Powerlink® System for Abdominal Aortic Aneurysm (AAA)

(Bifurcated Model – Infrarenal)

INSTRUCTIONS FOR USE

IMPORTANT NOTES:

- **Please read all instructions carefully that are contained within this packet before attempting to use any Endologix Powerlink System.**
- ***Caution:* Federal Law (U.S.) restricts this device to sale by or on the order of a physician.**
- **Endologix Powerlink System is provided sterile and for single use only. Therefore, carefully inspect the package before use. If the product is opened, damaged or the label is illegible do not use the device.**

*US Patents: 6,077,296 6,090,128 6,156,063 6,187,036 6,197,049 6,210,422 6,261,316 6,331,190 6,660,030
Other U.S. and Foreign Patents Pending
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1.0 PRODUCT DESCRIPTION OF SYSTEM

The Powerlink System Bifurcated Infrarenal Stent Graft for AAA consists of two components: a unibody bifurcated stent graft and a delivery catheter.

The stent graft is a self-expanding cobalt chromium alloy stent with the main body constructed from a single wire and covered with a thin-walled, low porosity ePTFE graft. The material is attached to the stent only at the proximal and distal ends of the stent cage with surgical suture to minimize graft holes. The graft material is fully supported by the stent throughout its length. The Powerlink System also includes proximal cuff and limb extension accessories to accommodate specific patient anatomy or to repair endoleaks. Refer to the Powerlink Proximal Cuff Instructions For Use and the Powerlink Limb Extension Instructions For Use.

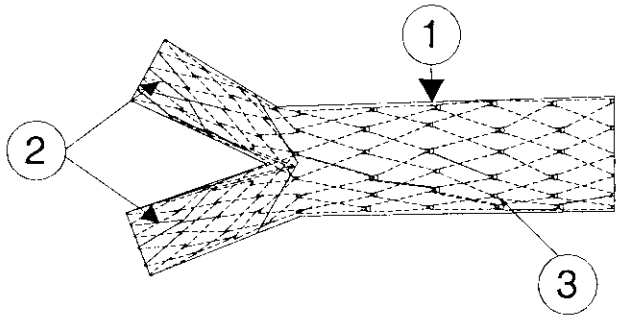

Figure 1. Powerlink Infrarenal Bifurcated Stent Graft

1	Main Body	3	Stent Cage (internal)
2	Limbs		

The delivery system is designed to provide accurate positioning of the Powerlink System Bifurcated Infrarenal Stent Graft during delivery while requiring minimally invasive access to the body. The delivery system also allows for readjustment during the delivery of the stent graft. The device is pre-loaded into its delivery system and enclosed in a sterile package. The delivery system is a coaxial design with inner, middle and outer sheaths constraining the self-expandable stent graft in a compressed state. Each sheath creates a pocket for containment of the stent graft body and limbs. As the pusher rod is advanced or the outer sheath and middle core retracted, the stent graft is pushed out and the constraints removed, allowing the self-expanding stent graft to expand within the vessel under the precise control of the implanting physician.

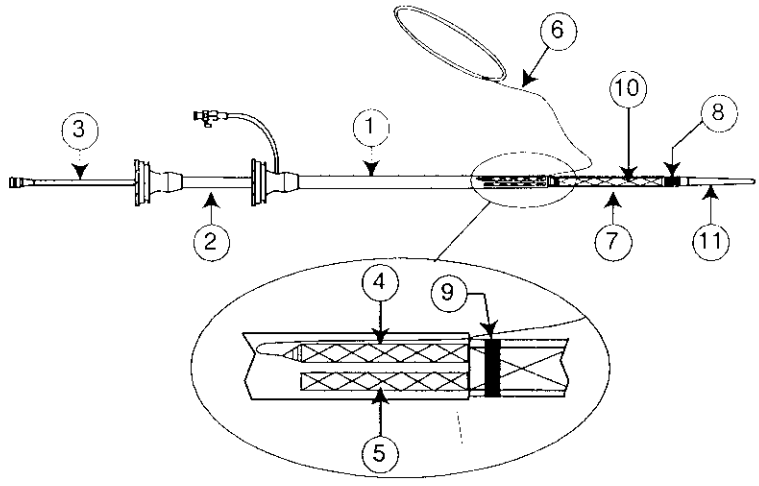

Figure 2. Powerlink Delivery System

1 Outer Sheath
2 Middle Core
3 Pusher Rod
4 Contralateral Limb Cover
5 Ipsilateral Limb Cover (attached to Middle Core)
6 Device Limb Wire & Hoop (attached to Contralateral Limb Cover)
7 Front Sheath (attached to Pusher Rod)
8 Radiopaque Front Stop (attached to Middle Core)
9 Radiopaque Marker (marks Caudal end of Front Sheath)
10 Stent Graft Main Body
11 Radiopaque Tip

To facilitate fluoroscopic visualization of the stent graft, the entire cobalt chromium alloy stent is radiopaque. The device wire for deployment of the contralateral device limb also has radiopaque markers for ease of visualization during deployment.

The bifurcated infrarenal stent graft delivery system is 21 Fr and is not delivered through a vascular introducer sheath in order to minimize the size of the incision needed in the femoral artery during introduction. The system is compatible with a .035 inch guidewire.

2.0 INDICATIONS FOR USE

The Powerlink System bifurcated models and proximal cuff and limb extension accessories are indicated for endovascular treatment in patients with AAA. It is indicated for patients with suitable aneurysm morphology for endovascular repair, including:

Adequate iliac/femoral access compatible with the required delivery systems (a diameter of ≥ 7 mm)

Non-aneurysmal aortic neck between the renal arteries and the aneurysm:

with a length of ≥ 15 mm

with a diameter of ≥ 18 mm and ≤ 26 mm (main body)

with a neck angle of ≤ 60° to the body of the aneurysm.

Aortic length ≥ 1.0 cm longer than the body portion of the chosen bifurcated model.

Common iliac artery distal fixation site:

with a distal fixation length of ≥ 15 mm

with ability to preserve at least one hypogastric artery

with a diameter of ≥ 10 mm and ≤ 14 mm (limbs)

with an iliac angle of ≤ 90° to the aortic bifurcation.

3.0 CONTRAINDICATIONS

There are no known contraindications for these devices.

4.0 WARNINGS AND PRECAUTIONS

4.1 General

- Read all instructions carefully. Failure to properly follow the instructions, warnings and precautions may lead to serious consequences or injury to the patient.
- The Powerlink System for AAA should only be used by physicians and teams trained in vascular interventional techniques and in the use of this device. Specific training expectations are described in *Section 10.1, Physician Training Program.*
- The long-term performance of endovascular grafts has not yet been established. All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and the performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the endovascular graft) should receive enhanced follow-up. Specific follow-up guidelines are described in *Section 12.0, Imaging Guidelines and Post-Operative Follow-up.*
- After endovascular graft placement, patients should be regularly monitored for perigraft flow, aneurysm growth or changes in the structure or position of the endovascular graft. At a minimum, annual imaging is required, including: 1) abdominal radiographs to examine device integrity (stent fracture, separation between bifurcated device and proximal cuffs or limb extensions, if applicable), and 2) contrast and non-contrast CT to examine aneurysm changes, perigraft flow, patency, tortuosity and progressive disease. If renal complications or other factors preclude the use of image contrast media, abdominal radiographs and duplex ultrasound may provide similar information.
- The Powerlink System for AAA is not recommended in patients unable to undergo, or who will not be compliant with the necessary preoperative and post-operative imaging and implantation studies as described in *Section 12.0, Imaging Guidelines and Post-Operative Follow-Up.*
- Additional endovascular intervention or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aneurysms, unacceptable decrease in fixation length (vessel and component overlap) and/or endoleak. An increase in aneurysm size and/or persistent endoleak may lead to aneurysm rupture.
- Patients experiencing reduced blood flow through the graft limb and/or endoleaks may be required to undergo secondary interventions or surgical procedures.
- Always have a vascular surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

4.2 Patient Selection, Treatment and Follow-Up

- The safety and effectiveness of the Powerlink System for AAA 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 endovascular grafts
  - Uncorrectable coagulopathy

- Indispensable mesenteric artery
- Genetic connective tissue disease (e.g., Marfan's or Ehlers-Danlos' Syndromes)
- Concomitant thoracic aortic or thoracoabdominal aneurysms
- Patients with active systemic infections
- Pregnant or nursing females
- Morbidly obese patients
- Less than 18 years of age
- Patients with < 15 mm in length or > 60 degrees angulation of the proximal aortic neck relative to the long axis of the aneurysm.

- Access vessel diameter and morphology (minimal tortuosity, occlusive disease, and/or calcification) should be compatible with vascular access techniques and delivery systems of a 21 Fr profile. The Powerlink System for AAA is not delivered through a vascular introducer sheath. Vessels that are significantly calcified, occlusive, tortuous or thrombus-lined may preclude placement of the endovascular graft and/or may increase the risk of embolization.
- Key anatomic elements that may affect successful exclusion of the aneurysm include severe proximal neck angulation (> 60 degrees for infrarenal neck to axis of AAA); short proximal aortic neck (< 15 mm); and thrombus and/or calcium at the arterial implantation sites, specifically the proximal aortic neck and distal iliac artery interface. Irregular calcification and/or plaque may compromise the fixation and sealing of the implantation sites. Necks exhibiting these key anatomic elements may be more conducive to graft migration.
- The Powerlink System for AAA is not recommended in patients who cannot tolerate contrast agents necessary for intra-operative and post-operative follow-up imaging.
- The Powerlink System for AAA is not recommended in patients with known sensitivities or allergies to cobalt chromium, ePTFE, or polypropylene.
- Patients with a systemic infection may be at increased risk of endovascular graft infection.
- Inability to maintain patency of at least one internal iliac artery or occlusion of an indispensable inferior mesenteric artery may increase the risk of pelvic/bowel ischemia.
- Multiple large, patent lumbar arteries, mural thrombus and a patent inferior mesenteric artery may all predispose a patient to Type II endoleaks. Patients with uncorrectable coagulopathy may also have an increased risk of Type II endoleak or bleeding complications.

4.3 Implant Procedure

- The Powerlink System is designed for single use only. Do not reuse or resterilize.
- 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 stent graft during preparation and insertion to decrease the risk of stent graft contamination and infection.
- Maintain guidewire position during delivery system insertion.
- Do not bend or kink the delivery system. Doing so may cause damage to the delivery system and the Powerlink System Stent Graft.
- If outer sheath kinks during insertion, do not attempt deployment. Replace with a new Powerlink System.
- If outer sheath kinks during insertion, do not attempt deployment. Replace with a new Powerlink System.

- The use of the Powerlink System for AAA requires administration of intravascular contrast. Patients with pre-existing renal insufficiency may have an increased risk of renal failure post-operatively. Care should be taken to limit the amount of contrast media used during the procedure.
- Excess traction of the device limb wire could prematurely deploy the contralateral limb.
- Inaccurate placement, inadequate fixation and/or incomplete sealing of the Powerlink System Stent Graft within the vessel may result in increased risk of endoleak, migration or inadvertent occlusion of the renal or internal iliac arteries. Renal artery patency must be maintained to prevent/reduce the risk of renal failure and subsequent complications. Incorrect deployment or migration of the stent graft may require surgical intervention.
- Catheter advancement should be performed under fluoroscopic guidance. Do not use excessive force to advance or withdraw the catheter when resistance is encountered. Vessel or catheter damage may occur. Care should be taken in areas of stenosis intravascular thrombosis or in calcified and/or tortuous vessels.
- Unless medically indicated, do not deploy the Powerlink System Stent Graft in a location that will occlude arteries necessary to supply blood flow to organs or extremities. Do not cover significant renal or mesenteric arteries (exception is the inferior mesenteric artery) or both hypogastric vessels with the stent graft. Vessel occlusion may occur. During the clinical study, this device was not studied in patients with two occluded internal iliac arteries.
- Take care during manipulation of catheters, wires and sheaths within an aneurysm. Significant disturbances may dislodge fragments of thrombus which can cause distal embolization.
- Fluoroscopic visualization during withdrawal of the Powerlink Delivery Catheter is necessary to ensure that it does not move the stent graft. Any resistance during withdrawal must be carefully monitored.
- When placing a proximal cuff or limb extension, the proximal cuff or limb extension must overlap the stent graft by 15 to 20 mm.

4.4 MRI (Magnetic Resonance Imaging) Safety and Compatibility

- Through non-clinical testing, the Powerlink Stent Graft has been shown to be MRI safe at field strengths of 1.5 Tesla or less, a maximum spatial gradient of 450 gauss per centimeter, and a maximum whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 30 min of MR imaging. The stent should not migrate in this MR environment. In this testing, the stent graft produced a temperature rise of less than 0.3 °C at a maximum whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 30 minutes of MR imaging.
- Heating has not been determined for overlapping components or stent grafts with fractured struts. MR imaging quality may be comprised if the area of interest is in the exact same area or relatively close to the position of the stent graft. The Powerlink stent graft has not been evaluated to determine if it is safe in MRI systems with field strengths greater than 1.5 Tesla.
- The Powerlink System Stent Graft exhibited minimal image artifact as observed in non-clinical MRI testing at 1.5 Tesla.

5.0 ADVERSE EVENTS

5.1 Observed Adverse Events

A U.S. multicenter, prospective study conducted at 15 centers, which included 192 test patients and 66 control patients, provides the basis of the observed adverse events rates presented in Tables 5.1.1 and 5.1.2. The control group included patients whose vascular anatomy may not have been suitable for endovascular AAA repair.

Table 5.1.1. Serious Adverse Events between Powerlink and Control Groups (0-30 days)

Serious Adverse Event/Complication	Powerlink[1] n/N (%)	Control[1] n/N (%)	P-value
Patients Experiencing at least One Serious AE	36/192 (18.75)	23/66 (34.85)	**0.0104**
Access Failure	1/192 (0.52)	--	--
Anemia	1/192 (0.52)	2/66 (3.03)	0.1618
Bleeding	4/192 (2.08)	3/66 (4.55)	0.3767
Cardiac Disorders	12/192 (6.25)	10/66 (15.15)	**0.0384**
Coagulation	1/192 (0.52)	0/66 (0.00)	>0.9999
Conversion	3/192 (1.56)	--	--
Death	2/192 (1.04)	4/66 (6.06)	**0.0389**
Delivery Failure	1/192 (0.52)	0/66 (0.00)	>0.9999
Device Kink	1/192 (0.52)	--	--
Endoleak	5/192 (2.60)	--	--
Genital Disorder	0/192 (0.00)	1/66 (1.52)	0.2558
Gastrointestinal or Bowel Disorders	2/192 (1.04)	5/66 (7.58)	**0.0131**
Graft Occlusion	1/192 (0.52)	--	--
Graft Thrombosis	0/192 (0.00)	2/66 (3.03)	0.0647
Hepatobiliary Disorders	0/192 (0.00)	1/66 (1.52)	0.2558
Infections and Infestations	1/192 (0.52)	2/66 (3.03)	0.1618
Multi-Organ Failure	0/192 (0.00)	1/66 (1.52)	0.2558
Neoplasms	1/192 (0.52)	1/66 (1.52)	0.4469
Neurological Disorders	2/192 (1.04)	0/66 (0.00)	>0.9999
Other[2]	5/192 (2.60)	3/66 (4.55)	0.4255
Pain	2/192 (1.04)	0/66 (0.00)	>0.9999
Pulmonary	4/192 (2.08)	11/66 (16.67)	**0.0001**
Renal and Urinary Disorders	2/192 (1.04)	5/66 (7.58)	**0.0131**
Reproductive System and Breast Disorders	0/192 (0.00)	1/66 (1.52)	0.2558
Sepsis	0/192 (0.00)	1/66 (1.52)	0.2558
Supplemental Procedure	4/192 (2.08)	0/66 (0.00)	0.5750
Thrombocytopenia	0/192 (0.00)	1/66 (1.52)	0.2558
Vascular Disorders	15/192 (7.81)	7/66 (10.61)	0.4548
Wound	1/192 (0.52)	1/66 (1.52)	0.4469

[1] Adding the sub groups will not necessary result in the group total because some patients may experience more than one adverse event.

[2] Test: (1) Right leg weakness, (1) Pulseless right lower extremity, (1) Delirum, (1) Right leg pain/necrotic feet and toes, (1) minimal hempotysis. Control: (1) Creatinine increase, (1) Hypovolemia, (1) Colstridium difficile enterocolitis

Table 5.1.2. Serious Adverse Events between Powerlink and Control Groups (31 days – 12 months)

Serious Adverse Event/Complication	Powerlink[1] n/N (%)	Control[1] n/N (%)	P-value
Patients Experiencing at least One Serious AE	45/190 (23.68)	12/62 (19.35)	0.6003
Bleeding	3/190 (1.58)	0/62 (0.00)	>0.9999
Cardiac Disorders	13/190 (6.84)	1/62 (1.61)	0.1987
Conversion	1/190 (0.53)	--	--
Death	11/190 (5.79)	5/62 (8.06)	0.5515
Endoleak	3/190 (1.58)	--	--
Gastrointestinal or Bowel Disorders	3/190 (1.58)	2/62 (3.23)	0.5992
Graft Occlusion	2/190 (1.05)	--	--
Infections and Infestations	7/190 (3.68)	2/62 (3.23)	>0.9999
Neoplasms	11/190 (5.79)	1/62 (1.61)	0.3035
Neurological Disorders	6/190 (3.16)	0/62 (0.00)	0.3409
Other[2]	4/190 (2.11)	2/62 (3.23)	0.6378
Pain	1/190 (0.53)	0/62 (0.00)	>0.9999
Pulmonary	5/190 (2.63)	2/62 (3.23)	0.6822
Renal and Urinary Disorders	2/190 (1.05)	0/62 (0.00)	>0.9999
Sepsis	2/190 (1.05)	0/62 (0.00)	>0.9999
Supplemental Procedure	2/190 (1.05)	0/62 (0.00)	>0.9999
Urinary	1/190 (0.53)	0/62 (0.00)	>0.9999
Vascular Disorders	5/190 (2.63)	1/62 (1.61)	>0.9999
Wound	0/190 (00.00)	2/62 (3.23)	0.0598

[1]Adding the sub groups will not necessary result in the group total because some patients may experience more than one adverse event.
[2]Test: (1) Left eye blindness, (1) Multiple fractures/pulmonary contusion, (1) Parathyroidism, (1) Hip replacement. Control: (1) Necrotic fascia, (1) Incisional hernia.

5.2 Potential Adverse Events

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

- Amputation
- Anesthetic complications and subsequent attendant problems (e.g., aspiration)
- Aneurysm enlargement
- Aneurysm rupture and death
- Aortic damage, including perforation, dissection, bleeding, rupture and death
- Arterial or venous thrombosis and/or pseudoaneurysm
- Arteriovenous fistula
- Bleeding, hematoma or coagulopathy
- Bowel complications (e.g., ileus, transient ischemia, infarction, necrosis)
- Cardiac complications and subsequent attendant problems (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension, hypertension)
- Claudication (e.g., buttock, lower limb)
- Death
- Edema
- Embolization (micro and macro) with transient or permanent ischemia or infarction
- Endoleak
- Stent graft: improper component placement; incomplete component deployment; component migration; suture break; occlusion; infection; stent fracture; graft material wear; dilatation; erosion; puncture and perigraft flow

- Fever and localized inflammation
- Genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection)
- Hepatic failure
- Impotence
- Infection of the aneurysm, device access site, including abscess formation, transient fever and pain.
- Lymphatic complications and subsequent attendant problems (e.g., lymph fistula)
- Neurologic local or systemic complications and subsequent attendant problems (e.g., stroke, transient ischemic attack, paraplegia, paraparesis, paralysis)
- Occlusion of device or native vessel.
- Pulmonary/respiratory complications and subsequent attendant problems (e.g., pneumonia, respiratory failure, prolonged intubation)
- Renal complications and subsequent attendant problems (e.g., artery occlusion, contrast toxicity, insufficiency, failure)
- Surgical conversion to open repair
- Vascular access site complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula
- Vessel damage
- Wound complications and subsequent attendant problems (e.g., dehiscence, infection)
- Vascular spasm or vascular trauma (e.g., iliofemoral vessel dissection, bleeding, rupture, death)

5.3 Device Related Adverse Event Reporting

Any adverse event (clinical incident) involving the Powerlink System Stent Graft should be reported to Endologix, Inc. immediately. To report an incident, call the Customer Service Department at 800-983-2284 (24 hours message service).

6.0 SUMMARY OF CLINICAL STUDIES

6.1 Objectives

The primary objective of the clinical study was to evaluate the safety and effectiveness of the Powerlink System for AAA as an alternative to open surgical repair in the primary treatment of infrarenal abdominal aortic aneurysms. Safety was determined by evaluating whether the Powerlink System for AAA subjects would have a total proportion of major adverse events that is non-inferior to the subjects treated with open surgical repair as evaluated through one year follow-up. Effectiveness was based on evaluating whether the Powerlink System for AAA subjects survival is non-inferior to the subjects treated with open surgical repair. Secondary objectives included an assessment of clinical benefits.

6.2 Study Design

This clinical study was a prospective, multicenter, non-randomized study designed to compare standard medical risk patients who received an endovascular graft to an open surgical repair control group. Fifteen sites enrolled 192 Powerlink System Stent Graft patients and 66 surgical control patients. The control group included patients whose vascular anatomy may not have been suitable for endovascular AAA repair. Follow-up evaluations were scheduled for pre-discharge, 1 month, 6 months, 12 months and annually thereafter. Patient follow-up and accountability at 1 month, 6 months and 12 months (follow-up window 10 to 14 months) are provided in this summary, as these were the primary data analysis time points (refer to Table 6.2.1). Imaging data provided in this summary is based on findings from an independent centralized image analysis laboratory (Core Lab), which 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. Safety was monitored by a data safety monitoring committee.

Table 6.2.1 Patient Follow-up and Accountability[1]

Item	Powerlink N=192			Surgical Control N=66		
Interval	**1 m**	**6 m**	**12 m**	**1 m**	**6 m**	**12 m**
No Device[2]	1	1	0	0	0	0
Conversion to open Repair[3]	3	3	3	n/a	n/a	n/a
Expired	2	8	8	3	5	8
Withdrawn/lost to follow-up	0	4	11	0	0	6
Available	190	180	173	63	61	52
Site CT imaging	186	171	157	n/a	n/a	n/a
Core Lab CT imaging	121	117	144	n/a	n/a	n/a
Site KUB imaging	129	118	146	n/a	n/a	n/a
Core Lab KUB imaging	129	118	146	n/a	n/a	n/a
Site evaluated for endoleak	186	171	157	n/a	n/a	n/a
Core Lab evaluated for endoleak	110	101	128	n/a	n/a	n/a
Site evaluated for aneurysm enlargement	n/a	80	100	n/a	n/a	n/a
Core Lab evaluated for aneurysm enlargement	n/a	78	96	n/a	n/a	n/a

[1]Data analysis sample size varies for each of the timepoints above and in the following tables. This variability is due to patient availability 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 of 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. Totals at time points are not cumulative, unless otherwise noted.

[2]Access failure, commercially available device implanted.

[3]The conversion patients continued to return for follow-up.

6.3 Patient Demographics

Tables 6.3.1 and 6.3.2 compare the subject characteristics and initial aneurysm diameter of the Powerlink Stent Graft and open surgical patients, respectively.

Table 6.3.1 Comparison of Subjects Characteristics

Item	Powerlink		Surgical Control		P-value
Age[1]	73.2 ± 7.0		69.7 ± 7.9		**0.0008**[1]
Gender (Male)	88.5%	(170/192)	86.4%	(57/66)	0.6627
Current Medical Conditions					
Peripheral Vascular Disease	16.7%	32/192	15.2%	10/66	0.8488
Hypertension	63.9%	122/191[2]	69.7%	46/66	0.4541
Renal Failure	2.6%	5/192	1.5%	1/66	>0.9999
COPD	31.8%	61/192	24.2%	16/66	0.2779
Coronary Artery Disease	45.8%	88/192	59.1%	39/66	0.0657
Liver Disease	4.2%	8/192	1.5%	1/66	0.4549
Diabetes	13.1%	25/191[2]	18.2%	12/66	0.3142
Coagulopathy	1.0%	2/192	0.0%	0/66	>0.9999
Previous Medical Conditions					
MI (≤ 6 mos ago)	2.1%	4/192	4.6%	3/66	0.3767
MI (> 6 mos ago)	24.5%	47/192	28.8%	19/66	0.5149
Angina	13.0%	25/192	12.1%	8/66	>0.9999
Congestive Heart Failure	6.8%	13/192	3.0%	2/66	0.3675
Valvular Disease	3.7%	7/192	7.6%	5/66	0.1911
Arrhythmia	16.2%	31/192	7.6%	5/66	0.1002
Prior CABG	28.1%	54/192	30.3%	20/66	0.7538
Prior PTCA/Stent	13.0%	25/192	18.2%	12/66	0.3127
Valve Replacement	2.6%	5/192	1.5%	1/66	>0.9999
Renal Failure	2.6%	5/192	1.5%	1/66	>0.9999
Cerebrovascular Disease	19.8%	38/192	15.2%	10/66	0.4668
Previous Abdominal Surgery	47.4%	91/192	37.9%	25/66	0.1987
History of Aneurysmal Disease	13.8%	26/189[2]	18.2%	12/66	0.4230
Alcohol Abuse	2.6%	5/192	9.1%	6/66	**0.0349**
Smoking History					
Never Smoked	17.2%	33/192	14.3%	9/63[2]	**0.0359**[3]
Past Smoker	64.1%	123/192	50.8%	32/63[2]	
Current Smoker	18.8%	36/192	34.9%	22/63[2]	

[1]The Powerlink patients were older than the control patients on an average of 3.5 years.
[2]One patient in the Powerlink group did not have a record of this condition. Three Powerlink patients did not report on a history of aneurysmal disease. Three surgical control patients did not report smoking status.
[3]The statistical method for "smoking history" tests the uniformity or lack of uniformity of the distribution of "smoking history" across the treatment groups. Since the patient cannot be in more than one smoking class, the three classes generate a multinomial variable and the proper statistical test is a chi-square that provides a single p-value.

Table 6.3.2 Aneurysm Diameter Distribution

Diameter Range	Powerlink	Surgical Control
< 30 mm	0.5% 1/188[1]	0.0% 0/58[1]
30-39 mm	0.0% 0/188[1]	1.7% 1/58[1]
40-49 mm	40.4% 76/188[1]	17.2% 10/58[1]
50-59 mm	48.9% 92/188[1]	39.7% 23/58[1]
60-69 mm	9.6% 18/188[1]	25.9% 15/58[1]
70-79 mm	0.5% 1/188[1]	12.1% 7/58[1]
80-89 mm	0.0% 0/188[1]	0.0% 0/58[1]
> 89 mm	0.0% 0/188[1]	3.5% 2/58[1]

[1]Four Powerlink and eight surgical control patients did not have an aneurysm diameter reported preoperatively.

6.4 Results

Data gathered in Tables 6.4.1 through 6.8.1 were collected by the clinical study sites and Core Lab. The majority of the results are presented up to 12 months. Where available, 24 month data are provided. Table 6.4.1 describes the types of devices implanted into the clinical study patients. Tables 6.4.2 through 6.7.1, describe the primary results from the clinical study. Figures 3 and 4 are the Kaplan-Meier plots of all-cause and AAA-related survival to 12 months, respectively. All early deaths (0-30 days) were considered AAA-related. Deaths after 30 days were considered AAA-related if AAA disease, related to a subsequent procedure, or device involvement was confirmed. Figure 5 is the Kaplan-Meier plot of Freedom from Serious Adverse Events.

Table 6.4.1 Devices Implanted

Item	Powerlink
Bifurcated	97.9% 188/192
Proximal Cuff	46.3% 87/188
Limb Extension	15.4% 29/188

The Powerlink System Bifurcated Infrarenal Stent Graft has a main body that is available in only two lengths (80 mm and 100 mm). Proximal Cuffs were used to treat intraoperative proximal Type I endoleaks or to accommodate the distance from the lowest renal artery to the aortic bifurcation. This accommodation for the distance is unique to the Powerlink Stent Graft due to its long main body design.

Table 6.4.2 Primary Results

Item	Powerlink		Surgical Control		P-Value
All Death (0-30 days)[1]	1.0%	2/192	6.06%	4/66	**0.0389**
All Death (31 days - 12 Months)[2]	5.7%	11/192	7.6%	5/66	0.5460
AAA-related	1.0%	2/192	0.0%	0/66	>0.9999
Non AAA-related	4.7%	9/192	7.6%	5/66	0.3584
All Death (0 days - 12 Months)[1, 2]	6.8%	13/192	13.6%	9/66	0.1218
AAA-related	2.1%	4/192	6.1%	4/66	0.2091
Non AAA-related	4.7%	9/192	7.6%	5/66	0.3584
Rupture	0.0%	0/192	n/a		n/a
Conversion (0-30 days)[3]	1.6%	3/192	n/a		n/a
(31 days-12 months)[3]	0.5%	1/192	n/a		
(0-12 months)[3]	2.1%	4/192	n/a		
Serious Adverse Events[4] (0-30 days)	18.8%	36/192	34.9%	23/66	**0.0104**
(31 days-12 months)	23.4%	45/192	18.2%	12/66	0.3946
(0-12 months)[5]	34.9%	67/192	45.5%	30/66	0.1419

[1]All deaths (0-30 days) were considered AAA and procedure related.
[2]Of the deaths (31 days-12 months), two were considered AAA and procedure related: (1) ischemic heart disease at 33 days, (1) perforated aorta during operative repair of endoleak at 13 months.
[3]Patients underwent conversion due to: (1) access failure, (1) delivery catheter limb sheath problem during deployment, (1) bleeding of left external artery caused by a wire or catheter, (1) perforated aorta during operative repair of endoleak at 13 months (same patient as late AAA related death).
[4]Serious adverse events are included in Tables 5.1.1 and 5.1.2.
[5]Adding the sub groups will not necessarily result in the group total because some patients may experience an adverse event in both sub groups.

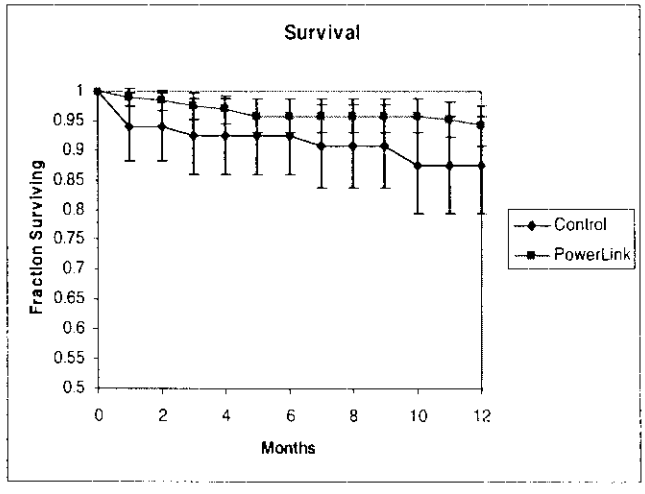

Figure 3. Survival at 12 Months (Error bars represent 95% confidence limits)

Item	1 month N	1 month %survival*	6 month N	6 month %survival	12 month N	12 month %survival
Powerlink	190	99.0	179	95.8	150	94.2
Surgical Control	62	93.9	58	92.4	45	87.5

*Log-rank p = 0.0708.

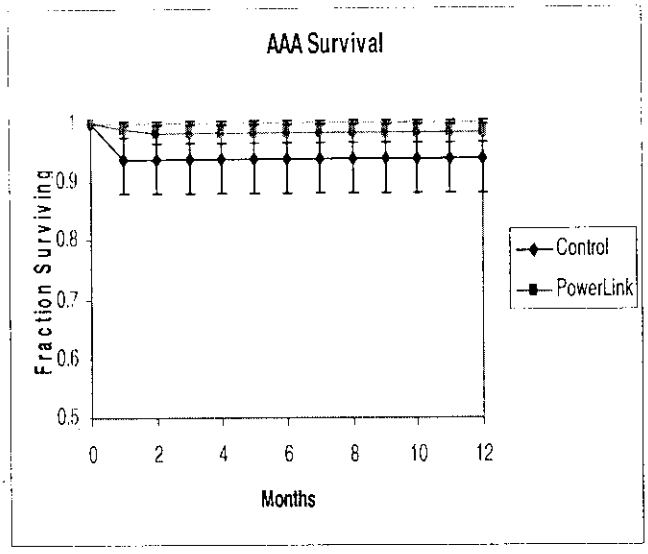

Figure 4. AAA Related Survival at 12 Months (Error bars represent 95% confidence limits)

Figure 4 presents AAA-related survival to 12 months. The accompanying table presents the Kaplan-Meier analysis at 1, 6 and 12 months.

	1 month		6 month		12 month	
Item	**N**	**%survival***	**N**	**%survival**	**N**	**%survival**
Powerlink	190	99.0	180	98.4	150	98.4
Surgical Control	62	93.9	60	93.9	45	93.9

*Log-rank p = 0.1039.

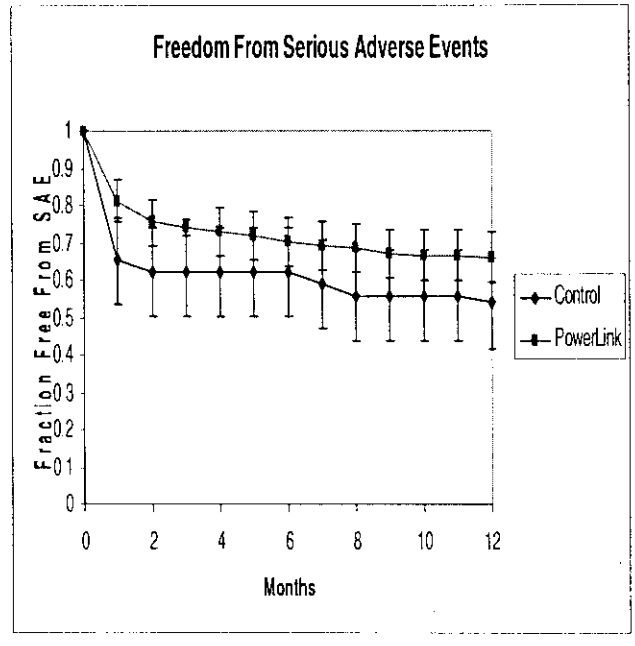

Figure 5. Freedom from Serious Adverse Events (0 – 12-months) (Error bars represent 95% confidence limits)

Figure 5 presents freedom from serious adverse events. The accompanying table presents the Kaplan-Meier analysis at 1, 6 and 12 months.

Item	1 month N	1 month % SAE Free*	6 month N	6 month % SAE Free*	12 month N	12 month % SAE Free*
Powerlink	156	81.3	133	70.3	103	66.0
Surgical Control	43	65.2	40	62.1	29	54.0

*Log-rank p = 0.0802.

Tables 6.4.3 through 6.4.5 describe results of the Powerlink System Stent Graft subjects as reported by the Core Lab. Device performance factors analyzed by the Core Lab include device integrity (Table 6.4.3), device patency (Table 6.4.4), and migration (Table 6.4.5).

Table 6.4.3 Abdominal Radiographic Findings

Item	Powerlink
Stent Fractures	
30 Days	0.0% (0/129)
6 Months	0.0% (0/118)
12 Months	0.0% (0/146)
24 Months	0.0% (0/81)

Table 6.4.4 CT Findings Graft Patency[1]

Item	Powerlink
Graft Patency	
30 Days	100.0% (115/115)
6 Months	100.0% (110/110)
12 Months	100.0% (140/140)
24 Months	100.0% (98/98)

[1]Core Lab definition is contrast-enhanced blood flow throughout the length of the graft.

Table 6.4.5 CT Findings Graft Migration

Item	Powerlink
Graft Migration (>5 mm) at 12 Months	
With clinical sequelae or intervention	0.0% (0/136)
Without clinical sequelae or intervention	4.4% (6/136)
Graft Migration (>10 mm) at 12 Months	0.7% (1/136)

6.5 Endoleak Management

During the clinical study, Type I endoleaks were treated during the initial procedure with the use of additional balloon seating or accessory stent grafts. Type II endoleaks were typically observed for a period of one to six months to determine if they would spontaneously thrombose. In the presence of Type II endoleaks and enlarging aneurysms, treatment by embolization or ligation was considered, and in some cases performed. As reported by the Core Lab, there were no Type III or Type IV endoleaks during this clinical study. Table 6.5.1, presents the incidence of endoleaks by evaluation interval, as identified by the Core Lab.

Table 6.5.1 Endoleaks (All Types, New and Persistent)

Item	Powerlink	
Endoleaks		
30 Days	22.7%	(25/121)
6 Months	12.9%	(13/117)
12 Months	14.1%	(18/144)
24 Months	4.9%	(5/103)

Table 6.5.2, presents the incidence of first occurrence of an endoleak according to evaluation interval, as identified by the Core Lab at or before the 30 day, 6 month and 12 month exams. The number of patients who are leak-free thereafter is also given.

Table 6.5.2 First Occurrence of Endoleaks[1]

Item	One-Month N=122			6-Month Exam N=139			12-Month Exam[3] N=141		
	%	Endo-leaks[1]	Leak-free there-after[2]	%	Endo-leaks[1]	Leak-free there-after[2]	%	Endo-leaks[1]	Leak-free there-after[2]
Endoleaks									
Proximal Type I	0.8	1	1	0.0	0	--	0.0	0	--
Distal Type I	0.0	0	--	0.0	0	--	0.0	0	--
Type II	17.2	21	8	15.1	21	4	12.1	17	4
Type III	0.0	0	--	0.0	0	--	0.0	0	--
Type IV	0.0	0	--	0.0	0	--	0.0	0	--
Multiple	2.5	3	1	0.7	1	0	0.7	1	0
Unknown	1.6	2	1	0.7	1	0	2.1	3	2

[1]Identifed by Core Lab
[2]Subsequent endoleaks may have been of different type than original.
[3]Follow-up after 24 months is not available.

6.6 Aneurysm Change

Tables 6.6.1 through 6.6.3 present the change in aneurysm diameter for the endovascular patients, as identified by the Core Lab. Table 6.6.1, presents maximum aneurysm diameter change by interval. Tables 6.6.2 and 6.6.3 present aneurysm change and endoleak at 12 and 24 months, respectively.

Table 6.6.1 Change in Maximum Aneurysm Diameter by Interval[1]

Item	Powerlink	
31 days to 6 Months		
Decrease (≥5 mm)	17.1%	(14/82)
Unchanged	82.9%	(68/82)
Increase (≥5mm)	0.0%	(0/82)
31 days to 12 Months		
Decrease (≥5 mm)	35.7%	(35/98)
Unchanged	62.2%	(61/98)
Increase (≥5mm)	2.0%	(2/98)
31 days to 24 Months		
Decrease (≥5 mm)	63.9%	(46/72)
Unchanged	34.7%	(25/72)
Increase (≥5 mm)	1.4%	(1/72)

[1]Only includes patients with interpretable films and measurements of aneurysm change from 1 to 24 months.

Table 6.6.2 Change in Aneurysm Diameter and Endoleak at 12 Months[1]

Item	Endoleak N	n	%
Aneurysm Change from 31 days to 12 Months			
Decrease (≥5 mm)	34	2	5.9
Unchanged	55	10	18.2
Increase (≥5mm)	2	0	0.0

[1]Only includes patients with interpretable films and measurements of aneurysm change and endoleak at 12 months.

Table 6.6.3 Change in Aneurysm Diameter and Endoleak at 24 Months[1]

Item	Endoleak N	n	%
Aneurysm Change from 31 days to 24 Months			
Decrease (≥5 mm)	41	1	2.4
Unchanged	19	2	9.5
Increase (≥5mm)	1	1	100.0

[1]Only includes patients with interpretable films and measurements of aneurysm change and endoleak at 24 months.

Tables 6.6.4 to 6.6.6 present the change in aneurysm volume for the endovascular patients, as identified by the Core Lab. Table 6.6.4 presents maximum aneurysm volume change by interval. Tables 6.6.5 and 6.6.6 present aneurysm change and endoleak at 12 and 24 months, respectively

Table 6.6.4 Change in Aneurysm Volume by Interval[1]

Item	Powerlink
31 days to 6 Months	
Decrease (≥5%)	37.8% (31/82)
Unchanged	50.0% (41/82)
Increase (≥5%)	12.2% (10/82)
31 days to 12 Months	
Decrease (≥5%)	57.9% (55/95)
Unchanged	29.5% (28/95)
Increase (≥5%)	12.6% (12/95)
31 days to 24 Months	
Decrease (≥5 %)	68.6% (48/70)
Unchanged	20.0% (14/70)
Increase (≥5%)	11.4% (8/70)

[1]Only includes patients with interpretable films and measurements of aneurysm volume from 1 to 24 months.

Table 6.6.5 Change in Aneurysm Volume and Endoleak at 12 Months[1]

Item	Endoleak N	n	%
Aneurysm Change from 31 days to 12 Months			
Decrease (≥5%)	53	4	7.6
Unchanged	27	5	18.5
Increase (≥5%)	9	3	33.3

[1]Only includes patients with interpretable films and measurements of aneurysm volume and endoleak at 12 months.

Table 6.6.6 Change in Aneurysm Volume and Endoleak at 24 Months[1]

Item	Endoleak		
	N	n	%
Aneurysm Change from 31 days to 24 Months			
Decrease (≥5%)	42	1	2.4
Unchanged	12	1	8.3
Increase (≥5%)	6	2	33.3

[1]Only includes patients with interpretable films and measurements of aneurysm volume and endoleak at 24 months.

6.7 AAA-related Secondary Interventions

AAA-related secondary interventions within the first year were performed in 9.9% of the Powerlink System Stent Graft patients as shown in Table 6.7.1. 5.7% of the secondary interventions were to treat an endoleak.

Table 6.7.1 Secondary Interventions (to 12 months)

Item	Powerlink N = 192	
Intervention	N	%
Subjects with at least 1 intervention	19	9.9%
Treat an endoleak:		
Embolization	6	3.1%
Ancillary component	5	2.6%
Treat a graft limb occlusion	5	1.3%
Other native vessel procedure	3	1.6%

6.8 Secondary Outcome Measures

As described in Table 6.8.1, treatment of AAA with the Powerlink System Stent Graft compared to the surgical control group demonstrated significant benefits in recovery measures.

Table 6.8.1 Secondary Outcomes by Treatment Group

Item	Powerlink		Surgical Control		P-value
Anesthesia Time (min)	185.1 ± 82.2		293.8 ± 111.5		**<0.0001**
Procedure Time (min)	135.9 ± 65.9		222.3 ± 100.1		**<0.0001**
Blood Loss (ml)	341.0 ± 412.6		1582.9 ± 1608.9		**<0.0001**
Days in ICU	0.78 ± 1.5		4.1 ± 8.4		**<0.0001**
Days to Discharge	3.3 ± 3.4		9.5 ± 7.7		**<0.0001**
Anesthesia Type:	%	n/N	%	n/N	**<0.0001[1]**
Local	21.4	41/192	0.0	0/66	
Epidural/Regional	11.5	22/192	0.0	0/66	
General	67.2	129/192	100.0	66/66	

[1]The statistical method for "anesthesia type" tests the uniformity or lack of uniformity of the distribution of anesthesia types across the treatment groups. Since the patient cannot have more than one "anesthesia type", the three types generate a multinomial variable and the proper statistical test is a chi-square that provides a single p-value.

7.0 PATIENT SELECTION AND TREATMENT

(See Section 4 – Warnings and Precautions)

7.1 Individualization of Treatment

Endologix recommends that the Powerlink System Stent Graft component diameters be selected as described in Table 10.4.1. The length of the Powerlink System Stent Graft should extend from the lowest renal artery to just above the origin of the internal iliac (hypogastric) artery. In addition, the aortic length should be ≥ 1.0 cm longer than the main body portion of the chosen bifurcated model. 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 *Section 6.0, Summary of Clinical Studies,* should be carefully considered for each patient before use of the Powerlink System for AAA. 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 Powerlink System for AAA.
- Ability to tolerate general, regional or local anesthesia
- Iliofemoral access vessel size and morphology (minimal thrombus, calcium and/or tortuosity) should be compatible with vascular access techniques of the 21 Fr delivery catheter profile. The Powerlink System for AAA is not delivered through a vascular introducer sheath.
- Adequate iliac/femoral access compatible with the required delivery systems (a diameter of ≥ 7 mm).
- Non-aneurysmal aortic neck between the renal arteries and the aneurysm:
  - with length of ≥ 15 mm
  - with a diameter of ≥ 18 mm and ≤ 26 mm (main body)
  - with a neck angle of ≤ 60° to the body of the aneurysm.
- Aortic length ≥ 1.0 cm longer than the body portion of the chosen bifurcated model.
- Common iliac artery distal fixation site:
  - with a distal fixation length of ≥ 15 mm
  - with ability to preserve at least one hypogastric artery
  - with a diameter of ≥ 10 mm and ≤ 14 mm (limbs)
  - with an iliac angle of ≤ 90° to the aortic bifurcation.
- Freedom from significant femoral/iliac artery occlusive disease that would impede flow through the vascular graft.

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

8.0 PATIENT COUNSELING INFORMATION

The physician and patient (and/or family members) should review the risks and benefits when discussing this endovascular device and procedure including:

- Risks and differences between endovascular repair and 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 performance of endovascular grafts has not yet been established. All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and the performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the endovascular graft) should receive enhanced follow-up. Specific follow-up guidelines are described in *Section 12, Imaging Guidelines and Post-Operative Follow-Up.*
- Patients should be counseled on the importance of adhering to the follow-up schedule, both during the first year and at yearly intervals thereafter. Patients should be told that regular and consistent follow-up is a critical part of ensuring the ongoing safety and effectiveness of endovascular treatment of AAAs. At a minimum, annual imaging and adherence to routine post-operative follow-up requirements is required and should be considered a life-long commitment to the patient's health and well-being.
- 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 at rest or discoloration or coolness of the leg. Aneurysm rupture may be asymptomatic, but usually presents as: pain; numbness; weakness in the legs; 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, neurological, bowel and bleeding complications. Device related risks include occlusion, endoleak, aneurysm enlargement, fracture, potential for reintervention and open surgical conversion, rupture and death (See *Sections 5.1* and *5.2, Observed Adverse Events* and *Potential Adverse Events*). The physician should complete the *Patient Implant 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 card anytime they visit additional health practitioners, particularly for any additional diagnostic procedures (e.g., MRI).

9.0 HOW SUPPLIED

- The Powerlink System for AAA is supplied sterile and enclosed in two peel-open packages, one sealed inside the other.
- The device is intended for single use only. Do not re-sterilize the device.
- Inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use this device if damage has occurred or if the sterilization barrier has been damaged or broken. If damage has occurred, do not use the product and return to Endologix, Inc.
- Prior to use, verify correct devices (quantity and size) have been supplied for the patient by matching the device to the order prescribed by the physician for that particular patient.

- Do not use after the "USE BY" (EXPIRATION) date printed on the label.
- Store in a cool, dry place.
- The device packaging includes a label with peel-away stickers containing the model number and lot number. These stickers are intended to be used with the enclosed Patient Implant Card and Device Tracking Form. Please refer to Section 13.0 for information regarding the Patient Implant Card and Device Tracking Form.

Table 9.1 Bifurcated Infrarenal Stent Graft

Model No.	Main Body Diameter (mm)	Main Body Length (mm)	Limb Diameter (mm)	Limb Length (mm)	Delivery System Fr (no introducer needed)
25-16-135BL	25	80	16	55	21
25-16-155BL	25	100	16	55	21
25-16-140BL	25	100	16	40	21
28-16-135BL	28	80	16	55	21
28-16-155BL	28	100	16	55	21
28-16-140BL	28	100	16	40	21

10.0 CLINICAL USE INFORMATION

10.1 Physician Training Program

CAUTION: Always have a vascular surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

CAUTION: The Powerlink System for AAA should only be used by physicians and teams trained in vascular interventional techniques and in the use of this device. The recommended skill/knowledge requirements for physicians using the Powerlink system for AAA 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 cut-down, 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

10.2 Inspection Prior to Use

Inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use this device if damage has occurred or if the sterilization barrier has been damaged or broken. If damage has occurred, return device to Endologix, Inc. Prior to use, verify correct devices (quantity and size) have been supplied for the patient by matching the device to the order prescribed by the physician for that particular patient.

10.3 Materials Required

1. Powerlink proximal cuffs or limb extensions of various lengths and diameters may be required in order to properly fit the implant to the anatomy of the patient or to repair any endoleaks.
2. Fluoroscopic imaging and the ability to record all imaging.
3. Assorted .035" stiff and standard guidewires of adequate length (e.g., EV3 Nitrex guidewire, 180 cm).
4. Power injector for fluoroscopic dye studies.
5. Radiopaque (ruler) in millimeter increments is recommended.
6. Heparinized solution and sterile saline solution.
7. Assorted catheters for passage through tortuous vessels, including angioplasty catheters to dilate stenotic vessels prior to passage of the delivery catheter.
8. Endologix Dual Lumen Catheter
9. 12.5 Fr tear-away introducer sheath (for management of wires prior to introduction of the delivery system)
10. 9 Fr introducer sheath (for contralateral limb deployment)
11. Snare
12. Radiopaque contrast media

10.4 Device Diameter Sizing Guidelines

Under sizing or over sizing may result in incomplete sealing or compromised flow.

Table 10.4.1 Bifurcated Stent Graft

Intended Aortic Vessel Diameter	Renals to Bifurcation Length	Renals to Hypogastric Length	Intended Iliac Vessel Diameter	Main Body Diameter	Main Body Length	Limb Diameter	Limb length	Del. Cath
18-23mm	≥ 90mm	145-164mm	10-14mm	25mm	80mm	16mm	55mm	21Fr
18-23mm	≥ 110mm	≥ 165mm	10-14mm	25mm	100mm	16mm	55mm	21Fr
18-23mm	≥ 110mm	≥ 150mm	10-14mm	25mm	100mm	16mm	40mm	21Fr
20-26mm	≥ 90mm	145-164mm	10-14mm	28mm	80mm	16mm	55mm	21Fr
20-26mm	≥ 110mm	≥ 165mm	10-14mm	28mm	100mm	16mm	55mm	21Fr
20-26mm	≥ 110mm	≥ 150mm	10-14mm	28mm	100mm	16mm	40mm	21Fr

11.0 DIRECTIONS FOR USE

Prior to use of the Endologix Powerlink System for AAA, review this *Instructions for Use* booklet. The following instructions embody a basic guideline for device placement. Variations in the following procedures may be necessary. These instructions are intended to help guide the physician and do not take the place of physician judgment.

11.1 General Use Information

1. Standard techniques for placement of arterial access sheathes, guiding catheters, angiographic catheters and guidewires should be employed during use of the Powerlink System for AAA. The Powerlink System for AAA is compatible with a .035 inch diameter guidewire.

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.

11.2 Pre-Implant Determinants

Verify from pre-implant planning that the correct device has been selected. Determinants include:

1. The Powerlink System may be introduced via either iliac artery. Common femoral artery access and aneurysm sac orientation are other considerations. If one iliac artery is more tortuous, aneurysmal or diseased, this side may be considered preferable for delivery catheter access as the vessel is exposed allowing for more manipulation and control.
2. Angulation of aortic neck, aneurysm and iliac arteries.
3. Quality of the aortic neck.
4. Diameters of infrarenal aortic neck and distal iliac arteries.
5. Distance from renal arteries to the aortic bifurcation.
6. Length from the aortic bifurcation to the internal iliac arteries/attachment site(s).
7. Aneurysm(s) extending into the iliac arteries may require special consideration in selecting a suitable graft/artery interface site.
8. Pre-dilation of the iliac arteries may ease deployment procedure.

WARNING: THE USE OF THE POWERLINK SYSTEM FOR AAA REQUIRES ADMINISTRATION OF INTRAVASCULAR CONTRAST. PATIENTS WITH PRE-EXISTING RENAL INSUFFICIENCY MAY HAVE AN INCREASED RISK OF RENAL FAILURE POST-OPERATIVELY. CARE SHOULD BE TAKEN TO LIMIT THE AMOUNT OF CONTRAST MEDIA USED DURING THE PROCEDURE.

WARNING: UNLESS MEDICALLY INDICATED, DO NOT DEPLOY THE POWERLINK SYSTEM STENT GRAFT IN A LOCATION THAT WILL OCCLUDE ARTERIES NECESSARY TO SUPPLY BLOOD FLOW TO ORGANS OR EXTREMITIES. DO NOT COVER SIGNIFICANT RENAL OR MESENTERIC ARTERIES (EXCEPTION IS THE INFERIOR MESENTERIC ARTERY) OR BOTH HYPOGASTRIC VESSELS WITH THE STENT GRAFT. VESSEL OCCLUSION MAY OCCUR. DURING THE CLINICAL STUDY, THIS DEVICE WAS NOT STUDIED IN PATIENTS WITH TWO OCCLUDED INTERNAL ILIAC ARTERIES.

11.3 Patient Preparation

1. Refer to institutional protocols relating to anesthesia, anticoagulation and monitoring of vital signs.
2. Position patient on imaging table allowing fluoroscopic visualization from the aortic arch to the femoral bifurcations.
3. Expose the common femoral artery on the chosen access side using standard surgical technique.

4. Establish adequate proximal and distal vascular control of the surgically exposed femoral artery.

5. Perform standard percutaneous vessel access on the opposite side.

11.4 Device Preparation

WARNING: THE POWERLINK SYSTEM IS DESIGNED FOR SINGLE USE ONLY. DO NOT REUSE OR RESTERILIZE.

CAUTION: MINIMIZE HANDLING OF THE CONSTRAINED STENT GRAFT DURING PREPARATION AND INSERTION TO DECREASE THE RISK OF STENT GRAFT CONTAMINATION AND INFECTION.

CAUTION: DO NOT BEND OR KINK THE DELIVERY SYSTEM. DOING SO MAY CAUSE DAMAGE TO THE DELIVERY SYSTEM AND THE POWERLINK SYSTEM STENT GRAFT.

1. Tighten red and white connectors by turning the hubs clock-wise.
2. Flush lumen and side port of the delivery system with sterile saline solution.

11.5 Procedure

1. Perform a cut-down of the access vessel using standard surgical techniques.
2. Place vessel loops distal and proximal to the cut-down site for hemostatic control.
3. Insert a 12.5 Fr tear-away introducer sheath in the limb in which the Powerlink is to be introduced and a 9 Fr introducer sheath into the other limb.
4. Pass a guidewire from the 12.5 Fr sheath into the distal aorta. From the 9 Fr sheath, pass a snare into the aorta catching the guidewire and retracting it through the sheath.
5. Insert pigtail catheter to perform angiography. Mark renal arteries and fix the C-arm.
6. Confirm length and diameter of required Powerlink System. Endologix suggests that the stent graft diameter be at least 2 mm larger than the normal aortic inner diameter (e.g., 25 mm diameter stent graft should not be deployed in a normal aortic inner diameter > 23 mm). Refer to *Section 10.4, Device Diameter Sizing Guidelines*.
7. Load the Dual Lumen Catheter onto the transfemoral guidewire, and pass it through the 9 Fr sheath. The "skives" (cut-aways) of the Dual Lumen Catheter should be maintained in a lateral position (See Figure 6). To facilitate advancement, the transfemoral guidewire should be kept taut. Advance the Dual Lumen Catheter over the aortic bifurcation, exiting through the 12.5 Fr sheath of the ipsilateral limb. Maintain position of the 12.5 Fr sheath as the Dual Lumen Catheter engages the hemostatic valve of the sheath. The radiopaque marker of the Dual Lumen Catheter should be positioned in the ipsilateral common iliac artery. If the radiopaque marker is not lateral to the transfemoral wire, remove the Dual Lumen Catheter and re-orient it. Once the Dual Lumen Catheter is in its proper position, remove the transfemoral guidewire.

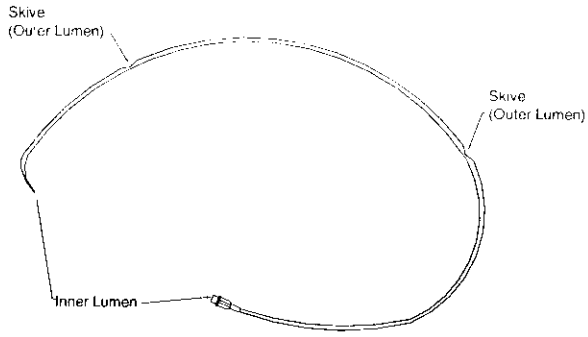

Figure 6. Dual Lumen Catheter Orientation

8. Pass a stiff guidewire through the proximal skive of the Dual Lumen Catheter, and into the thoracic aorta. Pass the Device Limb Wire through the central lumen of the Dual Lumen Catheter.
9. Retract the Dual Lumen Catheter from the contralateral sheath, while holding and separating the stiff guidewire and the Device Limb Wire (See Figure 7).

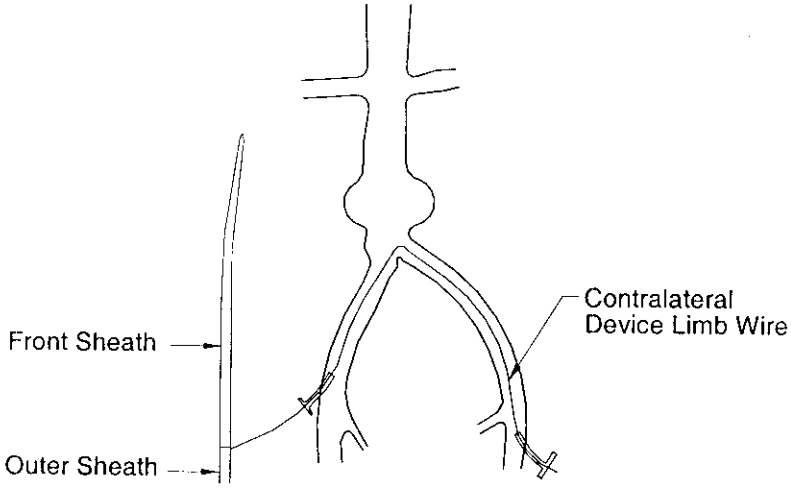

Figure 7. Device Limb Wire Placement (Guidewire not shown)

Note: To ensure successful passage of the delivery catheter, sequential dilators may be advanced through the common femoral artery and external iliac arteries if there is any question of vessel caliber. Pre-dilation with the appropriate sized balloon will also facilitate delivery catheter advancement. Pre-dilation "lifts" the aortic bifurcation and dilates any stenosis or calcium that is not identified by CT or arteriogram. If you are unsure of vessel diameter, select a balloon smaller than the vessel diameter for safety.

10. Load the delivery catheter onto the wire. While maintaining hemostatic control, retract the tear away introducer, snap the hemostatic valve and peel away the sheath.

    CAUTION: MAINTAIN GUIDEWIRE POSITION DURING DELIVERY SYSTEM INSERTION.

11. Advance the delivery system over the wire through the arteriotomy and up into the aorta under fluoroscopy. Position the distal end of the stent-graft limbs above the bifurcation and verify the visible four (4) dots, indicating the distal end of the contralateral limb sheath, are lateral. *Ensure that the side port of the Delivery Catheter maintains a medial orientation.*

12. Cephalic tube angulation should be considered when aligning the top of the Powerlink delivery catheter with the lowest renal artery. Generally, 10° to 15° should place the radiographic beam perpendicular to the anterior angulation of the abdominal aorta as it passes from suprarenal aortic segment to abdominal. This angulation will help reduce parallax and foreshortening, and aid in the visualization of the aortic neck length for more accurate placement.

    WARNING: CATHETER ADVANCEMENT SHOULD BE PERFORMED UNDER FLUOROSCOPIC GUIDANCE. DO NOT USE EXCESSIVE FORCE TO ADVANCE OR WITHDRAW THE CATHETER WHEN RESISTANCE IS ENCOUNTERED. VESSEL OR CATHETER DAMAGE MAY OCCUR. CARE SHOULD BE TAKEN IN AREAS OF STENOSIS, INTRAVASCULAR THROMBOSIS OR IN CALCIFIED AND/OR TORTUOUS VESSELS.

    CAUTION: *INACCURATE PLACEMENT, INADEQUATE FIXATION AND/OR INCOMPLETE SEALING OF THE POWERLINK SYSTEM STENT GRAFT WITHIN THE VESSEL MAY RESULT IN INCREASED RISK OF ENDOLEAK, MIGRATION OR INADVERTENT OCCLUSION OF THE RENAL OR INTERNAL ILIAC ARTERIES. RENAL ARTERY PATENCY MUST BE MAINTAINED TO PREVENT/REDUCE THE RISK OF RENAL FAILURE AND SUBSEQUENT COMPLICATIONS. INCORRECT DEPLOYMENT OR MIGRATION OF THE STENT GRAFT MAY REQUIRE SURGICAL INTERVENTION.*

    CAUTION: *IF OUTER SHEATH KINKS DURING INSERTION, DO NOT ATTEMPT DEPLOYMENT. REPLACE WITH A NEW POWERLINK SYSTEM.*

    CAUTION: *FAILURE TO CONSTANTLY MONITOR DEPLOYMENT OF THE STENT GRAFT MAY CAUSE TWISTING, KINKING OR ALIGNMENT PROBLEMS.*

    CAUTION: *TAKE CARE DURING MANIPULATION OF CATHETERS, WIRES AND SHEATHS WITHIN AN ANEURYSM. SIGNIFICANT DISTURBANCES MAY DISLODGE FRAGMENTS OF THROMBUS WHICH CAN CAUSE DISTAL EMBOLIZATION.*

13. Loosen the white hub of the connector and retract the outer sheath to separate the limbs. Re-advance the Outer Sheath into its original position over the compressed ipsilateral limb cover. If resistance is encountered, do not use excessive force, or damage may occur to the ipsilateral limb cover adversely affecting deployment. Just proceed to the next step.

14. To ensure proper stent-graft deployment, reduce tension and angulation in delivery catheter and to ensure proper placement in the aorta, remove your hands from delivery catheter to allow device to find the correct alignment. Begin deployment following this maneuver and maintain the angle of the delivery catheter to further reduce any tension.

15. Gently retract the Delivery Catheter, placing the radiopaque front stop at the most caudal renal artery. This will ensure the proximal end of the stent graft will not cover the renal artery. Simultaneously apply ***gentle*** traction on the Device Limb Wire to remove slack in the wire.

    CAUTION: *EXCESS TRACTION ON THE DEVICE LIMB WIRE COULD PREMATURELY DEPLOY THE CONTRALATERAL LIMB.*

16. While holding the red hub (Middle Core) stationary, advance the Pusher Rod deploying the main body of the stent. Leave one stent segment covered by the front sheath (See Figure 8).

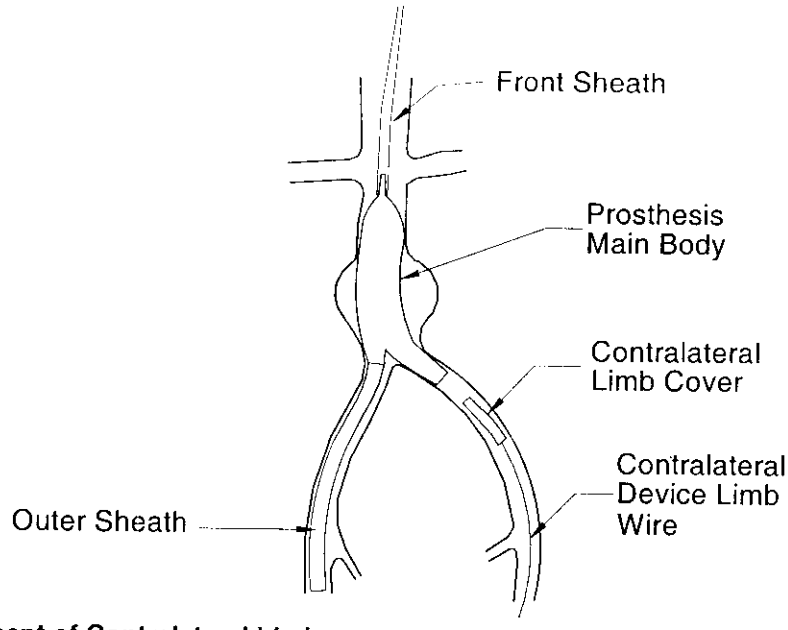

Figure 8. Deployment of Contralateral Limb

17. While holding the Delivery Catheter stationary, pull the Device Limb Wire deploying the contralateral limb. Remove the Device Limb Wire and cover (See Figure 8). While continuously monitoring the cephalad end of the graft, complete the deployment of the main body by advancing the Pusher Rod completely to the red hub. With the Pusher Rod fully advanced and stent-graft body fully deployed, loosen the white hub and maintain stent-graft position with slight upward pressure on the outer sheath. Pull back slowly on the middle core bringing the radiopaque front stop through the main body of the stent-graft. If the stent graft begins to move downward, apply more upward pressure on the outer sheath to maintain position. The front sheath radiopaque marker should be positioned on the distal one third of the radiopaque front stop (See Figure 9).

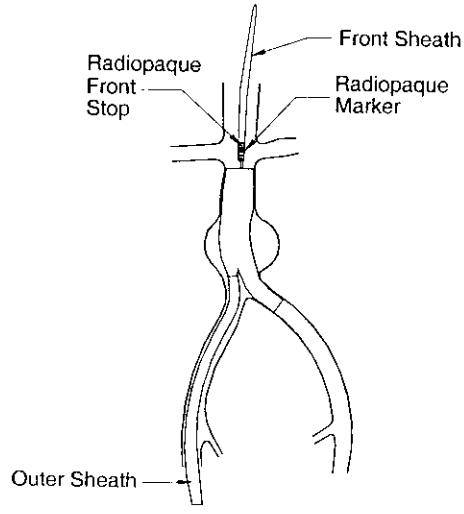

Figure 9. Deployment of Main Body of Stent Graft

18. Tighten the red hub fully and loosen the white hub. Retract the red hub (Middle Core) to deploy the ipsilateral limb within the outer sheath. The radiopaque front stop will move through the stent graft. If any resistance is felt, stop immediately and assess the source of resistance. Rotation of the catheter or manual manipulation of the abdomen may be used to withdraw a resistive front stop. Stop retracting the red hub when the front stop is slightly above the bifurcation.
19. Complete the deployment of the ipsilateral limb by retracting the white hub (Outer Sheath) while holding the red hub (Middle Core) steady (See Figure 10).

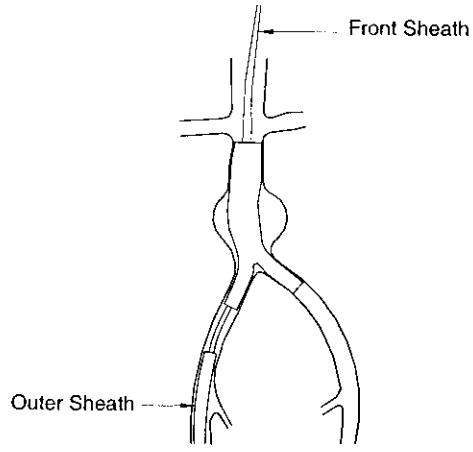

Figure 10. Deployment of Stent Graft Ipsilateral Limb

CAUTION: FLUOROSCOPIC VISUALIZATION DURING WITHDRAWAL OF THE POWERLINK DELIVERY CATHETER IS NECESSARY TO ENSURE THAT IT DOES NOT MOVE THE STENT GRAFT. ANY RESISTANCE DURING WITHDRAWAL MUST BE CAREFULLY MONITORED.

20. Continue to retract the red hub (Middle Core) until resistance is felt in order to position the radiopaque front stop within or in close proximity to the Outer Sheath. Remove Delivery Catheter while maintaining the guidewire in place. When removing the delivery catheter tighten the red and white hubs. Remove the delivery catheter by pulling on the red hub (middle core) and not the outer sheath. Pulling on the outer sheath for removal separates the outer sheath and front sheath. Subsequently the radiopaque front stop can damage the vessel during its removal.
21. Insert a hemostatic introducer sheath. Perform completion angiogram to detect the presence of endoleaks. If an endoleak is detected, balloon angioplasty with the appropriate sized balloon may be performed, or a Powerlink Proximal Cuff or Limb Extension may be deployed. Refer to the Powerlink System for AAA for the Proximal Cuff and Limb Extension Instructions For Use.

Table 11.5.1 Balloon Recommendation

Balloon Diameter (mm)	Balloon Length (cm)	Recommended Introducer (Fr)	Shaft size (Fr)	Rated Burst Pressure (atm)	Shaft Usable Length (cm)	Recommended Guidewire Diameter (in)
20.0	4.0	12	8.0	4.0	100	0.035
22.0	4.0	12	9.0	3.0	100	0.035
25.0	4.0	12	9.0	3.0	100	0.035

CAUTION: ***WHEN PLACING A PROXIMAL CUFF OR LIMB EXTENSION, THE PROXIMAL CUFF OR LIMB EXTENSION MUST OVERLAP THE STENT GRAFT BY 15 – 20 MM.***

WARNING: THE POWERLINK SYSTEM IS DESIGNED FOR SINGLE USE ONLY. DO NOT REUSE OR RESTERILIZE.

12.0 IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP

12.1 General

The long-term performance of endovascular grafts has not yet been established. All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the endovascular graft) should receive additional follow-up. Patients should be counseled on the importance of adhering to the follow-up schedule, both during the first year and at yearly intervals thereafter. Patient should be told that regular and consistent follow-up is a critical part of ensuring the ongoing safety and effectiveness of endovascular treatment of AAAs.

Physicians should evaluate patients on an individual basis and prescribe their follow-up relative to the needs and circumstances of each individual patient. The recommended imaging schedule is presented in Table 12.1.1. This schedule continues to be the minimum requirement for patient follow-up and should be maintained even in the absence of clinical symptoms (e.g., pain, numbness, weakness). Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the stent graft) should receive follow-up at more frequent intervals.

Annual imaging follow-up should include abdominal radiographs and both contrast and non-contrast CT examinations. If renal complications or other factors preclude the use of image contrast media, abdominal radiographs, non-contrast CT and duplex ultrasound may be used.

- The combination of contrast and non-contrast CT imaging provides information on aneurysm diameter change, endoleak, patency, tortuosity, progressive disease, fixation length and other morphological changes.
- The abdominal radiographs provide information on device integrity (separation between components and stent fracture).
- Duplex ultrasound imaging may provide information on aneurysm diameter change, endoleak, patency, tortuosity and progressive disease. In this circumstance, a non-contrast CT should be performed to use in conjunction with the ultrasound. Ultrasound may be a less reliable and sensitive diagnostic method compared to CT.

Table 12.1.1 lists the minimum requirements for imaging follow-up for patients with the Powerlink System Stent Graft. Patients requiring enhanced follow-up should have interim evaluations.

Table 12.1.1 Recommended Imaging Schedule for Endovascular Graft Patients

	Angiogram	CT [Contrast & Non-Contrast]	Abdominal Radiographs
Pre-procedure	X[1]	X[1]	
Procedural	X		
Pre-discharge (within 7-days) or 1 month		X[2,3]	X
3 month		X[2,3,4]	
6 month		X[2,3]	X
12 month (annually thereafter)		X[2,3]	X

[1]Imaging should be performed within 6-months before the procedure.
[2]Duplex ultrasound may be used for those patients experiencing renal failure or who are otherwise unable to undergo contrast enhanced CT scan. With ultrasound, non-contrast CT is still recommended.
[3]If Type I or III endoleak present, prompt intervention and additional follow-up post-intervention is recommended. See Section 12.6, Additional Surveillance and Treatment.
[4]Recommended if endoleak reported at pre-discharge or 1-month.

12.2 Contrast and Non-Contrast CT Recommendations

- Film sets should include all sequential images at lowest possible slice thickness (≤ 3 mm). Do NOT perform large slice thickness (> 3 mm) and/or omit consecutive CT images/film sets, 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 inch X 17 inch sheets if film is used.
- Both non-contrast and contrast runs are required, with matching or corresponding table positions.
- 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 imaging are important for optimal patient surveillance. It is important to follow acceptable imaging protocols during the CT exam. Table 12.2.1 lists examples of acceptable imaging protocols.

Table 12.2.1 Acceptable Imaging Protocols

	Non-Contrast	Contrast
IV contrast	No	Yes
Acceptable machines	Spiral capable of > 40 seconds	Spiral capable of > 40 seconds
Injection volume	n/a	150 cc
Injection rate	n/a	> 2.5 cc/sec
Injection mode	n/a	Power
Bolus timing	n/a	Test bolus: SmartPrep, C.A.R.E. or equivalent
Coverage – start	Diaphragm	1 cm superior to celiac axis
Coverage – finish	Proximal femur	Profunda femoris origin
Collimation	< 3 mm	< 3 mm
Reconstruction	2.5 mm throughout – soft algorithm	2.5 mm throughout – soft algorithm
Axial DFOV	32 cm	32 cm
Post-injection runs	None	None

12.3 Abdominal Radiographs

The following views are required:

- Four films: supine-frontal (AP), cross-table lateral, 30 degree LPO and 30 degree RPO views centered on umbilicus.
- Record the table-to-film distance and use the same distance at each subsequent examination.

Ensure entire device is captured on each single image format lengthwise.

If there is any concern about the device integrity (e.g., kinking, stent breaks, 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.

12.4 Ultrasound

Ultrasound imaging may be performed in place of contrast CT when patient factors preclude the use of image contrast media. Ultrasound may be paired with non-contrast CT. A complete aortic duplex is to be videotaped for maximum aneurysm diameter, endoleaks, stent patency and stenosis. Included on the videotape should be the following information as outlined below:

- Transverse and longitudinal imaging should be obtained from the level of the proximal aorta demonstrating mesenteric and renal arteries to the iliac bifurcations to determine if endoleaks are present utilizing color flow and color power angiography (if accessible).
- Spectral analysis confirmation should be performed for any suspected endoleaks.
- Transverse and longitudinal imaging of the maximum aneurysm should be obtained.

12.5 MRI Safety and Compatibility

- Through non-clinical testing, the Powerlink stent graft has been shown to be MRI safe at field strengths of 1.5 Tesla or less, a maximum spatial gradient of 450 gauss per centimeter, and a maximum whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 30 min of MR imaging. The stent should not migrate in this MR environment. In this testing, the stent graft produced a temperature rise of less than 0.3 °C at a maximum whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 30 minutes of MR imaging.
- Heating has not been determined for overlapping components or stent grafts with fractured struts. MR imaging quality may be comprised if the area of interest is in the exact same area or relatively close to the position of the stent graft. The Powerlink stent graft has not been evaluated to determine if it is safe in MRI systems with field strengths greater than 1.5 Tesla.
- The Powerlink System Stent Graft exhibited minimal image artifact as observed in non-clinical MRI testing at 1.5 Tesla.

12.6 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)
- Migration
- Inadequate seal length

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 that subsequent reintervention including catheter based and open surgical conversion are possible following endograft placement.

13.0 DEVICE TRACKING INFORMATION

Federal Law (U.S.) requires that all Abdominal Aortic Aneurysm Stent Grafts be tracked according to Title 21 Code of Federal Regulations (CFR) Part 821. That tracking includes a Patient Implant Card to be given to the patient upon release from the institution and a Device Tracking Form to be mailed or faxed back to the manufacturer (Endologix, Inc.).

According to the regulation, the Final Distributor, defined as the person or institution that owns the device, must report the information to the manufacturer. The doctor or hospital, is considered the final distributor, therefore, it is their responsibility to forward that information to the manufacturer. Please fill in as much information on the Device Tracking Form as possible and mail or fax it to Endologix, Inc. The fax number is (949) 830-4463. For more information on the institutions' requirements please refer to the FDA website www.fda.gov.

In addition to these Instructions for Use, the Powerlink System for AAA is packaged with a Device Tracking Form which the hospital staff is required to complete and forward to Endologix, Inc. for the purposes of tracking all patients who receive the Powerlink System Stent Graft (as required by U. S. Federal Regulation).

14.0 SYMBOLS LEGEND

SYMBOL	DESCRIPTION
	Product expiration date "Use product by expiration date"
	Lot number or work order number for the product.
	Contents sterile unless package has been opened or damaged. Sterilized by ethylene oxide.
	Attention - see instructions for use
	Device is intended for use one time only. Do not re-use or re-sterilize.

15.0 RETURN GOODS

In the event an unused device must be returned for any reason, please place the Powerlink System for AAA into its original package and shipping box. Contact Customer Service at 800-983-2284 to receive a return goods authorization number (RGA) and ship the device to the address provided by customer service.

Part Number C00156 Rev. A

Powerlink® System for Abdominal Aortic Aneurysm (AAA) (Proximal Cuff – Infrarenal)

INSTRUCTIONS FOR USE

IMPORTANT NOTES:

- Please read all instructions carefully that are contained within this packet before attempting to use any Endologix Powerlink System.
- *Caution: Federal Law (U.S.) restricts this device to sale by or on the order of a physician.*
- Endologix Powerlink System is provided sterile and for single use only. Therefore, carefully inspect the package before use. If the product is opened, damaged or the label is illegible do not use the device.

*US Patents: 6,077,296 6,090,128 6,156,063 6,187,036 6,197,049 6,210,422 6,261,316 6,331,190 6,660,030
Other U.S. and Foreign Patents Pending
Endologix, Inc.
13900 Alton Parkway, Suite #122, Irvine, CA 92618
(800) 983-2284

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1.0 PRODUCT DESCRIPTION

The Powerlink System Proximal Cuff for AAA consists of two components: proximal cuff stent graft and a delivery system.

The stent graft is a self-expanding cobalt chromium alloy stent constructed from a single wire and covered with a thin-walled, low porosity ePTFE graft. The material is attached to the stent only at the proximal and distal ends of the stent cage with surgical suture to minimize graft holes. The graft material is fully supported by the stent throughout its length. The Powerlink System Proximal Cuff is designed to be used in conjunction with the Powerlink System Bifurcated Infrarenal Stent Graft for AAA to accommodate specific patient anatomy or to repair endoleaks.

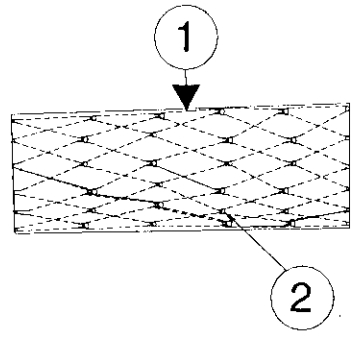

Figure 1. Proximal Cuff

1 Main Body
2 Stent Cage (internal)

The delivery system is designed to provide accurate positioning of the Powerlink System Proximal Cuff during delivery while requiring minimally invasive access to the body. The delivery system also allows for readjustment during the delivery of the stent graft. The device is pre-loaded into its delivery system and enclosed in a sterile package. The delivery system is a coaxial design with Pusher Rod and outer sheath constraining the self-expandable stent graft in a compressed state. As the outer sheath is retracted, the stent graft is pushed out and constraints removed, allowing the self-expanding stent graft to expand within the vessel under the precise control of the implanting physician.

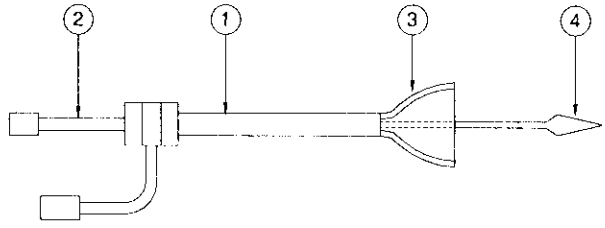

Figure 2. Powerlink Proximal Cuff Delivery System

1 Outer Sheath
2 Pusher Rod
3 Stent Graft
4 Radiopaque Tip

To facilitate fluoroscopic visualization of the stent graft, the entire cobalt chromium alloy stent is radiopaque.

The Proximal Cuff delivery system is 19 Fr and is not delivered through a vascular introducer sheath in order to minimize the size of the incision needed in the femoral artery during introduction. The delivery system is compatible with a .035 inch guidewire

2.0 INDICATIONS FOR USE

The Powerlink System bifurcated models, proximal cuff and limb extension accessories are indicated for endovascular use in patients with AAA. The proximal cuff is used to treat intraoperative or late proximal Type I endoleaks or to extend the length of the main body of a bifurcated device to fit specific patient anatomy. It is indicated for patients with suitable aneurysm morphology for endovascular repair, including:

Adequate iliac/femoral access compatible with the required delivery systems (a diameter of ≥ 7 mm)

Non-aneurysmal aortic neck between the renal arteries and the aneurysm:

with a diameter of ≥ 18 mm and ≤ 26 mm

with a neck angle of ≤ 60° to the body of the aneurysm.

Ability to overlap the bifurcated stent graft by 15 to 20 mm.

3.0 CONTRAINDICATIONS

There are no known contraindications for these devices.

4.0 WARNINGS AND PRECAUTIONS

4.1 General

- Read all instructions carefully. Failure to properly follow the instructions, warnings and precautions may lead to serious consequences or injury to the patient.
- The Powerlink System for AAA should only be used by physicians and teams trained in vascular interventional techniques and in the use of this device. Specific training expectations are described in *Section 10.1, Physician Training Program.*
- The long-term performance of endovascular grafts has not yet been established. All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and the performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the endovascular graft) should receive enhanced follow-up. Specific follow-up guidelines are described in *Section 12.0, Imaging Guidelines and Post-Operative Follow-up.*
- After endovascular graft placement, patients should be regularly monitored for perigraft flow, aneurysm growth or changes in the structure or position of the endovascular graft. At a minimum, annual imaging is required, including: 1) abdominal radiographs to examine device integrity (stent fracture, separation between bifurcated device and proximal cuffs or limb extensions, if applicable), and 2) contrast and non-contrast CT to examine aneurysm changes, perigraft flow, patency, tortuosity and progressive disease. If renal complications or other factors preclude the use of image contrast media, abdominal radiographs and duplex ultrasound may provide similar information.
- The Powerlink System for AAA is not recommended in patients unable to undergo, or who will not be compliant with the necessary preoperative and post-operative imaging and implantation studies as described in *Section 12.0, Imaging Guidelines and Post-Operative Follow-Up.*
- Additional endovascular intervention or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aneurysms, unacceptable decrease in fixation length (vessel and component overlap) and/or endoleak. An increase in aneurysm size and/or persistent endoleak may lead to aneurysm rupture.

- Patients experiencing reduced blood flow through the graft limb and/or endoleaks may be required to undergo secondary interventions or surgical procedures.
- Always have a vascular surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

4.2 Implant Procedure

- The Powerlink System is designed for single use only. Do not reuse or resterilize..
- 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 stent graft during preparation and insertion to decrease the risk of stent graft contamination and infection.
- Maintain guidewire position during delivery system insertion.
- Do not bend or kink the delivery system. Doing so may cause damage to the delivery system and the Powerlink System Stent Graft.
- If outer sheath kinks during insertion, do not attempt deployment. Replace with a new Powerlink System.
- Failure to constantly monitor deployment of the stent graft may cause kinking or alignment problems.
- The use of the Powerlink System for AAA requires administration of intravascular contrast. Patients with pre-existing renal insufficiency may have an increased risk of renal failure post-operatively. Care should be taken to limit the amount of contrast media used during the procedure.
- Inaccurate placement, inadequate fixation and/or incomplete sealing of the Powerlink System Stent Graft within the vessel may result in increased risk of endoleak, migration or inadvertent occlusion of the renal arteries. Renal artery patency must be maintained to prevent/reduce the risk of renal failure and subsequent complications. Incorrect deployment or migration of the stent graft may require surgical intervention.
- Catheter advancement should be performed under fluoroscopic guidance. Do not use excessive force to advance or withdraw the catheter when resistance is encountered. Care should be taken in areas of stenosis, intravascular thrombosis or in calcified and/or tortuous vessels.
- Fluoroscopic visualization during withdrawal of the Powerlink Delivery Catheter is necessary to ensure that it does not move the stent graft. Any resistance during withdrawal must be carefully monitored.
- Care should be taken not to damage the graft or disturb graft positioning after graft placement in the event re-instrumentation of the graft is necessary.
- Unless medically indicated, do not deploy the Powerlink System Stent Graft in a location that will occlude arteries necessary to supply blood flow to organs or extremities. Do not cover significant renal or mesenteric arteries (exception is the inferior mesenteric artery) with the stent graft. Vessel occlusion may occur. During the clinical study, this device was not studied in patients with two occluded internal iliac arteries.

4.3 MRI (Magnetic Resonance Imaging) Safety and Compatibility

- Through non-clinical testing, the Powerlink Stent Graft has been shown to be MRI safe at field strengths of 1.5 Tesla or less, a maximum spatial gradient of 450 gauss per centimeter, and a maximum whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 30 min of MR imaging. The stent should not migrate in this MR environment. In this testing, the stent graft produced a temperature rise of less than 0.3 °C at a maximum whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 30 minutes of MR imaging.

- Heating has not been determined for overlapping components or stent grafts with fractured struts. MR imaging quality may be comprised if the area of interest is in the exact same area or relatively close to the position of the stent graft. The Powerlink stent graft has not been evaluated to determine if it is safe in MRI systems with field strengths greater than 1.5 Tesla.
- The Powerlink System Stent Graft exhibited minimal image artifact as observed in non-clinical MRI testing at 1.5 Tesla.

5.0 ADVERSE EVENTS

5.1 Observed Adverse Events

A U.S. multicenter, prospective study conducted at 15 centers, which included 192 test patients and 66 control patients, provides the basis of the observed adverse events rates presented in Tables 5.1.1 and 5.1.2. The control group included patients whose vascular anatomy may not have been suitable for endovascular AAA repair.

For details, refer to the Instructions For Use for the Powerlink System Bifurcated Infrarenal.

5.2 Potential Adverse Events

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

- Amputation
- Anesthetic complications and subsequent attendant problems (e.g., aspiration)
- Aneurysm enlargement
- Aneurysm rupture and death
- Aortic damage, including perforation, dissection, bleeding, rupture and death
- Arterial or venous thrombosis and/or pseudoaneurysm
- Arteriovenous fistula
- Bleeding, hematoma or coagulopathy
- Bowel complications (e.g., ileus, transient ischemia, infarction, necrosis)
- Cardiac complications and subsequent attendant problems (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension, hypertension)
- Claudication (e.g., buttock, lower limb)
- Death
- Edema
- Embolization (micro and macro) with transient or permanent ischemia or infarction
- Endoleak
- Stent graft: improper component placement; incomplete component deployment; component migration; suture break; occlusion; infection; stent fracture; graft material wear; dilatation; erosion; puncture and perigraft flow
- Fever and localized inflammation
- Genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection)
- Hepatic failure
- Impotence
- Infection of the aneurysm, device access site, including abscess formation, transient fever and pain.
- Lymphatic complications and subsequent attendant problems (e.g., lymph fistula)
- Neurologic local or systemic complications and subsequent attendant problems (e.g., stroke, transient ischemic attack, paraplegia, paraparesis, paralysis)
- Occlusion of device or native vessel.

- Pulmonary/respiratory complications and subsequent attendant problems (e.g., pneumonia, respiratory failure, prolonged intubation)
- Renal complications and subsequent attendant problems (e.g., artery occlusion, contrast toxicity, insufficiency, failure)
- Surgical conversion to open repair
- Vascular access site complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula
- Vessel damage
- Wound complications and subsequent attendant problems (e.g., dehiscence, infection)
- Vascular spasm or vascular trauma (e.g., iliofemoral vessel dissection, bleeding, rupture, death)

5.3 Device Related Adverse Event Reporting

Any adverse event (clinical incident) involving the Powerlink System Stent Graft should be reported to Endologix, Inc. immediately. To report an incident, call the Customer Service Department at 800-983-2284 (24 hours message service).

6.0 SUMMARY OF CLINICAL STUDIES

Refer to the Instructions For Use for the Powerlink System Bifurcated Infrarenal.

7.0 PATIENT SELECTION AND TREATMENT

Refer to the Instructions For Use for the Powerlink System Bifurcated Infrarenal.

7.1 Individualization of Treatment

Endologix recommends that the Powerlink Proximal Cuff diameters be selected as described in Table 10.4.1. The length of the Powerlink Proximal Cuff should extend from the lowest renal artery to 15 to 20 mm of overlap inside the chosen bifurcated model. 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 should be carefully considered for each patient before use of the Powerlink System for AAA (refer to *Section 6.0 Summary of Clinical Studies* in the Instructions For Use for the Powerlink System Bifurcated Infrarenal)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 Powerlink System for AAA.
- Ability to tolerate general, regional or local anesthesia
- Iliofemoral access vessel size and morphology (minimal thrombus, calcium and/or tortuosity) should be compatible with vascular access techniques of the 19 Fr delivery catheter profile. The Powerlink System for AAA is not delivered through a vascular introducer sheath.
- Adequate iliac/femoral access compatible with the required delivery systems (a diameter of $\geq$ 7 mm).
- Non-aneurysmal aortic neck between the renal arteries and the aneurysm:

with length of ≥ 15 mm

with a diameter of ≥ 18 mm and ≤ 26 mm

with a neck angle of ≤ 60° to the body of the aneurysm.

- Ability to overlap the bifurcated stent graft by 15 to 20 mm.
- Freedom from significant femoral/iliac artery occlusive disease that would impede flow through the vascular graft.

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

8.0 PATIENT COUNSELING INFORMATION

The physician and patient (and/or family members) should review the risks and benefits when discussing this endovascular device and procedure including:

- Risks and differences between endovascular repair and 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 performance of endovascular grafts has not yet been established. All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and the performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the endovascular graft) should receive enhanced follow-up. Specific follow-up guidelines are described in *Section 12, Imaging Guidelines and Post-Operative Follow-Up.*
- Patients should be counseled on the importance of adhering to the follow-up schedule, both during the first year and at yearly intervals thereafter. Patients should be told that regular and consistent follow-up is a critical part of ensuring the ongoing safety and effectiveness of endovascular treatment of AAAs. At a minimum, annual imaging and adherence to routine post-operative follow-up requirements is required and should be considered a life-long commitment to the patient's health and well-being.
- 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 at rest or discoloration or coolness of the leg. Aneurysm rupture may be asymptomatic, but usually presents as: pain; numbness; weakness in the legs; 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, neurological, bowel and bleeding complications. Device related risks include occlusion, endoleak, aneurysm enlargement, fracture, potential for reintervention and open surgical conversion, rupture and death (See *Sections 5.1* and *5.2, Observed Adverse Events* and *Potential Adverse Events*). The physician should complete the *Patient Implant 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 card anytime they visit additional health practitioners, particularly for any additional diagnostic procedures (e.g., MRI).

9.0 HOW SUPPLIED

- The Powerlink System for AAA is supplied sterile and enclosed in two peel-open packages, one sealed inside the other.
- The device is intended for single use only. Do not re-sterilize the device.

- Inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use this device if damage has occurred or if the sterilization barrier has been damaged or broken. If damage has occurred, do not use the product and return to Endologix, Inc.
- Prior to use, verify correct devices (quantity and size) have been supplied for the patient by matching the device to the order prescribed by the physician for that particular patient.
- Do not use after the "USE BY" (EXPIRATION) date printed on the label.
- Store in a cool, dry place.
- The device packaging includes a label with peel-away stickers containing the model number and lot number. These stickers are intended to be used with the enclosed Patient Implant Card and Device Tracking Form. Please refer to Section 13.0 for information regarding the Patient Implant Card and Device Tracking Form.

Table 9.1 Proximal Cuffs

Model No.	Cuff Diameter (mm)	Cuff Length (mm)	Delivery System Fr (no introducer needed)
25-25-55L	25	55	19
25-25-75L	25	75	19
28-28-55L	28	55	19
28-28-75L	28	75	19

10.0 CLINICAL USE INFORMATION

10.1 Physician Training Program

CAUTION: Always have a vascular surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

CAUTION: The Powerlink System for AAA should only be used by physicians and teams trained in vascular interventional techniques and in the use of this device. The recommended skill/knowledge requirements for physicians using the Powerlink system for AAA 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 cut-down, 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
- Appropriate use of radiographic contrast material
- Techniques to minimize radiation exposure
- Expertise in necessary patient follow-up modalities

10.2 Inspection Prior to Use

Inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use this device if damage has occurred or if the sterilization barrier has

been damaged or broken. If damage has occurred, return device to Endologix, Inc. Prior to use, verify correct devices (quantity and size) have been supplied for the patient by matching the device to the order prescribed by the physician for that particular patient.

10.3 Materials Required

1. Powerlink Proximal Cuffs or Limb Extensions of various lengths and diameters may be required in order to properly fit the implant to the anatomy of the patient or to repair any endoleaks.
2. Fluoroscopic imaging and the ability to record all imaging.
3. Assorted .035" stiff and standard guidewires of adequate length (e.g., EV3 Nitrex guidewire, 180 cm).
4. Power injector for fluoroscopic dye studies.
5. Radiopaque (ruler) in millimeter increments is recommended.
6. Heparinized solution and sterile saline solution.
7. Assorted catheters for passage through tortuous vessels, including angioplasty catheters to dilate stenotic vessels prior to passage of the delivery catheter.
8. 12.5 Fr tear-away introducer sheath (for management of wires prior to introduction of the delivery system)
9. Radiopaque contrast media

10.4 Device Diameter Sizing Guidelines

Under sizing or over sizing may result in incomplete sealing or compromised flow.

Table 10.4.1 Proximal Cuff Sizing

Intended Aortic Vessel Diameter	Cuff Diameter	Cuff Length	Delivery Cath
18-23mm	25 mm	75 mm	19 Fr
18-23mm	25 mm	55 mm	19 Fr
20-26mm	28 mm	75 mm	19 Fr
20-26mm	28 mm	55 mm	19 Fr

11.0 DIRECTIONS FOR USE

Prior to use of the Endologix Powerlink System for AAA, review this *Instructions for Use* booklet. The following instructions embody a basic guideline for device placement. Variations in the following procedures may be necessary. These instructions are intended to help guide the physician and do not take the place of physician judgment.

11.1 General Use Information

Standard techniques for placement of arterial access sheathes, guiding catheters, angiographic catheters and guidewires should be employed during use of the Powerlink System for AAA. The Powerlink System for AAA is compatible with a .035 inch diameter guidewire.

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.

11.2 Pre-Implant Determinants

Verify from pre-implant planning that the correct device has been selected. Determinants include:

1. The Powerlink System may be introduced via either iliac artery. Common femoral artery access and aneurysm sac orientation are other considerations.

2. Angulation of aortic neck, aneurysm and iliac arteries.
3. Quality of the aortic neck.
4. Diameters of infrarenal aortic neck.
5. Distance from renal arteries to proximal end of bifurcated device with ability to overlap by 15 to 20 mm.
6. Pre-dilation of the iliac arteries may ease deployment procedure.

WARNING: THE USE OF THE POWERLINK SYSTEM FOR AAA REQUIRES ADMINISTRATION OF INTRAVASCULAR CONTRAST. PATIENTS WITH PRE-EXISTING RENAL INSUFFICIENCY MAY HAVE AN INCREASED RISK OF RENAL FAILURE POST-OPERATIVELY. CARE SHOULD BE TAKEN TO LIMIT THE AMOUNT OF CONTRAST MEDIA USED DURING THE PROCEDURE.

WARNING: UNLESS MEDICALLY INDICATED, DO NOT DEPLOY THE POWERLINK SYSTEM STENT GRAFT IN A LOCATION THAT WILL OCCLUDE ARTERIES NECESSARY TO SUPPLY BLOOD FLOW TO ORGANS OR EXTREMITIES. DO NOT COVER SIGNIFICANT RENAL OR MESENTERIC ARTERIES (EXCEPTION IS THE INFERIOR MESENTERIC ARTERY) WITH THE STENT GRAFT. VESSEL OCCLUSION MAY OCCUR. DURING THE CLINICAL STUDY, THIS DEVICE WAS NOT STUDIED IN PATIENTS WITH TWO OCCLUDED INTERNAL ILIAC ARTERIES.

11.3 Patient Preparation

1. Refer to institutional protocols relating to anesthesia, anticoagulation and monitoring of vital signs.
2. Position patient on imaging table allowing fluoroscopic visualization from the aortic arch to the femoral bifurcations.
3. Expose the common femoral artery on the chosen access side using standard surgical technique.
4. Establish adequate proximal and distal vascular control of the surgically exposed femoral artery.

11.4 Device Preparation

WARNING: THE POWERLINK SYSTEM IS DESIGNED FOR SINGLE USE ONLY. DO NOT REUSE OR RESTERILIZE.

CAUTION: MINIMIZE HANDLING OF THE CONSTRAINED STENT GRAFT DURING PREPARATION AND INSERTION TO DECREASE THE RISK OF STENT GRAFT CONTAMINATION AND INFECTION.

CAUTION: DO NOT BEND OR KINK THE DELIVERY SYSTEM. DOING SO MAY CAUSE DAMAGE TO THE DELIVERY SYSTEM AND THE POWERLINK SYSTEM STENT GRAFT.

1. Tighten white connector by turning the hub clock-wise.
2. Flush lumen and side port of the delivery system with sterile saline solution.

11.5 Procedure

1. If part of a secondary procedure, perform the cut-down of the access vessel using standard surgical techniques.
2. If applicable, place vessel loops distal and proximal to the cut-down site for hemostatic control.

3. Insert a .035 inch stiff "J-tip" guidewire into the vasculature through the stent graft utilizing fluoroscopic guidance. Maintain the position of the guidewire across the implant site until the procedure is completed. Be aware of the possibility of the guidewire tangling with the stent cage of existing stent graft if caution is not properly used.
4. Angiography and road mapping should now be completed and recorded. Mark the lowest renal artery orifices and fix the C-arm. This will allow the stent graft to be accurately deployed.
5. Confirm length and diameter of required Powerlink stent graft. Endologix suggests that the stent graft diameter be at least 2 mm larger than the normal aortic inner diameter (e.g., 25 mm diameter stent graft should not be deployed in a normal aortic inner diameter > 23 mm). The length of the Powerlink Proximal Cuff should extend from the lowest renal artery to 15 to 20 mm of overlap inside the chosen bifurcated model.

CAUTION: MAINTAIN GUIDEWIRE POSITION DURING DELIVERY SYSTEM INSERTION.

6. Advance the Powerlink delivery catheter over the guidewire just above the caudal renal artery orifice.

WARNING: INACCURATE PLACEMENT, INADEQUATE FIXATION AND/OR INCOMPLETE SEALING OF THE POWERLINK SYSTEM STENT GRAFT WITHIN THE VESSEL MAY RESULT IN INCREASED RISK OF ENDOLEAK, MIGRATION OR INADVERTENT OCCLUSION OF THE RENAL ARTERIES. RENAL ARTERY PATENCY MUST BE MAINTAINED TO PREVENT/REDUCE THE RISK OF RENAL FAILURE AND SUBSEQUENT COMPLICATIONS. INCORRECT DEPLOYMENT OR MIGRATION OF THE STENT GRAFT MAY REQUIRE SURGICAL INTERVENTION.

WARNING: CATHETER ADVANCEMENT SHOULD BE PERFORMED UNDER FLUOROSCOPIC GUIDANCE. DO NOT USE EXCESSIVE FORCE TO ADVANCE OR WITHDRAW THE CATHETER WHEN RESISTANCE IS ENCOUNTERED. CARE SHOULD BE TAKEN IN AREAS OF STENOSIS, INTRAVASCULAR THROMBOSIS OR IN CALCIFIED AND/OR TORTUOUS VESSELS.

CAUTION: IF OUTER SHEATH KINKS DURING INSERTION, DO NOT ATTEMPT DEPLOYMENT. REPLACE WITH A NEW POWERLINK SYSTEM.

7. While holding the Pusher Rod of the delivery system stationary, gently retract the Outer Sheath. This action will deploy the stent graft. Deploy the first 1 – 2 cm of the stent graft, then gently retract the device and fix the stent graft at the appropriate implant site. Once fixed into place, fully deploy the rest of the stent graft. (Refer to Figure 3).

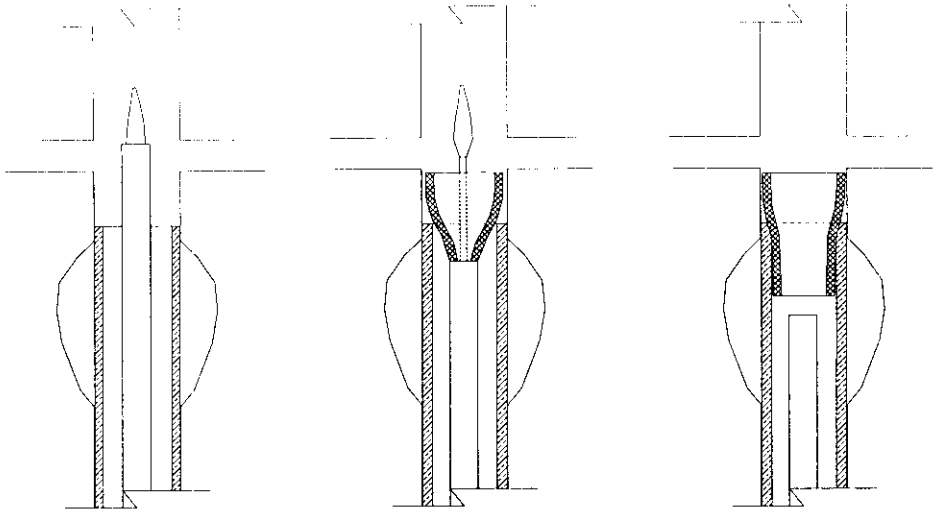

Figure 3
Infrarenal Proximal Cuff Deployment

CAUTION: FAILURE TO CONSTANTLY MONITOR DEPLOYMENT OF THE STENT GRAFT MAY CAUSE KINKING OR ALIGNMENT PROBLEMS.

8. If the stent graft is kinked or did not expand completely, perform balloon dilation or surgically remove.

CAUTION: TAKE CARE DURING MANIPULATION OF CATHETERS, WIRES AND SHEATHS WITHIN AN ANEURYSM. SIGNIFICANT DISTURBANCES MAY DISLODGE FRAGMENTS OF THROMBUS WHICH CAN CAUSE DISTAL EMBOLIZATION.

9. Perform an angiogram to detect the presence of any endoleaks. If an endoleak is detected, balloon angioplasty with appropriate size balloon or a Powerlink Proximal Cuff may be deployed. A proximal cuff can also be deployed to extend the length or properly anchor the stent graft.

Table 11.5.1 Balloon Recommendation

Balloon Diameter (mm)	Balloon Length (cm)	Recommended Introducer (Fr)	Shaft Size (Fr)	Rated Burst Pressure (atm)	Shaft Usable Length (atm)	Recommended Guidewire Diameter (in)
20.0	4.0	12	8.0	4.0	100	0.035
22.0	4.0	12	9.0	3.0	100	0.035
25.0	4.0	12	9.0	3.0	100	0.035

10. After complete deployment, the Pusher Rod of the catheter should be fully retracted and removed.

CAUTION: FLUOROSCOPIC VISUALIZATION DURING WITHDRAWAL OF THE POWERLINK DELIVERY CATHETER IS NECESSARY TO ENSURE THAT IT DOES NOT MOVE THE STENT GRAFT. ANY RESISTANCE DURING WITHDRAWAL MUST BE CAREFULLY MONITORED.

12.0 IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP

12.1 General

The long-term performance of endovascular grafts has not yet been established. All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the endovascular graft) should receive additional follow-up. Patients should be counseled on the importance of adhering to the follow-up schedule, both during the first year and at yearly intervals thereafter. Patient should be told that regular and consistent follow-up is a critical part of ensuring the ongoing safety and effectiveness of endovascular treatment of AAAs.

Physicians should evaluate patients on an individual basis and prescribe their follow-up relative to the needs and circumstances of each individual patient. The recommended imaging schedule is presented in Table 12.1.1. This schedule continues to be the minimum requirement for patient follow-up and should be maintained even in the absence of clinical symptoms (e.g., pain, numbness, weakness). Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the stent graft) should receive follow-up at more frequent intervals.

Annual imaging follow-up should include abdominal radiographs and both contrast and non-contrast CT examinations. If renal complications or other factors preclude the use of image contrast media, abdominal radiographs, non-contrast CT and duplex ultrasound may be used.

- The combination of contrast and non-contrast CT imaging provides information on aneurysm diameter change, endoleak, patency, tortuosity, progressive disease, fixation length and other morphological changes.
- The abdominal radiographs provide information on device integrity (separation between components and stent fracture).
- Duplex ultrasound imaging may provide information on aneurysm diameter change, endoleak, patency, tortuosity and progressive disease. In this circumstance, a non-contrast CT should be performed to use in conjunction with the ultrasound. Ultrasound may be a less reliable and sensitive diagnostic method compared to CT.

Table 12.1.1 lists the minimum requirements for imaging follow-up for patients with the Powerlink System Stent Graft. Patients requiring enhanced follow-up should have interim evaluations.

Table 12.1.1 Recommended Imaging Schedule for Endovascular Graft Patients

	Angiogram	CT [Contrast & Non-Contrast]	Abdominal Radiographs
Pre-procedure	X[1]	X[1]	
Procedural	X		
Pre-discharge (within 7-days) or 1 month		X[2,3]	X
3 month		X[2,3,4]	
6 month		X[2,3]	X
12 month (annually thereafter)		X[2,3]	X

[1]Imaging should be performed within 6-months before the procedure.
[2]Duplex ultrasound may be used for those patients experiencing renal failure or who are otherwise unable to undergo contrast enhanced CT scan. With ultrasound, non-contrast CT is still recommended.
[3]If Type I or III endoleak present, prompt intervention and additional follow-up post-intervention is recommended. See Section 12.6, Additional Surveillance and Treatment.
[4]Recommended if endoleak reported at pre-discharge or 1-month.

12.2 Contrast and Non-Contrast CT Recommendations

- Film sets should include all sequential images at lowest possible slice thickness (≤ 3 mm). DO NOT perform large slice thickness (> 3 mm) and/or omit consecutive CT images/film sets, 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 inch X 17 inch sheets if film is used.
- Both non-contrast and contrast runs are required, with matching or corresponding table positions.
- 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 imaging are important for optimal patient surveillance. It is important to follow acceptable imaging protocols during the CT exam. Table 12.2.1 lists examples of acceptable imaging protocols.

Table 12.2.1 Acceptable Imaging Protocols

	Non-Contrast	Contrast
IV contrast	No	Yes
Acceptable machines	Spiral capable of > 40 seconds	Spiral capable of > 40 seconds
Injection volume	n/a	150 cc
Injection rate	n/a	> 2.5 cc/sec
Injection mode	n/a	Power
Bolus timing	n/a	Test bolus: SmartPrep, C.A.R.E. or equivalent
Coverage – start	Diaphragm	1 cm superior to celiac axis
Coverage – finish	Proximal femur	Profunda femoris origin
Collimation	< 3 mm	< 3 mm
Reconstruction	2.5 mm throughout – soft algorithm	2.5 mm throughout – soft algorithm
Axial DFOV	32 cm	32 cm
Post-injection runs	None	None

12.3 Abdominal Radiographs

The following views are required:

- Four films: supine-frontal (AP), cross-table lateral, 30 degree LPO and 30 degree RPO views centered on umbilicus.
- Record the table-to-film distance and use the same distance at each subsequent examination.

Ensure entire device is captured on each single image format lengthwise.

If there is any concern about the device integrity (e.g., kinking, stent breaks, 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.

12.4 Ultrasound

Ultrasound imaging may be performed in place of contrast CT when patient factors preclude the use of image contrast media. Ultrasound may be paired with non-contrast CT. A complete aortic duplex is to be videotaped for maximum aneurysm diameter, endoleaks, stent patency and stenosis. Included on the videotape should be the following information as outlined below:

- Transverse and longitudinal imaging should be obtained from the level of the proximal aorta demonstrating mesenteric and renal arteries to the iliac bifurcations to determine if endoleaks are present utilizing color flow and color power angiography (if accessible).
- Spectral analysis confirmation should be performed for any suspected endoleaks.
- Transverse and longitudinal imaging of the maximum aneurysm should be obtained.

12.5 MRI Safety and Compatibility

1. Through non-clinical testing, the Powerlink stent graft has been shown to be MRI safe at field strengths of 1.5 Tesla or less, a maximum spatial gradient of 450 gauss per centimeter, and a maximum whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 30 min of MR imaging. The stent should not migrate in this MR environment. In this testing, the stent graft produced a temperature rise of less than 0.3 °C at a maximum whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 30 minutes of MR imaging.
2. Heating has not been determined for overlapping components or stent grafts with fractured struts. MR imaging quality may be comprised if the area of interest is in the exact same area or relatively close to the position of the stent graft. The Powerlink stent graft has not been evaluated to determine if it is safe in MRI systems with field strengths greater than 1.5 Tesla.
3. The Powerlink System Stent Graft exhibited minimal image artifact as observed in non-clinical MRI testing at 1.5 Tesla.

12.6 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)
- Migration
- Inadequate seal length

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 that subsequent reintervention including catheter based and open surgical conversion are possible following endograft placement.

13.0 DEVICE TRACKING INFORMATION

Federal Law (U.S.) requires that all Abdominal Aortic Aneurysm Stent Grafts be tracked according to Title 21 Code of Federal Regulations (CFR) Part 821. That tracking includes a Patient Implant Card to be given to the patient upon release from the institution and a Device Tracking Form to be mailed or faxed back to the manufacturer (Endologix, Inc.).

According to the regulation, the Final Distributor, defined as the person or institution that owns the device, must report the information to the manufacturer. The doctor or hospital, is considered the final distributor, therefore, it is their responsibility to forward that information to the manufacturer. Please fill in as much information on the Device Tracking Form as possible and mail or fax it to

Endologix, Inc. The fax number is (949) 830-4463. For more information on the institutions' requirements please refer to the FDA website www.fda.gov.

In addition to these Instructions for Use, the Powerlink System for AAA is packaged with a Device Tracking Form which the hospital staff is required to complete and forward to Endologix, Inc. for the purposes of tracking all patients who receive the Powerlink System Stent Graft (as required by U. S. Federal Regulation).

14.0 SYMBOLS LEGEND

SYMBOL	DESCRIPTION
	Product expiration date "Use product by expiration date"
LOT	Lot number or work order number for the product.
STERILE EO	Contents sterile unless package has been opened or damaged. Sterilized by ethylene oxide.
	Attention - see instructions for use
	Device is intended for use one time only. Do not re-use or re-sterilize.

15.0 RETURN GOODS

In the event an unused device must be returned for any reason, please place the Powerlink System for AAA into its original package and shipping box. Contact Customer Service at 800-983-2284 to receive a return goods authorization number (RGA) and ship the device to the address provided by customer service.

Part Number C00157 Rev. A

Powerlink® System for Abdominal Aortic Aneurysm (AAA) (Limb Extension)

INSTRUCTIONS FOR USE

IMPORTANT NOTES:

- **Please read all instructions carefully that are contained within this packet before attempting to use any Endologix Powerlink System.**
- ***Caution:* Federal Law (U.S.) restricts this device to sale by or on the order of a physician.**
- **Endologix Powerlink System is provided sterile and for single use only. Therefore, carefully inspect the package before use. If the product is opened, damaged or the label is illegible do not use the device.**

*US Patents: 6,077,296 6,090,128 6,156,063 6,187,036 6,197,049 6,210,422 6,261,316 6,331,190 6,660,030
Other U.S. and Foreign Patents Pending
Endologix, Inc.
13900 Alton Parkway, Suite #122, Irvine, CA 92618
(800) 983-2284

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1.0 PRODUCT DESCRIPTION

The Powerlink System Limb Extension for AAA consists of two components: a limb extension stent graft and a delivery system.

The stent graft is a self-expanding cobalt chromium alloy stent constructed from a single wire and covered with a thin-walled, low porosity ePTFE graft. The material is attached to the stent only at the proximal and distal ends of the stent cage with surgical suture to minimize graft holes. The graft material is fully supported by the stent throughout its length. The Powerlink System Limb Extension is designed to be used in conjunction with the Powerlink System Bifurcated Infrarenal Stent Graft for AAA to accommodate specific patient anatomy or to repair endoleaks.

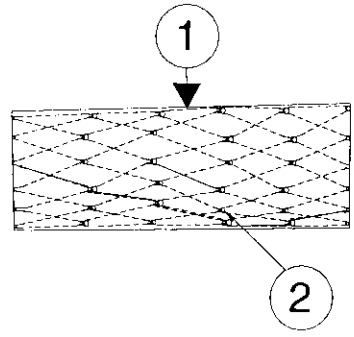

Figure 1. Limb Extension

1 Main Body
2 Stent Cage (internal)

The delivery system is designed to provide accurate positioning of the Powerlink System Limb Extension during delivery while requiring minimally invasive access to the body. The delivery system also allows for readjustment during the delivery of the stent graft. The device is pre-loaded into its delivery system and enclosed in a sterile package. The delivery system is a coaxial design with Pusher Rod and outer sheath constraining the self-expandable stent graft in a compressed state. As the outer sheath is retracted, the stent graft is pushed out and constraints removed, allowing the self-expanding stent graft to expand within the vessel under the precise control of the implanting physician.

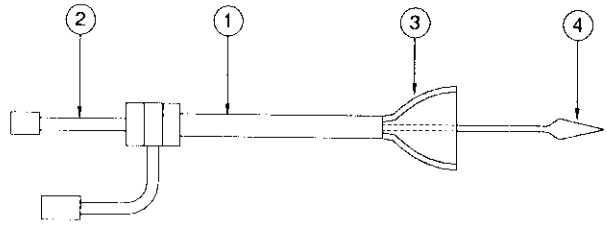

Figure 2. Powerlink Limb Extension Delivery System

1 Outer Sheath
2 Pusher Rod
3 Stent Graft
4 Radiopaque Tip

To facilitate fluoroscopic visualization of the stent graft, the entire cobalt chromium alloy stent is radiopaque.

The Limb Extension delivery system is 17 Fr and is not delivered through a vascular introducer sheath in order to minimize the size of the incision needed in the femoral artery during introduction. The delivery system is compatible with a .035 inch guidewire

2.0 INDICATIONS FOR USE

The Powerlink System bifurcated models, proximal cuff and limb extension accessories are indicated for endovascular use in patients with AAA. The Limb Extension is used to treat intraoperative or late distal Type I endoleaks or to extend the length of the limbs of a bifurcated device to fit specific patient anatomy. It is indicated for patients with suitable aneurysm morphology for endovascular repair, including:

Adequate iliac/femoral access compatible with the required delivery systems (a diameter of ≥ 7 mm)

Common iliac artery distal fixation site:

with ability to preserve at least one hypogastric artery

with a diameter of ≥ 10 mm and ≤ 18 mm

with an iliac angle of ≤ 90° to the aortic bifurcation.

Ability to overlap the bifurcated stent graft by 15 to 20 mm.

3.0 CONTRAINDICATIONS

There are no known contraindications for these devices.

4.0 WARNINGS AND PRECAUTIONS

4.1 General

- Read all instructions carefully. Failure to properly follow the instructions, warnings and precautions may lead to serious consequences or injury to the patient.
- The Powerlink System for AAA should only be used by physicians and teams trained in vascular interventional techniques and in the use of this device. Specific training expectations are described in *Section 10.1, Physician Training Program.*
- The long-term performance of endovascular grafts has not yet been established. All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and the performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the endovascular graft) should receive enhanced follow-up. Specific follow-up guidelines are described in *Section 12.0, Imaging Guidelines and Post-Operative Follow-up.*
- After endovascular graft placement, patients should be regularly monitored for perigraft flow, aneurysm growth or changes in the structure or position of the endovascular graft. At a minimum, annual imaging is required, including: 1) abdominal radiographs to examine device integrity (stent fracture, separation between bifurcated device and proximal cuffs or limb extensions, if applicable), and 2) contrast and non-contrast CT to examine aneurysm changes, perigraft flow, patency, tortuosity and progressive disease. If renal complications or other factors preclude the use of image contrast media, abdominal radiographs and duplex ultrasound may provide similar information.
- The Powerlink System for AAA is not recommended in patients unable to undergo, or who will not be compliant with the necessary preoperative and post-operative imaging and implantation studies as described in *Section 12.0, Imaging Guidelines and Post-Operative Follow-Up.*
- Additional endovascular intervention or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aneurysms, unacceptable decrease in fixation length (vessel and component overlap) and/or endoleak. An increase in aneurysm size and/or persistent endoleak may lead to aneurysm rupture.

- Patients experiencing reduced blood flow through the graft limb and/or endoleaks may be required to undergo secondary interventions or surgical procedures.
- Always have a vascular surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

4.2 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 stent graft during preparation and insertion to decrease the risk of stent graft contamination and infection.
- Maintain guidewire position during delivery system insertion.
- Do not bend or kink the delivery system. Doing so may cause damage to the delivery system and the Powerlink System Stent Graft.
- If outer sheath kinks during insertion, do not attempt deployment. Replace with a new Powerlink System.
- Failure to constantly monitor deployment of the stent graft may cause kinking or alignment problems.
- The use of the Powerlink System for AAA requires administration of intravascular contrast. Patients with pre-existing renal insufficiency may have an increased risk of renal failure post-operatively. Care should be taken to limit the amount of contrast media used during the procedure.
- Inaccurate placement, inadequate fixation and/or incomplete sealing of the Powerlink System Stent Graft within the vessel may result in increased risk of endoleak, migration or inadvertent occlusion of the hypogastric arteries. Incorrect deployment or migration of the stent graft may require surgical intervention.
- Catheter advancement should be performed under fluoroscopic guidance. Do not use excessive force to advance or withdraw the catheter when resistance is encountered. Care should be taken in areas of stenosis intravascular thrombosis or in calcified and/or tortuous vessels.
- Take care during manipulation of catheters, wires and sheaths within an aneurysm. Significant disturbances may dislodge fragments of thrombus which can cause distal embolization.
- Fluoroscopic visualization during withdrawal of the Powerlink Delivery Catheter is necessary to ensure that it does not move in the stent graft. Any resistance during withdrawal must be carefully monitored.

4.3 MRI (Magnetic Resonance Imaging) Safety and Compatibility

- Through non-clinical testing, the Powerlink Stent Graft has been shown to be MRI safe at field strengths of 1.5 Tesla or less, a maximum spatial gradient of 450 gauss per centimeter, and a maximum whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 30 min of MR imaging. The stent should not migrate in this MR environment. In this testing, the stent graft produced a temperature rise of less than 0.3 °C at a maximum whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 30 minutes of MR imaging.
- Heating has not been determined for overlapping components or stent grafts with fractured struts. MR imaging quality may be comprised if the area of interest is in the exact same area or relatively close to the position of the stent graft. The Powerlink stent graft has not been evaluated to determine if it is safe in MRI systems with field strengths greater than 1.5 Tesla.
- The Powerlink System Stent Graft exhibited minimal image artifact as observed in non-clinical MRI testing at 1.5 Tesla.

5.0 ADVERSE EVENTS

5.1 Observed Adverse Events

A U.S. multicenter, prospective study conducted at 15 centers, which included 192 test patients and 66 control patients, provides the basis of the observed adverse events rates presented in Tables 5.1.1 and 5.1.2. The control group included patients whose vascular anatomy may not have been suitable for endovascular AAA repair.

For details, refer to the Instructions For Use for the Powerlink System Bifurcated Infrarenal.

5.2 Potential Adverse Events

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

- Amputation
- Anesthetic complications and subsequent attendant problems (e.g., aspiration)
- Aneurysm enlargement
- Aneurysm rupture and death
- Aortic damage, including perforation, dissection, bleeding, rupture and death
- Arterial or venous thrombosis and/or pseudoaneurysm
- Arteriovenous fistula
- Bleeding, hematoma or coagulopathy
- Bowel complications (e.g., ileus, transient ischemia, infarction, necrosis)
- Cardiac complications and subsequent attendant problems (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension, hypertension)
- Claudication (e.g., buttock, lower limb)
- Death
- Edema
- Embolization (micro and macro) with transient or permanent ischemia or infarction
- Endoleak
- Stent graft: improper component placement; incomplete component deployment; component migration; suture break; occlusion; infection; stent fracture; graft material wear; dilatation; erosion; puncture and perigraft flow
- Fever and localized inflammation
- Genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection)
- Hepatic failure
- Impotence
- Infection of the aneurysm, device access site, including abscess formation, transient fever and pain.
- Lymphatic complications and subsequent attendant problems (e.g., lymph fistula)
- Neurologic local or systemic complications and subsequent attendant problems (e.g., stroke, transient ischemic attack, paraplegia, paraparesis, paralysis)
- Occlusion of device or native vessel.
- Pulmonary/respiratory complications and subsequent attendant problems (e.g., pneumonia, respiratory failure, prolonged intubation)
- Renal complications and subsequent attendant problems (e.g., artery occlusion, contrast toxicity, insufficiency, failure)
- Surgical conversion to open repair
- Vascular access site complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula

- Vessel damage
- Wound complications and subsequent attendant problems (e.g., dehiscence, infection)
- Vascular spasm or vascular trauma (e.g., iliofemoral vessel dissection, bleeding, rupture, death)

5.3 Device Related Adverse Event Reporting

Any adverse event (clinical incident) involving the Powerlink System Stent Graft should be reported to Endologix, Inc. immediately. To report an incident, call the Customer Service Department at 800-983-2284 (24 hours message service).

6.0 SUMMARY OF CLINICAL STUDIES

Refer to the Instructions For Use for the Powerlink System Bifurcated Infrarenal.

7.0 PATIENT SELECTION AND TREATMENT

Refer to the Instructions For Use for the Powerlink System Bifurcated Infrarenal.

7.1 Individualization of Treatment

Endologix recommends that the Powerlink Limb Extension diameters be selected as described in Table 10.4.1. The length of the Powerlink Limb Extension should extend from the distal fixation site to 15 to 20 mm of overlap inside the limb of the bifurcated stent graft. 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, should be carefully considered for each patient before use of the Powerlink System for AAA (refer to *Section 6.0 Summary of Clinical Studies* in the Instructions For Use for the Powerlink System Bifurcated Infrarenal). 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 Powerlink System for AAA.
- Ability to tolerate general, regional or local anesthesia
- Iliofemoral access vessel size and morphology (minimal thrombus, calcium and/or tortuosity) should be compatible with vascular access techniques of the 17 Fr delivery catheter profile. The Powerlink System for AAA is not delivered through a vascular introducer sheath.
- Adequate iliac/femoral access compatible with the required delivery systems (a diameter of $\geq$ 7 mm).
- Common iliac artery distal fixation site:

  with a distal fixation length of $\geq$ 15 mm

  with ability to preserve at least one hypogastric artery

  with a diameter of $\geq$ 10 mm and $\leq$ 18 mm

  with an iliac angle of $\leq$ 90° to the aortic bifurcation.
- Ability to overlap the bifurcated stent graft by 15 to 20 mm.

- Freedom from significant femoral/iliac artery occlusive disease that would impede flow through the vascular graft.

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

8.0 PATIENT COUNSELING INFORMATION

The physician and patient (and/or family members) should review the risks and benefits when discussing this endovascular device and procedure including:

- Risks and differences between endovascular repair and 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 performance of endovascular grafts has not yet been established. All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and the performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the endovascular graft) should receive enhanced follow-up. Specific follow-up guidelines are described in *Section 12, Imaging Guidelines and Post-Operative Follow-Up.*
- Patients should be counseled on the importance of adhering to the follow-up schedule, both during the first year and at yearly intervals thereafter. Patients should be told that regular and consistent follow-up is a critical part of ensuring the ongoing safety and effectiveness of endovascular treatment of AAAs. At a minimum, annual imaging and adherence to routine post-operative follow-up requirements is required and should be considered a life-long commitment to the patient's health and well-being.
- 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 at rest or discoloration or coolness of the leg. Aneurysm rupture may be asymptomatic, but usually presents as: pain; numbness; weakness in the legs; 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, neurological, bowel and bleeding complications. Device related risks include occlusion, endoleak, aneurysm enlargement, fracture, potential for reintervention and open surgical conversion, rupture and death (See *Sections 5.1* and *5.2, Observed Adverse Events* and *Potential Adverse Events*). The physician should complete the *Patient Implant 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 card anytime they visit additional health practitioners, particularly for any additional diagnostic procedures (e.g., MRI).

9.0 HOW SUPPLIED

- The Powerlink System for AAA is supplied sterile and enclosed in two peel-open packages, one sealed inside the other.
- The device is intended for single use only. Do not re-sterilize the device.
- Inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use this device if damage has occurred or if the sterilization barrier has been damaged or broken. If damage has occurred, do not use the product and return to Endologix, Inc.

- Prior to use, verify correct devices (quantity and size) have been supplied for the patient by matching the device to the order prescribed by the physician for that particular patient.
- Do not use after the "USE BY" (EXPIRATION) date printed on the label.
- Store in a cool, dry place.
- The device packaging includes a label with peel-away stickers containing the model number and lot number. These stickers are intended to be used with the enclosed Patient Implant Card and Device Tracking Form. Please refer to Section 13.0 for information regarding the Patient Implant Card and Device Tracking Form.

Table 9.1 Limb Extensions

Model No.	Extension Diameter (mm)	Extension Length (mm)	Delivery System Fr (no introducer needed)
16-16-55L	16	55	17
16-16-88L	16	88	17
20-20-55L	20	55	17

10.0 Clinical use information

10.1 Physician Training Program

CAUTION: Always have a vascular surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

CAUTION: The Powerlink System for AAA should only be used by physicians and teams trained in vascular interventional techniques and in the use of this device. The recommended skill/knowledge requirements for physicians using the Powerlink system for AAA 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 cut-down, 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
- Appropriate use of radiographic contrast material
- Techniques to minimize radiation exposure
- Expertise in necessary patient follow-up modalities

10.2 Inspection Prior to Use

Inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use this device if damage has occurred or if the sterilization barrier has been damaged or broken. If damage has occurred, return device to Endologix, Inc. Prior to use, verify correct devices (quantity and size) have been supplied for the patient by matching the device to the order prescribed by the physician for that particular patient.

10.3 Materials Required

1. Powerlink cuffs or limb extensions of various lengths and diameters may be required in order to properly fit the implant to the anatomy of the patient or to repair any endoleaks.
2. Fluoroscopic imaging and the ability to record all imaging.
3. Assorted .035" stiff and standard guidewires of adequate length (e.g., EV3 Nitrex guidewire, 180 cm).
4. Power injector for fluoroscopic dye studies.
5. Radiopaque (ruler) in millimeter increments is recommended.
6. Heparinized solution and sterile saline solution.
7. Assorted catheters for passage through tortuous vessels, including angioplasty catheters to dilate stenotic vessels prior to passage of the delivery catheter.
8. 12.5 Fr tear-away introducer sheath (for management of wires prior to introduction of the delivery system)
9. Radiopaque contrast media

10.4 Device Diameter Sizing Guidelines

Under sizing or over sizing may result in incomplete sealing or compromised flow.

Table 10.4.1 Limb Extension Sizing

Intended Iliac Vessel Diameter	Extension Diameter	Extension Length	Delivery Catheter
10–14 mm	16 mm	55 mm	17 Fr
10–14 mm	16 mm	88 mm	17 Fr
14–18 mm	20 mm	55 mm	17 Fr

11.0 DIRECTIONS FOR USE

Prior to use of the Endologix Powerlink System for AAA, review this *Instructions for Use* booklet. The following instructions embody a basic guideline for device placement. Variations in the following procedures may be necessary. These instructions are intended to help guide the physician and do not take the place of physician judgment.

11.1 General Use Information

Standard techniques for placement of arterial access sheathes, guiding catheters, angiographic catheters and guidewires should be employed during use of the Powerlink System for AAA. The Powerlink System for AAA is compatible with a .035 inch diameter guidewire.

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.

11.2 Pre-Implant Determinants

Verify from pre-implant planning that the correct device has been selected. Determinants include:

1. The Powerlink System may be introduced via either iliac artery. Common femoral artery access and aneurysm sac orientation are other considerations.
2. Angulation of aneurysm and iliac arteries.
3. Quality of the iliac fixation site.
4. Diameters of iliac fixation site.

5. Distance from iliac fixation site to distal end of bifurcated device limb with ability to overlap by 15 to 20 mm.

6. Pre-dilation of the iliac arteries may ease deployment procedure.

WARNING: THE USE OF THE POWERLINK SYSTEM FOR AAA REQUIRES ADMINISTRATION OF INTRAVASCULAR CONTRAST. PATIENTS WITH PRE-EXISTING RENAL INSUFFICIENCY MAY HAVE AN INCREASED RISK OF RENAL FAILURE POST-OPERATIVELY. CARE SHOULD BE TAKEN TO LIMIT THE AMOUNT OF CONTRAST MEDIA USED DURING THE PROCEDURE.

WARNING: UNLESS MEDICALLY INDICATED, DO NOT DEPLOY THE POWERLINK SYSTEM STENT GRAFT IN A LOCATION THAT WILL OCCLUDE ARTERIES NECESSARY TO SUPPLY BLOOD FLOW TO ORGANS OR EXTREMITIES. DO NOT COVER SIGNIFICANT RENAL OR MESENTERIC ARTERIES (EXCEPTION IS THE INFERIOR MESENTERIC ARTERY) WITH THE STENT GRAFT. VESSEL OCCLUSION MAY OCCUR. DURING THE CLINICAL STUDY, THIS DEVICE WAS NOT STUDIED IN PATIENTS WITH TWO OCCLUDED INTERNAL ILIAC ARTERIES.

11.3 Patient Preparation

1. Refer to institutional protocols relating to anesthesia, anticoagulation and monitoring of vital signs.

2. Position patient on imaging table allowing fluoroscopic visualization from the aortic arch to the femoral bifurcations.

3. Expose the common femoral artery on the chosen access side using standard surgical technique.

4. Establish adequate proximal and distal vascular control of the surgically exposed femoral artery.

11.4 Device Preparation

WARNING: THE POWERLINK SYSTEM IS DESIGNED FOR SINGLE USE ONLY. DO NOT REUSE OR RESTERILIZE.

CAUTION: MINIMIZE HANDLING OF THE CONSTRAINED STENT GRAFT DURING PREPARATION AND INSERTION TO DECREASE THE RISK OF STENT GRAFT CONTAMINATION AND INFECTION.

CAUTION: DO NOT BEND OR KINK THE DELIVERY SYSTEM. DOING SO MAY CAUSE DAMAGE TO THE DELIVERY SYSTEM AND THE POWERLINK SYSTEM STENT GRAFT.

1. Tighten white connector by turning the hub clock-wise.
2. Flush lumen and side port of the delivery system with sterile saline solution.

11.5 Procedure

1. If part of a secondary procedure, perform the cut-down of the access vessel using standard surgical techniques.
2. If applicable, place vessel loops distal and proximal to the cut-down site for hemostatic control.
3. Insert a .035 inch stiff "J-tip" guidewire into the vasculature through the stent graft utilizing fluoroscopic guidance. Maintain the position of the guidewire across the implant site until the procedure is completed. Be aware of the possibility of the guidewire tangling with the stent cage of existing stent graft if caution is not properly used.

4. Angiography and road mapping should now be completed and recorded. Mark the appropriate anatomical landmarks and fix the C-arm. This will allow the stent graft to be accurately deployed.

5. Confirm length and diameter of required Powerlink stent graft. Endologix suggests that the stent graft diameter be at least 2 mm larger than the normal iliac inner diameter (e.g., 20 mm diameter stent graft should not be deployed in a normal iliac inner diameter > 18 mm). The length of the Powerlink Limb Extension should extend from the iliac fixation site to 15 to 20 mm of overlap inside the chosen bifurcated model limb.

   CAUTION: MAINTAIN GUIDEWIRE POSITION DURING DELIVERY SYSTEM INSERTION.

6. Advance the Powerlink delivery catheter over the guidewire until the distal end of the compressed graft is just above the intended iliac fixation site

   WARNING: INACCURATE PLACEMENT, INADEQUATE FIXATION AND/OR INCOMPLETE SEALING OF THE POWERLINK SYSTEM STENT GRAFT WITHIN THE VESSEL MAY RESULT IN INCREASED RISK OF ENDOLEAK, MIGRATION OR INADVERTENT OCCLUSION OF THE HYPOGASTRIC ARTERIES. INCORRECT DEPLOYMENT OR MIGRATION OF THE STENT GRAFT MAY REQUIRE SURGICAL INTERVENTION.

   WARNING: CATHETER ADVANCEMENT SHOULD BE PERFORMED UNDER FLUOROSCOPIC GUIDANCE. DO NOT USE EXCESSIVE FORCE TO ADVANCE OR WITHDRAW THE CATHETER WHEN RESISTANCE IS ENCOUNTERED. CARE SHOULD BE TAKEN IN AREAS OF STENOSIS, INTRAVASCULAR THROMBOSIS OR IN CALCIFIED AND/OR TORTUOUS VESSELS.

   CAUTION: IF OUTER SHEATH KINKS DURING INSERTION, DO NOT ATTEMPT DEPLOYMENT. REPLACE WITH A NEW POWERLINK SYSTEM.

7. While holding the Pusher Rod of the delivery system stationary, gently retract the Outer Sheath. This action will deploy the stent graft. Deploy the first 1 – 2 cm of the stent graft, then gently retract the device and fix the stent graft at the appropriate implant site. Once fixed into place, fully deploy the rest of the stent graft. (Refer to Figure 3).

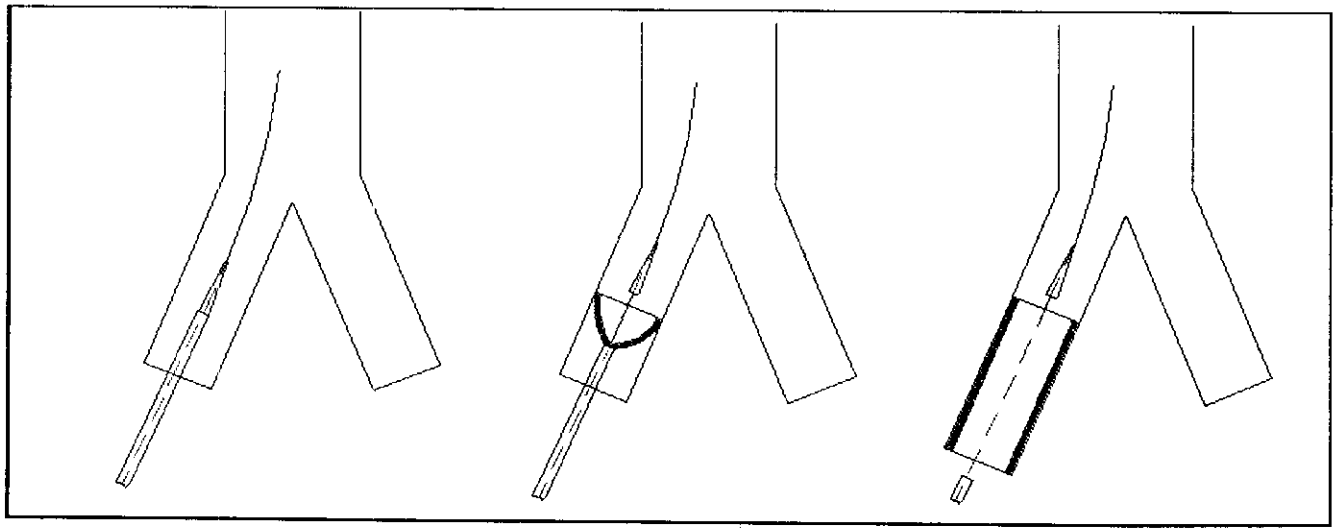

Figure 3
Limb Extension Deployment

CAUTION: FAILURE TO CONSTANTLY MONITOR DEPLOYMENT OF THE STENT GRAFT MAY CAUSE KINKING OR ALIGNMENT PROBLEMS.

8. If the stent graft is kinked or did not expand completely, perform balloon dilation or surgically remove.

WARNING: TAKE CARE DURING MANIPULATION OF CATHETERS, WIRES AND SHEATHS WITHIN AN ANEURYSM. SIGNIFICANT DISTURBANCES MAY DISLODGE FRAGMENTS OF THROMBUS WHICH CAN CAUSE DISTAL EMBOLIZATION.

9. Perform an angiogram to detect the presence of any endoleaks. If an endoleak is detected, balloon angioplasty with appropriate size balloon or a Powerlink Limb Extension may be deployed. A Limb Extension can also be deployed to extend the length or properly anchor the stent graft.

Table 11.5.1 Balloon Recommendation

Balloon Diameter (mm)	Balloon Length (cm)	Recommended Introducer (Fr)	Shaft Size (Fr)	Rated Burst Pressure (atm.)	Shaft Usable Length (cm)	Recommended Guidewire Diameter (in)
12.0	4.0	9	7.0	5.0	100	0.035
14.0	4.0	9	7.0	5.0	100	0.035
16.0	4.0	9	7.0	5.0	100	0.035
20.0	4.0	12	8.0	4.0	100	0.035

10. After complete deployment, the Pusher Rod of the catheter should be fully retracted and removed.

CAUTION: FLUOROSCOPIC VISUALIZATION DURING WITHDRAWAL OF THE POWERLINK DELIVERY CATHETER IS NECESSARY TO ENSURE THAT IT DOES NOT MOVE THE STENT GRAFT. ANY RESISTANCE DURING WITHDRAWAL MUST BE CAREFULLY MONITORED.

12.0 IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP

12.1 General

The long-term performance of endovascular grafts has not yet been established. All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the endovascular graft) should receive additional follow-up. Patients should be counseled on the importance of adhering to the follow-up schedule, both during the first year and at yearly intervals thereafter. Patient should be told that regular and consistent follow-up is a critical part of ensuring the ongoing safety and effectiveness of endovascular treatment of AAAs.

Physicians should evaluate patients on an individual basis and prescribe their follow-up relative to the needs and circumstances of each individual patient. The recommended imaging schedule is presented in Table 12.1.1. This schedule continues to be the minimum requirement for patient follow-up and should be maintained even in the absence of clinical symptoms (e.g., pain, numbness, weakness). Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the stent graft) should receive follow-up at more frequent intervals.

Annual imaging follow-up should include abdominal radiographs and both contrast and non-contrast CT examinations. If renal complications or other factors preclude the use of

image contrast media, abdominal radiographs, non-contrast CT and duplex ultrasound may be used.

- The combination of contrast and non-contrast CT imaging provides information on aneurysm diameter change, endoleak, patency, tortuosity, progressive disease, fixation length and other morphological changes.
- The abdominal radiographs provide information on device integrity (separation between components and stent fracture).
- Duplex ultrasound imaging may provide information on aneurysm diameter change, endoleak, patency, tortuosity and progressive disease. In this circumstance, a non-contrast CT should be performed to use in conjunction with the ultrasound. Ultrasound may be a less reliable and sensitive diagnostic method compared to CT.

Table 12.1.1 lists the minimum requirements for imaging follow-up for patients with the Powerlink System Stent Graft. Patients requiring enhanced follow-up should have interim evaluations.

Table 12.1.1 Recommended Imaging Schedule for Endovascular Graft Patients

	Angiogram	CT [Contrast & Non-Contrast]	Abdominal Radiographs
Pre-procedure	X[1]	X[1]	
Procedural	X		
Pre-discharge (within 7-days) or 1 month		X[2,3]	X
3 month		X[2,3,4]	
6 month		X[2,3]	X
12 month (annually thereafter)		X[2,3]	X

[1]Imaging should be performed within 6-months before the procedure.
[2]Duplex ultrasound may be used for those patients experiencing renal failure or who are otherwise unable to undergo contrast enhanced CT scan. With ultrasound, non-contrast CT is still recommended.
[3]If Type I or III endoleak present, prompt intervention and additional follow-up post-intervention is recommended. See Section 12.6, Additional Surveillance and Treatment.
[4]Recommended if endoleak reported at pre-discharge or 1-month.

12.2 Contrast and Non-Contrast CT Recommendations

- Film sets should include all sequential images at lowest possible slice thickness (≤ 3 mm). Do NOT perform large slice thickness (> 3 mm) and/or omit consecutive CT images/film sets, 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 inch X 17 inch sheets if film is used.
- Both non-contrast and contrast runs are required, with matching or corresponding table positions.
- 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 imaging are important for optimal patient surveillance. It is important to follow acceptable imaging protocols during the CT exam. Table 12.2.1 lists examples of acceptable imaging protocols.

Table 12.2.1 Acceptable Imaging Protocols

	Non-Contrast	Contrast
IV contrast	No	Yes
Acceptable machines	Spiral capable of > 40 seconds	Spiral capable of > 40 seconds
Injection volume	n/a	150 cc
Injection rate	n/a	> 2.5 cc/sec
Injection mode	n/a	Power
Bolus timing	n/a	Test bolus: SmartPrep, C.A.R.E. or equivalent
Coverage – start	Diaphragm	1 cm superior to celiac axis
Coverage – finish	Proximal femur	Profunda femoris origin
Collimation	< 3 mm	< 3 mm
Reconstruction	2.5 mm throughout – soft algorithm	2.5 mm throughout – soft algorithm
Axial DFOV	32 cm	32 cm
Post-injection runs	None	None

12.3 Abdominal Radiographs

The following views are required:

- Four films: supine-frontal (AP), cross-table lateral, 30 degree LPO and 30 degree RPO views centered on umbilicus.
- Record the table-to-film distance and use the same distance at each subsequent examination.

Ensure entire device is captured on each single image format lengthwise.

If there is any concern about the device integrity (e.g., kinking, stent breaks, 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.

12.4 Ultrasound

Ultrasound imaging may be performed in place of contrast CT when patient factors preclude the use of image contrast media. Ultrasound may be paired with non-contrast CT. A complete aortic duplex is to be videotaped for maximum aneurysm diameter, endoleaks, stent patency and stenosis. Included on the videotape should be the following information as outlined below:

- Transverse and longitudinal imaging should be obtained from the level of the proximal aorta demonstrating mesenteric and renal arteries to the iliac bifurcations to determine if endoleaks are present utilizing color flow and color power angiography (if accessible).
- Spectral analysis confirmation should be performed for any suspected endoleaks.
- Transverse and longitudinal imaging of the maximum aneurysm should be obtained.

12.5 MRI Safety and Compatibility

1. Through non-clinical testing, the Powerlink stent graft has been shown to be MRI safe at field strengths of 1.5 Tesla or less, a maximum spatial gradient of 450 gauss per centimeter, and a maximum whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 30 min of MR imaging. The stent should not migrate in this MR environment. In this testing, the stent graft produced a temperature

rise of less than 0.3 °C at a maximum whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 30 minutes of MR imaging.

2. Heating has not been determined for overlapping components or stent grafts with fractured struts. MR imaging quality may be comprised if the area of interest is in the exact same area or relatively close to the position of the stent graft. The Powerlink stent graft has not been evaluated to determine if it is safe in MRI systems with field strengths greater than 1.5 Tesla.

3. The Powerlink System Stent Graft exhibited minimal image artifact as observed in non-clinical MRI testing at 1.5 Tesla.

12.6 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)
- Migration
- Inadequate seal length

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 that subsequent reintervention including catheter based and open surgical conversion are possible following endograft placement.

13.0 DEVICE TRACKING INFORMATION

Federal Law (U.S.) requires that all Abdominal Aortic Aneurysm Stent Grafts be tracked according to Title 21 Code of Federal Regulations (CFR) Part 821. That tracking includes a Patient Implant Card to be given to the patient upon release from the institution and a Device Tracking Form to be mailed or faxed back to the manufacturer (Endologix, Inc.).

According to the regulation, the Final Distributor, defined as the person or institution that owns the device, must report the information to the manufacturer. The doctor or hospital, is considered the final distributor, therefore, it is their responsibility to forward that information to the manufacturer. Please fill in as much information on the Device Tracking Form as possible and mail or fax it to Endologix, Inc. The fax number is (949) 830-4463. For more information on the institutions' requirements please refer to the FDA website www.fda.gov.

In addition to these Instructions for Use, the Powerlink System for AAA is packaged with a Device Tracking Form which the hospital staff is required to complete and forward to Endologix, Inc. for the purposes of tracking all patients who receive the Powerlink System Stent Graft (as required by U. S. Federal Regulation).

14.0 SYMBOLS LEGEND

SYMBOL	DESCRIPTION
	Product expiration date "Use product by expiration date"
LOT	Lot number or work order number for the product.
STERILE EO	Contents sterile unless package has been opened or damaged. Sterilized by ethylene oxide.
	Attention - see instructions for use
	Device is intended for use one time only. Do not re-use or re-sterilize.

15.0 RETURN GOODS

In the event an unused device must be returned for any reason, please place the Powerlink System for AAA into its original package and shipping box. Contact Customer Service at 800-983-2284 to receive a return goods authorization number (RGA) and ship the device to the address provided by customer service.

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