

INSTRUCTIONS FOR USE FOR:



AAA ENDOPROSTHESIS

us

US English

Low Permeability Design

en

English

Low Permeability Design

bg

Български

Модел с ниска пропускливост

cz

Čeština

Provedení s nízkou propustností

dk

Dansk

Design med lav permeabilitet

nl

Nederlands

Ontwerp met geringe permeabiliteit

ee

Eesti

Vähese läbilaskvusega endoprotees

fi

Suomi

Vähäinen läpäisevyys

fr

Français

Faible perméabilité

de

Deutsch

Konstruktion mit geringer Durchlässigkeit

gr

Ελληνικά

Σχέδιο χαμηλής διαπερατότητας

hu

Magyar

Alacsony átteresztő képességű kivitel

it

Italiano

Design a bassa permeabilità

lt

Lietuvių

Mažo pralaidumo konstrukcija

no

Norsk

Design med lav permeabilitet

pl

Polska

Model niskoprzepuszczalny

pt

Português

Concepção de Baixa Permeabilidade

ro

Română

Modelul de joasă permeabilitate

sk

Slovenčina

Konstrúcia s nízkou priepustnosťou

es

Español

Diseño de baja permeabilidad

se

Svenska

Design med låg permeabilitet

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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® AAA ENDOPROSTHESIS

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

DESCRIPTION

Trunk-Ipsilateral Leg Endoprosthesis and Contralateral Leg Endoprosthesis

The GORE EXCLUDER® AAA Endoprosthesis provides endovascular treatment of infrarenal abdominal aortic aneurysms (AAAs).

The GORE EXCLUDER® AAA Endoprosthesis is comprised of two components, the Trunk-Ipsilateral Leg Endoprosthesis (Trunk) (Figures 1A and 1B) and the Contralateral Leg Endoprosthesis (Figures 2A and 2B). The graft material is expanded polytetrafluoroethylene and fluorinated ethylene propylene (ePTFE and 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 aortic end of the trunk (Figures 1A and 1B). An ePTFE / FEP sleeve is used to constrain the endoprosthesis on the leading end of the delivery catheter (Figures 3A, 3B, 3C and 3D).

Deployment of both endoprosthesis components initiates from the leading (aortic) end and proceeds toward the trailing (iliac) end of the delivery catheter (Figures 3A, 3B, 3C and 3D). The ePTFE / FEP sleeve remains *in situ* between the endoprosthesis and the vessel wall.

The low permeability GORE EXCLUDER® Endoprosthesis is the only available design, and it differs from the original by the addition of film layers that decrease the overall permeability of the graft. The luminal and abluminal ePTFE surface materials, microstructure, and characteristics of the low permeability GORE EXCLUDER® Endoprosthesis meet the same specifications as the original GORE EXCLUDER® Endoprosthesis.

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

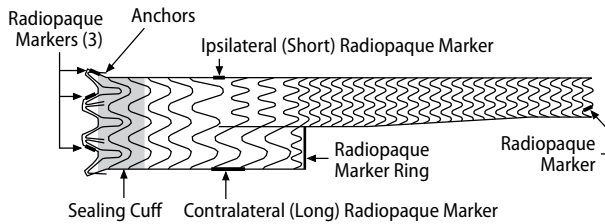
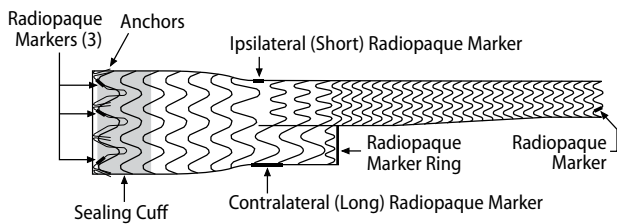


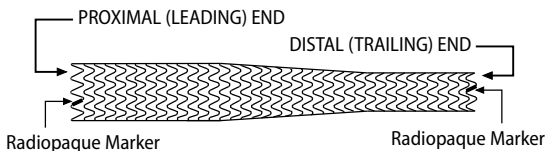
Figure 1B: Trunk-Ipsilateral Leg Endoprosthesis; (Aortic Diameter of 31 mm)



Trunk-Ipsilateral Leg Endoprosthesis Radiopaque Markers:

- Three (3) short markers at the aortic end.
- One (1) long and one (1) short marker at the endoprosthesis 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.

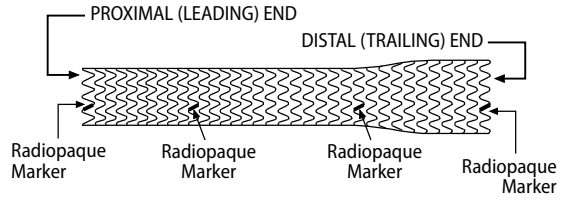
Figure 2A: Contralateral Leg Endoprosthesis; (Distal Iliac Diameters of 12 and 14.5 mm)



Contralateral Leg Endoprosthesis Radiopaque Markers:

- One (1) marker at each end

Figure 2B: Contralateral Leg Endoprosthesis; (Distal Iliac Diameters of 16, 18, and 20 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

Figure 3A: GORE EXCLUDER® AAA Endoprosthesis Delivery Catheter

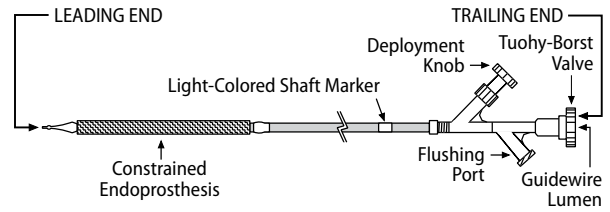


Figure 3B: Constrained GORE EXCLUDER® AAA Endoprosthesis (Trunk-Ipsilateral) on Delivery Catheter with Radiopaque Markers

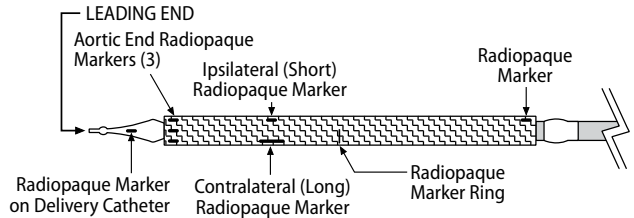


Figure 3C: Constrained GORE EXCLUDER® AAA Endoprosthesis (Contralateral Distal Iliac Diameters of 12 and 14.5 mm) on Delivery Catheter with Radiopaque Markers

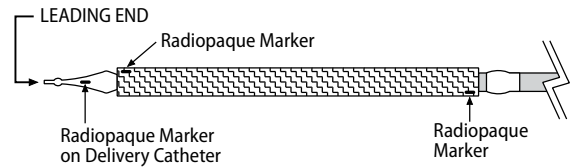
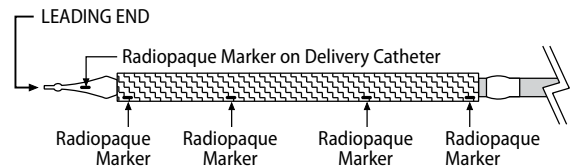


Figure 3D: Constrained GORE EXCLUDER® AAA Endoprosthesis (Contralateral Iliac Diameters of 16, 18, and 20 mm) on Delivery Catheter with Radiopaque Markers

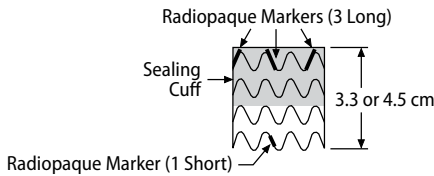


Aortic Extender Endoprosthesis and Iliac Extender Endoprosthesis Components

Aortic Extender Endoprosthesis

The Aortic Extender Endoprosthesis (Aortic Extender) provides an extension of approximately 1.6 cm or 2.2 cm of the leading (proximal) end of the Trunk-Ipsilateral Leg Endoprosthesis (Trunk). The Aortic Extender can be placed at variable extension lengths from 0 cm to 1.6 or 2.2 cm of the leading (proximal) end of the Trunk-Ipsilateral Leg Endoprosthesis (Trunk), allowing customization of extender treatment length based on patient anatomy and physician preference. This extension requires a minimum of approximately 1.6 cm or 2.2 cm overlap with the Trunk. The graft material is expanded polytetrafluoroethylene and fluorinated ethylene propylene (ePTFE and FEP), and is supported by nitinol (nickel titanium alloy) wire along its external surface. An ePTFE / FEP sealing cuff is located near the proximal end of the endoprosthesis (Figure 4). An ePTFE / FEP sleeve is used to constrain the endoprosthesis on the leading end of the delivery catheter (Figures 5A and 5B). Deployment of the Aortic Extender initiates from the trailing (trunk) end and proceeds toward the leading (aortic) end of the endoprosthesis and delivery catheter. Following deployment, the ePTFE / FEP sleeve remains *in situ* between the endoprosthesis and the vessel wall.

Figure 4: Aortic Extender Endoprosthesis*



Aortic Extender Radiopaque Markers (4 total):

- Three (3) long markers at the proximal or top end
 - One (1) short marker at the distal or bottom end
- * Note: All dimensions are nominal.

Figure 5A: Aortic Extender Endoprosthesis Delivery Catheter

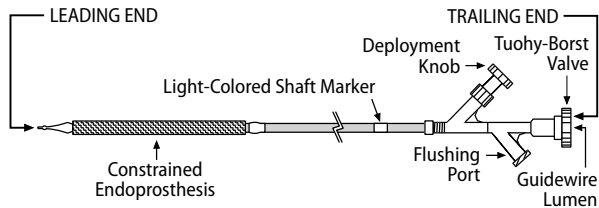
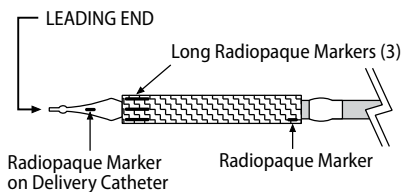


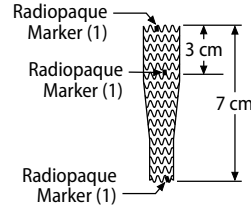
Figure 5B: Constrained Aortic Extender Endoprosthesis



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 limb. 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. The graft material is ePTFE / FEP, and is supported by nitinol wire along its external surface. A radiopaque marker is located 3 cm from the proximal or top end (Figure 6A). This marker denotes the recommended minimum overlap with the ipsilateral or contralateral limb of the GORE EXCLUDER® AAA Endoprosthesis. An ePTFE / FEP sleeve is used to constrain the endoprosthesis on the leading end of the delivery catheter (Figure 6B). Deployment of the Iliac Extender initiates from the leading (aortic) end and proceeds toward the trailing (iliac) end of the delivery catheter. Following deployment, the ePTFE / FEP sleeve remains *in situ* between the endoprosthesis and the vessel wall.

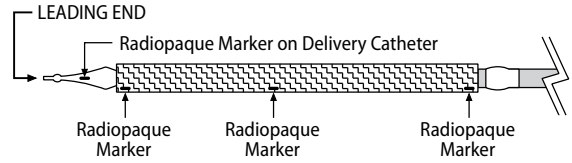
Figure 6A: Iliac Extender Endoprosthesis*



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.

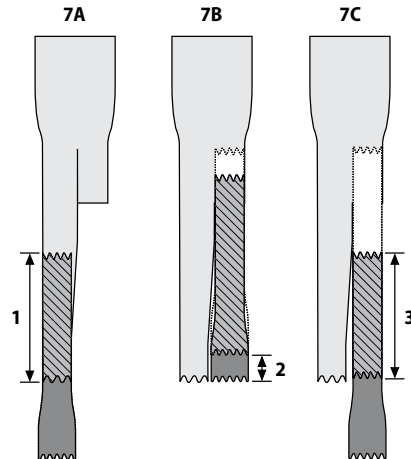
Figure 6B: Constrained Iliac Extender Endoprosthesis (Distal Iliac Diameters of 10, 12, and 14.5 mm)



Contralateral Leg Endoprosthesis Used as Iliac Extender Endoprosthesis (Distal Iliac Diameters of 16, 18, and 20 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 original Ipsilateral Leg (Figure 7A) or Contralateral Leg (Figure 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 and 20 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® AAA Endoprosthesis if the distal end diameters are 12 or 14.5 mm. A radiopaque marker located 4 cm above the distal end 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).

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



1. Overlap zone must be at least 3 cm within host device.
2. Most distal Contralateral Leg may extend 0 to 4 cm from another 16, 18, or 20 mm Contralateral Leg.
3. Most distal Contralateral Leg should overlap at least 3 cm within host device.

INDICATIONS FOR USE

Trunk-Ipsilateral Leg Endoprosthesis and Contralateral Leg Endoprosthesis Components

The GORE EXCLUDER® AAA Endoprosthesis is intended to exclude the aneurysm from the blood circulation in patients diagnosed with infrarenal abdominal aortic aneurysm (AAA) disease and who have appropriate anatomy as described below:

- Adequate iliac / femoral access
- Infrarenal aortic neck treatment diameter range of 19 – 29 mm and a minimum aortic neck length of 15 mm
- Proximal aortic neck angulation $\leq 60^\circ$
- Iliac artery treatment diameter range of 8 – 18.5 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® AAA Endoprosthesis. These extensions are intended to be used when additional length and / or sealing for aneurysmal exclusion is desired.

CONTRAINDICATIONS

There are no known contraindications for these devices.

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 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® 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® 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 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® 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 $> 60^\circ$ angulation of the proximal aortic neck
- 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 (4.7 mm), 18 Fr (6.8 mm) or 20 Fr (7.6 mm) vascular introducer sheath.
- Key anatomic elements that may affect successful exclusion of the aneurysm include severe proximal neck angulation, short proximal aortic neck and significant thrombus and / or calcium at the arterial implantation sites, specifically the proximal aortic neck and distal iliac artery interface. The US clinical studies quantify significant thrombus as thrombus ≥ 2 mm in thickness and / or $\geq 25\%$ 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® AAA Endoprosthesis is not recommended in patients who cannot tolerate contrast agents necessary for intraoperative and post-operative follow-up imaging.
- The GORE EXCLUDER® AAA Endoprosthesis is not recommended in patients exceeding weight and / or size limits which compromise or prevent the necessary imaging requirements.
- The GORE EXCLUDER® AAA Endoprosthesis is not recommended in patients with known sensitivities or allergies to ePTFE, FEP, 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. The sheath will protect the device from catheter breakage or premature deployment while tracking it into position.
- Do not attempt to advance the Aortic Extender through the 12 Fr introducer sheath. The Aortic Extender is designed for a 18 Fr or 20 Fr sheath.
- Do not rotate the Trunk or the Contralateral Leg delivery catheter while the endoprosthesis is inside the introducer sheath. Catheter breakage or premature deployment may occur.
- Do not rotate the Trunk delivery catheter beyond 360° to avoid delivery system damage and / or premature deployment.
- Do not rotate the Contralateral Leg delivery catheter during delivery, positioning or deployment. Catheter breakage or premature deployment may occur.
- Do not attempt to withdraw any undeployed endoprosthesis through the 12 Fr, 18 Fr or 20 Fr introducer sheath. The sheath and catheter must be removed together.
- **Do not attempt to reposition the endoprosthesis after deployment has been initiated. 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 may occur.
- **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 separation and reintervention.**
- Incorrect deployment or migration of the endoprosthesis may require surgical intervention.
- 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, or 20 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® 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, or 20 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 and 20 mm Contralateral Leg. Inadequate sealing may lead to endoleak.

MRI Safety and Compatibility



Non-clinical testing has demonstrated that the GORE EXCLUDER® AAA Endoprosthesis is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Spatial gradient field of ≤ 720 Gauss / cm
- Maximum scanner displayed whole-body-averaged specific absorption rate (SAR) of 3.0W / kg for 15 minutes of scanning

3.0 Tesla Temperature Rise:

In non-clinical testing, the GORE EXCLUDER® AAA Endoprosthesis produced a temperature rise of 2.5°C at an MR system reported maximum whole-body-averaged specific absorption rate (SAR) of 3.0W / kg for 15 minutes of MR scanning in a 3.0 Tesla, Excite, General Electric active-shield, horizontal field MR scanner using G3.0-052B Software and placed in a worst-case location in a phantom designed to simulate human tissue. The SAR calculated using calorimetry was 2.8 W / kg.

1.5 Tesla Temperature Rise:

In non-clinical testing, the GORE EXCLUDER® AAA Endoprosthesis produced a temperature rise of 1.9°C at an MR system reported maximum whole-body-averaged specific absorption rate (SAR) of 2.8W / kg for 15 minutes of MR scanning in a 1.5 Tesla, Magnetom, Siemens Medical Solutions, active-shield, horizontal field MR scanner using Numaris / 4 Software and placed in a worst-case location in a phantom designed to simulate human tissue. The SAR calculated using calorimetry was 1.5 W / kg.

Image Artifact:

For each vascular device and assembly, the artifacts that appeared on the MR images were shown as localized signal voids (i.e., signal loss) that were minor in size relative to the size and shape of these implants. The gradient echo pulse sequence produced larger artifacts than the T1 – weighted, spin echo pulse sequence for the GORE EXCLUDER® AAA Endoprosthesis. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the GORE EXCLUDER® AAA Endoprosthesis. Therefore, it may be necessary to optimize the MR imaging parameters to compensate for the presence of this implant.

CLINICAL STUDY OUTCOMES* (98-03 AND 99-04)

Two US clinical studies were conducted to evaluate the safety and efficacy of the GORE EXCLUDER® AAA Endoprosthesis. The first, referred to as 98-03, evaluated the original design of the GORE EXCLUDER® AAA Endoprosthesis. This study enrolled 235 test subjects and 99 control subjects; 49 test subjects were enrolled in Continued Access. The second US clinical study, referred to as 99-04, evaluated a modified version of the GORE EXCLUDER® AAA Endoprosthesis. This study enrolled 193 test subjects; 88 test subjects were enrolled in Continued Access. Collectively, 565 test subjects were treated with the GORE EXCLUDER® AAA Endoprosthesis in these studies and are described herein as the "Combined IDE Cohort". Safety outcomes of the Combined IDE Cohort are compared to the 99 control subjects treated with open surgery in the 98-03 study and are described herein as "98-03 Controls."

* Please note that the Contralateral Leg components with distal iliac diameters of 16, 18, and 20 mm were not evaluated under any clinical studies.

Baseline Characteristics

Overall, baseline characteristics were comparable in the Combined IDE Cohort vs. 98-03 Controls (Tables 1 and 2). The Combined IDE Cohort was an average of three years older and had a higher proportion of males vs. the 98-03 Controls. Smoking history, coronary artery disease, and chronic obstructive pulmonary disease were the most common comorbidities in each treatment group. Subjects with aneurysm diameter between 50-59 mm were most commonly treated, regardless of treatment group.

Table 1. Subject Demographics and Medical History

	98-03 Control	Combined IDE Cohort
Number of Subjects Enrolled	99	565
Age at Treatment (Years)		
n	99	565
Mean (Std Dev)	70.6 (8.5)	73.9 (7.9)
Median	71.8	74.3
Range	(51.8, 87.6)	(48.9, 93.0)
Gender		
Male	73 (73.7%)	456 (80.7%)
Female	26 (26.3%)	109 (19.3%)
Ethnic Background		
Caucasian	99 (100.0%)	553 (97.9%)
Black	0 (0.0%)	5 (0.9%)
Hispanic	0 (0.0%)	5 (0.9%)
Asian	0 (0.0%)	2 (0.4%)
NYHA Functional Class		
1	64 (64.6%)	289 (51.2%)
2	24 (24.2%)	201 (35.6%)
3	11 (11.1%)	48 (8.5%)
Missing	0 (0.0%)	27 (4.8%)
ASA Functional Class		
1	2 (2.0%)	8 (1.4%)
2	21 (21.2%)	111 (19.6%)
3	60 (60.6%)	373 (66.0%)
4	15 (15.2%)	73 (12.9%)
Missing	1 (1.0%)	0 (0.0%)
SVS Summary Risk Score		
n	99	565
Mean (Std Dev)	4.6 (2.7)	4.9 (2.7)
Median	4.0	5.0
Range	(0.0, 12.0)	(0.0, 13.3)
Aneurysm Symptomatic	15 (15.2%)	38 (6.7%)
Arrhythmia	21 (21.2%)	135 (23.9%)
Bleeding Disorder	1 (1.0%)	16 (2.8%)
Cancer	19 (19.2%)	150 (26.5%)
Congestive Heart Failure	8 (8.1%)	58 (10.3%)
COPD	25 (25.3%)	167 (29.6%)
Coronary Artery Disease	53 (53.5%)	344 (60.9%)
Erectile Dysfunction (Males Only)	10 (13.7%)	78 (17.1%)
Family History of AAA	9 (9.1%)	42 (7.4%)
Hepatic Dysfunction	1 (1.0%)	9 (1.6%)
Inflammatory AAA	1 (1.0%)	7 (1.2%)
Long-Term Use of Steroids	1 (1.0%)	23 (4.1%)
Other Concomitant Aneurysms	13 (13.1%)	47 (8.3%)
Peripheral Arterial Occlusive Disease	14 (14.1%)	108 (19.1%)
Paraplegia	0 (0.0%)	2 (0.4%)
Prior Vascular Intervention	10 (10.1%)	63 (11.2%)
Renal Dialysis	0 (0.0%)	2 (0.4%)
Smoking History	85 (85.9%)	484 (85.7%)
Stroke	10 (10.1%)	59 (10.4%)
Thromboembolic Event	4 (4.0%)	34 (6.0%)
Valvular Heart Disease	7 (7.1%)	45 (8.0%)

Table 2. Distribution of Pre-Treatment Aneurysm Diameter

	98-03 Control	Combined IDE Cohort
Subjects Enrolled	99	565
Diameter Range		
<30 mm	0 (0.0%)	0 (0.0%)
30-39 mm	0 (0.0%)	0 (0.0%)
40-49 mm	15 (15.2%)	122 (21.6%)
50-59 mm	46 (46.5%)	298 (52.7%)
60-69 mm	21 (21.2%)	99 (17.5%)
70-79 mm	10 (10.1%)	31 (5.5%)
80-89 mm	5 (5.1%)	10 (1.8%)
≥ 90 mm	1 (1.0%)	5 (0.9%)
Missing ¹	1 (1.0%)	0 (0.0%)

¹ Missing indicates no pre-treatment diameter measurement was available.

Subject Compliance and Disposition

Subjects in each group were followed for five years post-treatment. Of 565 subjects in the Combined IDE Cohort, 255 returned for the five-year follow-up visit, 149 died, and 177 were discontinued from the study (Table 3). The number of "Subjects with Visit in Window" (compliance) is an exclusive category from the "Death," "Discontinued," and "Not Due for Next Follow-Up" (disposition) categories. A subject may have had a visit within a follow-up window and died or discontinued from the study later in the same window. Therefore, adding these entries will not necessarily equal the number of subjects "Eligible for Follow-Up." Follow-up visit and imaging compliance remained high throughout the five-year follow-up period. Of 99 subjects in the 98-03 Control group, 14 died, and 46 were discontinued from the five-year follow-up visit. Abdominal x-rays were not required for the 98-03 Controls.

Table 3. Subject Compliance and Disposition by Study Interval: Combined IDE Cohort

Study Period	Eligible for Follow-Up	Follow-Up Compliance			Events Prior to Next Interval			
		Subjects with Visit in Window ¹	With CT ¹	With XRay ¹	With ABI ¹	Death ¹	Discontinued ¹	Not Due for Next Follow-Up ¹
Procedure	565	—	—	—	—	2 (0.4%)	1 (0.2%)	0 (0.0%)
Post-Procedure	562	—	—	—	—	1 (0.2%)	1 (0.2%)	0 (0.0%)
1 Month	560	545 (97.3%)	522 (93.2%)	103 (18.4%)	461 (82.3%)	6 (1.1%)	1 (0.2%)	0 (0.0%)
3 Months	553	94 (17.0%)	85 (15.4%)	11 (2.0%)	37 (6.7%)	6 (1.1%)	0 (0.0%)	0 (0.0%)
6 Months	547	507 (92.7%)	486 (88.8%)	411 (75.1%)	422 (77.1%)	7 (1.3%)	7 (1.3%)	0 (0.0%)
12 Months	533	501 (94.0%)	484 (90.8%)	412 (77.3%)	414 (77.7%)	37 (6.9%)	13 (2.4%)	0 (0.0%)
24 Months	483	441 (91.3%)	412 (85.3%)	360 (74.5%)	350 (72.5%)	25 (5.2%)	31 (6.4%)	0 (0.0%)
36 Months	427	340 (79.6%)	319 (74.7%)	274 (64.2%)	265 (62.1%)	28 (6.6%)	38 (8.9%)	0 (0.0%)
48 Months	361	306 (84.8%)	285 (78.9%)	240 (66.5%)	219 (60.7%)	26 (7.2%)	44 (12.2%)	0 (0.0%)
60 Months	291	255 (87.6%)	236 (81.1%)	185 (63.6%)	178 (61.2%)	11 (3.8%)	41 (14.1%)	—

¹ Denominators are based on the number of subjects eligible for follow-up
 Study period definitions: Procedure (0-0 days), Post-Procedure (1-14 days), 1 Month (15-60 days), 3 Months (61-120 days), 6 Months (121-242 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).

Table 4. Subject Compliance and Disposition by Study Interval: 98-03 Controls

Study Period	Eligible for Follow-Up	Follow-Up Compliance			Events Prior to Next Interval			
		Subjects with Visit in Window ¹	With CT ¹	With XRay ¹	With ABI ¹	Death ¹	Discontinued ¹	Not Due for Next Follow-Up ¹
Procedure	99	—	—	—	—	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Procedure	99	—	—	—	—	0 (0.0%)	1 (1.0%)	0 (0.0%)
1 Month	98	89 (90.8%)	0 (0.0%)	0 (0.0%)	67 (68.4%)	1 (1.0%)	1 (1.0%)	0 (0.0%)
3 Months	96	11 (11.5%)	0 (0.0%)	0 (0.0%)	5 (5.2%)	1 (1.0%)	1 (1.0%)	0 (0.0%)
6 Months	94	81 (86.2%)	4 (4.3%)	0 (0.0%)	66 (70.2%)	2 (2.1%)	5 (5.3%)	0 (0.0%)
12 Months	87	83 (95.4%)	74 (85.1%)	4 (4.6%)	67 (77.0%)	1 (1.1%)	5 (5.7%)	0 (0.0%)
24 Months	81	70 (86.4%)	67 (82.7%)	6 (7.4%)	56 (69.1%)	2 (2.5%)	9 (11.1%)	0 (0.0%)
36 Months	70	52 (74.3%)	46 (65.7%)	4 (5.7%)	46 (65.7%)	3 (4.3%)	9 (12.9%)	0 (0.0%)
48 Months	58	47 (81.0%)	40 (69.0%)	5 (8.6%)	37 (63.8%)	3 (5.2%)	9 (15.5%)	0 (0.0%)
60 Months	46	40 (87.0%)	34 (73.9%)	7 (15.2%)	33 (71.7%)	1 (2.2%)	6 (13.0%)	—

¹ Denominators are based on the number of subjects eligible for follow-up
 Study period definitions: Procedure (0-0 days), Post-Procedure (1-14 days), 1 Month (15-60 days), 3 Months (61-120 days), 6 Months (121-242 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).

Procedure and Recovery

Endovascular access was successful in 99.6% of cases in the Combined IDE Cohort (Table 5). The Combined IDE Cohort experienced less procedural blood loss, required fewer transfusions, had a shorter treatment time, and had shorter convalescence compared to 98-03 Controls (Table 6).

Table 5. Device Use at Initial Procedure

	Combined IDE Cohort
Number of Subjects Enrolled	565
Number of Subjects with Devices Implanted	563
Subjects with Trunks Implanted	563 (100.0%)
Subjects with Contralateral Legs Implanted	556 (98.8%)
Subjects with Aortic Extender(s) Implanted	66 (11.7%)
Subjects with Iliac Extender(s) Implanted	152 (27.0%)

Table 6. Procedure and Recovery

	98-03 Control	Combined IDE Cohort
Number of Subjects Enrolled	99	565
Blood Loss During Procedure (mL)		
n	98	557
Mean (Std Dev)	1589 (1226)	324 (331)
Median	1175	200
Range	(100, 7000)	(0, 3000)
Procedure Transfusion	88 (88.9%)	77 (13.6%)
Procedure Time (Minutes)		
n	95	563
Mean (Std Dev)	196 (78)	143 (57)
Median	175	132
Range	(67, 420)	(45, 509)
ICU Stay	86 (86.9%)	114 (20.2%)
Length of Hospital Stay (Days)		
n	99	565
Mean (Std Dev)	10 (14)	2 (1)
Median	7	2
Range	(3, 114)	(0, 15)
Time to First Oral Intake (Days)		
n	98	561
Mean (Std Dev)	2.7 (1.7)	0.4 (0.6)
Median	3.0	0.0
Range	(0.0, 10.0)	(0.0, 7.0)
Time to Ambulation (Days)		
n	98	559
Mean (Std Dev)	2.6 (2.3)	1.0 (0.7)
Median	2.0	1.0
Range	(0.0, 18.0)	(0.0, 8.0)
Time to Return to Normal Daily Activities (Days)		
n	90	530
Mean (Std Dev)	101.1 (137.4)	40.7 (60.9)
Median	41.0	26.0
Range	(1.0, 828.0)	(0.0, 527.0)

Safety Outcomes

Adverse events were classified as major or minor¹. An adverse event classified as major required therapy and short hospitalization (24-48 hours), major therapy, unplanned increase in level of care, prolonged hospitalization (> 48 hours), or resulted in permanent adverse sequelae, or death. Freedom from a major adverse event was statistically greater (p < 0.001) in the Combined IDE Cohort (39%) vs. 98-03 Controls (15%) through five years post-treatment (Figure 8, Table 7). Cardiac and pulmonary complications were the most commonly reported major adverse events in the Combined IDE Cohort (Table 8); blood loss (> 1 L) and cardiac events were the most commonly reported major adverse events in 98-03 Controls (Table 9). Cumulative major adverse events per subject were statistically lower in the Combined IDE Cohort (1.6 / subject) vs. 98-03 Controls (2.8 / subject) through five years post-treatment (Figure 9, Table 10).

¹ Sacks D, Marinelli DL, Martin LG, et al. Reporting standards for clinical evaluation of new peripheral arterial revascularization devices. *Journal of Vascular and Interventional Radiology* 1997; 8: 137-149.

Figure 8. Freedom From Major Adverse Event Through Five Years Post-Treatment

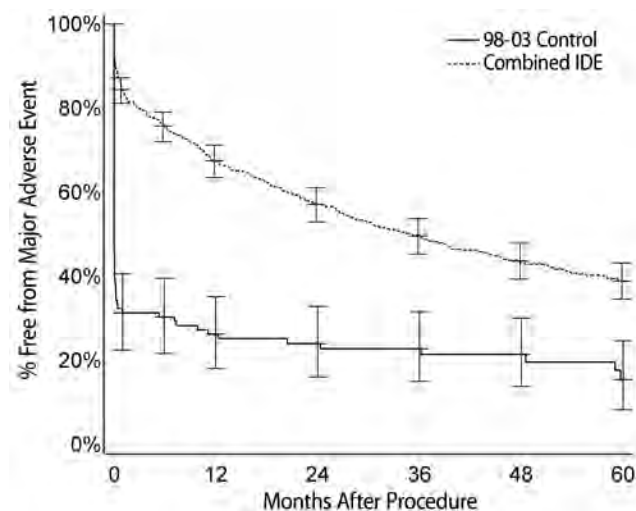


Table 7. Freedom From Major Adverse Event Through Five Years Post-Treatment

	Months After Procedure							
	Day 0	1 month	6 months	1 year	2 years	3 years	4 years	5 years
98-03 Control								
Subjects at Risk	99	32	30	26	20	16	12	7
% Free From Major Adverse Event	47%	31%	30%	26%	24%	23%	21%	15%
Combined IDE								
Subjects at Risk	565	477	428	371	302	243	190	110
% Free From Major Adverse Event	94%	84%	76%	67%	57%	50%	44%	39%

Table 8. Major Adverse Events Through Five Years Post-Treatment by Visit Interval: Combined IDE Cohort

	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Overall
Subjects Available at Beginning of Interval ¹	565	553	533	483	427	361	291	565
Subjects with Any Major Safety Adverse Event ²	105 (18.6%)	72 (13.0%)	91 (17.1%)	81 (16.8%)	64 (15.0%)	53 (14.7%)	22 (7.6%)	326 (57.7%)
Bleeding Complications	27 (4.8%)	2 (0.4%)	1 (0.2%)	3 (0.6%)	1 (0.2%)	5 (1.4%)	0 (0.0%)	38 (6.7%)
Pulmonary Complications	13 (2.3%)	13 (2.4%)	17 (3.2%)	10 (2.1%)	24 (5.6%)	10 (2.8%)	7 (2.4%)	81 (14.3%)
Cardiac Complications	22 (3.9%)	21 (3.8%)	24 (4.5%)	23 (4.8%)	23 (5.4%)	21 (5.8%)	10 (3.4%)	124 (21.9%)
Renal Function Complications	9 (1.6%)	6 (1.1%)	5 (0.9%)	6 (1.2%)	6 (1.4%)	1 (0.3%)	3 (1.0%)	30 (5.3%)
Wound Complications	22 (3.9%)	9 (1.6%)	3 (0.6%)	4 (0.8%)	1 (0.2%)	1 (0.3%)	0 (0.0%)	37 (6.5%)
Bowel Complications	12 (2.1%)	5 (0.9%)	10 (1.9%)	10 (2.1%)	4 (0.9%)	2 (0.6%)	2 (0.7%)	43 (7.6%)
Vascular Complications	16 (2.8%)	10 (1.8%)	9 (1.7%)	8 (1.7%)	5 (1.2%)	2 (0.6%)	2 (0.7%)	44 (7.8%)
Neurologic Complications	7 (1.2%)	5 (0.9%)	12 (2.3%)	9 (1.9%)	8 (1.9%)	3 (0.8%)	0 (0.0%)	38 (6.7%)
Other Complications	8 (1.4%)	12 (2.2%)	26 (4.9%)	19 (3.9%)	8 (1.9%)	11 (3.0%)	2 (0.7%)	77 (13.6%)
Genitourinary	6 (1.1%)	5 (0.9%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	3 (0.8%)	1 (0.3%)	16 (2.8%)
Sepsis	1 (0.2%)	2 (0.4%)	0 (0.0%)	2 (0.4%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	7 (1.2%)
Neoplasm	3 (0.5%)	8 (1.4%)	16 (3.0%)	10 (2.1%)	11 (2.6%)	14 (3.9%)	1 (0.3%)	61 (10.8%)
Death of Unknown Cause	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)

1 Number of subjects with study day of last contact \geq lower limit of specified time window. This is the denominator for all cells.
 2 Entries represent number of subjects with the event (percentage). Time frames for each interval are as follows: 1 Month (0-60 days), 6 Months (61-242 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), Overall (0-2006 days).

Table 9. Major Adverse Events Through Five Years Post-Treatment by Visit Interval: 98-03 Controls

	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Overall
Subjects Available at Beginning of Interval ¹	99	96	87	81	70	58	46	99
Subjects with Any Major Safety Adverse Event ²	68 (68.7%)	15 (15.6%)	10 (11.5%)	11 (13.6%)	12 (17.1%)	13 (22.4%)	3 (6.5%)	80 (80.8%)
Bleeding Complications	45 (45.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	45 (45.5%)
Pulmonary Complications	12 (12.1%)	3 (3.1%)	1 (1.1%)	2 (2.5%)	1 (1.4%)	4 (6.9%)	0 (0.0%)	19 (19.2%)
Cardiac Complications	16 (16.2%)	7 (7.3%)	7 (8.0%)	6 (7.4%)	6 (8.6%)	6 (10.3%)	1 (2.2%)	36 (36.4%)
Renal Function Complications	3 (3.0%)	0 (0.0%)	1 (1.1%)	0 (0.0%)	1 (1.4%)	3 (5.2%)	0 (0.0%)	7 (7.1%)
Wound Complications	4 (4.0%)	3 (3.1%)	0 (0.0%)	1 (1.2%)	2 (2.9%)	1 (1.7%)	0 (0.0%)	10 (10.1%)
Bowel Complications	17 (17.2%)	2 (2.1%)	1 (1.1%)	1 (1.2%)	2 (2.9%)	1 (1.7%)	1 (2.2%)	22 (22.2%)
Vascular Complications	7 (7.1%)	1 (1.0%)	3 (3.4%)	1 (1.2%)	0 (0.0%)	0 (0.0%)	1 (2.2%)	12 (12.1%)
Neurologic Complications	3 (3.0%)	3 (3.1%)	2 (2.3%)	0 (0.0%)	0 (0.0%)	2 (3.4%)	0 (0.0%)	9 (9.1%)
Other Complications	1 (1.0%)	2 (2.1%)	2 (2.3%)	2 (2.5%)	2 (2.9%)	1 (1.7%)	0 (0.0%)	9 (9.1%)
Genitourinary	1 (1.0%)	0 (0.0%)	2 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (3.0%)
Sepsis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Neoplasm	0 (0.0%)	1 (1.0%)	2 (2.3%)	0 (0.0%)	3 (4.3%)	0 (0.0%)	0 (0.0%)	6 (6.1%)
Death of Unknown Cause	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

1 Number of subjects with study day of last contact \geq lower limit of specified time window. This is the denominator for all cells.
 2 Entries represent number of subjects with the event (percentage). Time frames for each interval are as follows: 1 Month (0-60 days), 6 Months (61-242 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), Overall (0-2006 days).

Figure 9. Cumulative Major Adverse Events Through Five Years Post-Treatment

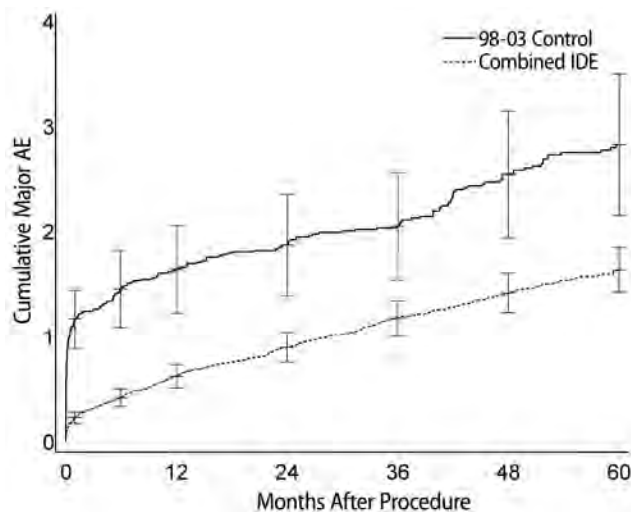


Table 10. Cumulative Major Adverse Events Through Five Years Post-Treatment

	Months After Procedure							
	Day 0	1 month	6 months	1 year	2 years	3 years	4 years	5 years
98-03 Control								
Subjects at Risk	99	97	91	86	79	64	52	35
Cumulative Major AE	0.60	1.17	1.46	1.64	1.88	2.06	2.55	2.83
Combined IDE								
Subjects at Risk	565	556	545	512	457	402	332	196
Cumulative Major AE	0.08	0.24	0.43	0.63	0.91	1.18	1.42	1.64

Mortality

Freedom from aneurysm-related death was similar in the Combined IDE Cohort (98%) vs. 98-03 Controls (98%) through five years post-treatment (Figure 10, Table 11). Survival was lower ($p < 0.05$) in the Combined IDE Cohort (70%) vs. 98-03 Controls (81%) through five years post-treatment (Figure 11, Table 12). However, the Combined IDE Cohort was an average of three years older vs. the 98-03 Controls (73.9 vs. 70.6 years), and after controlling for age, no difference between groups was observed in survival through five years post-treatment.

Figure 10. Freedom from Aneurysm-Related Death Through Five Years Post-Treatment

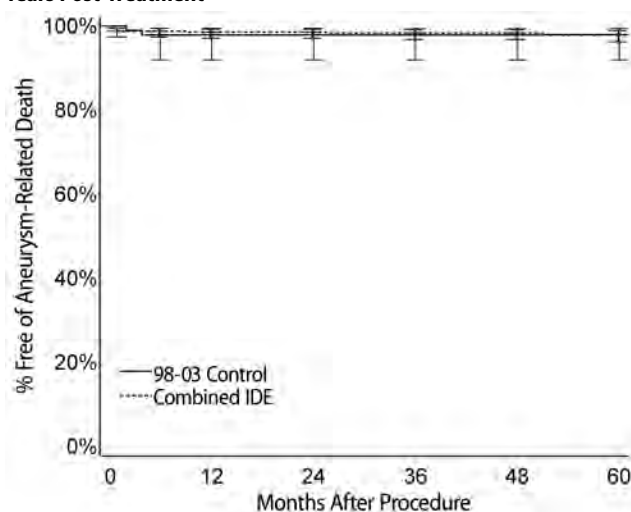


Table 11. Freedom from Aneurysm-Related Death Through Five Years Post-Treatment

	Months After Procedure							
	Day 0	1 month	6 months	1 year	2 years	3 years	4 years	5 years
98-03 Control								
Subjects at Risk	99	97	91	86	79	64	52	35
% Free of Aneurysm-Related Death	100%	100%	98%	98%	98%	98%	98%	98%
Combined IDE								
Subjects at Risk	565	556	545	512	457	401	332	196
% Free of Aneurysm-Related Death	100%	99%	99%	99%	99%	98%	98%	98%

Figure 11. Survival Through Five Years Post-Treatment

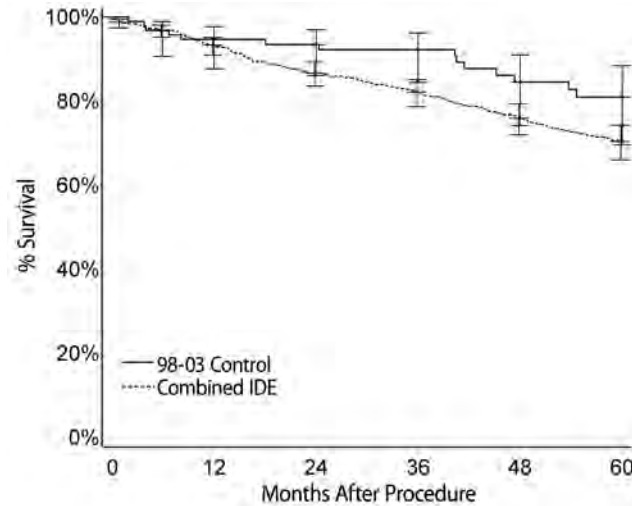


Table 12. Survival Through Five Years Post-Treatment

	Months After Procedure							
	Day 0	1 month	6 months	1 year	2 years	3 years	4 years	5 years
98-03 Control								
Subjects at Risk	99	97	91	86	79	64	52	35
% Survival	100%	100%	97%	95%	94%	92%	85%	81%
Combined IDE								
Subjects at Risk	565	556	545	512	457	401	332	196
% Survival	100%	99%	97%	93%	87%	82%	76%	70%

Device Efficacy Outcomes

A major device event was observed in 14.3% of the Combined IDE Cohort through five years post-treatment (Table 13); endoleak and aneurysm diameter increase were the most-commonly reported major device events. Aneurysm rupture was noted in one subject during the five-year follow-up period. The rupture was non-hemorrhagic and the subject was successfully converted to open surgical repair during an elective procedure. Endoleak incidence ranged from 14 – 27% at each follow-up period through five years post-treatment (Table 14). New onset of endoleak became less frequent over time. Type II endoleak was most common. Incidence of type I or III endoleak ranged from 0 – 2.6% at all follow-up visits through five years post-treatment. The incidence of aneurysm diameter increase was 34% at the five-year follow-up visit in the Combined IDE Cohort (Table 15). However, most (78%, 62 / 79) of these subjects were free from a detectable endoleak. Reintervention for endoleak or aneurysm diameter increase was performed in 1.9 – 5.3% of subjects at each follow-up visit (Table 16). Common treatments for aneurysm enlargement were explant (n = 12), endovascular stent graft (n = 10), and embolization (n = 8); endoleak treatments were embolization (n = 61), stent graft (n = 10), and explant (n = 3). Treatments for these events are not additive as a single treatment may be used to treat aneurysm enlargement and endoleak.

Table 13. Major Device Events Through Five Years Post-Treatment by Visit Interval: Combined IDE Cohort

	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Overall
Subjects Available at Beginning of Interval ¹	565	553	533	483	427	361	291	565
Subjects with Any Major Efficacy Adverse Event ²	32 (5.7%)	16 (2.9%)	12 (2.3%)	18 (3.7%)	8 (1.9%)	9 (2.5%)	6 (2.1%)	81 (14.3%)
Branch Vessel Occlusion	4 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.7%)
Endoleak	24 (4.2%)	15 (2.7%)	7 (1.3%)	10 (2.1%)	3 (0.7%)	4 (1.1%)	1 (0.3%)	55 (9.7%)
Access Failure	2 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.4%)
Deployment Failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Lumen Obstruction	1 (0.2%)	1 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.4%)
Prosthesis Material Failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Aneurysm Rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
Other Device-Related Event	1 (0.2%)	0 (0.0%)	0 (0.0%)	2 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)
Extrusion / Erosion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Prosthesis Migration	1 (0.2%)	0 (0.0%)	2 (0.4%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	0 (0.0%)	4 (0.7%)
Prosthesis Realignment	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Aneurysm Increase with Reintervention	2 (0.4%)	1 (0.2%)	3 (0.6%)	8 (1.7%)	4 (0.9%)	7 (1.9%)	5 (1.7%)	29 (5.1%)

¹ Number of subjects with study day of last contact ≥ lower limit of specified time window. This is the denominator for all cells.
² Entries represent number of subjects with the event (percentage). Time frames for each interval are as follows: 1 Month (0-60 days), 6 Months (61-242 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), Overall (0-2006 days).

Table 14. Endoleaks Through Five Years Post-Treatment by Visit Interval: Combined IDE Cohort

	Treatment	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months
Subjects Available at Beginning of Interval	565	562	553	533	483	427	361	291
Subjects with Endoleak Evaluation or Ongoing Endoleak	565	538	509	489	425	335	297	244
Subjects With One or More Endoleak Adverse Events Ongoing in Window	79 (14.0%)	147 (27.3%)	130 (25.5%)	110 (22.5%)	93 (21.9%)	74 (22.1%)	61 (20.5%)	40 (16.4%)
New	79 (14.0%)	83 (15.4%)	46 (9.0%)	26 (5.3%)	33 (7.8%)	11 (3.3%)	13 (4.4%)	6 (2.5%)
Ongoing	—	77 (14.3%)	90 (17.7%)	91 (18.6%)	72 (16.9%)	65 (19.4%)	51 (17.2%)	35 (14.3%)
Type I	11 (1.9%)	14 (2.6%)	6 (1.2%)	2 (0.4%)	4 (0.9%)	4 (1.2%)	3 (1.0%)	2 (0.8%)
New	11 (1.9%)	5 (0.9%)	1 (0.2%)	2 (0.4%)	2 (0.5%)	1 (0.3%)	0 (0.0%)	1 (0.4%)
Ongoing	—	9 (1.7%)	5 (1.0%)	1 (0.2%)	2 (0.5%)	3 (0.9%)	3 (1.0%)	1 (0.4%)
Type II	66 (11.7%)	123 (22.9%)	106 (20.8%)	99 (20.2%)	85 (20.0%)	65 (19.4%)	50 (16.8%)	30 (12.3%)
New	66 (11.7%)	61 (11.3%)	37 (7.3%)	24 (4.9%)	25 (5.9%)	8 (2.4%)	7 (2.4%)	4 (1.6%)
Ongoing	—	66 (12.3%)	72 (14.1%)	79 (16.2%)	66 (15.5%)	58 (17.3%)	44 (14.8%)	27 (11.1%)
Type III	1 (0.2%)	3 (0.6%)	6 (1.2%)	4 (0.8%)	2 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
New	1 (0.2%)	2 (0.4%)	3 (0.6%)	2 (0.4%)	1 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ongoing	—	1 (0.2%)	3 (0.6%)	2 (0.4%)	1 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other	3 (0.5%)	8 (1.5%)	6 (1.2%)	4 (0.8%)	0 (0.0%)	1 (0.3%)	3 (1.0%)	2 (0.8%)
New	3 (0.5%)	6 (1.1%)	1 (0.2%)	1 (0.2%)	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)
Ongoing	—	2 (0.4%)	5 (1.0%)	3 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	2 (0.8%)
Indeterminate	3 (0.5%)	14 (2.6%)	15 (2.9%)	10 (2.0%)	13 (3.1%)	10 (3.0%)	11 (3.7%)	7 (2.9%)
New	3 (0.5%)	11 (2.0%)	5 (1.0%)	2 (0.4%)	7 (1.6%)	1 (0.3%)	4 (1.3%)	1 (0.4%)
Ongoing	—	3 (0.6%)	11 (2.2%)	8 (1.6%)	7 (1.6%)	9 (2.7%)	8 (2.7%)	6 (2.5%)
Subjects With No Endoleak Adverse Events Ongoing in Window	486 (86.0%)	391 (72.7%)	379 (74.5%)	379 (77.5%)	332 (78.1%)	261 (77.9%)	236 (79.5%)	204 (83.6%)

Note: Denominators are the number of subjects with endoleak evaluation or ongoing endoleak at each interval. Time frames for each interval are as follows: Treatment (0-0 days), 1 Month (1-60 days), 6 Months (61-242 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).

Table 15. Aneurysm Diameter Change Through Five Years Post-Treatment by Visit Interval: Combined IDE Cohort

	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months
Subjects Available at Beginning of Interval ¹	553	533	483	427	361	291
Subjects with Aneurysm Evaluation ²	476 (86.1%)	458 (85.9%)	397 (82.2%)	311 (72.8%)	279 (77.3%)	231 (79.4%)
≥ 5 mm Aneurysm Size Decrease ³	66 (13.9%)	100 (21.8%)	100 (25.2%)	79 (25.4%)	65 (23.3%)	53 (22.9%)
No Change in Aneurysm Diameter	401 (84.2%)	335 (73.1%)	251 (63.2%)	174 (55.9%)	134 (48.0%)	99 (42.9%)
≥ 5 mm Aneurysm Size Increase ⁴	9 (1.9%)	23 (5.0%)	46 (11.6%)	58 (18.6%)	80 (28.7%)	79 (34.2%)
Subjects with Aneurysm Increase and an Endoleak	4	13	20	16	22	17
Type I	0	1	1	0	0	1
Type II	3	12	19	15	18	13
Type III	0	0	1	0	0	0
Indeterminate	1	0	2	1	4	3

¹ The number eligible for evaluation is based on the number of subjects that enter the beginning of the follow-up interval alive and in the study.
² The denominator used to calculate percentages at each interval is based on the number of subjects eligible for evaluation.
³ The denominator used to calculate percentages at each interval is based on the number of subjects with aneurysm evaluation at each timepoint.
⁴ Increase is based on a change of greater than or equal to 5 mm from baseline. Time frames for each interval are as follows: 6 Months (61-242 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).

Table 16. Reinterventions Due to Aneurysm Diameter Increase or Endoleak: Combined IDE Cohort

	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months
Subjects Available at Beginning of Interval	565	553	533	483	427	361	291
Subjects with Endoleak or Aneurysm Increase AEs Requiring an Intervention	30 (5.3%)	19 (3.4%)	17 (3.2%)	19 (3.9%)	8 (1.9%)	9 (2.5%)	6 (2.1%)
Aneurysm Increase Interventions							
Embolization	1	0	2	3	1	1	0
Endovascular Stent Graft	0	0	0	2	3	3	2
Explant	2	0	1	3	1	3	2
Other	0	1	0	0	1	0	1
Endoleak Interventions							
Embolization	19	17	12	8	2	2	1
Endovascular Stent Graft	5	0	1	3	1	0	0
Explant	2	0	0	0	0	1	0
Other	5	3	1	1	0	0	0

Note: Time frames for each interval are as follows: 1 Month (0-60 days), 6 Months (61-242 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).

Imaging Core Laboratory Outcomes

An independent imaging core laboratory assessed follow-up CTs and x-rays for device events through five years post-treatment in the Combined IDE Cohort (Table 17). Endoleak incidence ranged from 6.6 – 23.5% at each follow-up visit through five years post-treatment; most endoleaks were type II. Aneurysm enlargement was observed in 36.1% of subjects at the five-year follow-up visit. Most subjects with aneurysm enlargement had no detectable endoleak.

Table 17. Imaging Core Laboratory Results Through Five Years Post-Treatment by Visit Interval: Combined IDE Cohort

	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months
Subjects Available at Beginning of Interval	565	553	533	483	427	361	291
Subjects with CT Imaging (sent to Core Lab)	443	409	408	339	249	211	170
Subjects with X-Ray Imaging (sent to Core Lab)	423	327	325	295	213	186	139
Trunk Migration	—	0 / 370 (0.0%)	0 / 382 (0.0%)	0 / 320 (0.0%)	0 / 226 (0.0%)	0 / 197 (0.0%)	0 / 155 (0.0%)
Component Migration	—	1 / 254 (0.4%)	2 / 301 (0.7%)	0 / 281 (0.0%)	0 / 206 (0.0%)	0 / 184 (0.0%)	0 / 135 (0.0%)
Fracture	1 / 352 (0.3%)	1 / 304 (0.3%)	1 / 301 (0.3%)	1 / 278 (0.4%)	0 / 209 (0.0%)	0 / 184 (0.0%)	0 / 133 (0.0%)
Narrowing of Flow Channel	8 / 427 (1.9%)	3 / 391 (0.8%)	4 / 389 (1.0%)	4 / 326 (1.2%)	3 / 238 (1.3%)	2 / 197 (1.0%)	1 / 155 (0.6%)
Endoleak	68 / 351 (19.4%)	76 / 324 (23.5%)	60 / 310 (19.4%)	41 / 271 (15.1%)	26 / 198 (13.1%)	14 / 179 (7.8%)	9 / 137 (6.6%)
Type I	7	9	4	3	0	0	0
Type II	41	45	40	31	18	10	7
Type III	1	2	5	0	1	1	0
Indeterminate	20	29	16	8	9	3	1
Missing	0	1	0	1	0	0	1
Aneurysm Size Change From Baseline							
≥ 5 mm Aneurysm Size Decrease	—	44 / 372 (11.8%)	58 / 374 (15.5%)	65 / 314 (20.7%)	45 / 226 (19.9%)	47 / 193 (24.4%)	35 / 158 (22.2%)
No Change in Aneurysm Diameter	—	315 / 372 (84.7%)	292 / 374 (78.1%)	205 / 314 (65.3%)	119 / 226 (52.7%)	87 / 193 (45.1%)	66 / 158 (41.8%)
≥ 5 mm Aneurysm Size Increase	—	13 / 372 (3.5%)	24 / 374 (6.4%)	44 / 314 (14.0%)	62 / 226 (27.4%)	59 / 193 (30.6%)	57 / 158 (36.1%)
Subjects with Aneurysm Increase and an Endoleak	—	4	8	12	15	10	5
Type I	—	1	0	1	0	0	0
Type II	—	2	5	7	10	7	4
Type III	—	0	0	0	1	1	0
Indeterminate	—	2	3	4	5	2	1
Missing	—	0	0	1	0	0	0

Note: Denominators for each variable are based on the number of evaluable images at each follow-up visit. Time frames for each interval are as follows: 1 Month (0-60 days), 6 Months (61-242 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). Note: Migration and Aneurysm Size Change use on month as baseline, and therefore are not assessed at the one month time point.

CLINICAL STUDY OUTCOMES (04-04)

Gore launched a design enhancement to the GORE EXCLUDER® AAA Endoprosthesis in response to aneurysm enlargement concerns. The low permeability GORE EXCLUDER® AAA Endoprosthesis was approved by the FDA and released in June 2004. Gore is currently conducting a post-approval clinical study (04-04) of 139 subjects to evaluate the clinical performance of the low permeability GORE EXCLUDER® AAA Endoprosthesis. These subjects are described herein as the "04-04 Test Group." Controls in this study are 120 randomly selected subjects treated with the GORE EXCLUDER® AAA Endoprosthesis from the 98-03 clinical study.

Subjects in the 04-04 Test Group have completed follow-up through one year post-treatment (Table 18). Partial two-year follow-up data are reported as 62 subjects returned for the follow-up visit and 61 are not yet due for this visit. Follow-up visit and CT compliance remain high through one year post-treatment. Six subjects died during the first year of the study. Causes of death included myocardial infarction (2), lung cancer, esophageal cancer, pneumonia, and unknown cause. Seven subjects were discontinued from the study. Aneurysm enlargement at the one-year follow-up visit, assessed by diameter and volume, was less frequent in the 04-04 Test Group vs. Controls (Tables 19 and 20). Furthermore, aneurysm shrinkage was more frequent in the 04-04 Test Group vs. Controls. Outcomes of the 04-04 study suggest that the design enhancement of the low permeability GORE EXCLUDER® AAA Endoprosthesis mitigate the risk of aneurysm enlargement without endoleak.

Table 18. Reinterventions Due to Aneurysm Diameter Increase or Endoleak: Combined IDE Cohort

Study Period	Eligible for Follow-Up	Follow-Up Compliance			Events Prior to Next Interval		
		Subjects with Visit in Window ¹	Site Reported CT Scan Read ²	Site Reported X-Ray Read ²	Corelab CT Scan Read ¹	Death ¹	Discontinued ¹
Procedure	139	139 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Procedure	139	139 (100.0%)	0 (0.0%)	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
1 Month	139	134 (96.4%)	130 (93.5%)	60 (43.2%)	130 (93.5%)	0 (0.0%)	3 (2.2%)
6 Months	136	115 (84.6%)	111 (81.6%)	35 (25.7%)	111 (81.6%)	3 (2.2%)	1 (0.7%)
12 Months	132	123 (93.2%)	120 (90.9%)	28 (21.2%)	121 (91.7%)	3 (2.3%)	3 (2.3%)
24 Months	126	62 (49.2%)	53 (42.1%)	13 (10.3%)	53 (42.1%)	0 (0.0%)	61 (48.4%)

¹ Denominators are based on number of subjects eligible for follow-up.
² X-rays were not required as part of the 04-04 Protocol.
 Time frames for each interval are as follows: Procedure: days 0-0, Post-Procedure: days 1-14, 1 Month: days 15-60, 6 Months: days 61-244, 12 Months: days 245-548 and 24 Months: days 549-912.

Table 19. Aneurysm Diameter Change Through Two Years Post-Treatment: Imaging Core Laboratory: 04-04 Test Subjects

	6 Months		12 Months		24 Months	
	Test	Control	Test	Control	Test	Control
Number of Subjects Enrolled	139	120	139	120	139	120
Subjects with Available Data ¹	103	88	114	94	50	100
≥5 mm Increase	2 (1.9%)	2 (2.3%)	0 (0.0%)	3 (3.2%)	1 (2.0%)	19 (19.0%)
No Change	76 (73.8%)	75 (85.2%)	69 (60.5%)	76 (80.9%)	26 (52.0%)	60 (60.0%)
≥5 mm Decrease	25 (24.3%)	11 (12.5%)	45 (39.5%)	15 (16.0%)	23 (46.0%)	21 (21.0%)

¹ Subjects are considered to be available for evaluation if they had both a baseline (one month) and post-baseline measurement.

Table 20. Aneurysm Volume Change Through Two Years Post-Treatment: Imaging Core Laboratory: 04-04 Test Subjects

	6 Months		12 Months		24 Months	
	Test	Control	Test	Control	Test	Control
Number of Subjects Enrolled	139	120	139	120	139	120
Overall Aneurysm Change ¹						
Subjects with Available Data ²	102	86	112	92	50	101
≥5% Increase	6 (5.9%)	20 (23.3%)	9 (8.0%)	31 (33.7%)	8 (16.0%)	47 (46.5%)
No Change	29 (28.4%)	32 (37.2%)	26 (23.2%)	26 (28.3%)	8 (16.0%)	23 (22.8%)
≥5% Decrease	67 (65.7%)	34 (39.5%)	77 (68.8%)	35 (38.0%)	34 (68.0%)	31 (30.7%)

¹ Subjects are considered to be available for evaluation if they had both a baseline (one month) and post-baseline measurement.
² Overall volume increase is computed as follows: if either distal renal to aortic bifurcation or right hypogastric to aortic bifurcation volume measurement increases ≥ 5% then the subject is considered an increaser. If either measure decreases ≥ 5% then the subject is considered a decreaser. Other non-missing combinations are considered No Change.

CLINICAL STUDY OUTCOMES (03-02)

The GORE EXCLUDER® Device product line has been expanded to include a 31 mm Trunk-Ipsilateral Leg and 32 mm Aortic Extender to treat patients with larger proximal aortic neck diameters. These large diameter devices were released outside of the US in February 2003. More than 2,000 patients have been treated worldwide with large diameter GORE EXCLUDER® Devices. In the US, the 03-02 clinical study is ongoing to evaluate the 31 mm GORE EXCLUDER® Device compared to open surgical repair and to compare device performance to the original GORE EXCLUDER® Device in the treatment of AAAs with large proximal aortic neck diameters. Preliminary outcomes in 35 subjects treated with the 31 mm GORE EXCLUDER® Device show a superior safety profile vs. open surgery and a comparable device efficacy profile vs. the original GORE EXCLUDER® Device.

Potential Device or Procedure Related Adverse Events

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

- amputation
- aneurysm enlargement
- aneurysm rupture and death
- arterial or venous thrombosis and / or pseudoaneurysm
- arteriovenous fistula
- bleeding, hematoma, or coagulopathy
- bowel (e.g., ileus, transient ischemia, infarction, necrosis)
- cardiac (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension or hypertension)
- claudication (e.g., buttock, lower limb)
- death
- edema
- embolization (micro and macro) with transient or permanent ischemia
- endoleak
- endoprosthesis: improper component placement; incomplete component deployment; component migration; separation of graft material from stent; occlusion; infection; stent fracture; graft material failure, dilatation, erosion, puncture, perigraft flow
- fever and localized inflammation
- genitourinary (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection)
- hepatic failure
- impotence
- infection (e.g., aneurysm, device or access sites)
- lymph fistula / complications
- neurologic damage, local or systemic (e.g., stroke, paraplegia, paraparesis)
- occlusion of device or native vessel
- pulmonary complications (e.g., pneumonia, respiratory failure)
- renal (e.g., artery occlusion, contrast toxicity, insufficiency, failure)
- surgical conversion
- wound (e.g., infection, dehiscence)
- vascular spasm or vascular trauma (e.g., ilio-femoral vessel dissection, bleeding, rupture, death)

Device Related Adverse Event Reporting

Any adverse event involving the GORE EXCLUDER® 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 SELECTION AND TREATMENT

(SEE WARNINGS AND PRECAUTIONS)

Individualization of Treatment

Gore recommends that the GORE EXCLUDER® AAA Endoprosthesis diameter be at least 2 mm larger than the aortic inner diameter (10 – 21% oversizing) and 1 mm larger than the iliac inner diameter (7 – 25% oversizing) as described in Tables 21 and 22. The length of the GORE EXCLUDER® AAA Endoprosthesis should be sufficient to reach from just inferior to the most distal (lowest) major renal artery to non-aneurysmal tissue in the common or external iliac arteries. All lengths and diameters of the devices necessary to complete the procedure should be available to the physician, especially when pre-operative case planning measurements (treatment diameters / lengths) are not certain. This approach allows for greater intraoperative flexibility to achieve optimal procedural outcomes.

Additional considerations for patient selection include but are not limited to:

- Patient's age and life expectancy
- Co-morbidities (e.g., cardiac, pulmonary or renal insufficiency prior to surgery, morbid obesity)
- Patient's suitability for open surgical repair
- Patient's anatomical suitability for endovascular repair
- The risk of aneurysm rupture compared to the risk of treatment with the GORE EXCLUDER® AAA Endoprosthesis
- Ability to tolerate general, regional, or local anesthesia
- 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 or 20 Fr vascular introducer sheath
- An infrarenal non-aneurysmal aortic neck length of at least 15 mm and a diameter of no greater than 29 mm
- Proximal neck angulation $\leq 60^\circ$ with minimal thrombus or calcification
- Distal segment iliac vessel lengths of at least 30 mm of which at least 10 mm must be less than or equal to 18.5 mm in diameter
- Freedom from significant femoral / iliac artery occlusive disease that would impede inflow or outflow of stent-grafts

The final treatment decision is at the discretion of the physician and patient.

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® 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® 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® 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, 145 cm or longer
- Angiographic radiopaque marker catheter
- Contrast media
- Syringe
- Heparin and heparinized saline
- **Trunk-Ipsilateral Leg Endoprosthesis and Contralateral Leg Endoprosthesis:**
 - 18 Fr or 20 Fr x 30 cm and 12 Fr x 30 cm 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:**
 - 18 Fr or 20 Fr x 30 cm introducer sheath
 - Large diameter, low pressure aortic balloon (monitor balloon volumes and pressures as recommended in balloon catheter Instructions for Use)
- **Iliac Extender Endoprosthesis:**
 - 18 Fr x 30 cm and 12 Fr x 30 cm 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 and 20 mm x 40 mm (Table 24)

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 x cm)
19 - 21	23	10 - 11	12	12, 14, 16, 18	18 x 30
		12 - 13.5	14.5		
22 - 23	26	10 - 11	12	12, 14, 16, 18	18 x 30
		12 - 13.5	14.5		
24 - 26	28.5	10 - 11	12	12, 14, 16, 18	18 x 30
		12 - 13.5	14.5		
27 - 29	31	12 - 13.5	14.5	13, 15, 17	20 x 30

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.
 * Note: All dimensions are nominal.

Table 22. Contralateral Leg Endoprosthesis Sizing Guide*

Intended Iliac Vessel Diameter (mm)	Iliac Endoprosthesis Diameter ¹ (mm)	Overall Device Lengths ^{2,3} (cm)	Recommended Contralateral Introducer Sheath ⁴ (Fr x cm)	Recommended Angioplasty Balloon Size (mm x mm)
10 - 11	12	10, 12, 14	12 x 30	12 x 40
12 - 13.5	14.5	10, 12, 14	12 x 30	14 x 40
13.5 - 14.5	16	9.5, 11.5, 13.5	18 x 30	16 x 40
14.5 - 16.5	18	9.5, 11.5, 13.5	18 x 30	18 x 40
16.5 - 18.5	20	9.5, 11.5, 13.5	18 x 30	20 x 40

1 Recommended endoprosthesis oversizing relative to the vessel is approximately 7-25%.
 2 Total treatable lengths include 4 cm of the trunk region of the Trunk-Ipsilateral Leg Endoprosthesis.
 3 Labeled Contralateral Leg length includes 3 cm overlap.
 4 GORE Introducer Sheaths are recommended.
 * 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 x cm)
19 - 21	23	3.3	18 x 30
22 - 23	26	3.3	18 x 30
24 - 26	28.5	3.3	18 x 30
27 - 29	32	4.5	20 x 30

1 Recommended endoprosthesis oversizing relative to the vessel diameter is approximately 10-21%.
 2 GORE Introducer Sheaths are recommended.
 * Note: All dimensions are nominal.

Table 24. Iliac Extender Endoprosthesis Sizing Guide*

Intended Iliac Vessel Diameter (mm)	Distal Iliac Extender Diameter ¹ (mm)	Endoprosthesis Length ² (cm)	Recommended Introducer Sheath ⁴ (Fr x cm)	Recommended Balloon Size (Proximal) (mm)	Recommended Angioplasty Balloon Size (Distal) (mm x mm)
8 - 9	10	7	12 x 30	14	10 x 40
10 - 11	12	7	12 x 30	14	12 x 40
12 - 13.5	14.5	7	12 x 30	14	14 x 40
13.5 - 14.5	16 ^{3a}	9.5, 11.5, 13.5	18 x 30	14	16 x 40
14.5 - 16.5	18 ^{3a}	9.5, 11.5, 13.5	18 x 30	14	18 x 40
16.5 - 18.5	20 ^{3a}	9.5, 11.5, 13.5	18 x 30	14	20 x 40

1 Recommended endoprosthesis oversizing relative to the vessel diameter is approximately 7-25%.
 2 7 cm long Iliac Extender Endoprosthesis provides a maximum extension of 4 cm when placed in the Trunk-Ipsilateral or Contralateral Leg Endoprosthesis; labeled length includes 3 cm overlap.
 3 16, 18, and 20 mm Contralateral Legs may be used as Iliac Extenders.
 4 GORE Introducer Sheaths are recommended.
 5 If extension of a 16, 18, or 20 mm Contralateral Leg is necessary, a 16 mm angioplasty balloon size is recommended for the proximal end of the extension.
 * 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 21 and 22) and Aortic and Iliac Extender Endoprostheses (Tables 23 and 24).
- 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) which is compatible with vascular access techniques and recommended accessories of the delivery profile of a 12 Fr (4.7 mm), 18 Fr (6.8 mm) or 20 Fr (7.6 mm) vascular introducer sheath.
- An infrarenal, non-aneurysmal aortic neck length of at least 15 mm and an infrarenal aortic neck treatment diameter range of 19-29 mm.
- For Trunk-Ipsilateral Leg Endoprosthesis and Aortic Extender Endoprosthesis: Proximal aortic neck angulation $\leq 60^\circ$ with minimal thrombus and / or calcification.
- Key anatomic elements that may affect successful exclusion of the aneurysm include severe proximal neck angulation, short proximal aortic neck and significant thrombus and / or calcium at the arterial implantation sites, specifically the proximal aortic neck and distal iliac artery interface. The US clinical studies quantify significant thrombus as thrombus ≥ 2 mm in thickness and / or $\geq 25\%$ 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 18.5 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 acceptable equivalent to the level of the renal arteries.
4. Following the manufacturer's instructions for use, prepare and advance the recommended introducer sheath (Tables 21 – 24) 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 (Figure 3A).
4. Flush with heparinized saline through the flushing port on the trailing end of the delivery catheter (Figure 3A).
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.

Trunk-Ipsilateral Leg Endoprosthesis Positioning and Deployment

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, through the 18 Fr or 20 Fr x 30 cm long 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 Trunk or the Contralateral Leg 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. For Trunk-Ipsilateral Leg Endoprosthesis utilizing 18 Fr x 30 cm long introducer sheath (Table 21), withdraw the introducer sheath to the light-colored shaft marker on the delivery catheter (Figure 3A). For Trunk-Ipsilateral Leg Endoprosthesis utilizing 20 Fr x 30 cm long introducer sheath (Table 21), withdraw the introducer sheath so that the proximal end (hub) of the introducer sheath comes in contact with the GORE EXCLUDER® Endoprosthesis delivery catheter hub (Figure 3A).
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. Maximize the separation between these two markers to achieve maximum lateral positioning of the iliac legs of the device. The long marker should be oriented toward the contralateral side (Figure 1).
WARNING: Do not rotate the Trunk delivery catheter beyond 360° to avoid delivery system damage and / or premature 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 12 Fr, 18 Fr or 20 Fr introducer sheath. The sheath and catheter must be removed together.
9. Loosen the deployment knob. Confirm final device position and orientation and deploy the Trunk using a steady and continuous pull of the deployment knob to release the endoprosthesis. Pull the deployment knob straight out from the catheter side arm. Deployment initiates from the leading end toward the trailing 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. During the US clinical studies, this device was not studied in patients with two occluded internal iliac arteries.

10. Use fluoroscopic guidance during the withdrawal of the delivery catheter to assure safe removal from, and to 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.
11. 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. 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.
12. Use fluoroscopic guidance to ensure the balloon is completely deflated and is safely removed from the endoprosthesis.
13. Advance and inflate the appropriate size PTA balloon catheter to seat the iliac end of the endoprosthesis. Follow the manufacturer's recommended method for size selection, preparation and use of PTA balloons. Carefully inflate the balloon to avoid complication.

Contralateral Leg Endoprosthesis Positioning and Deployment

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 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 rotating a formed pigtail catheter within the Trunk, or by standard practice used to verify guidewire location.
4. 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.
5. 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. The sheath will protect the device from catheter breakage or premature deployment while tracking it into position.
WARNING: Do not rotate the Trunk or the Contralateral Leg Endoprosthesis 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.
6. 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. With the alignment of these markers, an approximate 3 cm overlap will be achieved.
7. While maintaining the delivery catheter in position, withdraw the introducer sheath back to the light-colored shaft marker on the delivery catheter (Figure 3A).
WARNING: Do not rotate the Contralateral Leg Endoprosthesis delivery catheter during delivery, positioning or deployment. Catheter breakage or premature deployment may occur.
8. 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 12 Fr or 18 Fr introducer sheath. The sheath and catheter must be removed together.
9. 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. Deployment initiates from the leading (aortic) end toward the trailing (iliac) 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. During the US clinical studies, this device was not studied in patients with two occluded internal iliac arteries.
10. 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.
11. 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.

12. 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.

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, through the 18 Fr or 20 Fr x 30 cm 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 18 Fr or 20 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 Aortic or Iliac Extender 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. For Aortic Extender Endoprosthesis utilizing 18 Fr x 30 cm long introducer sheath (Table 23), withdraw the introducer sheath to the light-colored shaft marker on the delivery catheter (Figure 5A). For 32 mm diameter Aortic Extender Endoprosthesis utilizing 20 Fr x 30 cm long introducer sheath (Table 23), withdraw the introducer sheath so that the proximal end (hub) of the introducer sheath comes in contact with the GORE EXCLUDER® Endoprosthesis delivery catheter hub.
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. The maximum recommended extension with each Aortic Extender component is approximately one-half of the Extender length inside (1.6 cm or 2.2 cm) and one-half, outside (1.6 cm or 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).
5. 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.
6. 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 12 Fr, 18 Fr or 20 Fr introducer sheath. The sheath and catheter must be removed together.
7. Loosen the deployment knob. 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. Pull the deployment knob straight out from the catheter side-arm. Deployment initiates from the trailing end of the device toward the leading end of the device.
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.
8. Use fluoroscopic guidance during the withdrawal of the delivery catheter to assure safe removal from, and to 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.
9. 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.
10. Use fluoroscopic guidance to ensure the balloon is completely deflated and to assure safe removal from, and to avoid catching on, the endoprosthesis.

Iliac Extender Endoprosthesis Positioning and Deployment

- Use fluoroscopic visualization for all guidewire, sheath and device catheter manipulations.
- Advance the Iliac Extender Endoprosthesis delivery catheter into the distal end of the host device, via the recommended introducer sheath (Table 24).
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 Aortic or Iliac Extender 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.
- 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, or 20 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® 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, or 20 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 and 20 mm Contralateral Leg. Inadequate sealing may lead to endoleak.
- While maintaining the delivery catheter in position, withdraw the introducer sheath back to the light-colored shaft marker on the delivery catheter (Figure 5A).
- 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.
- Loosen the deployment knob. 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. The device deploys from the leading (proximal) end toward the trailing (distal) end.
WARNING: Do not attempt to withdraw any undeployed endoprosthesis through the 12 Fr or 18 Fr 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.
- 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.
- 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.
- 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

- 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® AAA Endoprosthesis Extender components as necessary. For Aortic Extenders, a minimum overlap of 1.6 cm or 2.2 cm is required, offering a maximum of 1.6 cm or 2.2 cm of extension; for Iliac Extenders, a minimum overlap of 3 cm is required.
- Close arterial access according to standard practice.
- 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 25) 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 CO₂ 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 25. Recommended Schedule for Patient Imaging Follow-Up

Visit	Schedule for Patient Imaging Follow-Up		
	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 26.

Table 26. 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 ISO: 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 and Compatibility



Non-clinical testing has demonstrated that the GORE EXCLUDER® AAA Endoprosthesis is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Spatial gradient field of ≤ 720 Gauss / cm
- Maximum scanner displayed whole-body-averaged specific absorption rate (SAR) of 3.0W / kg for 15 minutes of scanning

3.0 Tesla Temperature Rise:

In non-clinical testing, the GORE EXCLUDER® AAA Endoprosthesis produced a temperature rise of 2.5° C at an MR system reported maximum whole-body-averaged specific absorption rate (SAR) of 3.0W / kg for 15 minutes of MR scanning in a 3.0 Tesla, Excite, General Electric active-shield, horizontal field MR scanner using G3.0-052B Software and placed in a worst-case location in a phantom designed to simulate human tissue. The SAR calculated using calorimetry was 2.8 W / kg.

1.5 Tesla Temperature Rise:

In non-clinical testing, the GORE EXCLUDER® AAA Endoprosthesis produced a temperature rise of 1.9° C at an MR system reported maximum whole-body-averaged specific absorption rate (SAR) of 2.8W / kg for 15 minutes of MR scanning in a 1.5 Tesla, Magnetom, Siemens Medical Solutions, active-shield, horizontal field MR scanner using Numaris / 4 Software and placed in a worst-case location in a phantom designed to simulate human tissue. The SAR calculated using calorimetry was 1.5 W / kg.

Image Artifact:

For each vascular device and assembly, the artifacts that appeared on the MR images were shown as localized signal voids (i.e., signal loss) that were minor in size relative to the size and shape of these implants. The gradient echo pulse sequence produced larger artifacts than the T1 – weighted, spin echo pulse sequence for the GORE EXCLUDER® AAA Endoprosthesis. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the GORE EXCLUDER® AAA Endoprosthesis. Therefore, it may be necessary to optimize the MR imaging parameters to compensate for the presence of this implant.

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® 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® 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® AAA Endoprosthesis product (as required by US Federal Regulation).

DEFINITIONS

- Use By
- Attention, See Instructions for Use
- Do Not Re-Use
- Catalogue Number
- Batch Code
- European Authorized Representative
- STERILE
- Contents sterile unless package has been opened or damaged.
- STERILE EO
- Contents sterile unless enclosed package has been opened or damaged. Sterilized by ethylene oxide.
- Catheter Working Length
- Delivery Profile
- Do Not Re-Sterilize
- Guidewire Compatibility
- MR Conditional
- Store in a cool dry place



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- dk** CE-mærket gælder ikke for engelsk (USA)
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- ee** CE-vastavusmärgis ei kehti USA jaoks mõeldud ingliskeelse teksti juures
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W. L. GORE & ASSOCIATES, INC.

Flagstaff, Arizona 86004 • USA

Order Information: Tel.: 928.526.3030 • Tel.: 800.528.8763

Technical Information: Tel.: 928.779.2771 • Tel.: 800.437.8181

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