.3%)	-	-	-	-	1(1.3%)

Note: Column header counts and denominators are the number of subjects at risk at the start of each interval.
Study period definitions: Procedure(0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total(0-2006 days)

Imaging Core Laboratory Outcomes

In the study, there have been no Core Lab-reported Type I, Type III, or Type IV endoleaks. In addition, there have been no Core Lab-reported non-patent device components, AAA rupture, migration, wire fracture, extrusion / erosion, lumen obstruction, and device compression. Thirty-four (34) subjects have had a Core Lab-reported Type II endoleak, and six (6) subjects have had an indeterminate endoleak reported.

Table 20. Summary of Core Lab Device Findings by Follow-up period

	Post Treatment Follow-up Period							
	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total
Number of Subjects	80	79	79	19	0	0	0	80
Number of Subjects With CT Scan	79	75	74	13	-	-	-	80
Endoleak	33/75(44.0%)	25/70(35.7%)	21/67(31.3%)	4/10(40.0%)	-	-	-	36/78(46.2%)
Type I	0/75	0/70	0/67	0/10	-	-	-	0/78
Type IA	0/75	0/70	0/67	0/10	-	-	-	0/78
Type IB	0/75	0/70	0/67	0/10	-	-	-	0/78
Type II	31/75(41.3%)	24/70(34.3%)	18/67(26.9%)	4/10(40.0%)	-	-	-	34/78(43.6%)
Type III	0/75	0/70	0/67	0/10	-	-	-	0/78
Type IV	0/75	0/70	0/67	0/10	-	-	-	0/78
Indeterminate	3/75(4.0%)	1/70(1.4%)	3/67(4.5%)	0/10	-	-	-	6/78(7.7%)
Non-patent Component	0/35	0/33	0/30	0/4	-	-	-	0/37
Non-patent Trunk-Ispilateral Leg	0/77	0/72	0/68	0/10	-	-	-	0/80
Non-patent Contralateral Leg	0/77	0/72	0/68	0/10	-	-	-	0/80
Non-patent Iliac Extender	0/35	0/33	0/30	0/4	-	-	-	0/37
AAA Rupture	0/77	0/72	0/69	0/10	-	-	-	0/80
Migration	0/79	0/75	0/73	0/11	-	-	-	0/80
Prosthesis Migration >=10mm	0/79	0/75	0/73	0/11	-	-	-	0/80
Intercomponent Migration >=10mm	0/79	0/75	0/73	0/11	-	-	-	0/80
Wire Fracture[1]	0/73	0/69	0/71	0/11	-	-	-	0/80
Extrusion / Erosion	0/79	0/75	0/73	0/11	-	-	-	0/80
Lumen Obstruction	0/77	0/72	0/68	0/10	-	-	-	0/80
Device Compression	0/79	0/75	0/73	0/11	-	-	-	0/80

Denominators used in calculation of percentages are number of subjects with an evaluable result.
Study period definitions: 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total(15-2006 days)
[1] Wire fracture was considered assessed and included in denominator if any fracture was present or at a minimum the non-overlap areas of investigational device could be assessed. All subjects were evaluated for wire fracture in at least one follow-up period.

PATIENT COUNSELING INFORMATION

The physician and patient should review the risks and benefits when discussing this endovascular device and procedure including:

- Risks and differences between endovascular repair and open surgical repair
- Potential advantages of traditional open surgical repair
- Potential advantages of endovascular repair
- The possibility that subsequent interventional or open surgical repair of the aneurysm may be required after initial endovascular repair

In addition to the risks and benefits of an endovascular repair, the physician should assess the patient's commitment and compliance to post-operative follow-up as necessary to ensure continuing safe and effective results. Listed below are additional topics to discuss with the patient as to expectations after an endovascular repair:

- **The long-term safety and effectiveness of endovascular repair has not been established.** Physicians should advise all patients that this treatment modality requires long-term, regular follow-up to assess patients' health status and stent-graft performance. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms) should receive enhanced follow-up. Patients should be counseled on the need for regular follow-up, even in the absence of obvious symptoms, e.g., pain, numbness, weakness (see IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP).

- Regular follow-up including imaging of the device should be performed at least every 12 months for all patients and at least every 6 to 12 months for patients with known endoleaks or aneurysm enlargement for the duration of the implant (see IMAGING GUIDELINES AND POST- OPERATIVE FOLLOW-UP).
- Physicians must advise all patients that it is important to seek prompt medical attention if he / she experiences signs of limb occlusion, aneurysm enlargement or rupture. Signs of graft limb occlusion include pain in the hip(s) or leg(s) during walking, or discoloration or coolness of the leg. Aneurysm rupture may be asymptomatic, but usually presents as pain, numbness, weakness in the legs; any back, chest, abdominal, or groin pain, dizziness, fainting, rapid heartbeat, or sudden weakness.

US physicians are encouraged to refer the patient to the Patient Brochure regarding risks occurring during or after implantation of the device. Procedure related risks include cardiac, pulmonary, neurologic, bowel, and bleeding complications. Device related risks include occlusion, endoleak, aneurysm enlargement, fracture, potential for reintervention and open surgical conversion, rupture and death (See POTENTIAL DEVICE OR PROCEDURE RELATED ADVERSE EVENTS).
US physicians are encouraged to complete the Patient Wallet Card and give it to the patient so that he / she can carry it with them at all times. The patient should refer to the wallet card any time they visit additional health practitioners, particularly for any additional diagnostic procedures (e.g., MRI).

HOW SUPPLIED

The GORE® EXCLUDER® Conformable AAA Endoprosthesis is preloaded on a delivery catheter and supplied sterile and non-pyrogenic.

Storage and Handling

- Do not resterilize; for single use only.
- Do not use if damaged or if sterile barrier has been compromised.
- Do not use after the "use by" (expiration) date printed on the label.
- Store in a cool, dry place.

CLINICAL USE INFORMATION

Physician Training Program

CAUTION: Always have a vascular surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.
CAUTION: The GORE® EXCLUDER® Conformable AAA Endoprosthesis should only be used by physicians experienced in vascular interventional techniques, and who have successfully completed the appropriate physician training program.
The recommended skill / knowledge requirements for physicians using the GORE® EXCLUDER® Conformable AAA Endoprosthesis are outlined below:
Patient selection:

- Knowledge of the natural history of abdominal aortic aneurysms (AAA) and co-morbidities associated with AAA repair
- Knowledge of radiographic image interpretation, device selection and sizing

A multi-disciplinary team that has combined procedural experience with:

- Femoral cutdown, arteriotomy, and repair
- Percutaneous access and closure techniques
- Non-selective and selective guidewire and catheter techniques
- Fluoroscopic and angiographic image interpretation
- Embolization
- Angioplasty
- Endovascular stent placement
- Snare techniques
- Appropriate use of radiographic contrast material
- Techniques to minimize radiation exposure
- Expertise in necessary patient follow-up modalities

Recommended Materials

- 0.035" (0.89 mm) 'super stiff' guidewire (or similar guidewire with a long floppy tip), 145 cm or longer
- Angiographic radiopaque marker catheter
- Contrast media
- Snare Catheter
- Syringe
- Heparin and heparinized saline
- **Trunk-Ipsilateral Leg Endoprosthesis and Contralateral Leg Endoprosthesis:**
  - 12 Fr, 14 Fr, 15 Fr, 16 Fr or 18 Fr introducer sheaths (Tables 21 and 22)
  - Large diameter, low pressure aortic balloon (monitor balloon volumes and pressures as recommended in balloon catheter Instructions for Use)
  - Percutaneous transluminal angioplasty (PTA) balloons (Table 22)
- **Aortic Extender Endoprosthesis:**
  - 15 Fr, 16 Fr, or 18 Fr introducer sheath
  - Large diameter, low pressure aortic balloon (monitor balloon volumes and pressures as recommended in balloon catheter Instructions for Use)
- **Iliac Extender Endoprosthesis:**
  - 12 Fr, 14 Fr and 15 Fr introducer sheaths
  - PTA balloon catheters, 10 mm x 40 mm, 12 mm x 40 mm, 14 mm x 40 mm, 16 mm x 40 mm, 18 mm x 40 mm, 20 mm x 40 mm, 24 mm x 40 mm, and 28 mm x 40 mm (Table 22)

Table 21. Trunk-Ipsilateral Leg Endoprosthesis Sizing Guide*

Intended Aortic Vessel Diameter (mm)	Aortic Endoprosthesis Diameter[1] (mm)	Intended Iliac Vessel Diameter (mm)	Iliac Endoprosthesis Diameter[2] (mm)	Overall Device Lengths (cm)	Recommended Introducer Sheath[3] (Fr)
16 - 18	20	10 - 11	12	12, 14, 16	15
		12 - 13.5	14.5		
19 - 21	23	10 - 11	12	12, 14, 16, 18, 20	15
		12 - 13.5	14.5		
22 - 23	26	10 - 11	12	12, 14, 16, 18, 20	16
		12 - 13.5	14.5		
24 - 26	28.5	10 - 11	12	12, 14, 16, 18, 20	16
		12 - 13.5	14.5		
27- 29	32	12 - 13.5	14.5	14, 16, 18, 20	18
30 - 32	36	12 - 13.5	14.5	14, 16, 18, 20	18

1 Recommended endoprosthesis oversizing relative to the aortic vessel is approximately 10-21%, and for the iliac vessel approximately 7-25%.
2 Recommended angioplasty balloon size is 12 mm and 14 mm, respectively.
3 GORE® Introducer Sheaths are recommended. The GORE® EXCLUDER® Conformable AAA Endoprosthesis is not compatible with introducer sheaths longer than 40 cm (total length including the hemostatic valve).
* Note: All dimensions are nominal.

Table 22. Contralateral Leg and Iliac Extender Endoprosthesis Sizing Guide*

Intended Iliac Vessel Diameter (mm)	Distal Iliac Endoprosthesis Diameter[1] (mm)	Overall Device Lengths[2,3,4] (cm)	Recommended Introducer Sheath[5] (Fr)	Recommended Angioplasty Balloon Size (Proximal) (mm)	Recommended Angioplasty Balloon Size (Distal) (mm x mm)
8 - 9	10	7	12	14	10 x 40
10 - 11	12[8]	7, 10, 12, 14	12	14	12 x 40
12 - 13.5	14.5[8]	7, 10, 12, 14	12	14	14 x 40
13.5 - 14.5	16[6,7]	9.5, 11.5, 13.5	12	14	16 x 40
14.5 - 16.5	18[6,7]	9.5, 11.5, 13.5	12	14	18 x 40
16.5 - 18.5	20[6,7]	9.5, 11.5, 13.5	12	14	20 x 40
18.5 - 21.5	23[6,7]	10, 12, 14	14	14	24 x 40
21.5 - 25	27[6,7]	10, 12, 14	15	14	28 x 40

1 Recommended endoprosthesis oversizing relative to the vessel is approximately 7-25%.
2 Total treatable lengths include 5.5 cm of the trunk region of the 20, 23, 26, and 28.5 mm Trunk-Ipsilateral Leg Endoprostheses, and 6.5 cm of the trunk region of the 32 and 36 mm Trunk-Ipsilateral Leg Endoprostheses.
3 Labeled Contralateral Leg and Iliac Extender length includes 3 cm overlap.
4 7 cm long Iliac Extender Endoprosthesis provides a maximum extension of 4 cm when placed in the Trunk-Ipsilateral or Contralateral Leg Endoprosthesis.
5 GORE® Introducer Sheaths are recommended. The GORE® EXCLUDER® Conformable AAA Endoprosthesis is not compatible with introducer sheaths longer than 40 cm (total length including the hemostatic valve).
6 16, 18, 20, 23, and 27 mm Contralateral Legs may be used as Iliac Extenders.
7 If extension of a 16, 18, 20, 23, or 27 mm Contralateral Leg is necessary, a 16 mm angioplasty balloon size is recommended for the proximal end of the extension.
8 The 10, 12, 14 cm length 12 and 14.5 mm diameter Contralateral Legs have one radiopaque marker on the proximal and distal ends. They do not have a radiopaque marker to denote the required 3cm overlap if used as Iliac Extender.
* Note: All dimensions are nominal.

Table 23. Aortic Extender Endoprosthesis Sizing Guide*

Intended Aortic Vessel Diameter (mm)	Aortic Extender Diameter[1] (mm)	Endoprosthesis Length (cm)	Recommended Introducer Sheath[2] (Fr)
16 - 18	20	4.5	15
19 - 21	23	4.5	15
22 - 23	26	4.5	15
24 - 26	28.5	4.5	16
27 - 29	32	4.5	18
30 - 32	36	4.5	18

1 Recommended endoprosthesis oversizing relative to the vessel diameter is approximately 10-21%.
2 GORE® Introducer Sheaths are recommended. The GORE® EXCLUDER® Conformable AAA Endoprosthesis is not compatible with introducer sheaths longer than 40 cm (total length including the hemostatic valve).
* Note: All dimensions are nominal.

DIRECTIONS FOR USE

Pre-Treatment Planning

- Determine accurate size of anatomy and proper size of Trunk-Ipsilateral and Contralateral Endoprostheses (Tables 20 and 21) and Aortic and Iliac Extender Endoprostheses (Tables 21 and 22).
- Use high resolution, non-contrast and contrast enhanced computerized tomography (CT / CTA) at ≤ 3 mm acquisition and reconstruction collimation.
- Use multiple view, digital subtraction angiography with a radiopaque marker catheter or spiral CT multi-planar reconstruction.
- For angiography, use correct imaging angulation (cranial-caudal, lateral-oblique) to accurately identify origin of branch vessel anatomy.
- Consider breath-hold technique to optimize digital subtraction angiography image quality.

Anatomical Requirements

- Ilio-femoral access vessel size and morphology (minimal thrombus, calcium and / or tortuosity) should be compatible with vascular access techniques and accessories of the delivery profile of a 12 Fr - 18 Fr vascular introducer sheath.
- An infrarenal, non-aneurysmal aortic neck length of at least 15 mm and an infrarenal aortic neck treatment diameter range of 16 - 32 mm. Infrarenal, non-aneurysmal aortic neck length is defined as the length of vessel starting just inferior to the most distal (lowest) major renal artery that meets the intended sizing window of the selected device. For Trunk-Ipsilateral Leg Endoprosthesis and Aortic Extender Endoprosthesis: Proximal aortic neck angulation ≤ 60° with minimal thrombus and / or calcification.
- Key anatomic elements that may affect successful exclusion of the aneurysm include severe proximal neck angulation (> 60˚), short proximal aortic neck (< 15 mm), and significant thrombus and / or calcium at the arterial implantation sites, specifically the proximal aortic neck and distal iliac artery interface. Significant thrombus may be quantified as thrombus ≥ 2 mm in thickness and / or ≥ 25% of the vessel circumference in the intended seal zone of the aortic neck. Irregular calcium and / or plaque may compromise the fixation and sealing of the implantation sites.
- Distal segment iliac vessel lengths of at least 30 mm of which at least 10 mm must be less than or equal to 25 mm in diameter for Iliac Extender Endoprosthesis: Non-aneurysmal iliac artery length ≥ 10 mm of appropriate diameter.
- Freedom from significant femoral / iliac artery occlusive disease that would impede inflow or outflow of stent-grafts.
- Ability to tolerate general, regional, or local anesthesia.
- Patient's anatomical suitability for endovascular repair.

Arterial Access and Angiography

1. Following standard practices, access the intended contralateral side via a percutaneous diagnostic sheath, and perform marker catheter digital subtraction angiography (AP, oblique and lateral views as necessary) to confirm the correct device component sizing, and deployment locations. Consider breath-hold technique to optimize image quality. Leave marker catheter in place at the level of the renal arteries.
2. Following standard practices, perform percutaneous access and / or surgical exposure of the vessels selected to receive the Trunk-Ipsilateral and Contralateral side introducer sheaths.
3. Following the manufacturer's Instructions for Use, advance a 0.035" (0.89 mm) 'super stiff' guidewire (or similar guidewire with a long floppy tip), to the level of the renal arteries.
4. Following the manufacturer's Instructions for Use, prepare and advance the recommended introducer sheath (Tables 21 – 23) over the guidewire, through the ilio-femoral anatomy, aortic aneurysm, and up to the level of the proximal aortic neck according to standard practice.
5. **CAUTION:** Systemic anticoagulation should be used during the implantation procedure based on hospital and physician preferred protocol. If heparin is contraindicated, an alternative anticoagulant should be considered.
6. Use standard heparinized saline, pressure flush system technique to prevent thrombus formation in the introducer sheaths.
7. Use an accurate radiopaque patient marking method to assure accurate device positioning and deployment locations.

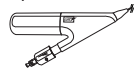
Catheter Preparation

1. Use new, sterile gloves when preparing device.
   CAUTION: Minimize handling of the constrained endoprosthesis during preparation and insertion to decrease the risk of endoprosthesis contamination and infection.
2. Remove the appropriately sized Trunk-Ipsilateral and Contralateral Leg delivery catheters from their packaging and examine for possible damage.
3. Remove protective packaging mandrel and packaging sheath(s) from the leading end of the delivery catheters (Figures 3A-3E, 5A-5B, and 6B).
4. Flush with heparinized saline through the flushing port on the trailing end of the delivery catheter (Figures 3A, 3E, and 5A).
5. Follow the manufacturer's recommended method for size selection, preparation and use of aortic and iliac dilation balloons. Carefully inflate the balloon to avoid complications.

GORE® EXCLUDER® Conformable Trunk-Ipsilateral Leg Endoprosthesis Positioning

1. Use fluoroscopic visualization for all guidewire, sheath, and device catheter manipulations.
2. Advance the Trunk delivery catheter over a 0.035" (0.89 mm) 'super stiff' guidewire (or similar guidewire with a long floppy tip) through the 15 Fr, 16 Fr, or 18 Fr introducer sheath into the aorta to the approximate level of intended positioning.
   WARNING: Do not advance the device outside of the sheath. The sheath will protect the device from catheter breakage or premature deployment while tracking it into position.
   WARNING: Do not rotate the device delivery catheter while the endoprosthesis is inside the introducer sheath. Catheter breakage or premature deployment may occur.
   WARNING: Do not continue advancing any portion of the delivery system if resistance is felt during advancement of the guidewire, sheath, or catheter. Stop and assess the cause of resistance. Vessel or catheter damage may occur.
3. While maintaining the delivery catheter in position, withdraw the introducer sheath (Table 21) and visually verify that the leading end of the introducer sheath is below the distal Trunk-Ipsilateral leg radiopaque marker.
4. Magnify and center the fluoroscopic image on the proximal trunk. Reposition and rotate the Trunk-Ipsilateral delivery catheter as necessary to properly position the proximal device marker as well as orient the long contralateral, and short ipsilateral radiopaque markers and device position on the appropriate side of the anatomy. The long marker should be oriented toward the contralateral side (Figures 1A, 1B, and 1C).
   Optional Angulation (Bending) of the Trunk-Ipsilateral Leg Endoprosthesis:
   A. Optional use of the Angulation Wire may be used to provide angulation (bending) of the proximal portion of the constrained Trunk device (Figure 8).
   B. To use the Angulation Wire, rotate the Gray Angulation Control Knob clockwise. A red indicator will appear adjacent to the Gray Angulation Control Knob as an alert that the Angulation Wire is advanced in the catheter (Figure 8).
   C. Turn the Gray Angulation Control Knob to a position that provides the desired amount of device angulation (bending) (Figure 8).
   D. To retract the Angulation Wire, rotate the Gray Angulation Control Knob counter-clockwise. When the Angulation Wire is completely retracted, the red indicator will not be visible and the Gray Angulation Control Knob will no longer be able to be rotated counter-clockwise.
   NOTE: The Trunk can be safely deployed regardless of the position of the Angulation Wire (retracted, fully advanced, or partially advanced).
   WARNING: Do not rotate the Trunk delivery catheter when the angulation wire is advanced. Device and / or catheter damage may occur.
   WARNING: Do not advance / retract Angulation Wire to angulate the proximal Trunk more than five times during a procedure. Device and / or catheter damage may occur.
   WARNING: Do not rotate the Trunk delivery catheter beyond 360° to avoid delivery system damage and / or premature deployment.
   CAUTION: Excessive torsion of the device may result in catheter damage.
   CAUTION: Deployment of the Trunk over a floppy (soft) section of a guidewire with the Angulation Wire in its most advanced position may cause the delivery catheter to bend excessively leading to distal movement of the Trunk during deployment.
5. It is recommended to view and confirm the distal position of the iliac end of the device relative to the internal iliac artery to ensure accurate and desired deployment position of the distal aspect of the device.
6. If clinically acceptable, lower the patient's mean arterial pressure to 60 – 70 mm Hg during Trunk deployment and aortic balloon inflation to decrease blood flow and reduce the risk of endoprosthesis movement.
7. Maintain a contralateral access side sheath, catheter or guidewire in position across the distal, native bifurcation to protect and ensure that contralateral access is maintained into the aneurysm sac and contralateral leg hole of the device during Trunk-Ipsilateral component deployment.
8. Re-center and magnify the image on the proximal Trunk of the device to assure final desired position of proximal device relative to anatomy. Stabilize the Trunk delivery catheter at the level of entry into the introducer sheath and stabilize the sheath relative to the patient's access site.
   WARNING: Do not attempt to withdraw any undeployed endoprosthesis through the introducer sheath. The sheath and catheter must be removed together.

GORE® EXCLUDER® CONFORMABLE DELIVERY SYSTEM - TRUNK IPSILATERAL ENDOPROSTHESIS DEPLOYMENT



1. Loosen the White Outer Deployment Knob by turning it 90° counter-clockwise (Figure 9A). Confirm desired device position and orientation, stabilize the delivery catheter, and deploy the Trunk using a steady and continuous pull of the deployment knob to release the proximal endoprosthesis past the contralateral leg hole of the Trunk. Pull the deployment knob straight out from the catheter handle. Deployment initiates from the leading end toward the trailing end. The Ipsilateral Leg will remain constrained on the delivery catheter. If the Trunk is not properly positioned following removal of the White Outer Deployment Knob, continue with Optional Repositioning of Trunk-Ipsilateral Leg Endoprosthesis, described below.
   WARNING: Incorrect deployment or migration of the endoprosthesis may require surgical intervention.
   WARNING: Do not attempt to remove a partially deployed Trunk component.
   CAUTION: Do not cover significant renal or mesenteric arteries with the endoprosthesis. Vessel occlusion may occur.
   CAUTION: Deployment of the Trunk over a floppy (soft) section of a guidewire with the Angulation Wire in its most advanced position may cause the delivery catheter to bend excessively leading to distal movement of the Trunk during deployment.
   BACKUP DEPLOYMENT MECHANISM: In the event that the removal of the White Outer Deployment Knob does not initiate the deployment of the proximal end of the Trunk device, and the problem is suspected to have occurred in the deployment handle, the deployment handle has a design feature that is intended to protect the patient against this problem becoming a harm. Remove the Deployment Line Access Hatch Lid (Figure 10B) and then pull the first deployment line (labeled "1") with an appropriate dull or blunt-edged tool. Fully remove the deployment line in a steady, continuous motion. This action will cause the proximal Trunk to deploy past the contralateral leg hole.
   WARNING: Do not cut the first deployment line (labeled "1"). Patient injury, catheter damage, and / or device damage may occur.
   Optional Repositioning of Trunk-Ipsilateral Leg Endoprosthesis
   Constraining of Proximal Trunk
   A. To constrain the proximal end of the Trunk, turn the Gray Constraining Dial clockwise until it stops (Figure 9B). The Black Nut within the Transparent Knob housing will move toward the trailing end of the handle when the Trunk end of the device is constrained. Verify the distance between the three proximal radiopaque markers is reduced (Figures 1A, 1B, 1C, and 9B).
   B. Magnify and center the fluoroscopic image on the proximal Trunk. Manually reposition and / or rotate the Trunk-Ipsilateral component delivery catheter as necessary to properly position the Trunk device. Maximize the separation between the long and short radiopaque markers to achieve maximum lateral iliac leg positioning of the device. The long marker should be oriented toward the contralateral side (Figures 1A, 1B, and 1C).
   Angulation (Bending) of Proximal Trunk
   C. Optional use of the Angulation Wire may be used to provide angulation (bending) of the proximal portion of the Trunk (Figure 9C).
      WARNING: Constrain the proximal end of the Trunk prior to advancement of the Angulation Wire. Vessel damage may occur due to anchors not being constrained.

D. To use the Angulation Wire, rotate the Gray Angulation Control Knob clockwise. A red indicator will appear adjacent to the Gray Angulation Control Knob as an indicator that the Angulation Wire is advanced in the catheter (Figure 9C).
E. Turn the Gray Angulation Control Knob to a position that provides the desired amount of device angulation (bending) (Figures 9B and 9C).
F. If additional angulation (bending) of the Trunk is desired, a floppy (soft) section of the guidewire may allow additional device angulation.
G. To retract the Angulation Wire, rotate the Gray Angulation Control Knob counter-clockwise. When the Angulation Wire is completely retracted, the red indicator will not be visible and the Gray Angulation Control Knob will no longer be able to be rotated counter-clockwise.
NOTE: The Trunk can be safely deployed regardless of the position of the Angulation Wire (retracted, fully advanced, or partially advanced).
WARNING: Do not rotate the Trunk delivery catheter when the Angulation Wire is advanced. Device and / or Catheter damage may occur.
WARNING: Do not rotate the Trunk delivery catheter beyond 90˚ when the Trunk is partially deployed to avoid delivery system damage and / or twisting / kinking of endoprosthesis.
H. When the Trunk is positioned to the desired location, turn the Gray Constraining Dial counter-clockwise until it stops to reopen the proximal end of the Trunk (Figures 9A and 9D). The Black Nut within the Transparent Knob housing will move toward the leading end of the catheter when the proximal end of the Trunk is reopened. Verify that the distance between the three proximal radiopaque markers is maximized (Figures 1A, 1B, and 1C).
WARNING: Do not constrain / reopen the Trunk device more than two times during a procedure. Device and / or catheter damage may occur.
WARNING: Do not advance / retract Angulation Wire to angulate the proximal Trunk more than five times during a procedure. Device and / or catheter damage may occur.
WARNING: Excessive rotational and / or longitudinal repositioning of the device in highly angulated anatomy may cause the primary constraining sleeve to be positioned proximal to device. Coverage of branch artery may occur.
WARNING: In the event that the complete counter-clockwise rotation of the Gray Constraining Dial does not initiate the reopening of the proximal end of the Trunk device, and the problem is suspected to have occurred in the deployment handle, the deployment handle has a design feature that is intended to protect the patient against this problem becoming a harm. Verify the final desired Trunk device position relative to anatomy. Stabilize the Trunk delivery catheter at the level of entry into the introducer sheath and stabilize the sheath relative to the patient's access site. Reopening the proximal end of the Trunk device can be achieved through either of the following options. Option 1: Remove the Deployment Line Access Hatch (Figure 10B) and then, with an appropriate dull or blunt-edged tool, grasp and move the Constraining Loop line (labeled "3") proximally or distally as desired to constrain or unconstrain the proximal end of the Trunk device. Option 2: Disengage the constraining mechanism by sliding the Red Safety Lock back while rotating the entire Transparent Knob 90˚ counter-clockwise (Figures 9E and 9F). Remove the constraining mechanism by pulling the Transparent Knob straight out from the catheter handle (Figures 9E and 9F). These actions will cause the constraining mechanism to be removed and the proximal end of the Trunk device to reopen. Note that if Option 2 is exercised, no further repositioning of the Trunk device will be possible.

Contralateral Leg Hole Guidewire Cannulation

1. Use fluoroscopic visualization for all guidewire, sheath, and device catheter manipulations.
2. Following manufacturer's Instructions for Use, advance a 0.035" (0.89 mm) 'super stiff' guidewire (or acceptable preferred guidewire for cannulation) into the contralateral leg hole of the Trunk according to standard practice.
3. Verify that the guidewire is within the contralateral leg hole of the Trunk by standard practice used to verify guidewire location. If multiple cannulation attempts fail, the Trunk-Ipsilateral Leg Endoprosthesis may be repositioned for better contralateral gate access by following the steps outlined above in "Optional Repositioning of Trunk-Ipsilateral Leg Endoprosthesis."
WARNING: Do not constrain / reopen the Trunk device more than two times during a procedure. Device and / or catheter damage may occur.
WARNING: Do not advance / retract Angulation Wire to angulate the proximal Trunk more than five times during a procedure. Device and / or catheter damage may occur.
4. Use fluoroscopic visualization and imaging angiography to verify Trunk device is properly positioned at desired location and branch arteries are patent. If additional repositioning is needed, follow steps outlined above in "Optional Repositioning of Trunk-Ipsilateral Leg Endoprosthesis."
WARNING: Excessive rotational and / or longitudinal repositioning of the device in highly angulated anatomy may cause the primary constraining sleeve to be positioned proximal to device. Coverage of branch artery may occur.
5. Following manufacturer's Instructions for Use, introduce the recommended introducer sheath (Table 22). Advance the sheath over the guidewire and through the contralateral leg hole of the Trunk.

Contralateral Leg Endoprosthesis Positioning and Deployment

1. Advance the prepped Contralateral Leg Endoprosthesis delivery catheter to the level of the long radiopaque marker (Figure 1).
WARNING: Do not advance the device outside of the sheath while tracking it into position. Catheter breakage or premature deployment have occurred and may result in potential patient harms, see ADVERSE EVENTS.
WARNING: Do not rotate the device delivery catheter while the endoprosthesis is inside the introducer sheath. Catheter breakage or separation or premature deployment have occurred and may result in potential patient harms, see ADVERSE EVENTS.
WARNING: Do not continue advancing any portion of the delivery system if resistance is felt during advancement of the guidewire, sheath, or catheter. Stop and assess the cause of resistance. Vessel or catheter damage or premature deployment have occurred and may result in potential patient harms, see ADVERSE EVENTS.
2. Use fluoroscopic visualization and imaging angiography to confirm Trunk is properly positioned and branch arteries are patent.
3. Align the radiopaque marker at the proximal end of the Contralateral Leg Endoprosthesis with the long contralateral radiopaque marker on the Trunk-Ipsilateral Leg Endoprosthesis (Figures 1 and 2). With the alignment of these markers, an approximate 3 cm overlap will be achieved.
4. While maintaining the delivery catheter in position, withdraw the introducer sheath and visually verify that the leading end of the introducer sheath is below the distal Contralateral Leg radiopaque marker.
WARNING: Do not rotate the Contralateral Leg Endoprosthesis delivery catheter during delivery, positioning or deployment. Catheter breakage or separation, or premature deployment have occurred and may result in potential patient harms, see ADVERSE EVENTS.
5. Stabilize the Contralateral Leg Endoprosthesis delivery catheter at the level of entry into the introducer sheath and stabilize the sheath relative to the patient's access site.
WARNING: Do not attempt to withdraw any undeployed endoprosthesis through the introducer sheath. The sheath and catheter must be removed together.
6. Loosen the deployment knob. Confirm final device position. Deploy the Contralateral Leg Endoprosthesis by using a steady, continuous pull of the deployment knob to release the endoprosthesis. Pull the deployment knob straight out from the catheter side-arm (Figures 3C, 3D, and 3E). Deployment initiates from the leading (proximal) end toward the trailing (distal) end.
WARNING: Do not attempt to reposition the endoprosthesis after deployment has been initiated. Vessel damage or device misplacement may result.
WARNING: Incorrect deployment or migration of the endoprosthesis may require surgical intervention.
CAUTION: Do not cover significant renal or mesenteric arteries with the endoprosthesis. Vessel occlusion may occur.
7. Use fluoroscopic guidance during withdrawal of the delivery catheter to assure safe removal from the endoprosthesis. If resistance is felt during removal of delivery catheter through the introducer sheath, stop and withdraw delivery catheter and introducer sheath together.
WARNING: Do not continue to withdraw the delivery catheter if resistance is felt during removal through the introducer sheath. Forcibly withdrawing the delivery catheter through the introducer sheath when resistance is encountered has resulted in adverse events including catheter breakage or separation resulting in potential patient harms, see ADVERSE EVENTS.
8. When withdrawing the device delivery system through the introduce sheath, verify all catheter components are intact.
WARNING: Catheter leading end separation or breakage and related potential patient harms have occurred, see ADVERSE EVENTS. If catheter separation occurs, use best medical judgment to determine the appropriate course of action for the patient. Effective removal of the catheter component has been reported through both surgical (e.g. cut down) and endovascular techniques (e.g. snaring, sheath removal).

Transparent Knob and Constraining Mechanism Removal

1. Verify the proximal end of the Trunk is fully open by turning the Gray Constraining Dial counter-clockwise until it stops (Figures 9D and 9E). The Black Nut within the Transparent Knob housing will move toward the leading end of the catheter when the proximal end of the Trunk is opened. Verify that the distance between the three proximal radiopaque markers is maximized (Figures 1A, 1B, and 1C).

2. Stabilize the Trunk delivery catheter at the level of entry into the introducer sheath and stabilize the sheath relative to the patient's access site.
3. Disengage the constraining mechanism by sliding the Red Safety Lock back while rotating the entire Transparent Knob 90° counter-clockwise (Figure 9E). Remove the constraining mechanism by pulling the Transparent Knob straight out from the catheter handle in a steady, continuous motion (Figure 9F).
   NOTE: Removal of the Constraining Mechanism will deploy the Secondary Sleeve of the Trunk body, and it will remove the Temporary Attachment Fiber (Secondary Sleeve Deployment Line) (Figures 9A, 9F, and 9G). Additionally, the Constraining Loop and Lock Pin will be removed (Figure 9F).
   WARNING: The constraining mechanism cannot be removed unless the proximal end of the Trunk device is fully opened. Verify the Gray Constraining Dial is rotated counter-clockwise until it stops, prior to removing the constraining mechanism. Attempting to remove the constraining mechanism while the Trunk is constrained may result in misplacement of the device, patient injury, and / or device damage.
   WARNING: Do not advance Angulation Wire after Transparent Knob and Constraining Mechanism Removal. Catheter damage and / or device misplacement may occur.
   BACKUP DEPLOYMENT MECHANISM: In the event, that the removal of the Transparent Knob does not initiate the removal of the Constraining Mechanism or deployment of the Secondary Sleeve and the problem is suspected to have occurred in the deployment handle, the deployment handle has a design feature that is intended to protect the patient against this problem becoming a harm. Remove the Deployment Line Access Hatch Lid (Figure 10B) and then cut the silver Lock Pin line (labeled "2") with an appropriate tool. Grasp, pull, and fully remove the silver Lock Pin line (labeled "2") in a steady, continuous motion. Cut the gray Constraining Loop line (labeled "3") with an appropriate tool. Grasp, pull, and fully remove the gray Constraining Loop line (labeled "3") in a steady, continuous motion. These actions will cause the constraining mechanism to be removed.
   Using an appropriate dull or blunt-edged tool, grasp and pull the Secondary Sleeve Deployment Line (labeled "4") in a steady, continuous motion. This will deploy the Secondary Sleeve and remove the Temporary Attachment Fiber that connects the Contralateral Leg Hole to the Ipsilateral Leg (Figures 9A, 9F, and 9G).
   WARNING: Do not cut the Secondary Sleeve Deployment Line (labeled "4"). Patient injury, catheter damage, and / or device damage may occur.

Ipsilateral Leg Deployment

1. Loosen the Gray Deployment Knob (Figure 9G). Deploy the Ipsilateral Leg of the Trunk device using a steady and continuous pull of the Gray Deployment Knob to release the endoprosthesis. Pull the deployment line straight out from the catheter handle.
   BACKUP DEPLOYMENT MECHANISM: In the event that the removal of the Gray Deployment Knob does not initiate the deployment of the Ipsilateral Leg and the problem is suspected to have occurred in the deployment handle, the deployment handle has a design feature that is intended to protect the patient against this problem becoming a harm. Remove the Deployment Line Access Hatch Lid (Figure 10B) and then pull the Second Deployment Line of the Primary Sleeve (labeled "5") with an appropriate dull or blunt-edged tool. Fully remove the deployment line in a steady, continuous motion. This action will cause the Ipsilateral Leg to deploy.
   WARNING: Do not cut the Second Deployment Line of the Primary Sleeve (labeled "5"). Patient injury, catheter damage, and / or device damage may occur.
2. Retract Angulation Wire before delivery catheter removal. To do this, turn the Gray Angulation Control Knob counter-clockwise until the red indicator is no longer visible and until the Gray Angulation Control Knob can no longer be turned counter-clockwise (Figure 10A).
   WARNING: Do not withdraw the delivery catheter when the Angulation Wire is advanced. Failure to fully retract the Angulation Wire prior to delivery catheter withdrawal may cause patient injury, device misplacement, device damage, and / or vessel damage to occur.
3. Use fluoroscopic guidance during the withdrawal of the delivery catheter to assure safe removal from, and to avoid catching on, the endoprosthesis and / or introducer sheath. If resistance is felt during removal of delivery catheter through the introducer sheath, stop, visually assess the cause of the resistance, and withdraw delivery catheter and introducer sheath together if appropriate.
4. Position the aortic balloon inside the proximal region of the trunk. Avoid balloon contact with the flow splitter which is aligned with the long and short radiopaque markers. Inflate and deflate the balloon quickly with dilute contrast solution to seat the aortic end of the endoprosthesis (Table 21). Follow the manufacturer's recommended method for size selection, preparation and use of aortic and iliac dilation balloons, carefully monitoring both volume and pressure to avoid complications.
   NOTE: For angulated proximal aortic necks, ballooning the proximal region of the trunk is at the discretion of the physician.
5. Use fluoroscopic guidance to ensure the balloon is completely deflated and is safely removed from the endoprosthesis.
6. Advance and inflate the appropriate size PTA balloon catheter to seat the iliac end of the Ipsilateral Leg endoprosthesis (Table 21). Follow the manufacturer's recommended method for size selection, preparation and use of PTA balloons. Carefully inflate the balloon to avoid complication.
7. Following manufacturer's instructions for use, advance and inflate a 14 mm PTA balloon catheter to seat the proximal end of the Contralateral Leg Endoprosthesis within the contralateral leg hole overlap region. Follow the manufacturer's recommended method for size selection, preparation and use of aortic and iliac dilation balloons, carefully monitoring both volume and pressure to avoid complications.
8. Following manufacturer's instructions for use, advance and inflate the appropriate size PTA balloon to seat the iliac end of the Contralateral Leg Endoprosthesis. Follow the manufacturer's recommended method for size selection, preparation and use of PTA balloons. Carefully inflate the balloon to avoid complications.

GORE® EXCLUDER® Conformable Aortic Extender Endoprosthesis Positioning and Deployment

1. Use fluoroscopic visualization for all guidewire, sheath, and device catheter manipulations.
2. Advance the Aortic Extender Endoprosthesis delivery catheter over a 0.035" (0.89 mm) 'super stiff' guidewire or acceptable similar guidewire, through the 15 Fr, 16 Fr, or 18 Fr long introducer sheath into the aorta, just proximal to the level of intended device positioning.
   WARNING: Do not attempt to advance the Aortic Extender through the 12 Fr introducer sheath. The Aortic Extender is designed for a 15 Fr, 16 Fr, or 18 Fr sheath.
   WARNING: Do not advance the device outside of the sheath. The sheath will protect the device from catheter breakage or premature deployment while tracking it into position.
   WARNING: Do not rotate the device delivery catheter while the endoprosthesis is inside the introducer sheath. Catheter breakage or premature deployment may occur.
   WARNING: Do not continue advancing any portion of the delivery system if resistance is felt during advancement of the guidewire, sheath, or catheter. Stop and assess the cause of resistance. Vessel or catheter damage may occur.
3. While maintaining the delivery catheter in position, withdraw the introducer sheath and visually verify that the leading end of the introducer sheath is below the distal Aortic Extender radiopaque marker.
4. Magnify and center the fluoroscopic image on the proximal Aortic Extender Endoprosthesis. Reposition the Aortic Endoprosthesis delivery catheter as necessary to position the proximal and distal radiopaque markers in appropriate position.
   Optional Angulation (Bending) of the Aortic Extender Endoprosthesis:
   A. Optional use of the Angulation Wire may be used to provide angulation (bending) of the constrained Aortic Extender.
   B. To use the Angulation Wire, rotate the Gray Angulation Control Knob clockwise (Figure 11A). A red indicator will appear adjacent to the Gray Angulation Control Knob alerting the user that the Angulation Wire is advanced. The Angulation Wire will be fully advanced when the Gray Angulation Control Knob cannot be rotated any further in the clockwise direction, and when the red indicator is fully visible (Figure 11A).
   C. Turn the Gray Angulation Control Knob to a position that provides the desired amount of device angulation (bending) (Figures 5A and 11A).
   D. To retract the Angulation Wire, rotate the Gray Angulation Control Knob counter-clockwise until the red indicator is no longer visible and until the Gray Angulation Control Knob cannot be rotated any further in the counter-clockwise direction.
   NOTE: The Aortic Extender can be safely deployed regardless of the position of the Angulation Wire (retracted, fully advanced, or partially advanced).
   WARNING: Do not rotate the device delivery catheter when the Angulation Wire is advanced. Device and / or catheter damage may occur.
   WARNING: Do not advance / retract Angulation Wire to angulate the Aortic Extender more than five times during a procedure. Device and / or catheter damage may occur.
   WARNING: Do not deploy the Aortic Extender over a floppy (soft) section of a guidewire. Distal movement of the device may occur during deployment.
5. The maximum recommended extension with each Aortic Extender component is approximately one-half of the Extender length inside (2.2 cm) and one-half, outside (2.2 cm), or proximal to the Trunk or Aortic Extender host component. The proximal three (3) and distal one (1) markers are visible relative to host device and anatomy pre and post-deployment (Figures 4 and 5B).
6. If clinically acceptable, lower the patient's mean arterial pressure to 60 – 70 mm Hg during Aortic Extender deployment and aortic balloon inflation to decrease blood flow and reduce the risk of endoprosthesis movement.

7. Stabilize the Extender delivery catheter at the level of entry into the introducer sheath and stabilize the sheath relative to the patient's access site.
   WARNING: Do not attempt to withdraw any undeployed endoprosthesis through the introducer sheath. The sheath and catheter must be removed together.
8. Loosen the White Outer Deployment Knob (Figure 11B). Using fluoroscopy, confirm final device position and deploy the Aortic Extender using a steady and continuous pull of the deployment knob to release the endoprosthesis. Deployment initiates from the trailing (distal) end of the device toward the leading (proximal) end of the device.
   WARNING: Incorrect deployment or migration of the endoprosthesis may require surgical intervention.
   CAUTION: Do not cover significant renal or mesenteric arteries with the endoprosthesis. Vessel occlusion may occur.
   BACKUP DEPLOYMENT MECHANISM: In the event that the removal of the White Outer Deployment Knob does not initiate deployment of the Aortic Extender and the problem is suspected to have occurred in the deployment handle, the deployment handle has a design feature that is intended to protect the patient against this problem from becoming a harm. Remove the Deployment Line Access Hatch Lid (Figure 11D) and then pull the white Aortic Extender Deployment Line (labeled "1") with an appropriate dull or blunt-edged tool. Fully remove the deployment line in a steady, continuous motion. This action will cause the Aortic Extender to deploy.
   WARNING: Do not cut the white Aortic Extender Deployment Line (labeled "1"). Patient injury, catheter damage, and / or device damage may occur.
9. Retract Angulation Wire before delivery catheter removal. To do this, turn the Gray Angulation Control Knob counter-clockwise until the red indicator is no longer visible and until the Gray Angulation Control Knob can no longer be turned counter-clockwise (Figure 11C).
   WARNING: Do not withdraw the delivery catheter when the Angulation Wire is advanced. Failure to fully retract the Angulation Wire prior to delivery catheter withdrawal may cause patient injury, device misplacement, device damage, and / or vessel damage to occur.
10. Use fluoroscopic guidance during the withdrawal of the delivery catheter to assure safe removal from, and to avoid catching on, the endoprosthesis and / or introducer sheath. If resistance is felt during removal of delivery catheter through the introducer sheath, stop and withdraw delivery catheter and introducer sheath together.
11. Advance the aortic dilation balloon until it is centered relative to the endoprosthesis. Inflate and deflate the balloon quickly with dilute contrast solution to seat the Aortic Extender Endoprosthesis. Follow the manufacturer's recommended method for size selection, preparation and use of aortic dilation balloons. Carefully inflate the balloon to avoid complications.
    NOTE: For angulated proximal aortic necks, ballooning the proximal region of the Aortic Extender is at the discretion of the physician.
12. Use fluoroscopic guidance to ensure the balloon is completely deflated and to assure safe removal from, and to avoid catching on, the endoprosthesis and / or introducer sheath.

Iliac Extender Endoprosthesis Positioning and Deployment

1. Use fluoroscopic visualization for all guidewire, sheath, and device catheter manipulations.
2. Advance the Iliac Extender Endoprosthesis delivery catheter into the distal end of the host device, via the recommended introducer sheath (Table 22).
   WARNING: Do not advance the device outside of the sheath while tracking it into position. Catheter breakage or premature deployment have occurred and may result in potential patient harms, see ADVERSE EVENTS.
   WARNING: Do not rotate the device delivery catheter while the endoprosthesis is inside the introducer sheath. Catheter breakage or separation or premature deployment have occurred and may result in potential patient harms, see ADVERSE EVENTS.
   WARNING: Do not continue advancing any portion of the delivery system if resistance is felt during advancement of the guidewire, sheath, or catheter. Stop and assess the cause of resistance. Vessel or catheter damage or premature deployment have occurred and may result in potential patient harms, see ADVERSE EVENTS.
3. For maximum extension, align the radiopaque marker at the iliac (distal) end of the host device with the marker located 3 cm below the proximal end of the Extender component (Figures 2B, 3D, 6A, and 6B).
   WARNING: While using 16, 18, 20, 23, or 27 mm Contralateral Legs as an Iliac Extender, ensure that the distal end including the taper zone will not be deployed inside the previously deployed Ipsilateral Leg or Contralateral Leg of the GORE® EXCLUDER® Conformable AAA Endoprosthesis. However, when the Contralateral Leg and Iliac Extender diameters are identical, the taper zone can be deployed inside the previously deployed Contralateral Leg (Figure 7B).
   WARNING: While using 16, 18, 20, 23, or 27 mm Contralateral Legs as an Iliac Extender, the 3 cm mandatory overlap must be achieved prior to the beginning of the distal taper zone of the 18, 20, 23, and 27 mm Contralateral Leg. Inadequate sealing may lead to endoleak.
4. While maintaining the delivery catheter in position, withdraw the introducer sheath and visually verify that the leading end of the introducer sheath is below the distal Iliac Extender radiopaque marker.
   WARNING: Do not rotate the Iliac Extender delivery catheter during delivery, positioning or deployment. Catheter breakage or separation or premature deployment have occurred and may result in potential patient harms, see ADVERSE EVENTS.
5. Stabilize the Iliac Extender delivery catheter at the level of entry into the introducer sheath and stabilize the sheath relative to the patient's access site.
   WARNING: Do not attempt to withdraw any undeployed endoprosthesis through the introducer sheath. The sheath and catheter must be removed together. Catheter breakage or separation or premature deployment have occurred and may result in potential patient harms, see ADVERSE EVENTS.
6. Loosen the deployment knob (Figure 3E). Confirm final device position. Using fluoroscopy, deploy the Iliac Extender Endoprosthesis by using a steady, continuous pull of the deployment knob to release the endoprosthesis. Pull the deployment knob straight out from the catheter side-arm (Figure 3E). The device deploys from the leading (proximal) end toward the trailing (distal) end.
   WARNING: Do not attempt to withdraw any undeployed endoprosthesis through the introducer sheath. The sheath and catheter must be removed together.
   WARNING: Do not attempt to reposition the endoprosthesis after deployment has been initiated. Vessel damage or device misplacement may result.
   WARNING: Incorrect deployment or migration of the endoprosthesis may require surgical intervention.
   CAUTION: Do not cover significant renal or mesenteric arteries with the endoprosthesis. Vessel occlusion may occur. During the US clinical studies, this device was not studied in patients with two occluded internal iliac arteries.
7. Use fluoroscopic guidance during the withdrawal of the delivery catheter to assure safe removal from, and avoid catching on, the endoprosthesis. If resistance is felt during removal of delivery catheter through the introducer sheath, stop and withdraw delivery catheter and introducer sheath together.
   WARNING: Do not continue to withdraw the delivery catheter if resistance is felt during removal through the introducer sheath. Forcibly withdrawing the delivery catheter through the introducer sheath when resistance is encountered has resulted in adverse events including catheter breakage or separation resulting in potential patient harms, see ADVERSE EVENTS.
8. When withdrawing the device delivery system through the introduce sheath, verify all catheter components are intact.
   WARNING: Catheter leading end separation or breakage and related potential patient harms have occurred. See ADVERSE EVENTS. If catheter separation occurs, use best medical judgment to determine the appropriate course of action for the patient. Effective removal of the catheter component has been reported through both surgical (e.g. cut down) and endovascular techniques (e.g. snaring, sheath removal).
9. Advance and inflate an appropriate size PTA balloon catheter to seat the proximal overlap end and the distal end of the Iliac Extender Endoprosthesis. Follow the manufacturer's recommended method for size selection, preparation and use of PTA balloons. Carefully inflate the balloon to avoid complications.
10. Use fluoroscopic guidance to ensure the balloon is completely deflated and to assure safe removal from, and to avoid catching on, the endoprosthesis.

Completion of the Procedure

1. Perform extended imaging angiography to confirm exclusion of the aneurysm. Consider breath-hold technique to optimize digital subtraction angiography image quality. Consider use of GORE® EXCLUDER® Conformable AAA Endoprosthesis Extender components as necessary. For Aortic Extenders, a minimum overlap of 2.2 cm is required, offering a maximum of 2.2 cm of extension; for Iliac Extenders, a minimum overlap of 3 cm is required.
2. Prior to removing wires and sheaths verify all catheter components have been withdrawn from the patient.
   WARNING: Catheter leading end separation or breakage and related potential patient harms have occurred. See ADVERSE EVENTS. If catheter separation occurs, use best medical judgment to determine the appropriate course of action for the patient. Effective removal of the catheter component has been reported through both surgical (e.g. cut down) and endovascular techniques (e.g. snaring, sheath removal).
3. Close arterial access according to standard practice.
4. Follow-up patients as necessary to provide proper surveillance of the long-term performance of the endoprosthesis, procedure and status of the aneurysm. Minimally, annual CTs, multiple view X-rays, and ultrasound may be used for such surveillance.

IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP

General

The long-term safety and effectiveness of endovascular repair has not been established. All patients should be advised this treatment modality requires long-term, regular follow-up to assess patients' health status and stent-graft performance. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms) should receive enhanced follow-up. Patients should be counseled on the need for regular follow-up, even in the absence of obvious symptoms (e.g., pain, numbness, weakness). Regular and consistent follow-up is a critical part of ensuring continuing safety and efficacy of aortic endovascular repair. Physicians should tailor patient follow-up to the needs and circumstances of each individual patient. In the US clinical studies, at least one annual physician visit and the imaging schedule (Table 23) were employed. Follow-up modalities include CT / CTA, multi-view abdominal X-ray, MRI / MRA, and ultrasound. Data from these modalities is acquired and used to compare baseline and subsequent exams to review devices and morphological changes over time and their effects on exclusion of the aneurysm.

- CT / CTA imaging provides information on aneurysm size, vascular morphological changes, proximal device-trunk fixation and migration, endoleak and patency / limb occlusion.
- Multi-view device X-ray imaging provides information on device wireform integrity (e.g., fracture, kinking) and relative component migration.
- MRI / MRA imaging provides information similar to CT / CTA and is often used as a surrogate for CT / CTA if patients are CT contrast intolerant.
- Ultrasound may be used to assess for endoleak and aneurysm size status but not for device integrity, specifically the wire form. Ultrasound is a less reliable and sensitive diagnostic method compared to CT.

Alternative imaging recommendations for patients with CT or angiography contrast intolerance issues include CO_2 angiography, MRI-MRA with or without contrast, and ultrasound. These imaging and surveillance modalities may be less sensitive and difficult to compare with diagnostic findings from previous or subsequent follow-up exams.

Table 23. Recommended Schedule for Patient Imaging Follow-Up

Schedule for Patient Imaging Follow-Up			
Visit	**Angiogram**	**Abdominal X-ray**	**CT Pre-Contrast and Contrast**
Pre-Treatment	X[1]		X[1]
Treatment (Pre and Post Deployment)	X		
Discharge		X	
1 Month			X
3 Month			X[2]
6 Month		X	X
12 Month (Annually Thereafter)		X	X

[1] Imaging should be performed ≤ six months prior to the procedure
[2] Recommended if endoleak reported at one month

Angiographic Imaging

Angiographic images are recommended pre-treatment to evaluate the length and tortuosity of abdominal aorta, iliac and common femoral arteries.

- Images should include an angiographic marker catheter with incremental one centimeter markers over a 10 – 20 cm length.
- The following views are recommended for optimal evaluation and case planning:
  - Abdominal aorta; Supine-AP, Lateral
  - Pelvis (to include bilateral common femorals); AP, both Obliques

Angiographic images are recommended during the treatment procedure both pre and post-deployment to evaluate device placement and orientation. Selective angiography during subsequent follow-up exams may provide useful device position and device integrity information.

CT / CTA Images

- Film sets should include all sequential images at lowest possible slice thickness (≤ 3 mm). Do NOT perform large slice thickness (> 3 mm) and / or omission of CT images / film sets (non-consecutive) as it prevents precise anatomical and device comparisons over time.
- All images should include a scale for each film / image. Images should be arranged no smaller than 20:1 images on 14" x 17" sheets if film is used.
- **If an endoleak is suspected or there is aneurysm enlargement, it is recommended that pre-contrast and contrast runs be performed.**
- Pre-contrast and contrast run slice thickness and interval must match.
- DO NOT change patient orientation or re-landmark patient between non-contrast and contrast runs.

Non-contrast and contrast enhanced baseline and follow-up exams are important for optimal patient surveillance. For the best results, use the following CT / CTA imaging guidelines listed in Table 24.

Table 24. CT / CTA Imaging Guidelines

	Pre-Contrast	CT / CTA
IV Contrast	No	Yes
Injection Volume (ml)	NA	150
Injection Rate (cc / sec)	NA	≥ 2.5
Delay	NA	Smart-Prep*, CARE or equivalent
Start Position	Diaphragm	1 cm above Celiac Axis
End Position	Proximal Femur	Femoral Bifurcation
Scan FOV	Large	Large
DFOV	32 cm	32 cm
Scan Type	Helical	Helical
Rotation Speed	0.8	0.8
Slice Thickness (mm)	≤ 3.0 mm	≤ 3.0 mm
Scan Mode	HS	HS
Table Speed (mm / rot)	15	15
Interval (mm)	2.0	2.0
KV / mA	120 / 300	120 / 300
Reconstruction / Algorithm	≤ 3.0 mm Soft	≤ 3.0 mm Soft

*** Smart Prep**	**ROI Loc:** 1 cm Sup. to Celiac Axis **Scan Phase:** 3 Sec **MA:** 40	**Monitor Delay:** 6 Sec **Monitor ISD:** 3 Sec **Enhance Thres:** 100 HU

Abdominal X-ray Film Series (plain film)

The following abdominal X-ray views are recommended for optimal visualization of the endograft:

- Supine – Frontal (AP)
- Lateral
- 30 degree LPO
- 30 degree RPO

Ensure entire device is captured on each single image format lengthwise.
If there is any concern about the device integrity (e.g., kinking, stent-wire breaks, relative component migration), it is recommended to use magnified views. The attending physician should evaluate films for device integrity (entire device length including components) using 2 – 4x magnification.

MRI Safety Information

Non-clinical testing demonstrated that the GORE® EXCLUDER® Conformable AAA Endoprosthesis is MR Conditional. A patient with this device can be safely scanned, immediately after device placement, in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla only
- Maximum spatial gradient magnetic field of 3,000-Gauss/cm (30 Tesla/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg (Normal Operating Mode)

Under the scan conditions defined above, the GORE® EXCLUDER® Conformable AAA Endoprosthesis is expected to produce a maximum temperature rise of 2.0˚C after 15 minutes of continuous scanning.
In non-clinical testing, the image artifact caused by the device extends approximately 8 mm from the GORE® EXCLUDER® Conformable AAA Endoprosthesis when imaged with a gradient echo pulse sequence and a 3-Tesla MRI system. The artifact does not obscure the device lumen.

Additional Surveillance and Treatment

Additional surveillance and possible treatment is recommended for:

- Aneurysms with Type I endoleak
- Aneurysms with Type III endoleak
- Aneurysm enlargement ≥ 5 mm of maximum diameter (regardless of endoleak status)

Consideration for reintervention or conversion to open repair should include the attending physician's assessment of an individual patient's co-morbidities, life expectancy, and the patient's personal choices. Patients should be counseled as to the possibility of subsequent reinterventions including catheter-based and open surgical conversion.

DEVICE-RELATED ADVERSE EVENT REPORTING

Any adverse event involving the GORE® EXCLUDER® Conformable AAA Endoprosthesis should be reported to W. L. Gore & Associates immediately. To report an event in the US, call 800.437.8181. Outside the US, contact your local technical representative.

PATIENT TRACKING INFORMATION

In addition to these Instructions for Use, the GORE® EXCLUDER® Conformable AAA Endoprosthesis is packaged with a Device Tracking Form which US hospital staff are required to complete and forward to Gore for the purposes of tracking all patients who receive a GORE® EXCLUDER® Conformable AAA Endoprosthesis product (as required by US Federal Regulation).

DEFINITIONS

Use By

Caution

Consult Instructions for Use

Do Not Resterilize

Do Not Reuse

REF Catalogue Number

Date of Manufacture

LOT Batch Code

SN Serial Number

EC REP Authorised Representative in the European Community

MR Conditional

℞ Only CAUTION: USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.

STERILE Sterile

STERILE EO Sterilized using Ethylene Oxide

Do Not Use if Package is Damaged

Keep Dry

Store in a Cool Place

Catheter Working Length

Delivery Profile

Guidewire Compatibility

Manufacturer

20063806

Manufacturer
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For international contact and additional product information,
visit **goremedical.com**

For product patent information, please refer to goremedical.com/patents.

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