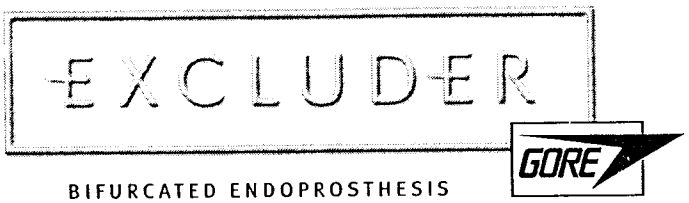
LABELING

INSTRUCTIONS FOR USE FOR:



en
English

TABLE OF CONTENTS

- **Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious surgical consequences or injury to the patient.**
- **CAUTION: USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.**

en

INSTRUCTIONS FOR USE

EXCLUDER BIFURCATED 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.**
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DESCRIPTION

Trunk-Ipsilateral Leg Endoprosthesis and Contralateral Leg Endoprosthesis

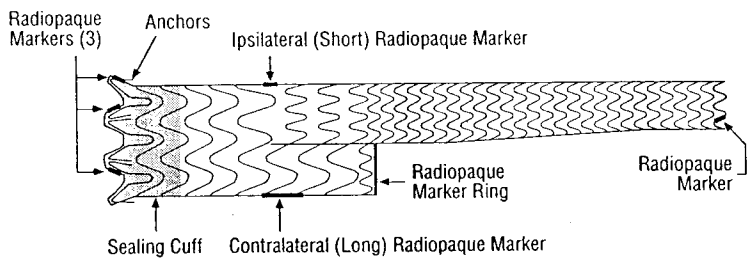
we are say the same thing

The EXCLUDER Bifurcated Endoprosthesis (EXCLUDER Bifurcated Endoprosthesis) provides endovascular treatment of infrarenal abdominal aortic aneurysms (AAAs).

The EXCLUDER Bifurcated Endoprosthesis is comprised of two components, the Trunk-Ipsilateral Leg Endoprosthesis (Trunk) (Figure 1) and the Contralateral Leg Endoprosthesis (Figure 2). The graft material is expanded polytetrafluoroethylene and fluorinated ethylene propylene (ePTFE and FEP), and is supported by nitinol wire along its external surface. Nitinol anchors and an ePTFE/FEP sealing cuff are located at the aortic end of the trunk (Figure 1). An ePTFE/FEP sleeve is used to constrain the endoprostheses on the leading end of the delivery catheters.

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, and 3C). The ePTFE/FEP sleeve remains in situ between the endoprosthesis and the vessel wall.

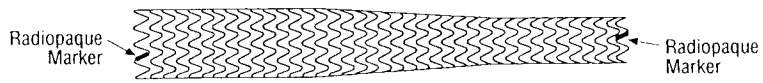
Figure 1: Trunk-Ipsilateral Leg Endoprosthesis



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 2: Contralateral Leg Endoprosthesis



Contralateral Leg Endoprosthesis Radiopaque Markers

- One (1) marker at each end

Figure 3A: EXCLUDER Bifurcated Endoprosthesis Delivery Catheter

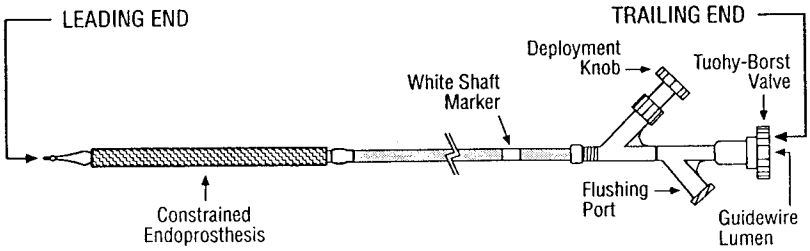


Figure 3B: Constrained EXCLUDER Bifurcated Endoprosthesis (Trunk-Ipsilateral) on Delivery Catheter with Radiopaque Markers

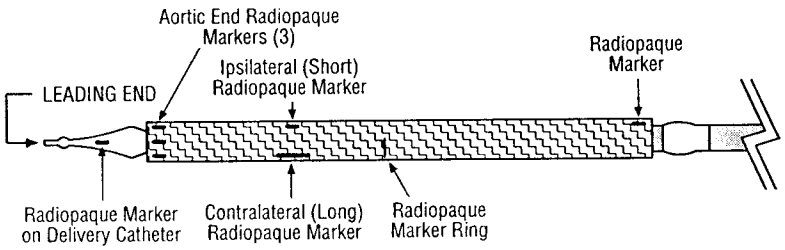
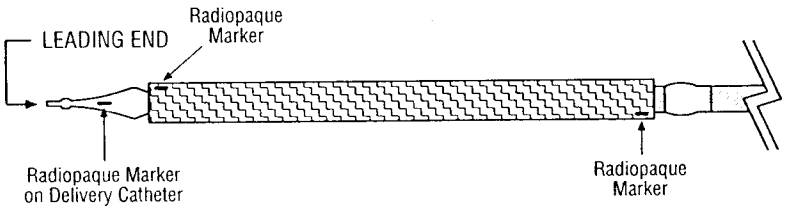


Figure 3C: Constrained EXCLUDER Bifurcated Endoprosthesis (Contralateral) on Delivery Catheter with Radiopaque Markers



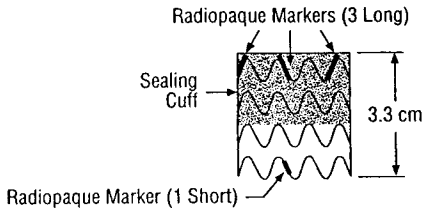
Aortic Extender Endoprosthesis and Iliac Extender Endoprosthesis Components

Aortic Extender Endoprosthesis

This wording should be approved earlier

The Aortic Extender Endoprosthesis (Aortic Extender) provides an extension of approximately 1.6 cm of the leading (proximal) end of the Trunk-Ipsilateral Leg Endoprosthesis (Trunk). This extension also allows a minimum of approximately 1.6 cm overlap with the Trunk, and can be overlapped with the Trunk at increasing length, until completely seated within the Trunk if necessary. This allows for customization of extender length based on patient anatomy and physician preference. The graft material is expanded polytetrafluoroethylene and fluorinated ethylene propylene (ePTFE and FEP), and is supported by nitinol 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: EXCLUDER Extender Endoprosthesis Delivery Catheter

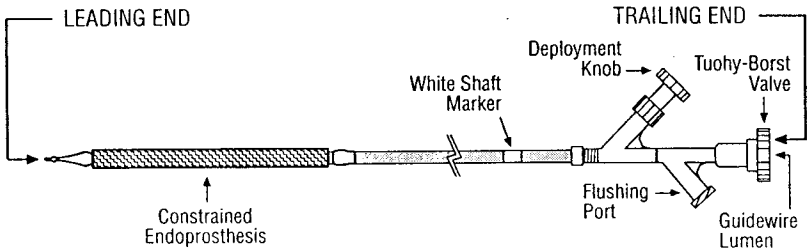


Figure 5B: Constrained EXCLUDER Extender Endoprosthesis (Aortic Extender)

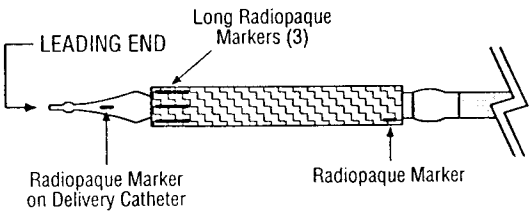
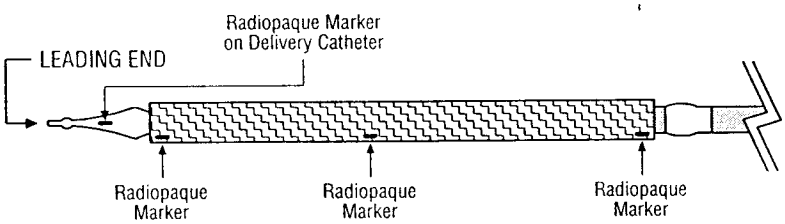


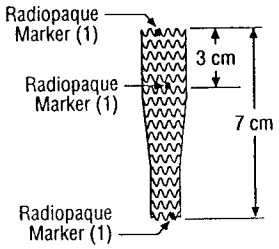
Figure 5C: Constrained EXCLUDER Extender Endoprosthesis (Iliac Extender)



Iliac Extender Endoprosthesis

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 4 cm to 0 cm for a complete overlap within the iliac leg component 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 (Figures 5C and 6). This marker denotes the recommended minimum overlap with the ipsilateral or contralateral limb of the EXCLUDER Bifurcated Endoprosthesis. An ePTFE/FEP sleeve is used to constrain the endoprosthesis on the leading end of the delivery catheter (Figures 5A and 5C). 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 6: 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.

INDICATIONS FOR USE

Trunk-Ipsilateral Leg Endoprosthesis and Contralateral Leg Endoprosthesis Components

The EXCLUDER Bifurcated 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 19-26 mm and a minimum aortic neck length of 15 mm.
- Proximal aortic neck angulation ≤ 60°.
- Iliac artery treatment diameter range of 8-13.5 mm and iliac distal vessel seal zone length of at least 10 mm.

Aortic Extender Endoprosthesis and Iliac Extender Endoprosthesis Components

The EXCLUDER Extender Endoprostheses (Aortic and Iliac) are intended to be used after deployment of the EXCLUDER Bifurcated 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 - page 28).
- The EXCLUDER Bifurcated Endoprosthesis should only be used by physicians experienced in vascular interventional techniques, and who have successfully completed the Gore Physician Training Program.
- The EXCLUDER Bifurcated 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 - page 28.

- 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 EXCLUDER Bifurcated Endoprosthesis has not been evaluated in the following patient populations:
  - traumatic aortic injury
  - leaking: pending rupture or ruptured aneurysms
  - mycotic aneurysms
  - pseudoaneurysms resulting from previous graft placement
  - revision of previously placed stent grafts
  - genetic connective tissue disease (e.g., Marfans or Ehlers-Danlos Syndromes)
  - concomitant thoracic aortic or thoracoabdominal aneurysms
  - inflammatory aneurysms
  - patients with active systemic infections
  - pregnant or nursing females
  - morbidly obese patients
  - patients less than 21 years old
  - patients with less than 15 mm in length or > 60° angulation of the proximal aortic neck.
- 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 an 18 Fr (6.8 mm) or 12 Fr (4.7 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 ≥ 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 EXCLUDER Bifurcated Endoprosthesis is not recommended in patients who cannot tolerate contrast agents necessary for inter-operative and post-operative follow-up imaging.
- The EXCLUDER Bifurcated Endoprosthesis is not recommended in patients exceeding weight and/or size limits which compromise or prevent the necessary imaging requirements.
- The EXCLUDER Bifurcated 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 postition.

- Do not attempt to advance the Aortic Extender through the 12 Fr introducer sheath. The Aortic Extender is designed for an 18 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 18 Fr or 12 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.
- Incorrect deployment or migration of the endoprosthesis may require surgical intervention.
- Do not cover significant renal or mesenteric arteries (exceptions are inferior mesenteric and ilio-femoral) with the endoprosthesis. Vessel occlusion may occur. During the clinical study, this device was not studied in patients with two occluded internal iliac arteries.

MRI Safety and Compatibility

- The EXCLUDER Bifurcated Endoprosthesis has been determined to be MR safe.
- The EXCLUDER Bifurcated Endoprosthesis may affect image quality (image artifact) depending on the pulse sequence that is used for MR imaging.
- The MR safety and compatibility of the EXCLUDER Bifurcated Endoprosthesis has been evaluated in MRI systems with static fields of ≤ 1.5 Tesla, gradient magnetic fields of ≤ 20 Tesla/second, and whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 30 minutes of imaging.

ADVERSE EVENTS

Observed Adverse Events

A US multi-center, prospective study conducted at 19 centers which included 235 test subjects and 99 control subjects provide the basis of the observed adverse event rates presented in Table 1.

Table 1. Major Adverse Events from Clinical Study

Major Adverse Events	Early (≤ 30 days)				Late (> 30 days to 12 months)			
	EXCLUDER Bifurcated Endoprosthesis		Control		EXCLUDER Bifurcated Endoprosthesis		Control	
	235	(%)	99	(%)	231	(%)	97	(%)
Deaths	3	1%	0	0%	14	6%	5	5%
Other Adverse Events								
Aneurysm Size Increase with an Intervention	0	0%	n/a	n/a	1	0.4%	n/a	n/a
Bleeding [1,2]	10	4%	32	32%	1	0.4%	1	1%
Bowel [1]	5	2%	16	16%	6	3%	3	3%
Cardiac[1]	7	3%	14	14%	16	7%	13	13%
Endoleak with an Intervention	0	0%	n/a	n/a	13	6%	n/a	n/a
Genitourinary	1	0.4%	1	1%	6	3%	1	1%
Neoplasm	1	0.4%	0	0%	3	1%	1	1%
Neurologic	1	0.4%	2	2%	7	3%	1	1%
Pulmonary [1]	3	1%	12	12%	10	4%	4	4%
Renal	2	1%	3	3%	5	2%	0	0%
Vascular [1]	3	1%	6	6%	7	3%	5	5%
Wound	7	3%	4	4%	9	4%	2	2%
Other Complications	0	0%	2	2%	12 [3]	5%	4	4%

1 Differences between groups are significantly different for Early Adverse Events (≤ 30 days).

2 The major adverse event Bleeding threshold for both EXCLUDER Bifurcated Endoprosthesis and control patients is defined as procedural blood loss > 1000 cc requiring intervention.

3 "Other Complications" in the EXCLUDER Bifurcated Endoprosthesis group were identified by physicians as follows:

1. Reaction to chemotherapy
2. Right axillary hematoma - post transaxillary arteriogram
3. Self inflicted gunshot wound to the head
4. Cholelithiasis with recurrent pancreatitis
5. Recurrent macular pucker, left eye
6. Fractured left humerus with hospitalization
7. Fractured left wrist, injured shoulder and right wrist (fall in hospital while there for ascites)
8. Thrombosis of known popliteal aneurysm
9. Fractured right femur
10. Bilateral carotid stenosis
11. Gynecomastia
12. Cataract and macular pucker, right eye

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, dehisence)
- vascular spasm or vascular trauma (e.g., ilio-femoral vessel dissection, bleeding, rupture, death)

Device Related Adverse Event Reporting

Any adverse event involving the EXCLUDER Bifurcated Endoprosthesis should be reported to W. L. Gore & Associates immediately. To report an event, call (800) 437-8181.

SUMMARY OF CLINICAL STUDIES

Objectives

The primary objective of the clinical study was to evaluate the safety and effectiveness of the EXCLUDER Bifurcated Endoprosthesis as an alternative to open surgical repair in the primary treatment of infrarenal abdominal aortic aneurysms. Safety was determined by evaluating whether the EXCLUDER Bifurcated Endoprosthesis subjects would have a total proportion of major adverse events that is less than the subjects treated with open surgical repair as evaluated through one year follow-up. Effectiveness was based on exclusion of the aneurysm including the absence of any endoleak, the absence of aneurysm enlargement (≥ 5 mm), and the absence of major device efficacy adverse events evaluated through one year follow-up. Secondary objectives included an assessment of clinical benefit and quality-of-life measures.

Study Design

This prospective, non-randomized, multi-center clinical study was designed to compare patients treated with endovascular repair to an open surgical repair control group. Nineteen US sites enrolled 235 EXCLUDER Bifurcated Endoprostheses and 99 control subjects. The control group included patients whose vascular anatomy may not have been suitable for endovascular AAA repair. The ratio of EXCLUDER Bifurcated Endoprostheses to control subjects was approximately 2:1. Follow-up evaluations were scheduled for pre-discharge, 1 month, 6 months, 12 months and annually thereafter. Twelve and 24 month data are provided in this summary based on findings from an independent Core Lab facility. An independent Core Lab facility reviewed CT scans and abdominal X-rays to assess aneurysm diameter changes, device and relative component migration, device integrity (wire and graft) and the presence and type of endoleaks.

Table 2: Patient Follow-up and Accountability

Treatment	EXCLUDER Bifurcated Endoprosthesis (N = 235)*			Control (N = 99)*		
Post-Procedure Interval	1 Month	12 Month	24 Month	1 Month	12 Month	24 Month
Expired	3	14	30	0	5	6
Withdrawn / Lost to Follow-up	0	6	17	2	13	20
Available Subjects	232	215	188	97	81	73
Actual Visit	226	202	177	88	74	67
Site CT Imaging	223	199	168	n/a	68	65
Core Lab CT Imaging	218	196	155	n/a	64	62
Site X-ray Imaging	n/a	163	148	n/a	n/a	n/a
Core Lab X-ray Imaging	n/a	154	129	n/a	n/a	n/a
Site Evaluated for Endoleak	221	199	165	n/a	n/a	n/a
Core Lab Evaluated for Endoleak	180	156	119	n/a	n/a	n/a
Site Evaluated for Aneurysm Enlargement	n/a	191	158	n/a	n/a	n/a
Core Lab Evaluated for Aneurysm Enlargement	n/a	181	146	n/a	n/a	n/a

* Data analysis sample size varies for each of the timepoints above and in the following tables. This variability is due to patients available for follow-up, as well as, quantity and quality of images available from specific timepoints for evaluation. For example, the number and quality of images available for evaluation of endoleak at 12 months is different than the number and quality of images available at 24 months due to variation in the number of image exams performed, the number of images provided from the clinical site to the Core Lab, and/or the number of images with acceptable evaluation quality. Another example is images that may have been interpretable by the Core Lab for flow channel narrowing but the same images may not necessarily have been interpretable for trunk migration.

Patient Demographics

Tables 3 and 4 compare the subject characteristics and initial aneurysm diameter of the EXCLUDER Bifurcated Endoprosthesis and open surgical population, respectively.

Table 3: Comparison of Subject Characteristics

Characteristic	EXCLUDER Bifurcated Endoprosthesis (N = 235) N	(%)	Control (N = 99) N	(%)	P-Value
Average Age (range in years)	73.0 (48 - 91)		70.1 (51 - 87)		0.002
Gender:					
Male	204	87%	73	74%	
Female	31	13%	26	26%	0.004
Aneurysm Symptomatic	11	5%	15	15%	< 0.001
Arrhythmia	56	24%	21	21%	0.591
Bleeding Disorder	11	5%	1	1%	0.119
Cancer	59	25%	19	19%	0.243
Congestive Heart Failure	22	9%	8	8%	0.708
COPD	62	26%	25	25%	0.830
Coronary Artery Disease	145	62%	53	54%	0.165
Erectile Dysfunction (males only)	33	16%	10	14%	0.616
Family History of AAA	14	6%	9	9%	0.307
Hepatic Dysfunction	6	3%	1	1%	0.679
Inflammatory AAA	2	1%	1	1%	1.00
Long-Term Use of Steroids	8	3%	1	1%	0.290
Other Concomitant Aneurysms	18	8%	13	13%	0.116
Peripheral Arterial Occlusive Disease	38	16%	14	14%	0.640
Paraplegia	0	0%	0	0%	n/a
Prior Vascular Intervention	26	11%	10	10%	0.796
Renal Dialysis	0	0%	0	0%	n/a
Smoking History	208	89%	84	85%	0.357
Stroke	26	11%	10	10%	0.818
Thrombotic Event	17	7%	4	4%	0.332
Valvular Heart Disease	18	8%	7	7%	0.852

Table 4: Aneurysm Diameter Distribution

Diameter Range	EXCLUDER Bifurcated Endoprosthesis (N = 235) N	(%)	Control (N = 99) N	(%)
< 30 mm	0	0%	0	0%
30 - 39 mm	0	0%	0	0%
40 - 49 mm	61	26%	15	15.3%
50 - 59 mm	109	46.4%	46	46.9%
60 - 69 mm	44	18.7%	22	22.2%
70 - 79 mm	15	6.4%	10	10.2%
80 - 89 mm	4	1.7%	5	5.1%
≥ 90 mm	2	0.9%	1	1.0%

Results

Data gathered in Tables 5 through 16 were collected by the clinical study sites and Core Lab. Table 5 describes the types of devices implanted into the clinical study patients. Table 6 summarizes longer-term device performance compared to control subjects, and Kaplan-Meier data at both 12 and 24 months. Figures 7 through 10 depict Survival at 24 months (Figure 7), Freedom from Aneurysm Related Mortality (Figure 8), Freedom from First Major Adverse Event (Figure 9), and Cumulative Major Adverse Event Rates (Figure 10).

Table 5: Devices Implanted

	N	(%)
Number of EXCLUDER Bifurcated Endoprosthesis Subjects	235	100%
Devices Implanted		
Trunk/Ipsilateral Leg and Contralateral Leg[1]	159	67%
with Aortic Extender(s)[2]	17	7%
with Iliac Extender(s)[3]	53	23%
with Aortic and Iliac Extender(s)[4]	6	3%

1 N = 5 Subjects received one Trunk-Ipsilateral Leg and two Contralateral Legs.
2 N = 2 Subjects received two Aortic Extenders.
3 N = 9 Subjects received more than one Iliac Extender (2, 3, or 4 Iliac Extenders).
4 N = 2 Subjects received two Iliac Extenders.

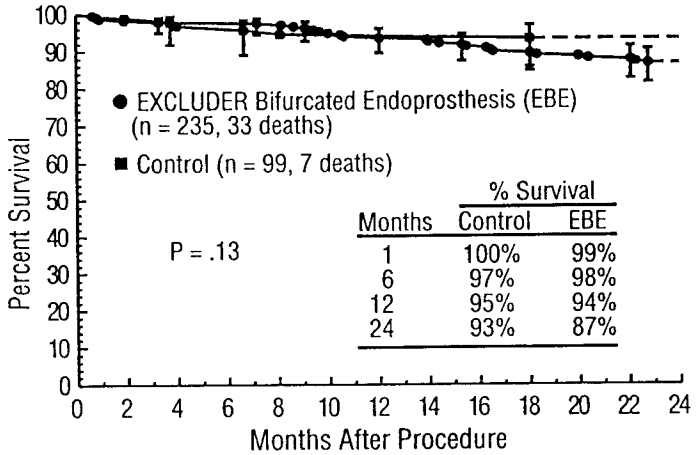
Table 6: Summary of Kaplan-Meier Curves to 24 Months

	Total Number of Patients Reaching Follow-up		Aneurysm Rupture		Conversion to Surgical Repair	Death		Aneurysm Related Death[1]		Major Adverse Event	
	T N	C N	T N	C N	T N	T N (%)	C N (%)	T N (%)	C N (%)	T N (%)	C N (%)
Intra-operative	235	99	0	0	0	0	0	0	0	n/a[2]	n/a[2]
≤ 30 Days	235	99	0	0	0	3 1%	0	3 1%	0	32[3] 14%[3]	56[3] 57%[3]
> 30 Days to 12 Months	232	97	0	0	0	11 5%	5 5%	1 0.4%	2 2%	57 27%	24 25%
12 Months to 24 Months	214	82	0	0	0[4]	16 7%	1 1%	0	0	37 17%	10 12%
Total Patients (at 24 Months)	214	82	0	0	0	30	6	4	2	110[5] 47%	65[5] 66%
Kaplan-Meier Summaries			Freedom from Aneurysm Rupture		Freedom from Conversion	Probability of Survival		Freedom from Aneurysm Related Death		Freedom from Major Adverse Event	
12 Month Kaplan-Meier	232	97	100%	100%	100%	94%	95%	98%	98%	65%[3]	36%[3]
24 Month Kaplan-Meier	214	82	100%	100%	100%	87%	93%	98%	98%	52%[3]	33%[3]

T = EXCLUDER Bifurcated Endoprosthesis C = Control

1 Aneurysm related death is defined as all deaths due to aneurysm rupture, a primary or secondary procedure, surgical conversion, or within 30 days of the primary or secondary procedure. (Chaikof; J Vasc Surg 2002;35:1048-60)
2 Major adverse events during the intraoperative period are reported in the < 30 day period.
3 Statistically significant, P < .05
4 Three elective conversions post 24 months. Three elective conversions occurred > 24 months post-operative. Two conversions were due to aneurysm enlargement and one conversion was due to aneurysm enlargement with a persistent Type II endoleak. All conversions were elective with no ruptures.
5 Total number of patients with a first adverse event only.

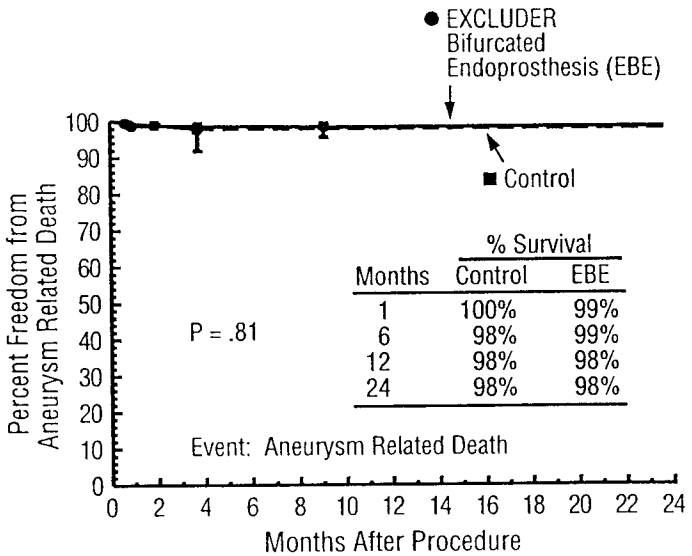
Figure 7: Survival at 24 Months



Control	99	88	82	74	59
EBE	235	231	214	193	112

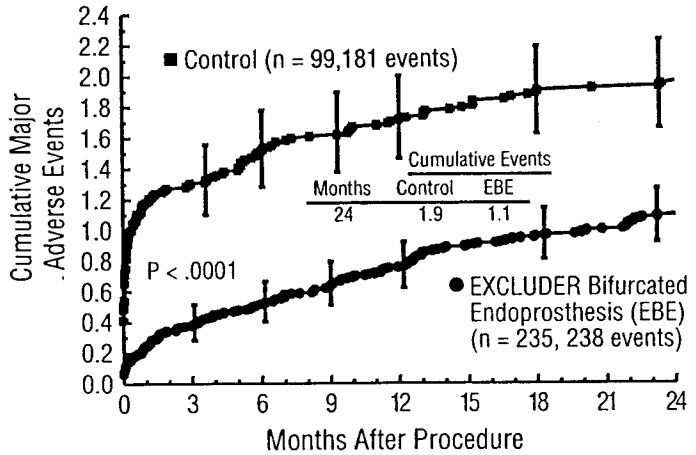
EXCLUDER Bifurcated Endoprosthesis subjects exhibited no significant differences between males and females for survival and freedom from major adverse events. (Error bars in Figures 7, 8, 9 and 10 represent a 95% confidence limit.)

Figure 8: Freedom from Aneurysm Related Mortality



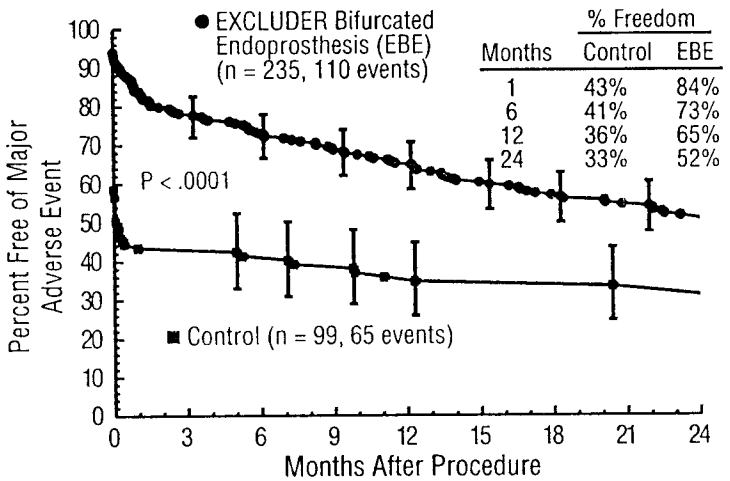
Control	99	88	82	74	59
EBE	235	231	214	193	112

Figure 9: Freedom from First Major Adverse Event



Control	99	88	82	74	59
EBE	235	231	214	193	112

Figure 10: Cumulative Major Adverse Event Rates



Control	94	39	32	27	17
EBE	235	170	147	121	64

Tables 7 through 14 describe results of the EXCLUDER Bifurcated Endoprosthesis subjects as reported by the Core Lab. Device performance factors analyzed by the Core Lab included device integrity (Table 7), device patency (Table 8), migration (Tables 9 and 10), and aneurysm exclusion (Tables 11-14). Device integrity encompasses the structural findings of the wire-form via abdominal X-ray images at the corresponding follow-up timepoints.

Table 7: Abdominal X-ray Findings - Device Integrity*

Device Integrity: Abdominal X-ray	Discharge (N = 171)		6 Months (N = 156)		12 Months (N = 140)		24 Months (N = 117)	
	N	(%)	N	(%)	N	(%)	N	(%)
Subjects Free from Device Integrity Issues	170	99%	156	100%	140	100%	117	100%
- Fracture	1	0.6%	0	0%	0	0%	0	0%

* None resulted in clinical sequelae.

Table 8: CT Findings - Narrowing of the Flow Channel*

CT - Narrowing	1 Month (N = 212)		6 Months (N = 193)		12 Months (N = 185)		24 Months (N = 148)	
	N	(%)	N	(%)	N	(%)	N	(%)
EXCLUDER Endoprosthesis	3	1.5%	0	0%	2	1.1%	2	1.4%

* None affected device patency.

Table 9: CT Findings – Trunk Migration*

CT - Trunk Migration	6 Months (N = 171)		12 Months (N = 175)		24 Months (N = 144)	
	N	(%)	N	(%)	N	(%)
Trunk Migration (≥ 10 mm)	5	3.0%	4	2.3%	2	1.4%

* None resulted in clinical sequelae.

Table 10: Abdominal X-ray Findings – Component Migration*

Abdominal X-ray - Component Migration	6 Months (N = 139)		12 Months (N = 139)		24 Months (N = 122)	
	N	(%)	N	(%)	N	(%)
Component Migration (≥ 10 mm)	2	1.4%	1	1.0%	1	1.0%

* None resulted in clinical sequelae.

Table 11: Endoleak Status According to Evaluation Interval

Type of Endoleak*	Evaluation Interval							
	1 Month (N = 180)		6 Months (N = 177)		12 Months (N = 156)		24 Months (N = 119)	
	N	(%)	N	(%)	N	(%)	N	(%)
Type I	7	4%	3	2%	2	1%	3	3%
Type II	21	12%	19	11%	19	12%	16	13%
Type III	0	0%	0	0%	0	0%	0	0%
Type IV	0	0%	0	0%	0	0%	0	0%
Indeterminate	11	6%	14	7%	6	4%	5	4%
Total	39	22%	36	20%	27	17%	24	20%

* As defined by White GH, et. al. JES 1997 and 1998.

Table 12: Change in Aneurysm Size by Interval

Change in Aneurysm Size	1 Month to 6 Months (N = 182)		1 Month to 12 Months (N = 181)		1 Month to 24 Months (N = 146)	
	N	(%)	N	(%)	N	(%)
Increase (≥ 5 mm)	5	3%	13	7%	21	14%
No Change	159	87%	142	79%	97	67%
Decrease (≥ 5 mm)	18	10%	26	14%	28	19%

Table 13: Maximum Aneurysm Diameter and Endoleaks at 12 Months

Aneurysm Change from 1 to 12 Months*	N	Endoleak at 12 Months*	
		N	(%)
Increase (≥ 5 mm)	10	4	40%
No Change	118	19	16%
Decrease (≥ 5 mm)	18	2	11%
Total	146	25	17%

* Only includes subjects with interpretable films (endoleak) and measurements of aneurysm change from 1 to 12 months.

Table 14: Maximum Aneurysm Diameter and Endoleaks at 24 Months*

Aneurysm Change from 1 to 24 Months**	N	Endoleak at 24 Months**	
		N	(%)
Increase (≥ 5 mm)	15	7	47%
No Change	74	10	14%
Decrease (≥ 5 mm)	23	2	9%
Total**	112	19	17%

* P = 0.004 for aneurysm size change and endoleak.

** Only includes subjects with interpretable films (endoleak) and measurements of aneurysm change from 1 to 24 months.

Secondary interventions within the first and second year each were performed in 6% of the EXCLUDER Bifurcated Endoprostheses subjects as shown in Table 15. All interventions were catheter-based except for one surgical ligation. Subjects may have a single intervention for an endoleak and an aneurysm enlargement. No other interventions were performed for any other reason, e.g., migration, limb occlusion, through 24 months.

Table 15: Interventions for Endoleak and Aneurysm Size Increases

Intervention	Post-procedure to 12 Months (N = 235)		> 12 Months to 24 Months (N = 203)	
	N	(%)	N	(%)
Number of Subjects with ≥ 1 Intervention	15	6%	12	6%
Treat an Endoleak:				
Embolization	15	6%	6	4%
Ligation	1	0.4%	0	0%
Conversion to Open Repair	0	0%	0*	0%
Treat an Aneurysm Increase:				
Embolization	0	0%	5**	3%
Ligation	1	0.4%	0	0%
Conversion to Open Repair	0	0%	0*	0%

* Total of three conversions post 24 months.

** Five also had endoleak.

As described in Table 16, treatment of AAA with EXCLUDER Bifurcated Endoprosthesis compared to the control group demonstrated significant benefits in recovery and quality of life measures.

Table 16: Secondary Outcomes by Treatment Group

Secondary Outcomes	EXCLUDER Bifurcated Endoprosthesis	Control
Blood Loss (ml) Mean (range)*	310 (50 - 2160)	1590 (100 - 7000)
Procedure Transfusion (%)*	14%	89%
Procedure Time (minutes) Mean (range)*	144 (51 - 320)	196 (67 - 420)
ICU Stay (%)*	24%	87%
Hospital Length of Stay (days) Mean (range)*	2 (1 - 11)	9.8 (3 - 114)
Time to First Oral Intake (days) Mean (range)*	0.5 (0 - 2.1)	2.6 (0.07 - 9.5)
Time to Ambulation (days) Mean (range)*	1.0 (0 - 5.0)	2.6 (0 - 18)
Time to Return to Normal Activities Mean (days)*	42	92

* Statistically significant ($P < 0.0001$).

PATIENT SELECTION AND TREATMENT

(SEE WARNING AND PRECAUTIONS)

Individualization of Treatment

Gore recommends that the EXCLUDER Bifurcated 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 17 and 18. The length of the EXCLUDER Bifurcated 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.

The risks and benefits previously described in SUMMARY OF CLINICAL STUDIES should be carefully considered for each patient before use of the EXCLUDER Bifurcated Endoprosthesis.

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 EXCLUDER Bifurcated 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 an 18 Fr or 12 Fr vascular introducer sheath.
- An infrarenal non-aneurysmal aortic neck length of at least 15 mm and a diameter of no greater than 26 mm.
- Proximal neck angulation ≤ 60° wth 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 13.5 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 - page 28).
- 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 - page 28).
- 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.

Physicians should 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 OBSERVED ADVERSE EVENTS - page 7, and POTENTIAL DEVICE or PROCEDURE RELATED ADVERSE EVENTS - page 8).

The physician should 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 anytime they visit additional health practitioners, particularly for any additional diagnostic procedures (e.g., MRI).

HOW SUPPLIED

The EXCLUDER Bifurcated 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 the conversion to open surgical repair is necessary.

CAUTION: The EXCLUDER Bifurcated Endoprosthesis should only be used by physicians experienced in vascular interventional techniques, and who have successfully completed the Gore Physician Training Program.

The recommended skill/knowledge requirements for physicians using the EXCLUDER Bifurcated 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 Endoproshtesis and Contralateral Leg Endoprosthesis:**
  - 18 Fr x 30 cm and 12 Fr x 30 cm introducer sheaths (Tables 17 and 18)
  - 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 18)
- **Aortic Extender Endoprosthesis:**
  - 18 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:**
  - 12 Fr (or larger) x 30 cm introducer sheath
  - PTA balloon catheters, 10 mm x 40 mm, 12 mm x 40 mm and 14 mm x 40 mm (Table 20)

Table 17: 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 (Fr x cm)
19 - 21	23	10 - 11	12	16, 18	18 x 30
		12 - 13.5	14.5		
22 - 23	26	10 - 11	12	16, 18	18 x 30
		12 - 13.5	14.5		
24 - 26.5	28.5	10 - 11	12	16, 18	18 x 30
		12 - 13.5	14.5		

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.

* Note: All dimensions are nominal.

Table 18: 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 (Fr x cm)	Recommended Angioplasty Balloon Size (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

1 Recommended endoprosthesis oversizing relative to the vessel is approximately 7-25%.

2 Total treatable lengths (e.g., 14, 16 or 18 cm) include 4 cm from the trunk region of the Trunk-Ipsilateral Leg Endoprosthesis.

3 Labeled Contralateral Leg length includes 3 cm overlap.

* Note: All dimensions are nominal.

Table 19: Aortic Extender Endoprosthesis Sizing Guide*

Intended Aortic Vessel Diameter (mm)	Aortic Extender Diameter[1] (mm)	Endoprosthesis Length (cm)	Recommended Introducer Sheath (Fr x mm)
19 - 21	23	3.3	18 x 30
22 - 23	26	3.3	18 x 30
24 - 26.5	28.5	3.3	18 x 30

1 Recommended endoprosthesis oversizing relative to the vessel diameter is approximately 10-21%.

* Note: All dimensions are nominal.

Table 20: Iliac Extender Endoprosthesis Sizing Guide*

Intended Iliac Vessel Diameter (mm)	Iliac Extender Diameter[1] (mm)	Endoprosthesis Length[2] (cm)	Recommended Introducer Sheath (Fr x mm)	Recommended Balloon Size (Proximal) (mm)	Recommended Balloon Size (Distal) (mm)
8 - 9	10	7	12 x 30	14	10
10 - 11	12	7	12 x 30	14	12
12 - 13.5	14.5	7	12 x 30	14	14

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.

* Note: All dimensions are nominal.

DIRECTIONS FOR USE

Pre-Treatment Planning

- Determine accurate size of anatomy and proper size of Trunk-Ipsilateral and Contralateral Endoprosthesis (Tables 17 and 18) and Aortic and Iliac Extender Endoprostheses (Tables 19 and 20).
- 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 accessories of the delivery profile of an 18 Fr (6.8 mm) or 12 Fr (4.7 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 19-26 mm.
- For Trunk-Ipsilateral Leg Endoprosthesis and Aortic Extender Endoprosthesis: Proximal aortic neck angulation ≤ 60° with minimal thrombus and/or calcification.
- Key anatomic elements that may affect successful exclusion of the aneurysm include severe proximal neck angulation, 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 ≥ 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 13.5 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 an 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 18 Fr diameter x 30 cm length, introducer sheath/dilator 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 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 postition.
   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. While maintaining the delivery catheter in position, withdraw the introducer sheath back to the white shaft marker on the delivery catheter (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 device.
6. If clinically acceptable, lower the patient's blood 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 18 Fr or 12 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 (exceptions are inferior mesenteric and ilio-femoral) with the endoprosthesis. Vessel occlusion may occur. During the clinical study, 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.
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 12 Fr x 30 cm long contralateral introducer sheath and dilator. Advance the sheath over the guidewire and through the contralateral leg hole of the Trunk.

5. Advance the prepped Contralateral 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 postition.
   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.
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, approximately a 3 cm overlap will be achieved.
7. While maintaining the delivery catheter in position, withdraw the introducer sheath back to the white shaft marker on the delivery catheter (Figure 3A).
   WARNING: Do not rotate the Contralateral Leg 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 18 Fr or 12 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 (exceptions are inferior mesenteric and ilio-femoral) with the endoprosthesis. Vessel occlusion may occur. During the clinical study, 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.
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 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 an 18 Fr sheath.
   WARNING: Do not advance the device outside of the sheath. The sheath will protect the device from catheter breakage or premature deployment while tracking it into postition.
   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. While maintaining the delivery catheter in position, withdraw the introducer sheath back to the white shaft marker on the delivery catheter (Figure 5A).
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 (16 mm) and one-half, outside (16 mm), 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 blood 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 18 Fr or 12 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 (exceptions are inferior mesenteric and ilio-femoral) with the endoprosthesis. Vessel occlusion may occur. During the clinical study, 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.
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

1. Use fluoroscopic visualization for all guidewire, sheath and device catheter manipulations.
2. Advance the Iliac Extender Endoprosthesis delivery catheter into the distal end of the host device, via the 12 Fr x 30 cm length introducer 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 postition.
   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 maximum extension (4 cm), align the radiopaque marker at the iliac (distal) end of the host device with the middle marker of the Extender component (Figures 5C and 6).
4. While maintaining the delivery catheter in position, withdraw the introducer sheath back to the white shaft marker on the delivery catheter (Figure 5A).
5. Stabilize the Iliac Extender delivery catheter at the level of entry into the introducer sheath and stabilize the sheath relative to the patient's access site.
6. 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 18 Fr or 12 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 (exceptions are inferior mesenteric and ilio-femoral) with the endoprosthesis. Vessel occlusion may occur. During the clinical study, this device was not studied in patients with two occluded internal iliac arteries.
7. Use fluoroscopic guidance during the withdrawal of the delivery catheter to assure safe removal from, and avoid catching on, the endoprosthesis.

8. 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.
9. Use fluoroscopic guidance to ensure the balloon is completely deflated and to assure safe removal from, and to avoid catching on, the endoprosthesis.

Completion of the Procedure

1. Perform extended imaging angiography to confirm exclusion of the aneurysm. Consider breath-hold technique to optimize digital subtraction angiography image quality. Consider use of EXCLUDER Bifurcated Endoprosthesis Extender components as necessary. For Aortic Extenders, a minimum overlap of 1.6 cm is required, offering a maximum of 1.6 cm of extension; for Iliac Extenders, a minimum overlap of 3 cm is required, offering a maximum of 4 cm extension.
2. Close arterial access according to standard practice.
3. 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 CT's, 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 19) were employed.

Follow-up modalities include CT/CTA, multi-view abdominal X-ray, MRI/MRA, and ultrasound. Data from these modalities is acquired and used to compare baseline and subsequent exams to review devices and morphological changes over time and their effects on exclusion of the aneurysm.

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

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

Table 21. Recommended Schedule for Patient Imaging Follow-up

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

[1] Imaging should be performed ≤ 6 months prior to the procedure
[2] Recommended if endoleak reported at Discharge
[3] Recommended if endoleak reported at 1 month

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 22.

Table 22. CT/CTA Imaging Guidelines

	Pre-Contrast	CT /CTA
IV Contrast	No	Yes
Injection Volume (ml)	n/a	150
Injection Rate (cc/sec)	n/a	≥ 2.5
Delay	n/a	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	**Monitor Delay:** 6 Sec
	Scan Phase: 3 Sec	**Monitor ISD:** 3 Sec
	MA: 40	**Enhance Thres:** 100 HU

Abdominal X-ray Film Series (plain film)

Abdominal X-rays are recommended at discharge and annually thereafter with various views. The following 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 visual aid and for device/radiology expertise.

MRI Safety and Compatibility

- The EXCLUDER Bifurcated Endoprosthesis has been determined to be MR safe.
- The EXCLUDER Bifurcated Endoprosthesis may affect image quality (image artifact) depending on the pulse sequence that is used for MR imaging.
- The MR safety and compatibility of the EXCLUDER Bifurcated Endoprosthesis has been evaluated in MRI systems with static fields of ≤ 1.5 Tesla, gradient magnetic fields of ≤ 20 Tesla/second, and whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 30 minutes of imaging.

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.

PATIENT TRACKING INFORMATION

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

DEFINITIONS

Use By

Attention, See Instructions for Use

Do Not Reuse

REF Catalogue Number

LOT Batch Code

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.

Store in a cool dry place

10LS1887.01

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