FEASIBILITY STUDY CLINICAL PROTOCOL
CP-0003 Rev. 03
Effective Date: March 15, 2012

Prospective, Multicenter, Single Arm Feasibility and Safety Study of the Endologix Fenestrated Stent Graft System for the Endovascular Repair of Juxtarenal/Pararenal (JAA/PAA) Aneurysms

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List of Attachments

1) **Instructions for Use (IFUs) (updated March 2012)**
2) **Sample Informed Consent Form (updated March 2012)**
3) **Template Case Report Forms**
4) **Investigator Agreement**
5) **Statistical Analysis Plan**

Revision 03. Change Summary

Section (Page)	Change and Reason for the Change
All pages	Changed protocol Revision From 01 (13 May 2011) to 03 (15 March 2012). Also made minor corrections of typos throughout. Reason: Reflect the revision change; to correct typos.
2.1 (6) 10.5 (43)	Revised sponsor contact personnel. Reason: Reflect current sponsor contact personnel.
3 (7) 5.1 (14)	Changed maximum number of sites to participate from 10 to 15. Changed total number of patients from 30 to 50. Reasons: Minor expansion of study numbers and sites will: - permit continued enrollment for the collection of additional safety and feasibility data to supplement patient numbers for sites not actively enrolling to expected totals plus; - assist sites who have experienced start-up delays and; - allow continued enrollment while awaiting CE Mark clearance
7 (18-21)	Updated fenestrated delivery system device description to reflect incremental changes. Reason: Modifications to the delivery system were made for user ease of use. These changes do not affect the implant delivery or method of deployment. Removed bifurcated delivery System schematic drawing Reason: Non-essential and obsolete
7.2 g(22)	Added Investigator training requirements for the changes to the delivery system.
8.6.7 (30-31)	Editorial revisions to text on instructions for each follow-up visit. Reason: For added clarity only.
Appendices	Appendix 1: Updated Ventana Instructions for Use document to reflect modified delivery system description and specific information. Appendix 2: Updated informed consent document to reflect update to the number of sites and participants. Reason: For consistency with the protocol. All other appendices: no-substantive changes.

1. INVESTIGATOR SIGNATURE PAGE

I agree to conduct the Ventana Study as detailed in the Investigational Plan and in accordance with all applicable laws and regulations. In addition, I agree to provide all the information requested in the case report forms presented to me by the sponsor in a manner to assure completeness, legibility and accuracy.

I agree to actively enroll patients into this study and confirm that I am not currently participating in any clinical investigations for similar types of medical devices.

I also agree that all information provided to me by the sponsor, including pre-clinical data, protocols, case report forms, and any verbal and written information, will be kept strictly confidential and confined to the clinical personnel involved in conducting the study. It is recognized that this information may be relayed in confidence to the ethics committee (EC) or Institutional Review Board (IRB) or to regulatory authorities.

In addition, no reports or information about the study or its progress will be provided to anyone not involved in the study other than the sponsor, the EC(s)/IRB(s) the core labs, the clinical events committee, or the data safety monitoring board. Any such submission will indicate that the material is confidential.

Investigator Signature Date

Investigator Printed Name

2. STUDY CONTACT PERSONNEL

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3. PROTOCOL SYNOPSIS

Title:	Prospective, Multicenter, Single Arm Feasibility and Safety Study of the Endologix Fenestrated Stent Graft System for the Endovascular Repair of Juxtarenal/Pararenal (JAA/PAA) Aneurysms
Objective:	To evaluate the feasibility and safety of the Endologix Fenestrated Stent Graft System in the treatment of patients with juxtarenal and/or pararenal aortic aneurysms. The primary purpose of this study is to support ongoing regulatory submissions in the United States and CE Mark countries.
Design:	Multicenter, prospective, single arm feasibility/safety study
Device:	Endologix, Inc. commercially-available bifurcated stent graft devices.
Study Devices:	Endologix Fenestrated JAA/PAA proximal extension stent graft devices Endologix renal stent graft devices
Study Sites:	Sites with fixed imaging, an adequate research infrastructure, and well established experience in open repair of JAA/PAA, renal stenting techniques, and endovascular aneurysm repair techniques may participate.
Patient Enrollment:	A maximum of 50 patients at up to 15 institutions will be enrolled. An enrollment rate of one to two patients per site per month is anticipated. All patients will be diagnosed with JAA/PAA with maximum diameter ≥5.5cm, or between 4.5 and 5.5cm and rapidly expanding (>0.5cm in six months), or >50% larger than the normal aortic diameter. Confirmation of patient anatomical eligibility for the device will be based on the independent core lab assessment of the reconstructed high resolution, contrast enhanced CT scan performed within the prior three months. Following informed consent, patient anatomical eligibility confirmation and screening/baseline assessments will be performed. A review of screening documentation will be conducted by Endologix and a CONFIRM or DENY response will be provided to the site. Anatomically eligible, consenting, and confirmed patients will be scheduled for the procedure. Labeling (instructions for use) is provided in Attachment 1; the template informed consent form is provided in Attachment 2; case report forms are provided in Attachment 3; and the investigator agreement is provided in Attachment 4.

Inclusion Criteria: Male or female at least 18 years old; informed consent understood and signed and patient agrees to all follow-up visits; have aortic aneurysm with maximum diameter ≥5.5cm, or between 4.5 and 5.5cm and rapidly expanding (>0.5cm in six months), or >50% larger than normal aortic diameter.

Anatomically eligible for the Endologix Bifurcated System per the FDA-approved indications for use (IFU) and for the Fenestrated Stent Graft System:

- Adequate iliac/femoral access compatible with the required delivery systems (diameter ≥8 mm) or eligible for an arterial conduit for delivery system access;
- Non-aneurysmal infrarenal aortic neck <15mm in length;
- Most caudal renal artery to aortoiliac bifurcation length ≥70mm;
- SMA to aortoiliac bifurcation length ≥90mm;
- Proximal non-aneurysmal aortic neck below the SMA with: diameter 18 to 34 mm; length ≥15 mm; angle ≤60° to the aneurysm sac;
- Angle ≤60° (clock face) between the SMA and CA;
- Angle ≤60° (clock face) between the SMA and CA;
- Renal arteries both distal to the SMA by ≤35mm, within ≤30mm of each other axially, with 4 to 8mm lumen diameter, and with clockface angle of 90° to 210° to each other;
- Common iliac artery distal fixation site with: distal fixation length ≥15 mm; ability to preserve at least one hypogastric artery; diameter ≥10 mm and ≤23 mm; angle ≤90° to the aortic bifurcation;
- The Endologix Fenestrated Proximal Extension Stent must have the ability to overlap the bifurcated stent graft by at least 3cm.

Exclusion Criteria: Exclusionary criteria and conditions are as follows:

- Life expectancy <2 years as judged by the investigator
- Psychiatric or other condition that may interfere with the study
- Participating in the enrollment or 30-day follow-up phase of another clinical study
- Known allergy to any device component
- Coagulopathy or uncontrolled bleeding disorder
- Contraindication to contrast media or anticoagulants
- Ruptured, leaking, or mycotic aneurysm
- Aortic dissection
- Serum creatinine (S-Cr) level >2.0 mg/dL†
- Traumatic vascular injury
- Active systemic or localized groin infection
- Connective tissue disease (e.g., Marfan's Syndrome)

†This criterion is waived for patients on dialysis prior to study screening/enrollment.

- Recent (within prior three months) cerebrovascular accident or myocardial infarction
- Prior renal transplant
- Length of either renal artery to be stented <13mm
- Significant occlusive disease of either renal artery (>70%)
- An essential accessory renal artery
- Indispensable inferior mesenteric artery
- Untreated aneurysmal disease of the descending thoracic aorta
- Clinically significant mural thrombus circumferentially in the suprarenal segment
- Prior iliac artery stent implanted that may interfere with delivery system introduction
- Unsuitable vascular anatomy
- Pregnancy (female patient of childbearing potential only)

Primary Endpoints:

Safety: Major adverse events at 1 month.[†]

Feasibility: Successful device delivery and deployment with patency of the renal and aortic endografts without Type I/III endoleak at 1 month. Procedural, clinical, and assisted clinical feasibility will be reported.[‡]

Additional Evaluations:

- Procedural and in-hospital evaluations: Anesthesia time; fluoroscopy time; contrast volume used; total procedure time; estimated blood loss; % of patients with transfusion; time in ICU; time to hospital discharge.
- Death (all-cause and aneurysm-related) within 30 days, at 6 months, and annually at 1 to 5 years;
- Major adverse events after 30 days, at 6 months, and annually at 1 to 5 years;
- Individual major adverse event components within 30 days, at 6 months, and annually at 1 to 5 years;
- Aneurysm rupture within 30 days, at 6 months, and annually at 1 to 5 years;
- Conversion to open repair within 30 days, at 6 months, and annually at 1 to 5 years;
- Adverse Events: All serious and non-serious events within 30 days, at 6 months, and annually at 1 to 5 years;
- Distal blood flow (ankle-brachial index evaluations) pre-discharge and at 30 days, 6 months, and annually at 1 to 5 years;

[†]Defined as all-cause death, bowel ischemia; myocardial infarction, paraplegia, renal failure, and respiratory failure; stroke; and blood loss ≥1,000cc.

[‡]Refer to protocol §6.2 for detailed definitions.

- Endograft performance (aneurysm sac diameter changes; device migration; incidence of endoleak) at 30 days, 6 months, and annually at 1 to 5 years;
- Renal function as assessed by estimated glomerular filtration rate (eGFR) pre-discharge and at 30 days, 6 months, and annually at 1 to 5 years;
- Renal stent graft patency and integrity at 30 days, 6 months, and annually at 1 to 5 years;
- Stent graft (fenestrated/bifurcated) patency and integrity at 30 days, 6 months, and annually at 1 to 5 years;
- Secondary procedures within 30 days, at six months, and at years 1 through 5 for resolution of endoleak, limb occlusion, migration, aneurysm sac expansion and/or a device defect.

Schedule of Tests: Pre-procedural high resolution, contrast-enhanced CT scan evaluation to determine anatomical eligibility for enrollment will be performed within three months of the procedure. A physical exam and laboratory testing will be performed prior to the procedure. Following EC/IRB approval and patient written informed consent, the patient will be screened for eligibility. Patients will be followed procedurally and to hospital discharge, and will then be followed at intervals: 1 month; 6 months; 1 year; and annually to 5 years. Tests and evaluations:

Schedule of Tests:	**Screening/ Baseline**	**Procedure (Day 0)**	**Pre-Discharge**	**1 Month***	**6 Months***	**1 to 5 Years***
Physical Exam[†]	x		x	x	x	x
Blood Labs[‡]	x		x	x	x	x
Contrast-Enhanced CT scan[¥]	x			x	x	x
Ankle Brachial Index	x		x	x	x	x
Adverse Events		x	x	x	x	x

[†]The physical exam includes overall health and physical assessment and vital signs.

[‡]Blood labs include serum creatinine, blood urea nitrogen, hematocrit, and hemoglobin.

[¥]The baseline high resolution, contrast-enhanced CT scan (3mm or less slice spacing) performed within three months prior to enrollment will be reviewed by the independent core lab for patient eligibility determination. Evaluations of endograft performance, renal stent graft patency and integrity, and stent graft patency and integrity will be made based upon post-operative CT scan evaluations by the core laboratory.

*Follow-up windows are ±2 weeks (1 month visit); ±1 month (6 month visit); ±2 months (Year 1 visit); ±3 months (Years 2 through 5 visits)

4. STUDY OVERVIEW

4.1. OBJECTIVE

The primary objective of this study is to assess the feasibility and safety of the Endologix Fenestrated Stent Graft System for the endovascular repair of juxtarenal or pararenal (JAA/PAA) aortic aneurysms in suitable patients. The primary purpose of this study is to support United States Regulatory and CE Mark approvals for the Endologix fenestrated proximal extension and renal stent graft devices.

4.2. BACKGROUND

An extensive summary of current scientific literature regarding surgical and endovascular techniques and devices used in the repair of JAA or PAA is provided in the Clinical Investigator's Brochure (CIB). A brief summary is provided below:

An arterial aneurysm is a permanent, localized dilatation of an artery with an increase in diameter of 50% or more than the normal artery diameter. Although any artery may develop an aneurysm, most commonly an aneurysm is seen in the abdominal aorta, thoracic aorta, popliteal artery or common iliac artery. Abdominal aortic aneurysm (AAA) is a progressive disease characterized by structural deterioration, gradual expansion, and eventual rupture of the abdominal aorta if left untreated. AAA is the most common type of aortic aneurysm, with more than 90% occurring inferior to the renal arteries. This vascular disorder causes significant mortality and morbidity in the aged population and is a leading cause of death.[1]

The complexity of AAA is commonly characterized based on location and involvement with visceral vessels. Infrarenal AAA generally involves the infrarenal aorta and may involve the aortoiliac vasculature. A subset of infrarenal AAA extends up to the level of but does not involve the renal arteries, and is termed juxtarenal AAA (JAA). A small proportion of AAA involves the renal arteries and as such is termed pararenal AAA (PAA). Extension of the disease to and beyond the superior mesenteric artery (SMA) or celiac artery (CA) into the thoracic aorta describes thoracoabdominal aneurysms. These more complex aneurysms are beyond the scope of this study.

It is estimated that approximately 25% to 40% of infrarenal AAA are not suitable for endovascular repair due to unfavorable proximal neck anatomy (e.g., highly angulated, dilated, short [JAA], or encroaching on or involving the renal arteries [JAA or PAA]).[2,3] In most US studies of endovascular AAA repair, including that for the Endologix Powerlink System, the infrarenal non-aneurysmal neck length and angulation to the aneurysm sac requirements are ≥15mm and ≤60°, respectively; shorter

[1]Hoyert DL, Arias E, Smith B L, et al. Deaths: final data for 1999. Natl Vital Stat Rep 2001; 49(8):1-113.

[2]Carpenter JP, Baum RA, Barker CF, et al. Impact of exclusion criteria on patient selection for endovascular abdominal aortic aneurysm repair. J Vasc Surg 2001;34:1050-4.

[3]Arko FA, Filis KA, Seidel SA, et al. How many patients with infrarenal aneurysms are candidates for endovascular repair? J Endovasc Ther 2004;11:33-40.

lengths or greater angulation have been reported to increase the risk of migration and Type 1A endoleak and associated need for intervention.[4,5]

Owing to the increased risk of renal complications, mesenteric ischemia and other complications following open repair of JAA or PAA compared to infrarenal AAA or hybrid open visceral debranching techniques,[6] researchers have sought to extend a totally endovascular technique to repair of these aneurysms. To consider application of an endovascular method to JAA or PAA repair, it is essential to maintain the patency of visceral vessels (i.e., renal arteries; SMA; CA). Browne and colleagues reported their feasibility experience in the construction and implant of home made fenestrated stent grafts using Dacron graft and stainless steel Z-stents in the canine model.[7] Each fenestration was sized to approximate the size of the arterial ostium, an improvement over prior reports suggesting that oversizing of the fenestration may be necessary to ensure the ostia are not covered.[8] Six hours after implant, animals were sacrificed and the positioning of all fenestrations verified. No ostial obstruction was observed, and the devices were widely patent. Several single center clinical case reports have described the use of 'homemade' fenestrated stent grafts fashioned by physicians from commercially available stent grafts for the endovascular repair of JAA/PAA. Although cited as technically feasible in some patients, the broad application of this approach does not appear to be generally accepted by the medical community.

A number of single center and several multicenter reports of a custom device based on the Cook Zenith stent graft are available in the literature. The key limitation to this approach is the need to customize the design and manufacture of each stent graft to a particular patient anatomy. This requires a lengthy period of time for planning, manufacture, and delivery of the device. More recently, several publications attempt to propose methods for modifying this customization algorithm to broaden the applicability of a particular device to more than one patient. That is, to create an 'off-the-shelf' fenestrated stent graft device.

Endologix, Inc. has developed a Stent Graft System based on the approved Powerlink design that is specifically intended as a potential 'off-the-shelf' endovascular repair option for JAA/PAA. This design couples the CE Marked and U.S. FDA-approved Powerlink bifurcated stent graft with a fenestrated/scalloped proximal extension and renal stent grafts with the intent to be applicable to approximately 80-90% of patients presenting with JAA/PAA. To date, 22 subjects have been successfully implanted with the Fenestrated Stent Graft System under controlled clinical trials.

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[4]Leurs LJ, Kievit J, Dagnelie PC, et al. Influence of infrarenal neck length on outcome of endovascular abdominal aortic aneurysm repair. J Endovasc Ther 2006;13:640–8.

[5]AbuRahma A, Campbell J, Stone PA, et al. The correlation of aortic neck length to early and late outcomes in endovascular repair patients. J Vasc Surg 2009;50:738-48.

[6]Fulton JJ, Farber MA, Marston WA, et al. Endovascular stent-graft repair of pararenal and type IV thoracoabdominal aortic aneurysms with adjunctive visceral reconstruction. J Vasc Surg 2005;41:191-8.

[7]Browne TF, Hartley D, Purchas S, et al. A fenestrated covered suprarenal aortic stent. Eur J Vasc Endovasc Surg 1999;18:445-9.

[8]Park JH, Chung JW, Cho IW, et al. Fenestrated stent grafts for preserving visceral brnaches in the treatment of abdominal aortic aneurysms: preliminary results. J Vasc Interventional Radiology 1996;7:819-23.

4.3. STUDY DESIGN

This is multicenter, prospective, single arm clinical feasibility/safety study. Patients with JAA/PAA who are suitable candidates for endovascular repair using the Endologix Stent Graft System will be considered for enrollment.

After this protocol and the patient informed consent form are reviewed and approved by the local Ethics Committee (EC) or responsible Institutional Review Board (IRB), potential patients will be offered participation in the study. This will be accomplished through the patient's reading of the informed consent form in the patient's native language and discussion of the study with the patient by the investigator and site personnel. Agreement to participate and to attend all follow-up visits will be documented with the patient's signature on the informed consent form, with appropriate signatures of the site investigator and an impartial witness.

After providing written informed consent, screening and eligibility determinations will be performed. Patients will undergo a high resolution, contrast-enhanced computed tomography (CT) scan of the relevant aortic and aortoiliac vasculature within three months of the scheduled procedure. Evaluation of the aortic and vascular anatomy suitability per this protocol, as depicted on the CT scan, will be performed by the site investigator and by an independent physician reviewer. Other tests include a physical examination, review of patient medical history for exclusionary conditions, selected blood chemistry and hematology analyses, and ankle-brachial index determination.

Upon acceptance for enrollment, patients will be scheduled for the endovascular repair procedure.

Following patient discharge from the hospital, the first follow-up visit will be made at one month (±2 weeks). A CT scan will be performed to assess aneurysm morphology and device integrity and patency, as well as the status of the renal arteries and implanted stent grafts. Subsequent follow-up will be made at six months, one year, and annually to five years.

Continued patient follow-up beyond five years is outside of the scope of this study. Nonetheless, all patients should be monitored and evaluated per the institutional standards of care for patients who receive an endovascular stent graft.

5. STUDY POPULATION

5.1. NUMBER OF PATIENTS

Up to 15 sites and up to 50 patients will participate in this Feasibility Study. Following investigator training, each investigator will screen patients for potential inclusion in the study. Screening results, including the independent core laboratory evaluation of the pre-operative CT scan, will be used to make a final determination as to patient suitability for enrollment. Early results from this study (i.e., immediate post-operative and to one month) will serve as the basis for determining the feasibility and initial safety of the Fenestrated Stent Graft System as defined in this protocol. Patients must meet **all** inclusion criteria and **no** exclusion criteria at the time of enrollment evaluation in order to participate.

5.2. PATIENT INCLUSION CRITERIA

A patient who meets ***all of the following criteria*** potentially ***may be included*** in the study:

(a) Male or female at least 18 years old;

(b) Informed consent form understood and signed and patient agrees to all follow-up visits;

(c) Have abdominal aortic aneurysm with maximum diameter ≥5.5cm, or between 4.5 and 5.5cm and rapidly expanding (>0.5cm in six months), or >50% larger than normal aortic diameter;

(d) Anatomically eligible for the Endologix Bifurcated System and for the Fenestrated Stent Graft System per the indications for use (IFU):

1) Adequate ipsilateral iliac/femoral access compatible with the required delivery systems (diameter ≥8 mm) or eligible for an arterial conduit for delivery system access
2) Non-aneurysmal infrarenal aortic neck <15mm in length;
3) Most caudal renal artery to the aortoiliac bifurcation length ≥70mm;
4) SMA to aortoiliac bifurcation length ≥90mm;
5) Infra-SMA non-aneurysmal[†] aortic neck diameter 18 to 34 mm;
6) Infra-SMA non-aneurysmal aortic neck length ≥15 mm;
7) Infra-SMA non-aneurysmal aortic neck angle ≤60° to the aneurysm sac;
8) Angle ≤60° (clock face) between the SMA and CA;
9) Renal arteries both distal to the SMA by ≤35mm;
10) Renal arteries axially within ≤30mm of each other;
11) Renal arteries both with luminal diameter of 4 to 8mm;
12) Renal arteries with an angle (clock face) of 90° to 210° to each other;
13) Common iliac artery distal fixation sites length ≥15 mm;
14) Common iliac artery distal fixation sites angle to the aortic bifurcation ≤90°;
15) Ability to preserve at least one hypogastric artery;

[†]Non-aneurysmal is defined as <20% diameter change over a length of at least 15mm below the SMA.

16) The Endologix Fenestrated Proximal Extension Stent must have the ability to overlap the Powerlink bifurcated stent graft by at least 3cm.

5.3. PATIENT EXCLUSION CRITERIA

A patient who meets ***any of the following criteria will not be included*** in the study:

(a) Life expectancy <2 years as judged by the investigator;
(b) Psychiatric or other condition that may interfere with the study;
(c) Participating in the enrollment or 30-day follow-up phase of another clinical study;
(d) Known allergy to any device component;
(e) Coagulopathy or uncontrolled bleeding disorder;
(f) Contraindication to contrast media or anticoagulants;
(g) Ruptured, leaking, or mycotic aneurysm;
(h) Aortic dissection;
(i) Serum creatinine (S-Cr) level >2.0 mg/dL;[†]
(j) Traumatic vascular injury;
(k) Active systemic or localized groin infection;
(l) Connective tissue disease (e.g., Marfan's Syndrome);
(m) Recent (within prior three months) cerebrovascular accident or myocardial infarction;
(n) Prior renal transplant;
(o) Length of either renal artery to be stented <13mm;
(p) Significant occlusive disease of either renal artery (>70% stenosis);
(q) An essential accessory renal artery (supplies more than 25% of the renal parenchyma);[‡]
(r) Indispensable inferior mesenteric artery;
(s) Untreated aneurysmal disease of the descending thoracic aorta;
(t) Clinically significant mural thrombus in the suprarenal segment;[¥]
(u) Prior iliac artery stent implanted that may interfere with delivery system introduction;
(v) Unsuitable vascular anatomy;
(w) Pregnancy (female patient of childbearing potential only).

[†]This criterion is waived for patients on dialysis prior to study screening/enrollment.
[‡]Patients who undergo prior embolization of an essential accessory renal artery may be considered for trial enrollment.
[¥]Mural thrombus >5mm in thickness over >60% of the aortic circumference.

6. RESPONSE MEASURES

6.1. SAFETY

The safety endpoint is defined as the incidence of Major Adverse Events (MAE), defined as the composite of the following as determined by the independent Clinical Events Committee (CEC). Event definitions are provided in §8.7.7.

- *All-Cause Death*;
- *Bowel Ischemia*;
- *Myocardial Infarction*;
- *Paraplegia*;
- *Renal Failure*;
- *Respiratory Failure*;
- *Stroke;*
- *Procedural Blood Loss ≥1000cc.*

6.2. FEASIBILITY/EFFECTIVENESS

Feasibility/effectiveness is defined as successful device delivery and deployment with patency of the renal and aortic endografts without Type I/III endoleak as determined by the Core Lab at 1 month.

Specific definitions applicable to this endpoint are as follows:

- *Procedural Feasibility*:
  - Successful bifurcated and fenestrated/scalloped proximal extension stent graft delivery and deployment without residual Type I or Type III endoleak; and,
  - Successful renal stent graft delivery and deployment with target vessel patency.
- *Clinical Feasibility*:
  - Maintenance of bifurcated and fenestrated/scalloped proximal extension stent graft patency, without Type I or Type III endoleak at each follow-up; and,
  - Maintenance of target visceral vessel patency at each follow-up.
- *Assisted Clinical Feasibility*:
  - Maintenance of bifurcated and fenestrated/scalloped proximal extension stent graft patency, without Type I or Type III endoleak aided with a secondary procedure; and,
  - Target visceral vessel patency at each follow-up aided with a secondary procedure.

6.3. ADDITIONAL EVALUATIONS

Additional evaluations include:[†]

- **Procedural and In-Hospital Evaluations**:
  - Volume of contrast media used
  - Fluoroscopy time
  - Total procedure time[‡]
  - Time in ICU[§]
  - Estimated blood loss
  - % requiring blood transfusion
  - Anesthesia time[¥]
  - Time to hospital discharge[£]
- **Mortality**, all-cause and aneurysm-related, within 30 days, at six months, and annually at 1 through 5 years.
- **MAE Individual Components** within 30 days, at six months, and annually at 1 through 5 years.
- **Composite MAEs** after 30 days, at six months, and annually at 1 through 5 years.
- **Aneurysm Rupture** within 30 days, at six months, and annually at 1 through 5 years.
- **Conversion to Open Repair** within 30 days, at six months, and annually at 1 through 5 years.
- **Adverse Events** (serious and non-serious) within 30 days, at six months, and annually at 1 through 5 years.
- **Distal Blood Flow** pre-discharge and at 30 days, six months, and annually at 1 through 5 years as determined by ankle-brachial index measurements and changes over time.
- **Endograft Performance** at 30 days, six months, and annually at 1 through 5 years as assessed by aneurysm sac diameter change from the first post-operative visit; device migration; and incidence of endoleak.
- **Renal Function** pre-discharge and at 30 days, six months, and annually at 1 through 5 years, as assessed by the estimated glomerular filtration rate (eGFR) and changes over time.
- **Renal Stent Graft Patency and Integrity** within 30 days, at six months, and annually at 1 through 5 years, as determined by contrast-enhanced CT scan, and as assessed by the independent core laboratory, inclusive of:
  - Patent luminal flow
  - Absence of stent fracture
  - Absence of renal infarct >30%
  - Absence of kinking, stenosis, or occlusion (>60%)
  - Absence of graft failure

[†]Event definitions are provided in §8.7.7.

[‡]Elapsed time from the first break of skin to final closure (i.e., skin to skin time).

[¥]Elapsed time from the initiation to the end of the anesthesia protocol.

[§]Elapsed time from the first administration of anesthesia to release from the ICU or post-anesthesia care unit providing ICU-level care. If the patient is not admitted to the ICU, this is defined as 0 hours.

[£]Elapsed time from initiation of the procedure to physical discharge from the hospital.

- **Stent Graft (Fenestrated/Bifurcated) Patency and Integrity** within 30 days, at six months, and annually at 1 through 5 years, as determined by contrast-enhanced CT scan and as assessed by the independent core laboratory, inclusive of:
  - Patent luminal flow
  - Absence of kinking or occlusion
  - Absence of stent fracture
  - Absence of graft fatigue or failure
- **Secondary Procedures** within 30 days, at six months, and annually at 1 through 5 years for resolution of endoleak, limb occlusion, migration, aneurysm sac expansion and/or a device defect.

7. STUDY MATERIALS

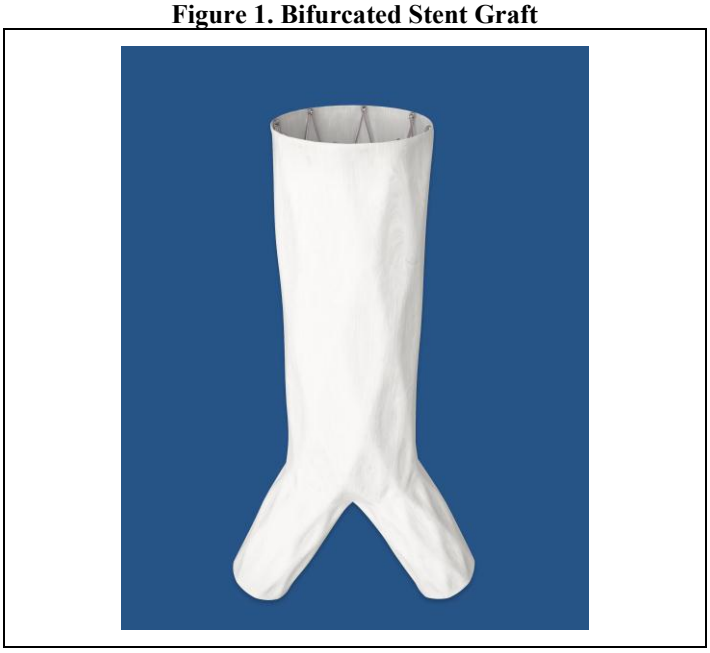
7.1. DEVICE DESCRIPTION

The commercially-available endovascular system consists of two primary components: an implantable bifurcated stent graft and a disposable delivery catheter. The pre-loaded stent graft is inserted endoluminally via the femoral artery over a .035" guidewire and upon deployment and withdrawal of the delivery system, expands to the indicated diameter.

Bifurcated stent grafts (**Figure 1**) are composed of a CoCr alloy wire stent cage[†] with a thin-walled, high density expanded polytetrafluoroethylene (ePTFE) graft cover that is attached proximally and distally to the stent cage with polypropylene suture. Bifurcated devices have body lengths ranging from 60 to 100mm. Limb dimensions include lengths ranging from 30mm to 55mm and diameters of 13 or 16mm to accommodate various patient anatomies. Devices are delivered through a 21Fr catheter system having an integrated introducer sheath. Accessory limb extensions in straight, stepped, flared, and tapered configurations are available.

[†]The incoming wire is certified to meet ASTM F1058:2002, *Standard Specification for Wrought 40Cobalt-20Chromium-16Iron-15Nickel-7Molybdenum Alloy Wire and Strip for Surgical Implant Applications (UNS R30003 and UNS R30008).*

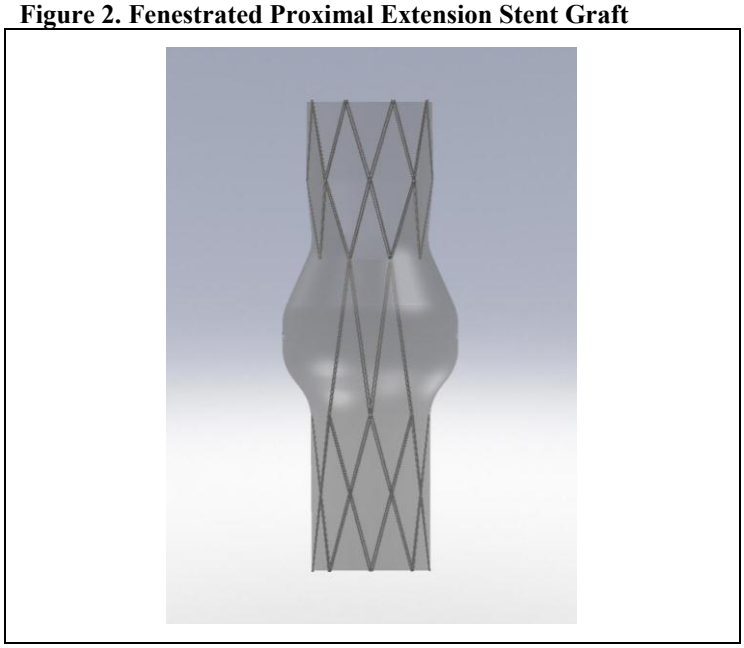
Figure 1. Bifurcated Stent Graft



The investigational fenestrated proximal extension stent graft system consists of two primary components: an implantable fenestrated/scalloped stent graft and a disposable delivery catheter system. The pre-loaded stent graft is inserted endoluminally via the femoral artery over a .035" guidewire and upon deployment and withdrawal of the delivery system, expands to the indicated diameter.

The fenestrated proximal extension stent graft (**Figure 2**) is composed of a CoCr alloy wire stent cage (having the same elements as the bifurcated device above) with a thin-walled, high density continuous ePTFE graft cover that is attached proximally and distally to the stent cage with polypropylene suture. The stent grafts have total lengths of 120 or 140mm. All fenestrated stent grafts have a distal segment with 28mm diameter and 4 or 6cm length to ensure significant overlap (at least 3cm) with the bifurcated stent graft. The proximal segment has diameters of 24, 28, 32, and 36mm, indicated for vessel diameters between 18 and 34mm. A scalloped section with length of 4cm from the most proximal edge of the stent graft is present to align below the SMA and CA. The midsection contains oversized unsupported graft having circular 3-mm diameter fenestrations that can expand up to 10mm for cannulation of the renal arteries and introduction of appropriate renal stent grafts. Each of the fenestrations and scallop are reinforced using the same polypropylene suture used to attach the graft to the stent. For visualization under fluoroscopy, the fenestrations include a Platinum coil encased in the graft around their circumference; the scallop includes Platinum markers encased within the graft at the sides and at the center of its distal edge.

Figure 2. Fenestrated Proximal Extension Stent Graft



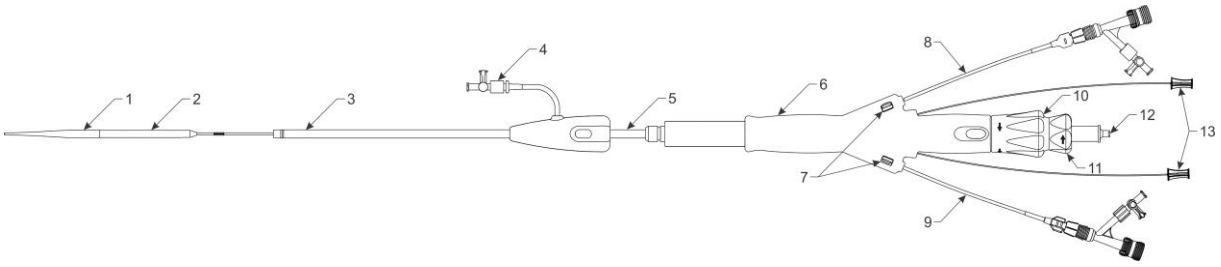
The mid-section of each stent has two 'W' stent segments (anterior and posterior) that serves to attach the proximal stent segment to the distal stent segment, while maintaining an open area laterally to avoid interference with the renal arteries or fenestrations. Unique to this device, the graft is produced having a 28mm distal diameter, a 24 to 36mm proximal diameter (depending on the device), and a 35 to 47mm (depending on the device) midsection diameter. The distal and proximal graft segments conform to the stent diameter, whereas the mid section contains the fenestrations for the renal arteries and is loose fitting. This feature permits the fenestrations to be moved *in situ* to accommodate renal artery locations that are up to 35mm away radially from the nominal location. Eight models are designed to accommodate patient anatomies where the renal arteries are at approximately the same level, and another 16 are designed to accommodate anatomies where one renal artery is higher than the other.

The delivery systems are single use, disposable systems used to deploy the bifurcated and fenestrated accessory stent graft configurations.

The bifurcated delivery system is an integrated design with inner main body and limbs covers and introducer sheath constraining the self-expandable stent graft in a compressed state. The main body and limb covers fully contain the stent graft body and limbs. As the introducer sheath is retracted, the main body and limb covers containing the stent graft are exposed. As the deployment control cord is retracted and the constraints removed, the self-expanding stent graft is allowed to expand within the vessel under the control of the implanting physician. The catheter is compatible with a 0.035 inch guidewire.

The accessory stent graft is delivered through a 22Fr OD delivery system (**Figure 3**) having integrated 6Fr guide sheaths. The 6Fr guide sheaths are preloaded through each of the fenestrations allowing for cannulation of the renal arteries prior to deployment of the stent graft. Radiopaque markers are present on the distal ends of the delivery system outer sheath, of the left 6Fr sheath (one marker) and of the right 6Fr sheath (two markers). The delivery system contains a hub and sideport for flushing. The catheter is compatible with a 0.035 inch guidewire.

Figure 3. Endologix Fenestrated Proximal Extension Accessory Delivery System

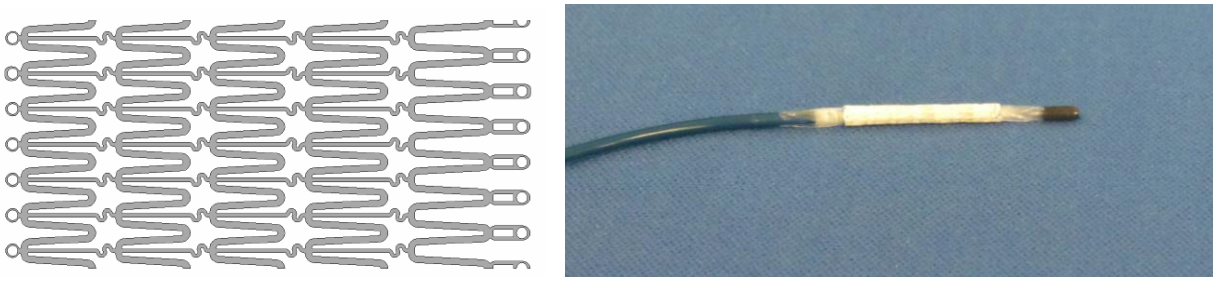


1: Radiopaque Tip; 2: Front Sheath; 3: Outer Sheath; 4: Flush port; 5: Inner Core; 6: Handle; 7: 6Fr Sheath Locks; 8: Left Renal Artery 6Fr sheath; 9: Right Renal Artery 6Fr sheath; 10: Large Knob for distal deployment; 11: Small Knob for proximal deployment; 12: Luer for Central Guidewire Lumen; 13: Fenestration Pushers

Renal Stent Grafts

Renal stent graft devices are intended for maintaining the patency of renal arteries ranging in diameter from 4 to 8mm. The stent graft (**Figure 4**) consists of a balloon-expandable CoCr alloy stent with high density ePTFE graft attached with polypropylene surgical suture to each end, and has lengths of 18, 25 or 35mm. The most proximal 5mm segment is intended to protrude into the aorta and undergo flaring using a 10mm balloon (not provided). Each device is premounted on a nylon balloon with diameter of 5 to 8mm. Radiopaque platinum/iridium markers are present on either end of the balloon. The delivery catheter shaft profile is 5Fr or 6Fr.

Figure 4. Renal Stent Graft. Stent design (left); stent graft crimped onto the balloon catheter (right).



7.2. INVESTIGATOR TRAINING AND EXPERIENCE

One principal investigator at each participating site will be responsible for supervision of study conduct. He/she and each any authorized sub-investigator must satisfy the following criteria prior to the enrollment of their first patient.

a) Complete review of the Investigator's Brochure, inclusive of nonclinical and clinical safety and effectiveness information regarding the marketed bifurcated stent graft, nonclinical testing regarding the fenestrated stent graft system, and the scientific literature review.

b) As an institutional team, have prior training and experience in the open surgical repair of JAA/PAA (≥25 cases in the prior year).

c) As an institutional team, have prior training and experience in visceral/renal artery stenting (≥25 cases in the prior year).

d) Hold a certification of completion of the physician training program for the commercially available Endologix bifurcated stent graft (inclusive of troubleshooting methods). This includes the completion of a minimum of three clinical cases using the commercially available Endologix devices for abdominal aortic aneurysm repair.

e) Undergo didactic training on the device design, patient selection criteria, and troubleshooting methods for the Fenestrated Stent Graft System and the Renal Stent Graft as detailed in the respective Instructions for Use (IFUs).

f) Practice using the Fenestrated Stent Graft System and the Renal Stent Graft in a simulated use bench top flow model.

g) Didactic training on the delivery system modifications and instructions for use.

Completion of each criterion will be documented for each Investigator prior to performance of the first clinical procedure under this protocol.

7.3. DEVICE ACCOUNTABILITY

Usage of the investigational devices, Fenestrated Stent Graft and Renal Stent Graft, will be documented in the Case Report Forms (CRFs) and on the Investigational Device Accountability Log. In the case of a device malfunction, the information will be noted in the CRFs and the device should be returned to Endologix for evaluation in accordance with the Instructions for Use. Investigational sites designate monitors and Endologix support staff will be trained on device inventory tracking prior to first cases and ongoing through the life of the study.

7.4. PATIENT AND DEVICE PREPARATION

All procedures must be performed in an operating room, or in an endovascular suite having vascular surgery and anesthesia services. The Investigator will refer to institutional protocols relating to anesthesia and monitoring of vital signs.

All institutions participating in this study must utilize fixed imaging equipment during the procedure.

The appropriate length bifurcated device (22 or 25mm diameter) and the appropriate Fenestrated proximal extension stent graft device will be selected in accordance with the patient eligibility determination. The devices will be prepared in accordance with their respective Instructions for Use. The Instructions for Use, inclusive of warnings and precautions, are provided in ***Attachment 1***.[†]

All devices will be prepared and handled in accordance with their Instructions for Use.

Other ancillary devices will be selected by the physician per institutional standards.

8. STUDY METHODS

8.1. GENERAL ENTRY PROCEDURES

Prospective patients as defined by the criteria in §5.2 and §5.3 will be considered for entry into this study. Following patient consent, complete screening documentation must be submitted to Endologix and to the Core Lab for review and evaluation.

Note: Prior to scheduling a patient for a procedure, it must be verified in writing by the sponsor that all criteria are met and the patient is accepted for enrollment.

If the patient meets all criteria, the Sponsor will fax a **CONFIRM** document to the investigator. The Investigator is required to sign and date the fax form and return to Endologix to document acknowledgement.

If the patient does not meet all criteria, the Sponsor will fax a **DENY** document to the investigator, and will identify the reason for denial. ***The patient cannot be enrolled***. The Investigator is required to sign and date the fax form and return to Endologix to document acknowledgement.

8.2. INFORMED CONSENT

Written informed consent, in accordance with applicable international standards and study center regulations, shall be obtained from each patient prior to the study procedures. The investigator will retain a copy of the signed informed consent document in each patient's record, and provide a copy to the patient.

The Investigator must not request the written informed consent of any patient, and must not allow any patient to participate in the investigation before obtaining governing Ethics Committee (EC) or Institutional Review Board (IRB) approval. In addition, Endologix clinical staff must give approval before active screening and consent can commence at a site.

[†]Accessories available and ancillary devices recommended for use during the procedure are listed in the respective IFU.

Attachment 2 provides an example of a consent form that may be used. The example form contains the minimal consent language content that must be incorporated into the Informed Consent document. Other elements may be added or minor language changes may be made for clarity by the investigator or by the EC/IRB, but substantial content may not be deleted.

Prior to starting the study, the investigator will provide Endologix with a copy of the final Informed Consent document approved by the EC/IRB with documented evidence that the EC/IRB has approved the protocol.

8.3. METHOD FOR ASSIGNMENT TO TREATMENT GROUP

Eligible patients enrolled and who undergo the procedure will be assigned a patient number to be used in all documentation. The patient identification number will use the following convention:

XXX-YYY-ZZZ (i.e. 001-201-DDD)

Where:

XXX is the designated site three-digit ID number assigned by Endologix.

YYY is a three digit sequential patient ID number beginning with 201.

ZZZ is the first letter of the patient's first, middle, and last name. For patients with the same initials at a site, the letter 'X' will be used as the middle initial for the second patient. For patients without a middle name, '---' will be used for the middle initial.

Upon satisfactory completion of all site start-up training and documentation requirements, Endologix will supply the site with written 'Go' notification that initiation of patient screening for study enrollment is authorized.

A Screening Log will be maintained by the site to document each patient who undergoes the screening process and the final determination of eligibility.

The actual procedure date will serve as the "start" date from which follow-up evaluations will be measured. After treatment, each patient will be evaluated prior to hospital discharge and will then be evaluated at one month (defined as 30 ± 14 days), at six months (defined as 180 ± 30 days), and at annual follow-ups beginning 1 year (± 60 days) following the procedure to 5 years.

8.4. SCHEDULE OF MEASUREMENTS

A summary of the tests and measurements to be conducted pre-study/at baseline (all tests to be done within 3 months of procedure), operatively, prior to discharge, and during follow-up is illustrated in the following chart.

Schedule of Tests:	**Screening/ Baseline**	**Procedure (Day 0)**	**Pre-Discharge**	**1 Month***	**6 Months***	**1 to 5 Years***
Physical Exam[†]	x		x	x	x	x
Blood Labs[‡]	x		x	x	x	x
Contrast-Enhanced CT Scan[¥]	x			x	x	x
Ankle Brachial Index	x		x	x	x	x
Adverse Events		x	x	x	x	x

[†]The physical exam includes overall health and physical assessment and vital signs.

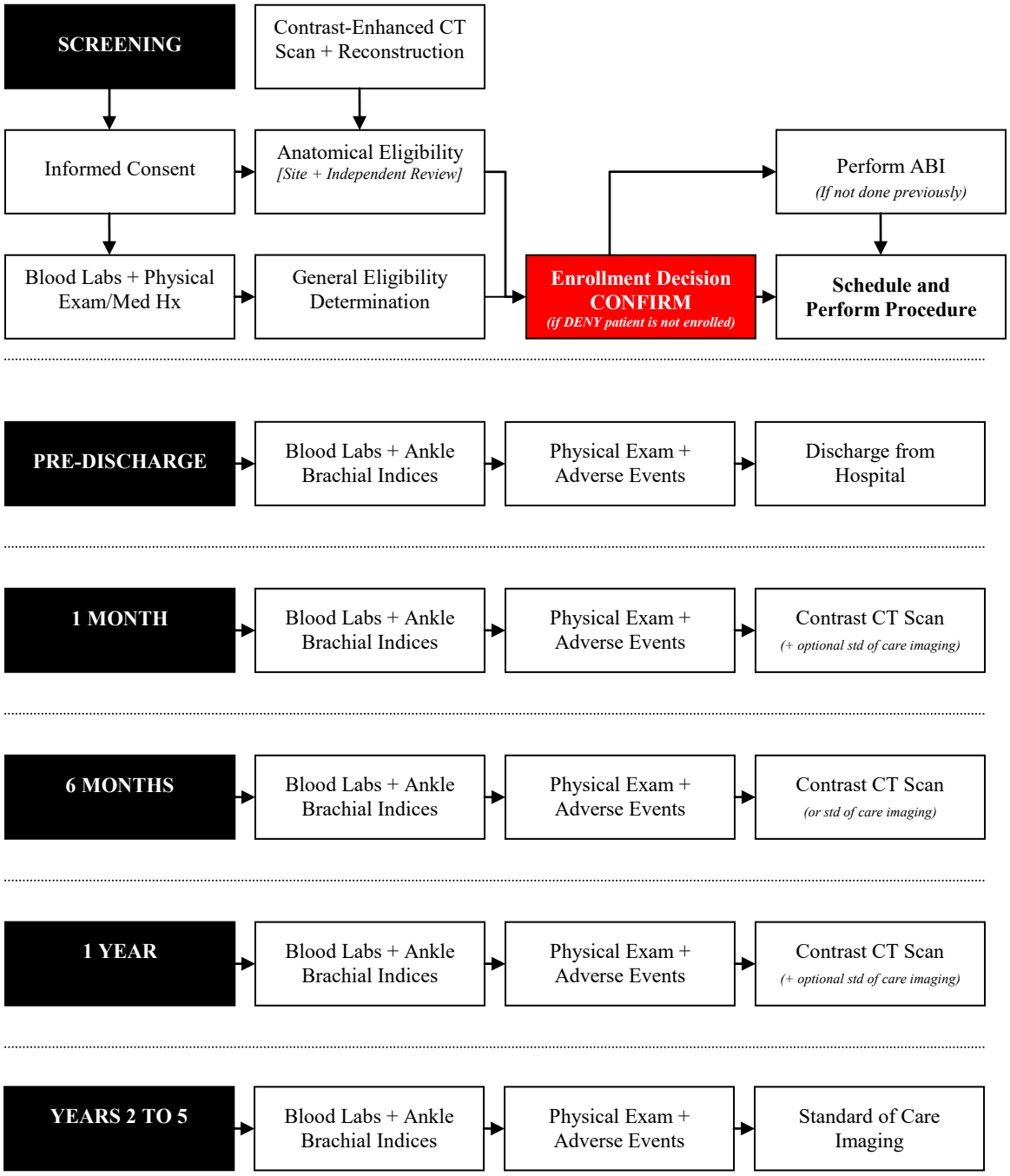
[‡]Blood labs include serum creatinine, blood urea nitrogen, hematocrit, and hemoglobin.

[¥]The baseline high resolution, contrast-enhanced CT scan (3mm or less slice spacing) performed within three months prior to enrollment will be reviewed by the independent core lab for patient eligibility determination. Evaluations of endograft performance, renal stent graft patency and integrity, and stent graft patency and integrity will be made based upon post-operative CT scan evaluations by the core laboratory.

*Follow-up windows are ±2 weeks (1 month visit); ±1 month (6 month visit); ±2 months (Year 1 visit); ±3 months (Years 2 through 5 visits)

8.5. FLOW CHART

A flow chart representing the key study methods and procedures is provided below:



8.6. STUDY PROCEDURES AND EVALUATIONS

8.6.1. Informed Consent

The patient, or his/her legal representative, is to be informed about the study and provide written consent. Confirmation of written consent will be recorded on the **SCREENING AND BASELINE** CRF for verification by the Sponsor prior to enrollment eligibility determination.

8.6.2. CT Scan Protocol

Patient enrollment into this study is based on the independent physician review and assessment of Core Lab produced three-dimensional reconstructions of high resolution, contrast-enhanced spiral CT scans. To ensure consistency, below are the requirements for acquisition of the CT Scan:

- Only high resolution, contrast-enhanced spiral CT scans are acceptable.
- Data must be uncompressed.
- Preferred maximum slice spacing is 2mm. ***In no case should it exceed 3mm***.
- The preferred protocol, shown below, is easier to attain with a multi-row scanner. If the preferred protocol cannot be used, an alternate protocol is provided.
- Instruct patient not to move during scan. Do not move table height, position, or field of view during scan. If such movement occurs, repeat scan in its entirety.
- Send data to the core lab identified in §2 via CD or per Core Lab instructions. Questions can also be forwarded to the Core Lab directly as identified in §2.

Parameter	Preferred	Alternate
Scan Mode	Helical/Spiral	
Scan Parameters	140kVp, Auto mA, 0.5sec	140kVp, 280mA (min), 1.0sec
Collimation	0.625 to 2mm	3mm
Slice Spacing	0.625 to 2mm	3mm
Superior Extent	Thoracic aorta, at least 5cm above celiac artery origin	
Inferior Extent	Lesser trochanter of femur	
Patient Instruction	Single breath hold	1st hold: 4cm above celiac to bifurcation 2nd hold: bifurcation to lesser trochanter
Contrast	Standard non-ionic	
Volume and Rate	150mL at 3 to 4 mL/sec	
Scan Delay	ROI - threshold 90Hu in aorta	ROI - threshold 90Hu in aorta or 25sec delay
Field of View	Large body	
Window Level	400/40	

8.6.3. Screening and Baseline Evaluations

Following informed consent, the patient is to be pre-screened for eligibility by the investigator. Any information provided by the patient's referring physician or from the patient's chart will be recorded on the relevant CRF. If any of this information is inadequate, procedures may be repeated / performed by the investigator to verify eligibility.

The following steps must be completed within three months prior to enrollment into the study unless otherwise indicated. All such steps that are not performed within three months of enrollment into the study must be repeated prior to the procedure.

[a] Assess eligibility criteria.

[b] Perform a physical examination, including patient height and weight, vital signs, and ASA Class determination.

[c] Review patient's medical history.

[d] Perform blood lab analyses including serum creatinine, blood urea nitrogen, hematocrit, and hemoglobin.

[e] Perform ankle-brachial index assessment bilaterally.
Note: The ABI test may be performed after initial screening but prior to the procedure if more convenient for the institution.

[f] Perform diagnostic imaging per institutional standard of care.

[g] Collect a baseline high resolution, contrast-enhanced CT scan per the protocol in §8.6.2. Follow the preferred protocol to the extent possible.

[h] Document the patient's relevant concomitant medications (cardiac/circulatory medications).

Fax the SCREENING FORM containing the information as requested in [a] through [h] to the Endologix Clinical Department at +1 (949) 595-7373.

The investigator is to proceed with enrollment of the patient and procedure scheduling **ONLY after receiving written documentation from the Sponsor** that the patient meets the respective enrollment criteria, and is confirmed to meet all other inclusion and exclusion criteria. **The Sponsor will clearly CONFIRM the patient for enrollment in the ELIGIBILITY Form faxed or e-mailed to the investigator**. The investigator will sign the bottom of the CRF in the space provided to acknowledge receipt of the fax.

Any patient who is determined to be a screen failure must have clear documentation of the reason(s) for failure in the CRFs. **In such cases, the Sponsor will clearly DENY the patient for enrollment in the ELIGIBILITY form to the investigator**. The investigator will sign the bottom of the CRF in the space provided to acknowledge receipt of the fax.

8.6.4. Enrollment

The investigator and the Sponsor will assure all **SCREENING AND BASELINE** CRFs are complete with no unresolved issues.

Only after the Sponsor notifies the investigator of the patient eligibility by fax with a **CONFIRM** designation is the patient to be scheduled for the procedure.

The date of study enrollment is the date of the procedure, as documented on the **PROCEDURE REPORT** CRF. This date is also considered Day 0 for follow-up date calculation.

Complete the **ENROLLMENT FORM** and fax to the Endologix Clinical Department at +1 (949) 595-7373.

8.6.5. Procedural

Prepare the patient for the procedure according to §7.4. Follow the Instructions for Use to select and prepare the Endologix Bifurcated System, the Fenestrated Stent Graft device, the renal stent grafts, and other ancillary devices for use.

[a] Introduce the bifurcated delivery system into the designated (ipsilateral) femoral artery. Refer to the corresponding Instructions for Use for all details related to placement of the bifurcated device.

[b] Deliver and deploy the bifurcated stent graft at the target location. Refer to the corresponding Instructions for Use to prepare and deliver any accessory stent grafts as needed.

[c] Introduce the Fenestrated stent graft delivery system into the designated (ipsilateral) femoral artery.

Refer to the Fenestrated Stent Graft System Instructions for Use for all details related to placement of the device, introduction and deployment of renal stent grafts through the indwelling 6.5Fr sheaths, deployment of the fenestrated stent graft, and delivery system removal.

[d] Document at the time (in 24 hour clock format) that the following procedural steps occurred:

- first breakage of skin
- bifurcated delivery system sheath entry
- bifurcated delivery system sheath removal
- fenestrated delivery system sheath entry
- cannulation of the renal arteries
- renal stent graft implant completion

- fenestrated stent graft deployment/implant
- renal stent graft flaring
- fenestrated delivery system sheath removal
- skin closure
- anesthesia end and heparin reversal

[e] Report any events that occurred during the procedure or recovery on the **ADVERSE EVENT** CRF. If an event is a serious adverse event, provide the additional event details on the **Serious Adverse Event** section of the CRF. See §8.7 for adverse event reporting requirements.

[f] A copy of the operative report is requested.

8.6.6. Pre-Discharge

Before the patient is discharged from the hospital the following steps are completed.

[a] Record the patient's weight and vital signs at the pre-discharge visit on this page.

[b] Obtain a blood sample for serum creatinine, blood urea nitrogen, hematocrit, and hemoglobin measurements.

[c] Perform Ankle-Brachial Index testing bilaterally.

[d] Perform a physical examination.

[e] Other tests or imaging as needed.

[f] Document any new or discontinued relevant medications (cardiac/circulatory).

[g] A copy of the hospital discharge report or note is requested.

[h] Report any adverse finding from the diagnostic testing, or specific events that occurred since the procedure. If an event is a serious adverse event, provide the additional event details on the **Serious Adverse Event** section of the CRF. See §8.7 for adverse event reporting requirements

[i] The hospital staff should complete the *Patient Implant Card* (provided in the bifurcated stent graft product packaging) and give it to the patient so that he or she can carry it at all times. The patient should be instructed to refer to the card anytime he or she visits a health practitioner, particularly for any additional diagnostic procedures (e.g., MRI).

8.6.7. Post-Discharge Follow-up Visits

The patient post-discharge follow-up visits occur at **30±14 days** (one month visit), **180±30 days** (six month visit), **365±60 days** (one year visit), **730±90 days** (two year visit), **1095±90 days** (three year visit), **1460±90 days** (four year visit), **and 1825±90 days** (five year visit).

[a] Obtain a blood sample for serum creatinine, blood urea nitrogen, hematocrit, and hemoglobin measurements.

[b] Perform a physical exam.

[c] Perform Ankle-Brachial Index testing bilaterally.

[d] Diagnostic Imaging:

- **CT Scan**: When a CT Scan is performed, collect it as a high resolution, contrast-enhanced CT scan using the same acquisition parameters required by the Core Lab as for the baseline exam. Forward the CT Scan to the Core Lab identified in §2.2. A copy of the diagnostic report is requested.

- As per institutional standard of care, record any other imaging performed and attach a copy of the diagnostic report[s].

[e] Document any new or discontinued relevant medications (cardiac/circulatory).

[f] Report any adverse finding from the diagnostic testing, or events that occurred since hospital discharge. If an event is a serious adverse event, provide the additional event details on the **Serious Adverse Event** section of the CRF. See §8.7 for adverse event reporting requirements.

8.7. ADVERSE EVENT REPORTING

Throughout the course of the study, all adverse events will be recorded on the applicable **ADVERSE EVENT** CRF and in the patient's medical records. The seriousness, date of onset, date of resolution, severity, action taken, relationship to the device, and relationship to the procedure will be identified by the Investigator.

8.7.1. General Definitions

An adverse event (AE) is any undesirable clinical occurrence in a patient administered a product and that does not necessarily have a causal relationship with the treatment. An AE can therefore be any unintended sign, symptom or disease temporally associated with the use of an investigational product, whether or not related to the use of the product.

A serious adverse event (SAE) is an AE that results in death, is life threatening, requires in-patient hospitalization or that prolongs hospitalization, results in persistent or significant disability/incapacity, or that is a congenital anomaly or birth defect.

An unanticipated adverse event (UAE) is any serious adverse effect on health or safety or any life threatening problem or death caused by or associated with a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence. Additionally, an unanticipated adverse event includes any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

Severity of an AE is a clinical determination of the event intensity. The severity assessment for a clinical AE should be completed using the following definitions as guidelines:

Mild (+1): Awareness of sign or symptom, but easily tolerated.

Moderate (+2): Discomfort enough to cause interference with usual activity.

Severe (+3): Incapacitating with inability to work or do usual activity.

NOTE: An event that is fatal should be recorded as death on the **ADVERSE EVENT** CRF. The cause of death will be detailed on the **Serious Adverse Events** section of the form.

Relationship to device or procedure of an AE is a judgment determination made by the Investigator that there is a logical connection between device use (e.g., delivery system manipulation) and the occurrence of the AE.

8.7.2. Reporting of Device or Procedure Related Events

For all patients, Investigators shall submit to Endologix and to the reviewing EC or IRB a report of any adverse device-related or procedure-related event, including, but not limited to, hospitalization or death within 10 working days after the Investigator first learns of the event. Each of these events will be investigated by Endologix. If it is determined that a UAE has occurred and presents an unreasonable risk to subjects, all investigations or parts of investigations presenting that risk will be terminated. Termination of the investigation will occur within five (5) working days after notice of the effect is received at Endologix. The terminated investigation will not be resumed without the approval of the EC.

8.7.3. Reporting of SAEs

Any SAE occurring during the study period must be recorded on the appropriate **ADVERSE EVENT** CRF and **Serious Adverse Events** section of the CRF.

For any SAE, fax the ADVERSE EVENT CRF within 24 hours of awareness to the Endologix Clinical department at (949) 595-7373. All patients with an SAE must be followed and outcomes reported. The Investigator should supply to Endologix and the responsible EC/IRB with a complete, written case history (AE forms) and any additional requested information (e.g., other diagnostic testing, discharge reports, autopsy reports, etc.).

Deaths

For any patient death, regardless of cause or timing, an autopsy should be requested. If the family has agreed to the conduct of an autopsy, the autopsy report is to be attached to the **ADVERSE EVENT** CRF where the death is reported.

A device explant kit will be provided to the hospital for processing and shipment to an independent pathologist per established methods. To request a kit, send a fax to Endologix at +1 (949) 595-7373, or contact Endologix by telephone at +1 (949) 595-7200.

In all cases, the death certificate is to be attached to the **ADVERSE EVENT** CRF where the

death is reported. Every attempt should be made to obtain as much detailed information on the events or conditions leading up to the death as possible. If the patient was hospitalized, a copy of the discharge summary source document is required.

Secondary Interventions

For patients that experience any non-diagnostic invasive secondary treatment of the groin access areas or of the abdominal aortoiliac vessels (e.g., hematoma drainage, vascular exploration for bleeding, iliac stenting, thrombectomy, additional device placement for endoleak, embolization for Type II endoleak, etc.), it is important to identify the area, region or vessel segment that is involved and the specific procedure performed on the relevant **ADVERSE EVENT** CRF. A copy of the discharge summary source document is required.

8.7.4. Anticipated Adverse Events

Adverse events that could potentially occur during this investigation are called anticipated adverse events and are listed in alphabetical order:

- Access site complications and sequelae (e.g., dehiscence, infection, pain, hematoma, pseudoaneurysm)
- Allergic reaction to contrast agent (e.g., pruritus, urticaria, bronchospasm, angioedema, hypotension or anaphylaxis that occurs during or post-procedure)
- Amputation
- Anesthetic complications and sequelae (e.g., aspiration)
- Aneurysm enlargement
- Aneurysm rupture
- Arterial damage or trauma (e.g., bleeding, perforation, dissection, rupture)
- Arterial or venous thrombosis and/or pseudoaneurysm
- Arteriovenous fistula
- Bleeding requiring transfusion and/or surgical intervention
- Bowel complications (e.g., ileus, ischemia, infarction, necrosis)
- Cardiac complications and sequelae (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension, hypertension)
- Catheter fragmentation and sequelae (e.g., embolization, vessel trauma)
- Claudication
- Coagulopathy
- Death (due to any cause)
- Edema
- Embolization (micro and macro) with transient or permanent ischemia or infarction
- Endoleak
- Fever and localized inflammation

- Genitourinary complications and sequelae (e.g., ischemia, fistula, incontinence, hematuria, impotence, infection)
- Hepatic failure
- Infection of the aneurysm, device access site, including abscess formation, transient fever and pain.
- Local or systemic neurologic complications and sequelae, transient or permanent (e.g., stroke, transient ischemic attack, paraplegia, paraparesis, paralysis, numbness and/or tingling in legs)
- Lymphatic complications and sequelae (e.g., lymph fistula)
- Thrombosis or occlusion of stent graft or arterial vessel of the lower extremities
- Pulmonary/respiratory complications and sequelae (e.g., pneumonia, respiratory failure, prolonged intubation, pulmonary embolism)
- Renal complications and sequelae (e.g., artery occlusion, infarction, insufficiency, failure)
- Secondary procedure
- Stent graft: improper component placement; incomplete component deployment; component migration; suture break; occlusion/thrombosis; infection; stent fracture; graft material wear; dilatation; erosion; puncture and perigraft flow
- Surgical conversion to open repair

8.7.5. Unanticipated Adverse Events

Investigators shall submit to Endologix and to the reviewing EC/IRB a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect. Investigators must submit to Endologix documentation of the report made to the EC/IRB.

8.7.6. Protocol Deviations

Reports of any deviation from the protocol conducted in an emergency situation, to protect the life or physical well-being of a patient, will be reported to Endologix and to the EC/IRB as soon as possible, but no later than 24 hours from the time of the event.

8.7.7. Clinical Events Committee Review

Overview

The clinical events committee (CEC) identified in §2 consists of at least three physicians who will serve as independent experts responsible for evaluation and categorization of adverse events reported by the investigators in the trial. Analyses of events described in this protocol will be based on the CEC-determined categorization.

The primary purpose of these individuals is to ensure a consistent, independent review of events and their clinical significance using standardized criteria and definitions. A curriculum vita for each CEC member is maintained by Endologix, and is available for regulatory review. Due to the need for independence, these individuals may not participate in this trial as investigators, and may not hold significant material, financial or other interests which create a potential conflict with respect to this role, including but not limited to significant equity interest in Endologix.

Process

Endologix will provide independently to the CEC the complete case report form event text that details all deaths and the events as reported by the clinical site investigators. This information will be provided without identification of the site name, and will identify patients by identification number and initials only. Non-serious events or events that are reported as clearly unrelated events will not be assessed by the CEC. The CEC will review events and any follow-up data requested from Endologix. This may include copies of such documents as progress notes, operative notes, discharge summaries, death summaries, and autopsy reports.

The CEC will document the event categorization for each event individually. Meeting notes and supporting information, requests for documentation, etc. will be maintained.

Event Definitions

The following event definitions will be applied to the Primary Endpoint Analysis during this study. Where possible, events will be categorized as being related to the AAA procedure or related to the access site closure.

- *Death*: Any death occurring during the study period, regardless of cause.

  Death will be further subcategorized as early (within 30 calendar days from the date of the procedure) or late (>30 days). It will also be subcategorized as aneurysm-related or not aneurysm-related.

  Aneurysm-related death is defined as: any death occurring within 30 days from the date of the procedure, regardless of cause, and death due to aneurysm rupture or following any procedure intended to treat the aneurysm.

- *Procedural Technical Failure*: An event occurring procedurally or within 30 days post-procedurally that meets one or more of the following criteria:
  - *Aortic Stent Graft Failure* is defined as a failure of the bifurcated or fenestrated proximal extension stent graft to be delivered and deployed, such that the procedure is not completed, or the device failure results in a serious complication. The presence of a residual Type I or III endoleak that cannot be resolved during the index procedure is also included in this category.
  - *Renal Stent Graft Failure* is defined as a failure of the renal stent graft to be delivered and deployed, such that the procedure is not completed, or the device failure results in a serious complication.

- *Major Adverse Event*: An event occurring during the trial that meets one of the following criteria:
  - *All-Cause Death* (see above).
  - *Bowel Ischemia*: the lack of adequate blood flow to the intestines that requires intensification of medical therapy or surgical/endovascular intervention.
  - *Myocardial Infarction*: the presence of raised cardiac biomarkers in comparison to laboratory reference ranges.
  - *Paraplegia*: Paralysis of the lower extremities inclusive of the lower trunk.
  - *Renal Dysfunction*: a reduction in estimated glomerular filtration rate (eGFR) of >30% from baseline.
  - *Renal Failure*: the need for temporary or permanent dialysis or >0.5mg/dL increase in pre-operative serum creatinine level at two consecutive intervals.
  - *Respiratory Failure*: pneumonia or respiratory failure requiring ventilator support beyond 24 hours post-procedure.
  - *Stroke*: a sudden development of neurological deficit due to vascular lesions of the brain such as hemorrhage, embolism, or thrombosis that persists for >24 hours.
  - *Blood Loss ≥1,000cc*: Estimated blood loss during the index procedure ≥1,000cc.

- *Other Definitions*:
  - *Aneurysm Enlargement*: Core Lab reported aneurysm sac diameter increase of >5mm in late follow-up as compared to the initial post-operative measurement.
  - *Aneurysm Rupture*: internal bleeding or leaking of blood from the aneurysm subsequent to the index procedure.

- *Conversion to Open Repair*: open surgical repair of the abdominal aortic aneurysm due to unsuccessful delivery or deployment of the stent graft, due to complications or other clinical situations that precluded successful endovascular treatment, or at any time following initial successful endovascular treatment for any reason.
- *Cardiac Morbidity*: acute myocardial infarction (diagnosed based on measured levels of one or more cardiac biomarkers in comparison to laboratory reference ranges); new onset heart failure (an acute episode or exacerbation of existing low cardiac output accompanied by distal and/or pulmonary edema); intractable or malignant arrhythmia requiring cardioversion or pacemaker placement; or coronary intervention (coronary artery bypass grafting [CABG] or percutaneous coronary intervention [PCI]).
- *Clinically Significant Device Migration*: Core Lab reported aortic stent graft movement >10mm from the original implant location resulting in an intervention or in a serious complication.
- *Renal Dysfunction*: a reduction in the estimated glomerular filtration rate (eGFR) of >30% from the preoperative value.
- *Secondary Procedure*: any non-diagnostic intervention after the index procedure intended to correct or repair an endoleak, limb occlusion, migration, aneurysm sac expansion and/or a device defect.
- *Stent Graft Occlusion*: intervention for aortic or renal stent graft occlusion or as reported by the Core Laboratory at any time in follow-up.
- *Transient Ischemic Attack*: a sudden development of neurological deficit due to vascular lesions of *the* brain such as hemorrhage, embolism, or thrombosis that persists for <24 hours.
- *Type I/III/IV Endoleak*: Core Lab reported endoleak: between the endograft and the vessel either at the proximal attachment point (Type IA), or at the distal attachment point (Type IB), or between endograft components (Type III) or transgraft (Type IV).
- *Type II Endoleak*: Core Lab reported endoleak emanating from a patent collateral vessel (e.g., inferior mesenteric artery, lumbar artery).

9. RISK ANALYSIS

The decision to repair an aortic aneurysm is generally based on the risk of rupture, the risk of complications of surgery, and patient preference. There are currently two methods used to repair aortic aneurysms. The most common and conventional method is an open surgical repair, with the implantation of a synthetic graft to replace the diseased aneurysmal vessel through a large abdominal incision. Recent technological developments have resulted in an alternative, minimally invasive, endovascular aneurysm repair, in which a stent graft is placed within the aorta through a small incision in the groin. Blood can then flow through the stent graft and is excluded from the aneurysmal portion of the aorta.

The disadvantages of open surgical repair are: general anesthesia is required, it is a major abdominal surgery (large incision), has a significant surgical complication rate, and typically requires a long hospital stay and recovery. EVAR enables local or regional anesthesia to be used, uses a minimally invasive groin incision for catheter-based access, and has been reported in US clinical studies to offer a lower operative complication rate, reduced blood loss and procedure times, and shorter hospital stay. In contrast to open repair, EVAR is a relatively new treatment, long term results have not been fully established, and lifelong surveillance is recommended to verify stent graft integrity and patency and continued aneurysm exclusion. Currently, five device systems are FDA-approved and marketed in the US for endovascular abdominal aortic aneurysm repair. All of these devices require the introduction of catheter-based treatment devices varying in outer diameter profile from 20Fr to 25Fr (ipsilateral). Standard vascular exposure is indicated for access. Prospective clinical study results support the safety and effectiveness of these stent grafts through early follow-up (to 30 days) and in late follow-up to one year and to up to five years. These and other devices are CE Marked and are available in other international regions. One custom device is CE Marked for JAA endovascular repair; however, no ‘off-the-shelf’ endovascular devices are currently commercially available.

As with any procedure there are risks of serious complications, such as death. The inclusion and exclusion criteria for this population have been carefully established to limit the risk of mortality and morbidity in this population. The overall risk will be evaluated on an individual basis and discussed with each patient. All of the potential adverse events outlined previously could cause prolonged illness, permanent impairment of daily function or, in rare cases, death. Possible treatments could include, but are not limited to, emergency cardiac or vascular surgery.

Eligibility criteria that exclude patients who are at higher risk for experiencing an anticipated adverse event have been selected to reduce the potential risks to patients who participate in this study. In addition, the assessment of patient anatomy for enrollment by an experienced Core Laboratory is also intended to reduce the potential risks to patients who participate in this study.

Pre-procedural high resolution, contrast-enhanced CT scanning and intraprocedural arteriography will be used to identify and target the aortic anatomy to facilitate the proper introduction, delivery, and deployment of the endovascular repair devices. Physician experience, rigorous application of a common protocol, and careful performance of the procedure with close monitoring of the patient after the procedure will also help to minimize risks.

Alternatives to endovascular repair of JAA/PAA include open surgical repair.

10. ADMINISTRATIVE PROCEDURES

10.1 RESPONSIBILITIES

a) *Sponsor*: The investigation will be conducted in compliance with ICH Guideline for Good Clinical Practice, 21CFR§812, relevant FDA guidelines, ISO 14155 and any relevant European directives. Endologix is responsible as the Sponsor to ensure proper site and investigator selection, availability of signed investigator agreements prior to study initiation, availability of regulatory and EC/IRB approval prior to the initiation of the study at any site, and management and monitoring of the study with special attention to verification of all clinical requirements, adherence to protocol, good clinical practices and compliance with applicable government and institutional regulations. Ongoing monitoring visits of the investigational center and hospital records will be conducted to verify the data recorded on the CRFs. Furthermore, the sponsor is responsible for ensuring obtaining proper regulatory approvals, and reporting to regulatory authorities per all applicable regulations.

b) *Investigators*: Each investigator and study site is required to conduct the clinical investigation in accordance with the protocol, the signed investigator agreement, all applicable laws and Federal regulations and any conditions or restrictions imposed by the reviewing EC. This includes compliance with requirements related to EC approval and reporting, and proper patient informed consent prior to participation in the study. The investigator is also responsible for protecting the rights, safety, and welfare of the patients under his or her care.

   Each investigator is responsible for supervising all procedures conducted under this protocol at his or her institution.

   Furthermore, the investigator is responsible for ensuring that data are completely, accurately, and promptly recorded on each patient's CRFs and related documents are available to verify the accuracy of the CRFs, and for ensuring the clinical monitor has access to all necessary records to ensure the integrity of the data.

c) Institutional Review Board (IRB) / Ethics Committee (EC): The protocol and supporting documents for this study will be reviewed and approved by an appropriately constituted IRB or EC prior to study initiation. All reviews and approvals will be in accordance with Good Clinical Practice (GCP) as contained in the International Conference on Harmonization (ICH): Consolidated Guidance, ISO 14155, ISO 5840, and the Declaration of Helsinki.

   A letter from the IRB or EC documenting approval of the investigator (must be identified by name), the protocol, (must be identified by title and revision number), and the Patient Information Sheet and Subject Consent Form must be received by ENDOLOGIX or its designee prior to study initiation. A progress report will be submitted by the investigator to the IRB or EC at intervals specified by the IRB or EC, but not less than annually. A copy of this progress report will be sent to ENDOLOGIX. After completion of the study, the investigator will submit a signed clinical safety summary of the study to the IRB or Written responses from the relevant Competent Authority and any other local approvals must also be obtained prior to starting the study.

d) Ethical Conduct of Study: The study will be conducted in accordance with GCP as contained in the ICH Guidelines and US CFR governing the protection of human subjects (Title 21, Part 50) and the obligations of clinical investigators (Title 21, Parts 312.60 through 312.69). ENDOLOGIX is responsible for the ongoing safety of the device and will promptly notify all participating investigators and regulatory authorities of findings that could adversely affect the safety of subjects, affect the conduct of the study, or alter the IRB/EC's approval to continue the study.

e) *Core Lab*: The Core Lab is responsible for the three-dimensional reconstructions and assessment of all submitted CT scans preoperatively and imaging postoperatively and for reporting of results.

f) *Data Management Group*: The data management group is responsible for database development, validation, control and management of input from monitored CRFs, issuance and resolution of queries, database maintenance, and reporting for statistical analysis.

g) *Clinical Events Committee*: The independent clinical events committee will consist of at least three physician members and is responsible for review of events and complications documented on CRFs and in source documents by the study investigators during the trial, and for categorization of these events according to the event definitions and primary endpoint criteria in this protocol. Reviews will occur on an ongoing basis throughout the trial as events are reported. The adjudicated events will be reviewed by the Data Safety Monitoring Board.

h) *Data Safety Monitoring Board (DSMB)*: Consistent with the U.S. FDA guidance document *Establishment and Operation of Clinical Trial Data Monitoring Committees*, Endologix has established a DSMB having pertinent expertise to review on a regular basis adjudicated safety data accumulated and trial progress (i.e., enrollment among groups; completeness and timeliness of data; protocol deviations; etc.) from its ongoing clinical investigations. The DSMB consists of five members, two of which must be physicians with specialty training in endovascular repair. One member of the DSMB is a statistician. The DSMB will be convened to review interim data accumulated during the trial and to render a recommendation for enrollment in the trial: continue; amend; suspend; or, terminate. All action items discussed during the meeting will be documented in the minutes, with agreed upon target completion dates for resolution. The final meeting minutes will be distributed to all DSMB members. Endologix will disclose the recommendations of the DSMB to the US FDA in its annual progress reports to the IDE.

i) *Biostatistician*: The independent biostatistician is responsible for the development and implementation of the data analysis plan, for conducting the data analysis, and for reporting it per the plan.

10.2 PATIENT PROTECTION

Written informed consent, in accordance with applicable international, federal, state and study center regulations, must be obtained from each patient, or from their legal representative, prior to the formal screening process as outlined in §8.6.1. The investigator will retain a copy of the signed informed consent document in each patient's record, and provide a copy to the patient. The Investigator will

not request the written informed consent of any patient, and will not allow any patient to participate in the investigation before obtaining IRB/EC approval.

Attachment 2 provides an example of the consent form that may be used for the study. The example contains the minimal consent language content that must be incorporated into the Informed Consent Document. Other elements or language may be added, or minor edits to the language may be made, but no substantial content may be deleted.

Prior to starting the study, the investigator will provide Endologix with a copy of the final Informed Consent Document approved by the IRB/EC with documented evidence that the EC has approved the protocol.

Appropriate precautions will be taken to maintain confidentiality of patient medical records and personal information. However, the patient's name may be disclosed to the sponsor or designee, or any health authorities if they inspect the study records. A report of this study may be published; however the patient's identity will not be disclosed.

10.3 PROTOCOL CHANGES

The investigator should not implement any deviation from or changes to the protocol without approval by Endologix and prior review and documented approval from the governing IRB/EC. The only exception to this is where necessary to eliminate immediate hazards to study patients, or when changes involve only administrative aspects (e.g., change in monitors, telephone numbers, etc.).

A report of withdrawal of IRB/EC approval must be submitted to the Sponsor within five working days.

10.4 DOCUMENTATION

Clinical Investigator's Brochure: Prior to or at the time of training for the study, the investigator will be provided with a clinical investigator's brochure (CIB). This document serves as a briefing document to provide reports of prior investigations regarding nonclinical and clinical safety and effectiveness studies, as well as published and unpublished information for reference and review.

Source Documents: Source documents may include a patient's medical record, hospital charts, clinic charts, the investigator's study files, questionnaires, as well as the results of diagnostic tests such as laboratory tests, CT scans, angiograms, and the like. The investigator's copy of the CRFs serves as part of the record of a patient's study-related data.

The following information should be included in the patient's medical record:

- Patient's name and contact information;
- The study title, number/name, and sponsor name;
- The date the patient was enrolled into the study and the patient ID number;
- A statement that written informed consent was obtained;
- Date of procedure and implanted device information;
- Dates of all visits;
- Occurrence of any hospitalizations, any adverse events, and any medications prescribed;
- Date patient exited the study, and a notation as to whether the patient completed the study or discontinued, with the corresponding reason.

Case Report Form Completion: The investigator who signs the protocol signature page must personally sign the CRFs to ensure that the observations and findings are recorded correctly and completely. The CRFs are to be completed in a timely manner at the intervals specified by Endologix and this protocol.

All forms must be filled out completely as instructed. An explanation must be provided for any missing data points. A CRF Completion Guide will be provided to each site for reference.

All CRFs will be reviewed and monitored for completeness and clarity. Queries for missing or unclear data will be made as necessary throughout the study.

Study Logs: Endologix will provide pre-printed forms to each study site for documentation of:

- Investigator and site training to the protocol (Training Log)
- Authorized study site personnel (Site Signature Log)
- Patient consent and screening (Screening Log)
- Monitoring visit tracking (Site Visit Log)
- Investigational Device Accountability (Investigational Device Accountability Log)

Document Retention: Study-related correspondence, patient records, consent forms, records of device implant, and CRF pages are to be maintained on file by the study site. Endologix requires that it be notified in writing if the investigator wishes to relinquish ownership of the data and information so that mutually agreed upon arrangements can be made for transfer of ownership to a qualified entity.

Publication: Endologix, as the sponsor of record, has a proprietary interest in this study. Authorship and manuscript composition will reflect joint cooperation between multiple investigators and sites, core laboratories, and Endologix. Authorship will be established prior to writing of the manuscript. No individual publications will be allowed prior to the completion of the final report for this study and as agreed in writing by Endologix.

10.5 MONITORING PLAN

Written procedures have been established by Endologix for monitoring clinical investigations, to assure the quality of the study and to assure that each person involved in the monitoring process carries out his or her duties. Standardized written procedures, sufficiently detailed to cover the general aspects of clinical investigations, will be used as a basic monitoring plan and will be supplemented by more specific or additional procedures, as required by the clinical investigation.

A pre-study monitoring visit or meeting will be conducted to ensure that the Investigator clearly understands and accepts the obligations incurred in undertaking the clinical investigation as set forth in relevant international standard, and that the facilities are acceptable. Periodic monitoring visits will be conducted with adequate frequency to ensure that the Investigator's obligations are being fulfilled and that the facilities continue to be acceptable. A study termination monitoring visit will be conducted at the completion of the clinical study to ensure that all data are properly documented and reported.

Site Termination: If a clinical monitor becomes aware that an Investigator is not complying with the signed Investigator's Agreement, the Investigational Plan, the requirements of applicable health authority regulations, or any conditions of approval imposed by the reviewing EC or health authority, Endologix will immediately either secure compliance or terminate the Investigator's participation in the study. The final action will be taken with the goal of assuring the rights, safety and welfare of the patients.

Monitor Name and Address: Monitoring procedures will be performed under the direction of:

Dana Deyette, RN, Sr. Director, Clinical Affairs

Endologix, Inc.
11 Studebaker, Irvine, CA 92618
Tel: (949) 595-7276

CRFs, AE reports, source documents as required, and correspondence are to be forwarded to:

Endologix, Inc. Clinical Affairs Department

c/o Jennifer Jelf, Project Manager 11 Studebaker, Irvine, CA 92618 Tel: (949) 595-7259; Fax: (949) 595-7373	c/o Cindi Witte, Project Manager 11 Studebaker, Irvine, CA 92618 Tel: (949) 598-4638; Fax: (949) 595-7373

10.6 REFERENCES

a) AbuRahma A, Campbell J, Stone PA, et al. The correlation of aortic neck length to early and late outcomes in endovascular repair patients. J Vasc Surg 2009;50:738-48.

b) Arko FA, Filis KA, Seidel SA, et al. How many patients with infrarenal aneurysms are candidates for endovascular repair? J Endovasc Ther 2004;11:33-40.

c) ASTM F1058:2002, Standard Specification for Wrought 40Cobalt-20Chromium-16Iron-15Nickel-7Molybdenum Alloy Wire and Strip for Surgical Implant Applications (UNS R30003 and UNS R30008).

d) Browne TF, Hartley D, Purchas S, et al. A fenestrated covered suprarenal aortic stent. Eur J Vasc Endovasc Surg 1999;18:445-9.

e) Carpenter JP, Baum RA, Barker CF, et al. Impact of exclusion criteria on patient selection for endovascular abdominal aortic aneurysm repair. J Vasc Surg 2001;34:1050-4.

f) Fulton JJ, Farber MA, Marston WA, et al. Endovascular stent-graft repair of pararenal and type IV thoracoabdominal aortic aneurysms with adjunctive visceral reconstruction. J Vasc Surg 2005;41:191-8.

g) Hoyert DL, Arias E, Smith B L, et al. Deaths: final data for 1999. Natl Vital Stat Rep 2001; 49(8):1-113.

h) ISO 14155:2011, Clinical Investigations of Medical Devices for Human Subjects: Good Clinical Practice

i) Leurs LJ, Kievit J, Dagnelie PC, et al. Influence of infrarenal neck length on outcome of endovascular abdominal aortic aneurysm repair. J Endovasc Ther 2006;13:640–8.

j) Park JH, Chung JW, Cho IW, et al. Fenestrated stent grafts for preserving visceral brnaches in the treatment of abdominal aortic aneurysms: preliminary results. J Vasc Interventional Radiology 1996;7:819-23.

k) U.S. Department of Health and Human Services, Guidance For Industry. ICH E6, Good Clinical Practice: Consolidated Guidance, April 1996

ATTACHMENT 1

Instructions for Use Draft

(IFUs)

- **Ventana Fenestrated System** ***(updated March 2012)***
- **Xpand Renal Stent Grafts**

ATTACHMENT 2

Informed Consent Form Template

ATTACHMENT 3

Case Report Forms

ATTACHMENT 4

Investigator Agreement Template

ATTACHMENT 5

Statistical Analysis Plan