AneuRx™ Stent Graft System

Instructions for Use

IMPORTANT!

- Do not attempt to use the AneuRx Stent Graft System before completely reading and understanding the information contained in this booklet.
- Carefully inspect all product packaging for damage or defects prior to use. Do not use product if any sign of damage or breach of the sterile barrier is observed.
- These devices are supplied STERILE for single use only. After use, dispose of the Delivery Catheters in accordance with hospital, administrative and/or government policy. Do not resterilize.
- The AneuRx Deployment Handle is supplied non-sterile. The Deployment Handle must be sterilized prior to first use using steam sterilization under vacuum. The Deployment Handle may be resterilized and reused as described in the Deployment Handle Instructions for Use.
- Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.

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1. DEVICE DESCRIPTION

The AneuRx Stent Graft System is designed to treat infrarenal abdominal aortic ar aorto-iliac aneurysms using an endovascular approach. When placed within the aneurysm, the AneuRx Stent Graft provides a permanent, alternative conduit for blood flow within the patient's vasculature by excluding the aneurysmal sac from blood flow and pressure. The AneuRx Stent Graft System provides an alternative treatment choice in lieu of major open surgery.

The Medtronic AneuRx Stent Graft System includes:

- a Stent Graft (either Bifurcated Stent Graft, Iliac Stent Graft, Iliac Extender Cuff Stent Graft or Aortic Extender Cuff Stent Graft) that is modular and fully stented along its length;
- a pre-loaded (with a Stent Graft), sterile Delivery Catheter;
- a reusable, non-sterile Deployment Handle (supplied separately); and
- radiopaque markers imbedded in the Stent Graft proximally and distally; the markers are visualized under fluoroscopy.

The AneuRx Stent Graft System is constructed from self-expanding nickel-titanium (Nitinol) alloy stent rings and woven polyester graft tubes. Each stent ring is a series of diamond-shaped segments connected side-to-side in the circumferential direction to form a ring. The diamond-shaped segments are laser cut from a single piece of Nitinol tubing.

The Stent Graft is loaded inside a Delivery Catheter which facilitates the placement of the Stent Graft via the arterial vasculature (e.g., femoral arteries). Using fluoroscopic guidance, the Delivery Catheter is properly positioned within the patient's vasculature and the Stent Graft is deployed from the Delivery Catheter using the AneuRx Deployment Handle. The Deployment Handle aids in the retraction of the graft cover on the Delivery Catheter, exposing the Stent Graft to aortic vasculature.

2. INDICATIONS

The AneuRx Stent Graft System is indicated for the endovascular treatment of infrarenal abdominal aortic or aorto-iliac aneurysms having:

- adequate iliac/femoral access;
- infrarenal non-aneurysmal neck length of at least 1 cm at the proximal and distal ends of the aneurysm and a vessel diameter 10-20% smaller than the labeled device diameter;
- morphology suitable for endovascular repair;
- one of the following:

  a diameter > 5 cm;

  a diameter of 4-5 cm and has increased in size by 0.5 cm in the last 6 months; or

  twice the diameter of the normal infrarenal aorta.

3. CONTRAINDICATIONS

There are no known contraindications currently associated with this device.

4. WARNINGS AND PRECAUTIONS
(See also Individualization of Treatment)

4.1 GENERAL

- Do not attempt to use the AneuRx Stent Graft System before completely reading and understanding the information contained in this booklet.
- This device should only be used by physicians and teams trained in vascular interventional techniques, including training in the use of the device. Specific training expectations are described in Section 10.1 PHYSICIAN TRAINING PROGRAM.
- Do not use the AneuRx Stent Graft in patients unable to undergo the necessary preoperative and postoperative imaging and implantation studies as described in Section 10.6 PREPARATION OF THE ANEURX STENT GRAFT SYSTEM.
- The results of the clinical studies indicated that patients who experience an unsuccessful endovascular repair attempt, and as a result undergo conversion to surgical Abdominal Aortic Aneurysm (AAA) repair, are likely to have increased complications arising from both procedures (i.e., cardiac complications, fever, infection, musculoskeletal complications, neurological complications, pulmonary complications, vascular disease, vessel dissection, wound healing issues, and mortality; reference Section 5. ADVERSE EVENTS for specific information on adverse event categories).
- The long-term performance of the graft has not been established. Patients should be regularly monitored for leaks and aneurysm growth.
- The safety and effectiveness of the AneuRx Stent Graft System for the treatment of abdominal aortic aneurysms has not been evaluated in patients:
  - with aneurysms pending rupture
  - with connective tissue disorder
  - with hypercoagulability
  - with mesenteric artery occlusive disease
  - with ilio-femoral, thoracic, or inflammatory aneurysms
  - with juxtarenal AAA
  - with pararenal AAA
  - with suprarenal or thorocoabdominal aneurysms
  - who are morbidly obese
  - pregnant or nursing
  - less than 18 years old
  - with less than one-year life expectancy.
- Always have a vascular surgery team available at institutions performing endovascular grafting in the event that conversion to open surgical repair is required.

4.2 PATIENT SELECTION, TREATMENT, AND FOLLOW-UP

- Do not use this device in patients having an active systemic infection.
- Do not use this device in patients with sensitivities or allergies to the device materials.

  The materials include: polyethylene-terephthalete (PET), nickel, titanium, tantalum, stainless steel, polyetheresterblock-copolymer (Hytrel), polyetherblockamide (Pebax), polyetheretherketone (PEEK), platinum, ethyl cyanoacrylate, poly (methyl methacrylate), and hydroquinone.
- The results of the clinical study indicate that women treated with this device may have a higher mortality rate as compared to their male counterparts.

- The use of this device requires administration of radiographic agents. Patients with preexisting renal insufficiency may have an increased risk of renal failure postoperatively.
- Proper use of this device requires accurate fluoroscopic imaging. This device is not recommended for patients whose weight exceeds 350 lbs (150 kg) or whose weight may impede accurate fluoroscopic imaging.
- Conversion to standard surgical repair should be considered for patients experiencing an increase in the size of their AAA.
- The results of the clinical study indicate that subjects experiencing reduced blood flow through the graft limbs and/or leaks may be required to undergo secondary interventions or minor surgical procedures.
- All patients should be monitored closely and checked periodically for aneurysmal size increase or occlusion of vessels in the treatment area. Patients who experience perigraft flow should undergo imaging studies more frequently.

4.3 HOW SUPPLIED

- For single use only. AneuRx Stent Graft Delivery Catheters are disposable; do not reuse. Note product "Use Before" date.
- Never attempt to resterilize an AneuRx Stent Graft or Delivery Catheter. Resterilization may adversely affect the proper mechanical function of the AneuRx Stent Graft and could result in patient injury and/or conversion to an open surgical procedure.
- Always inspect the device and packaging to verify that no damage has occurred as a result of shipping and that the sterile barrier has not been compromised. If damage occurs, do not use the product and return the device to Medtronic AneuRx.

4.4 MAGNETIC RESONANCE IMAGING (MRI) SAFETY

MRI may be used on the graft only under specific conditions. See Section 10.5 MRI INFORMATION for details.

4.5 IMPLANTATION PROCEDURES

- Do not bend or kink the Delivery Catheter because it may cause the AneuRx Stent Graft to improperly deploy.
- Do not deploy the AneuRx Stent Graft in a location that will occlude arteries necessary to supply blood flow to organs or extremities.
- Always use fluoroscopic guidance to advance the Delivery Catheter. Do not use excessive force to advance or withdraw the Delivery Catheter when resistance is encountered. Exercise particular care in areas of stenosis, intravascular thrombosis, or in calcified or tortuous vessels.
- Always monitor the implant procedure under fluoroscopy to detect kinking or alignment problems with the AneuRx Stent Graft components. If the Delivery Catheter kinks during insertion, do not attempt to deploy the AneuRx Stent Graft. Remove the system and insert a new Delivery Catheter.
- Inadequate anchoring may result in increased risk of leakage into the aneurysm or migration of the Stent Graft.
- Do not retract the cover of the AneuRx Stent Graft Delivery Catheter before placing the Delivery Catheter in the proper anatomical location. The AneuRx Stent Graft cannot be replaced or drawn back into the Delivery Catheter, even if the Stent Graft is only partially deployed.
- Improper placement may result in leakage or occlusion, necessitating surgical removal of the device.

5. ADVERSE EVENTS

5.1 OBSERVED ADVERSE EVENTS

A prospective, multi-center clinical investigation comparing the AneuRx Stent Graft System to conventional open surgery provides the basis of the observed adverse event rates. A total of four-hundred-sixteen (416) subjects were enrolled in the Stent Graft arm of the study; sixty-six (66) patients were enrolled in the Surgical Control arm of the study.

A total of 1105 devices (Bifurcated Stent Grafts, Iliac Stent Grafts, Iliac Extender Cuff Stent Grafts, and the Aortic Extender Cuff Stent Grafts).were successfully delivered and deployed in 405 patients. The cumulative follow-up was 498 years with a mean follow-up of 1.2 years (range 0 to 2.1 years).

Table 5.1 Adverse Events

Adverse Event	Early ≤30 Days Stent Graft % (n/N)	Early ≤30 Days Control % (n/N)	Late >30 Days Stent Graft % (n/N)	Late >30 Days Control % (n/N)
Deaths	2% (7/416)	0% (0/66)	5% (416)[7]	9% (6/66)
Other Adverse Events				
AAA Rupture	0.2% (1/416)	0% (0/66)	0.2% (1/416)	0% (0/66)
Bleeding[1]	4% (18/416)	3% (2/66)	0.2% (1/416)	0% (0/66)
Cardiac Failure/Infarction	2% (7/416)	6% (4/66)	0.7% (3/416)	0% (0/66)
Edema[2]	1% (5/416)	0% (0/66)	<1% (2/416)	0% (0/66)
Wound Healing Complications[3]	4% (17/416)	5% (3/66)	1% (4/416)	0% (0/66)
Impotence	0% (0/416)	0% (0/66)	0.2% (1/416)	0% (0/66)
Pulmonary Complications[4]	2% (7/416)[8]	8% (5/66)[8]	<1% (2/416)[9]	5% (3/66)[9]
Renal Failure[5]	4% (15/416)	0% (0/66)	1% (3/416)	0% (0/66)
Gastrointestinal Complications[6]	3% (4/416)[10]	14% (9/66)[10]	1% (5/416)	0% (0/66)
Vascular Occlusion (includes thrombosis and thromboembolism)				
Arterial	2% (8/416)	2% (1/66)	0.5% (2/416)	0% (0/66)
Venous	0% (0/416)	0% (0/66)	0.5% (2/416)	0% (0/66)

[1] Includes: hematuria, brachial and femoral hematomas, elevated PT/INR, groin hemorrhage, retroperitoneal bleed, urethral bleeding

[2] Includes: scrotal and foreskin edema, lower extremity swelling

[3] Includes: delayed wound healing, lymphatic leak, seroma

[4] Includes: bilateral pleural effusions, shortness of breath, respiratory failure/arrest, atelectasis, pneumonia

[5] Includes: renal insufficiency/failure, dialysis, elevated creatinine

[6] Includes: angiodyplasia of stomach, bowel ischemia, ileus, constipation, nausea/vomiting, ulcers, rectal bleeding, cholcystitis, diarrhea, bowel obstruction, GI bleed, small bowel mesentery bleed, sigmoid colon necrosis

[7] Four (1%, 4/416) late deaths (>30 days post-procedure) occurred that were classified as device related. One (≤1%, 1/416) death had an unknown cause at the time of the data analysis. One death was undetermined but possibly occurred by cerebral embolism. One death was due to renal failure and pulmonary complications. One death was due to neurological complications.

[8] $p = 0.015$

[9] $p = 0.02$

[10] $p = 0.002$

5.2 POTENTIAL ADVERSE EVENTS

Adverse events (in alphabetical order) which may be associated with the use of the device, the implant procedure or the attendant equipment and supplies (reference Table 5.1) include:

- Cardiac failure/infarction
- Thromboemolism
- Graft or native arterial occlusion
- Venous thrombosis and edema
- Ruptured vessel/aneurysm
- Gastrointestinal complications
- Impotence
- Renal failure
- Pulmonary/respiratory complications
- Central or peripheral nervous system impairment
- Wound infection or hematoma
- Device failures due to:

  Migration

  Dilation

  Endoleak

  Rupture

  Erosion with fistula or pseudo-aneurysm

5.3 ADVERSE EVENT REPORTING

Any adverse event (clinical incident) involving the AneuRx Stent Graft System should be reported to Medtronic AneuRx immediately. **To report an incident, call (800) 465-5533.**

6. CLINICAL STUDIES

A total of four-hundred-sixteen (416) patients were treated at 13 U.S. investigational centers in the Evaluation of the Safety and Efficacy of the AneuRx Stent Graft System in the Treatment of Abdominal Aortic Aneurysms (AAA). The study was a nonrandomized, prospective, multicenter clinical investigation designed to evaluate the safety and efficacy of the AneuRx Stent Graft System in the treatment of infrarenal abdominal aortic or aorto-iliac aneurysms.

6.1 PRIMARY ENDPOINTS

The prospective, controlled, clinical trial was designed to compare endovascular repair of abdominal aortic aneurysms to conventional open surgical repair of abdominal aortic aneurysms in terms of safety, procedural parameters and hospital activities. The primary endpoints used for the trial included:

- Delivery Success/Deployment Success
- Stent Graft Migration
- Aneurysm Exclusion
- Stent Graft Patency
- Device Integrity
- Morbidity and Mortality
- Aneurysm Rupture
- Expansion of the AAA by >5mm
- Conversion to Surgical Repair
- Additional Procedure Required

6.2 SECONDARY ENDPOINTS

The secondary treatment endpoints were defined as all endpoints outside the primary endpoints that can be compared to the Surgical Control Group. The secondary endpoints include:

- Duration of Surgical Procedure
- Amount of Blood Loss
- Number of Patients Requiring Blood Transfusion
- Time to Endotracheal Extubation
- Time to Unassisted Ambulation
- Time to Resumption of Normal Diet
- Time in ICU
- Hospital Length of Stay (LOS)

6.3 PATIENTS STUDIED

Patients were enrolled into two groups: the Surgical Control Group and the Stent Graft Treatment Group. All patients enrolled in the clinical trial were candidates for open surgical repair of an infrarenal aortic or aorto-iliac aneurysm fitting one of the following descriptions:

- aneurysm > 5cm in diameter
- aneurysm 4-5cm in diameter and has increased in size by 0.5cm in last 6 months
- aneurysm is twice the diameter of the normal infrarenal aorta
- aneurysm is saccular.

Additionally, patients enrolled in the Stent Graft Treatment Group were required to have adequate iliac/femoral access and an infrarenal non-aneurysmal neck of at least 1 cm.

6.4 METHODS

Patients enrolled in the Surgical Control Group underwent open surgical repair of their aneurysm by replacement with a prosthetic graft. Patients enrolled in the Stent Graft Treatment Group were implanted with an AneuRx Bifurcated Stent Graft and an AneuRx Iliac Stent Graft. Iliac and/or Aortic Extender Cuff Stent Grafts were used, as needed, in specific cases.

The Stent Graft Treatment Group and Surgical Control Group underwent baseline Spiral CT evaluation. The Stent Graft Treatment Group had IVUS immediately pre- and post-placement as well as post treatment Spiral CT evaluation. The numbers presented in the following summaries are based on core lab evaluations of the Spiral CTs.

Surgical Control Group patients and Stent Graft Treatment Group patients were followed at the same postoperative intervals: pre-discharge, 1 month, 6 months, and 12 months. All patients treated were included in the intent-to-treat analysis.

Table 6.1 Patient Demographics

Demographic	Stent Graft (N = 416)[1]	Control (N = 66)
Age (years)	73 (45-93)	69 (49-85)
Alcoholism	3%	5%
Angina pectoris	18%	23%
Cancer	26%	26%
Cerebrovascular disease	14%	12%
Chronic obstructive pulmonary disease[2]	24%	36%
Chronic renal failure	2%	6%
Diabetes	12%	9%
Family history of aneurysm disease	10% (n=415)	14%
Gender Female Male	 11% 89%	 15% 85%
History of CVA (n=49)	11%	8%
Hypertension	64%	56%
Immunodeficiency	0%	2%
Myocardial infarction prior to last 6 months	33%	24%
Myocardial infarction within previous 6 months	4%	3%
Obesity	18%	18%
Peripheral vascular disease	20% (n=415)	24%
Previous surgery in affected area[3]	26%	14%
Prior coronary intervention procedure	45% (n=415)	53%
Radiation of the affected area	3%	2%
Symptomatic cardiac arrhythmia[4]	12%	3%
Symptomatic congestive heart failure	8%	3%
Systemic infection - current	0%	0%
Thromboembolic events	4% (n=413)	6%
Tobacco use	86% (n=414)	82%

1 Unless otherwise noted, N = 416
2 p = 0.037
3 p = 0.027
4 p = 0.029

Table 6.2 Aneurysm Diameter Distribution

Diameter Range	Stent Graft				Control			
	Neck N=346		Aneurysm N=390		Neck N=47		Aneurysm N=53	
	n	%	n	%	n	%	n	%
<20	16	4.6	0	0	2	4.3	0	0
20 – 29 mm	325	93.9	0	0	41	87.2	0	0
30 – 39 mm	5	1.5	6	1.5	3	6.4	1	1.9
40 – 49 mm	0	0	68	17.4	0	0	8	15.1
50 – 59 mm	0	0	199	51.0	1	2.1	25	47.2
60 – 69 mm	0	0	80	20.5	0	0	9	17.0
70 – 79 mm	0	0	25	6.4	0	0	4	7.6
80 – 89 mm	0	0	9	2.3	0	0	4	7.6
≥90 mm	0	0	3	0.8	0	0	2	3.8

Table 6.3 Aneurysm Length Distribution

Length Range	Stent Graft				Control			
	Neck N=360		Aneurysm N=333		Neck N=46		Aneurysm N=44	
	n	%	n	%	n	%	n	%
<20	100	27.8	3	0.9	14	30.4	0	0
20 – 29 mm	126	35.0	1	0.3	24	52.2	0	0
30 – 39 mm	71	19.7	5	1.5	4	8.7	2	4.6
40 – 49 mm	40	11.1	8	2.4	2	4.4	1	2.3
50 – 59 mm	10	2.8	19	5.7	1	2.2	4	9.1
60 – 69 mm	10	2.8	41	12.3	0	0	8	18.2
70 – 79 mm	2	0.6	58	17.4	1	2.2	7	15.9
80 – 89 mm	1	0.3	70	21.0	0	0	0	0
≥90 mm	0	0	128	38.4	0	0	22	50.0

6.5 RESULTS

The safety and effectiveness results are presented in the tables below.

Principal Safety Results

The time intervals capture the events between the follow up time periods. Denominators that are < 416 reflect patients that were successfully treated with the Stent Graft, measures that are determined by cine, and the actual readable images sent to the corelab by the investigational sites. The denominators are determinable measures based on the image quality.

Five of 415 (1.2%) patients underwent open surgical repair (conversion) due to iliac access difficulty or due to the unsuccessful delivery, deployment or positioning of at least one of the stent graft components. One patient (0.2%) refused placement of an Extender Cuff for treatment of endoleak and instead opted for open surgical repair. Two patients (0.5%) were converted to open surgical repair following rupture of the AAA.

Patients with technical success underwent an additional procedure(s): 19 patients for Extender Cuff placement due to endoleak, with or without migration, and 8 for non-patent endovascular grafts.

Table 6.4 Principal Safety Results (N=416)

Safety Measures and other Clinical Events	**Pre-discharge to six months**	**Pre-discharge to one year**
Aneurysm Rupture	1/405 (0.2%)	1/405 (0.2%)
Conversion to Surgical Repair	7/415 (1.7%)	8/415(1.9%)
Additional Procedure Required	16/405 (3.9%)	27/405 (6.7%)

Principal Effectiveness Results

416 patients were enrolled in the study. Denominators that are < 416 reflect a subset of the patients implanted with a Stent Graft and with readable images sent to the corelab by the investigational sites.

Table 6.5 Principal Effectiveness Results

Efficacy Measures	Pre-discharge N=416	Pre-discharge N=189	6 months N=189	1 year N=189
Delivery Success/ Deployment Success	405/415 (97.6%)	——	——	——
Stent Graft Migration	Baseline	Baseline	3/173 (1.7%)	3/187 (1.6%)
Aneurysm non-Exclusion (evidence of endoleak)	165/354 (46.6%)	74/169 (43.8%)	38/162 (24.0%)	30/172 (17.4%)
Stent Graft Patency	352/352 (100%)	167/168 (99.4%)	156/162 (96.3%)	166/171 (97.1%)
Device Integrity[1]				
1. Stent graft fractures	1. 0/383 (0%)	1. 0/137 (0%)	1. 0/113 (0%)	1. 0/133 (0%)
2. Kinking and/or twisting	2. 14/351 (3.9%)	2. 11/186 (5.9%)	2. 3/174 (1.7%)	2. 5/188 (2.6%)
Morbidity and Mortality	*Contained in Section 5. ADVERSE EVENTS*			

[1]No patient with a device kink or twist had nonpatency, migration, or required additional procedures for correction.

Table 6.6 Aneurysm Expansion by Follow-up Period[1]

Type	Pre-discharge N=416	Pre-discharge N=158	6 months N=158	1 year N=158
Expansion of the AAA by >5mm	Baseline evaluation	Baseline evaluation	4/147[2] (2.7%)	6/158 (3.8%)

[1] 416 patients were enrolled in the study. Denominators that are < 416 reflect the number of patients implanted with a Stent Graft and the actual readable images sent to the corelab by the investigational sites. The denominators are determinable measures based on the image quality. One patient suffered an MI after enrollment and prior to implantation.

[2] Patients required to have both predischarge and 6 month data for determination. 11 patients did not have both values.

Table 6.7 Aneurysm Growth in the Presence of Endoleaks at 12 months (N = 172)

Location	Enlarged[1]	Unchanged	Decreased[2]	Unknown[3]
Proximal Attachment Site	0	1	0	0
Distal Attachment Site	0	2	0	0
Junctional (modular)	0	2	0	1
Collateral	1	15	0	0
Unknown	1	6	0	1
Total	2	26	0	2

[1] Defined as size change of >5 mm.
[2] Defined as size change of <5 mm.
[3] No data or no conclusion regarding aneurysm size changes.

Table 6.8 Secondary Outcome: Surgical Control vs. Stent Graft

Endpoint	Surgical Control Mean (range)	Stent Graft Mean (range)	Difference [95% CI]
Duration of Anesthesia (min)[1]	293 (125-623) N=65	255 (110-814) N=415	38 [14, 62]
Duration of Procedure (min)[2]	210 (90-498) N=65	174 (71-680) N=415	36 [16, 56]
Blood Loss (cc)[2]	1617 (200-8000) N=65	544 (0-3500) N=410	1073 [886,1261]
Patients Requiring Blood Transfusion (%)[2]	55 N=65	24 N=410	31 [18, 44]
Days to Endotracheal Extubation[2]	1.3 N=60	0.2 N=374	1.1 [0.6, 1.5]
Days to Unassisted Ambulation[2]	3.6 N=65	1.4 N=392	2.2 [1.8, 2.5]
Days to Resumption of Normal Diet[2]	4.9 N=60	1.3 N=389	3.6 [3.2, 3.9]
Days in ICU[2]	3.5 (0-72) N=66	0.9 (0-83) N=396	2.5 [1.1, 3.9]
Hospital Length of Stay (LOS, days)[2]	9.3 (3-72) N=50	3.4 (0.8-84) N=406	5.9 [4.3, 7.6]

1 $p < 0.002$
2 $p < 0.001$

Table 6.9 Emergent Conversions, by Primary Cause of Failure

Cause	During procedure	Before 30 days	1 month	6 months	1 year
AAA Rupture	0	1	0	0	1
Leak: Collateral Vessels Filling Aneurysm	0	0	0	0	0
Unsuccessful vessel access or device malposition	4	1	0	0	0
Total	4	2	0	0	1

Table 6.10 Elective Conversions, by Primary Cause of Failure

Cause	During procedure	Before 30 days	1 month	6 months	1 year
AAA Rupture	0	0	0	0	0
Leak: Collateral Vessels Filling Aneurysm	0	0	1	0	0
Unsuccessful vessel access or device malposition	0	0	0	0	0
Total	0	0	1	0	0

7. PATIENT SELECTION AND TREATMENT

7.1 INDIVIDUALIZATION OF TREATMENT (SEE WARNINGS AND PRECAUTIONS)

Medtronic AneuRx recommends that the AneuRx Stent Graft diameter be at least 2mm larger than the aortic diameter and 1mm larger than the iliac diameter (10-20% oversizing). The length of the AneuRx Stent Graft should be sufficient to reach from just inferior to the most caudal major renal artery to non-aneurysmal tissue in the common iliac artery. All lengths and diameters of the devices necessary to complete the procedure should be available to the operator.

The risks and benefits previously described in Section 6. CLINICAL STUDIES should be carefully considered for each patient before use of the AneuRx Stent Graft System. Patient selection factors to be assess should include:

- patient's age and life expectancy (reference 4. WARNINGS AND PRECAUTIONS)
- co-morbidities (e.g., cardiac, pulmonary or renal insufficiency prior to surgery, morbid obesity etc.)
- patient's morphologic suitability for endovascular repair
- the risk of aneurysm rupture balanced against the risk of treatment with the AneuRx Stent Graft System

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

7.2 SPECIFIC PATIENT POPULATIONS

The safety and effectiveness of the AneuRx Stent Graft System for the treatment of abdominal aortic aneurysms has not been evaluated in patients:

- with aneurysms pending rupture
- with connective tissue disorder
- with hypercoagulability
- with mesenteric artery occlusive disease
- with ilio-femoral, thoracic, or inflammatory aneurysms
- with juxtarenal AAA
- with pararenal AAA
- with suprarenal or thorocoabdominal aneurysms
- who are morbidly obese
- pregnant or nursing
- less than 18 years old
- with less than one-year life expectancy

8. PATIENT COUNSELING INFORMATION

The physician should consider the following points when counseling the patient about this device:

- differences between endovascular repair and surgical repair
- risks related to open surgical repair
- risks related to endovascular repair
- open surgical repair is considered the gold standard for AAA repair
- endovascular repair is a new option with potential advantages related to its minimally invasive approach
- it is possible that subsequent endovascular or open surgical repair of the aneurysm may be required
- the long term effectiveness of endovascular repair has not been established; annual imaging and surveillance is required
- details contained in the Patient Information Booklet regarding risks occurring after implantation of the device, e.g., cardiac complications, neurological complications, etc.
- results of the clinical study indicate that women treated with this device may have a higher mortality rate as compared to their male counterparts

Medtronic AneuRx recommends that the physician disclose to the patient (in written form) all risks associated with treatment using the AneuRx Stent Graft System.

9. HOW SUPPLIED

The AneuRx Stent Graft components are available in the following lengths and diameters:

Table 9.1 Product Specifications

Expanded Stent Graft Diameters	Expanded Stent Graft Length	Catheter Diameter (outer)	Catheter Length (working length)
AneuRx Bifurcated Stent Graft and Delivery Catheter			
20mm/12mm	13.5cm	21 Fr.	55cm
22mm/13mm	13.5cm	21 Fr.	55cm
24mm/14mm	13.5cm	21 Fr.	55cm
26mm/15mm	13.5cm	21 Fr.	55cm
28mm/16mm	13.5cm	21 Fr.	55cm
20mm/12mm	16.5cm	21 Fr.	55cm
22mm/13mm	16.5cm	21 Fr.	55cm
24mm/14mm	16.5cm	21 Fr.	55cm
26mm/15mm	16.5cm	21 Fr.	55cm
28mm/16mm	16.5cm	21 Fr.	55cm
AneuRx Iliac Stent Graft and Delivery Catheter			
12mm	8.5cm	16 Fr.	55cm
13mm	8.5cm	16 Fr.	55cm
14mm	8.5cm	16 Fr.	55cm
15mm	8.5cm	16 Fr.	55cm
16mm	8.5cm	16 Fr.	55cm
12mm	11.5cm	16 Fr.	55cm
13mm	11.5cm	16 Fr.	55cm
14mm	11.5cm	16 Fr.	55cm
15mm	11.5cm	16 Fr.	55cm
16mm	11.5cm	16 Fr.	55cm
AneuRx Iliac Extender Cuff Stent Graft and Delivery Catheter			
12cm	5.5cm	16 Fr.	55cm
13cm	5.5cm	16 Fr.	55cm
14cm	5.5cm	16 Fr.	55cm
15cm	5.5cm	16 Fr.	55cm
16cm	5.5cm	16 Fr.	55cm
AneuRx Aortic Extender Cuff Stent Graft and Delivery Catheter			
20mm	3.75cm	21 Fr.	55cm
22mm	3.75cm	21 Fr.	55cm
24mm	3.75cm	21 Fr.	55cm
26mm	3.75cm	21 Fr.	55cm
28mm	3.75cm	21 Fr.	55cm

STERILE: Each AneuRx Stent Graft (Bifurcated, Iliac, Iliac and Aortic Extender Cuff) is individually packaged inside of a Delivery Catheter. The Delivery Catheters are sterilized using gamma radiation and are supplied sterile for single use only.

Do not reuse or attempt to resterilize.

Do not use if package is opened or damaged.

NON-STERILE: The AneuRx Deployment Handle is supplied non-sterile and must be sterilized prior to first use using steam sterilization under vacuum. The Deployment Handle may be resterilized and reused as described in the Deployment Handle Instructions For Use.

CONTENTS:

One (1) AneuRx Stent Graft and Delivery Catheter
One (1) envelope containing patient materials and tracking information
One (1) Instructions for Use Manual

STORAGE: Store at room temperature.

10. CLINICIAN USE INFORMATION

10.1 PHYSICIAN TRAINING PROGRAM

CAUTION: Physicians performing the AneuRx Stent Graft procedure must be trained in vascular interventional procedures and are required to have successfully completed additional training and certification by Medtronic AneuRx in the use of the AneuRx Stent Graft System.

The recommended skill/knowledge requirements for physicians using the AneuRx Stent Graft System are outlined below.

Patient selection:

- knowledge of the natural history of abdominal aortic aneurysms (AAA) and comorbidities associated with AAA repair; and
- knowledge of image interpretation, Stent Graft selection and sizing.

Experience with:

- femoral cutdown, arteriotomy, and repair;
- nonselective and selective catheterization;
- live fluoroscopic and angiographic image interpretation
- embolization
- angioplasty;
- endovascular stent placement;
- snare techniques;
- endovascular ultrasound techniques and interpretation;
- appropriate use of contrast material; and
- techniques to minimize radiation exposure.

10.2 INSPECTION PRIOR TO USE

Carefully inspect the sterile package for damage or defects before opening. Do not use product after the "Use By" date on the package. If the integrity of the sterile package has been

compromised prior to the product "Use By" date or the package or product is defective, do not use the product and contact your Medtronic AneuRx representative for return information.

10.3 MATERIALS REQUIRED (NOT INCLUDED IN STENT GRAFT SYSTEM PACKAGING)

At the time of surgery, Medtronic AneuRx recommends that the physician have available:

- at least one additional AneuRx Stent Graft (the size intended for implantation) in the event that the device is damaged during attempted placement;
- at least one additional AneuRx Stent Graft one size larger and one size smaller in the event that the original measurement underestimated or overestimated the vessel size.

IVUS measurements performed at the time of treatment are currently considered to be highly accurate and may demonstrate that baseline non-invasive imaging has incorrectly estimated the vessel size.

In addition to the materials included in the AneuRx Stent Graft System package, the following items are required:

- The Medtronic AneuRx Deployment Handle (supplied non-sterile and requires sterilization prior to use).
- Additional AneuRx Stent Grafts (Bifurcated, Iliac, and Iliac and Aortic Extender Cuffs) of various lengths and diameters are recommended to customize the implant to fit the anatomy of the individual patient.
- Fluoroscope with digital angiography capabilities (C-arm or fixed unit). Fluoroscopic imaging and the ability to record and recall all imaging.
- Assorted guidewires of adequate length (260 cm). In addition to guidewires used for accessing the vessel, Amplatz Super-Stiff® 0.035/0.038 inch (0.89/0.97mm) diameter guidewires or equivalents must be used to maximally support the AneuRx Delivery Catheter into the aortic vasculature.
- Heparinized saline solution.

10.4 MATERIALS RECOMMENDED (NOT INCLUDED IN STENT GRAFT SYSTEM PACKAGING)

- An approved 21 French/65cm or larger and 16 French/35cm introducer sheath to provide an adequate conduit for the Delivery Catheter.
- Sterile introducer sheaths of 8 French or 10 French for introduction into femoral arteries during road mapping or further diagnostic imaging.
- Power Injector for angiographic contrast studies.
- Radiopaque ruler with centimeter increments.
- Assorted angiographic and guiding catheters as well as angioplasty catheters to potentially dilate blood vessels prior to or following insertion of the Delivery Catheter and device.
- Intravascular ultrasound (IVUS) imaging unit with compatible catheters for 12.5 - 20 MHz imaging.
- Radiopaque contrast media.
- Sterile silicone lubricant or sterile mineral oil.
- French pigtail catheter.

10.5 MRI INFORMATION

MRI may be used on the Stent Graft only under the following conditions:

- when used in shielded MRI systems with static magnetic fields of 1.5T or less;

- spatial gradient of 450 gauss/cm or less, gradient magnetic fields of 10 Tesla/second or less; and
- a maximum whole body averaged specific absorption rate (SAR) of 1.4 W/kg for 30 minutes of imaging.

MR imaging is possible but quality may be compromised depending on the pulse sequence that is used and if the area of interest is in the same exact position as the Medtronic AneuRx Stent Graft. The effects of performing MRI procedures using MR systems and conditions above these levels have not been determined.

10.6 PREPARATION OF THE ANEURX STENT GRAFT SYSTEM

Correct sizing of the aorta and iliac vessels must be determined before implantation of the AneuRx Bifurcated and Iliac Stent Graftsusing Spiral computer aided tomography (CT) as well as angiograms of both the iliacs and aorta. These images should be available for review during of the procedure. , IVUS will further aid in proper determination of aortic and iliac diameters for appropriate sizing and placement during the procedure.

Vascular instruments and other surgical supplies needed to perform surgical cutdowns and to catheterize of access vessels should also be available..

A surgical team should be readily available for emergency conversion to an open surgical repair.

To reduce the risk of thromboembolism, it is recommended that the patient be heparinized for the duration of the procedure (during the U.S. clinical trial evaluating the AneuRx Stent Graft System, the average initial heparin dose per patient was 5,000 units).

Always maintain the AneuRx Stent Graft at room temperature at the time of the procedure to avoid the risk of affecting the Nitinol expansion memory.

CAUTION: Do not retract the Graft Cover of the Delivery Catheter until the catheter is accurately placed within the vasculature and ready for deployment.

CAUTION: Never advance or retract equipment from the vasculature without the use of fluoroscopy.

10.7 DELIVERY PROCEDURE (BIFURCATED STENT GRAFT)

NOTE: Medtronic AneuRx recommends using an appropriate caliber introducer sheath to perform diagnostic tests.

WARNING: Never advance an introducer sheath before the obturator is fully inserted. Never advance the obturator without first having placed a guidewire.

1. Open required equipment. Establish vasculature access via a small oblique bilateral groin incision over the femoral arteries. Insert introducer sheath (8 French) bilaterally. Provide systemic heparin.
2. Traverse a 0.035/0.038 inch (0.89/0.97mm) guidewire and pigtail angiographic catheter through the sheath at the primary access site, via the iliac and above the renal arteries.
3. Remove the guidewire and obtain angiogram(s) of the renal arteries and proximal aortic neck, then the iliac arteries (common – landing zone [the area of the aorta or iliac arteries where the most proximal or distal stent is intended to be positioned], external access).

4. Insert 0.035/0.038 inch (0.89/0.97mm) Amplatz Super Stiff ® or comparable wire through an angiographic catheter and place above the renals well into the descending thoracic aorta.
5. Before using IVUS for evaluation, remove the angiographic catheter and insert the IVUS catheter. Record findings/measurements and manually pull back. Remove IVUS catheter.
6. Insert a straight multiside hole angiographic catheter via the contralateral sheath above the level of the renal arteries (check or control angio catheter).
7. Remove 8 French sheath from primary access site, perform arteriotomy and insert 21 Fr. or larger arterial sheath (optional).

NOTE: Due to the nature of the design and the flexibility of the AneuRx Stent Graft, the overall length of the Stent Graft may shorten due to compression during deployment or tortuous anatomy.

WARNING: To prevent thrombotic problems, a second bolus of IV heparin is recommended before inserting the device.

WARNING: If an AneuRx Stent Graft is placed into less than one centimeter length of non-aneurysmal tissue at the proximal or distal ends of the aneurysm, there is potential for leaking or migration due to inadequate anchoring. If possible, place the AneuRx Stent Graft so that there is greater than one centimeter of non-aneurysmal tissue at each end of the AneuRx Stent Graft.

WARNING: Carefully inspect the AneuRx Delivery Catheter packaging for damage or defects prior to use. Do not use product if any sign of damage or breach of the sterile barrier is observed. Do not attempt to resterilize the Delivery Catheter or the AneuRx Stent Graft.

See Figure 1. Deployment: Catheter into Vessel

8. Insert primary Bifurcated AneuRx Stent Graft Delivery Catheter into vessel, maintain continual fluoroscopy for proper positioning initially above the renal arteries. Traction or a slow pull on the wire is essential to facilitate device tracking.

See Figure 2. Bifurcated Catheter Nose Cone

9. Place the Delivery Catheter nose cone at or immediately above the renal arteries. Orient the NOTCH of the nose cone towards the contralateral "pant leg" or missing iliac limb, by rotating the catheter clockwise or counterclockwise. The cross hole of the nose cone should appear fully round under fluoroscopy when aligned.

See Figure 3. Delivery Catheter

10.8 DEPLOYMENT PROCEDURE (BIFURCATED STENT GRAFT)

1. Make certain that the geared Lead Nut (4) in the Deployment Handle is advanced fully forward.

2. Remove the blue Safety Clip from the Delivery Catheter (See figure 3). Open Latch (2) on the Deployment Handle.

1. Insert the Delivery Catheter into the body of the Deployment Handle. Align and engage the Delivery Catheter Slide Ring with the Lead Nut (4) of the Deployment Handle.

NOTE: When loading the Deployment Handle onto the Delivery Catheter be sure to maintain correct orientation of the AneuRx Stent Graft within the lumen.

NOTE: Ensure that the end of the introducer sheath has been withdrawn to prevent deployment of the AneuRx Stent Graft within the Introducer Sheath.

See Figure 4. Top Proximal Radiopaque Markers

1. Retract the graft cover 2-3 cm until you can see the four top proximal radiopaque markers. Watch for possible movement via fluoroscopy.

See Figure 5. Deployment Handle Top View

Deployment Handle Parts List:

1. Handle
2. Latch
3. Lead Screw
4. Lead Nut
5. Bearing (2 each)
6. Gear Assembly
7. Crank

See Figure 6. Rotational Adjustment: Proximal Radiopaque Markers

5. Small rotational adjustment with the Delivery Catheter can still be made to align the radiopaque markers. If required, perform an angiographic check via the contralateral straight catheter and confirm position of the straight catheter relative to the lower renal artery. Maintain Stent Graft position or pull down slowly to a position just below the lower renal artery then remove straight angiographic catheter by pulling it back into the abdominal aortic aneurysm.

WARNING: Failure to properly align the radiopaque markers may result in improper deployment of the Stent Graft and may necessitate surgical removal of the device.

See Figure 7. Distal Radiopaque Markers

6. Continue deployment of the Stent Graft until the Graft Cover is just below the distal radiopaque marker on the Delivery Catheter. This position is critical and must be carefully checked with fluoroscopy to prevent Stent Graft movement during retraction of the runners.

WARNING: If the Graft Cover is not retracted below the distal radiopaque marker on the AneuRx Stent Graft, re-sheathing of the Stent Graft may occur during retraction of the runners.

10.9 DELIVERY CATHETER REMOVAL PROCEDURE (BIFURCATED STENT GRAFT)

1. Depress the Quick Disconnect Button (see Figure 3) to retract the nose cone and runners. Use continual fluoroscopy and watch the top of end of the AneuRx Stent Graft while slowly pulling back the runners and the nose cone into the Graft Cover of the Delivery Catheter. To prevent the Stent Graft from being caught between the Graft Cover ensure graft cover is fully retracted.Separate the Deployment Handle from the Delivery Catheter and remove the Delivery Catheter from the patient. Maintain guidewire access and use an 8 Fr. sheath to maintain hemostasis.

10.10 ILIAC STENT GRAFT DEPLOYMENT

1. Insert a 0.035 inch (0.89mm) angled Glidewire into the straight flush catheter in the contralateral femoral artery. Remove the straight flush catheter and introduce a diagnostic catheter. Under fluoroscopy, carefully direct the Glidewire into the gate area (the opening in the Bifurcated Stent Graft where the contralateral leg is inserted) of the contralateral leg. A variety of angled catheters, (Multipurpose, Headhunter, Cobra) may be helpful. Confirm correct positioning with right and left oblique views of the catheter in the gate as well as a check angiogram and other techniques.

NOTE: Alternate access route: ipsilateral to contralateral "up and over the top" or direct guidewire from brachial approach.

10.11 DELIVERY, DEPLOYMENT, AND CATHETER REMOVAL PROCEDURE (ILIAC STENT GRAFT)

1. If using IVUS, insert the IVUS catheter and ensure correct wire placement in the short pant leg. Assess the distance from the gate to the aortic bifurcation and landing site of the contra-iliac leg.
2. Replace IVUS catheter or angiographic catheter with 0.035-inch (0.89mm) Amplatz Super Stiff® or comparable wire and position in the descending thoracic aorta.
3. Remove the 8 French sheath and insert the 16 French/35cm sheath into the pant leg of the Bifurcated Stent Graft under continuous fluoroscopy.

See Figure 8. Contralateral Delivery Catheter

4. Insert the contralateral Delivery Catheter into the sheath, well into the gate area.

See Figure 9. Alignment of Contralateral Delivery Catheter

5. Align the Delivery Catheter within the four radiopaque markers of the pant leg in the middle or upper portion of the gate. Pull 16 French sheath back until enough clearance is obtained.

See Figure 10. Deployment of Contralateral Iliac Leg

6. Attach the Deployment Handle as previously described in Deployment Procedure (Bifurcated Stent Graft) section. Deploy the Stent Graft under continuous fluoroscopy watching carefully for any position changes.
7. Continue deployment of the Stent Graft until the Graft Cover is just below the distal radiopaque marker on the Stent Graft. This position is critical and must be carefully checked with fluoroscopy to prevent Stent Graft movement during retraction of the runners.
8. Depress the Quick Disconnect Button to retract the nose cone and runners. Use continuous fluoroscopy and watch the top end of the AneuRx Stent Graft while slowly pulling back the runners and nose cone into the Graft Cover of the Delivery Catheter. To prevent the Stent Graft from being caught between the Graft Cover and the runners, ensure the graft cover is fully retracted. Remove the Delivery Catheter from the sheath while maintaining guidewire access.
9. Reinsert angiographic pigtail catheter and obtain final angiogram from renal to hypogastric arteries. Check for Stent Graft apposition and seal below the renal arteries then Stent Graft position and seal in the iliac landing zone.
10. Perform adjunctive maneuvers as needed: balloon angioplasty and/or proximal or distal Extender Cuff insertion.

11. If it is necessary to deploy an Extender Cuff, a Delivery Catheter with the proper size Extender Cuff is passed to the area at the proximal or distal end of the AneuRx Stent Graft. The Extender Cuff is then deployed with adequate overlap (at least 1 cm) inside the already placed AneuRx Stent Graft. Extender Cuffs are deployed in the same manner as other straight Stent Grafts as described earlier. Completion angiography should be repeated. Proper overlap is assessed when the end radiopaque marker of the Extender Cuff is inserted approximately 1 cm past the end radiopaque markers of the AneuRx Stent Graft being extended.

NOTE: IVUS may be used to interrogate the inner lumen of the graft and attachment points to the vessel wall. Specific attention should be paid to unwanted wrinkles or kinks in the Stent Graft or to unwanted space between the AneuRx Stent Graft and vessel wall at the proximal and distal ends.

NOTE: A non-compliant balloon catheter (angioplasty) – diameter equivalent to the vessel diameter – may be inserted over the guidewire and positioned into the AneuRx Stent Graft and inflated to smooth out any remaining wrinkles in the graft fabric or at the proximal and distal ends of the AneuRx Stent Graft. Two different diameter balloon catheters may be required for this procedure (iliac and aortic). This optional procedure is not required, but may be performed if necessary.

WARNING: Do not overinflate dilatation catheters. Follow all manufacturer instructions regarding catheter operation and use only a commercial inflation device that allows for precise control and monitoring of balloon pressure.

12. Remove sheaths and wires followed by arteriotomy and groin wound closure. Check distal lower extremity perfusion at the end of the procedure.

See Figure 11. The Medtronic AneuRx Stent Graft System

11. PATIENT INFORMATION

Patient follow-up should be individualized to meet patient specific needs. Periodic imaging should be scheduled based on the physician's clinical assessment of the patient pre- and post-discharge. Periodic imaging is typically scheduled at 6 to 12 month intervals and may be performed more frequently if necessary, e.g., if a patient presents with an endoleak, imaging may be scheduled between 3 to 6 months.

In addition to this Instructions for Use, the AneuRx Stent Graft System is packaged with additional specific information which includes:

- a Patient Implant Card that includes both patient information and Stent Graft implant information. All patients will be instructed to keep this card in their possession at all times for procedure/Stent Graft identification.
- a Patient Information Booklet which includes information on abdominal aortic aneurysms, the AneuRx Stent Graft implant procedure and the AneuRx Stent Graft System.
- a Device Tracking Form which will be completed by the hospital staff and forwarded to AneuRx for the purposes of tracking all patients who received an AneuRx Stent Graft product (as required by Federal Regulation).

12. EXPLANATION OF SYMBOLS

W "Attention, See Instructions for Use	h "Use By"
k "Do Not Reuse"	l "Batch Code"
REF "Model Number"	q "Method of Sterilization Using Irradiation"

13. DISCLAIMER OF WARRANTY

DISCLAIMER OF WARRANTY FOR THE U.S.

ALTHOUGH THE MEDTRONIC ANEURX STENT GRAFT AND DELIVERY CATHETER, HEREAFTER REFERRED TO AS THE ANEURX STENT GRAFT, HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, MEDTRONIC HAS NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS PRODUCT IS USED. MEDTRONIC, THEREFORE, DISCLAIMS ALL WARRANTIES, BOTH EXPRESSED AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. MEDTRONIC SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND MEDTRONIC TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

TRADEMARKS

AneuRx is a trademark of Medtronic AneuRx, Inc.
Medtronic is a registered trademark of Medtronic, Incorporated
Amplatz Super Stiff is a trademark of Boston Scientific Corporation

U.S. and International Patents Pending

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Medtronic

AneuRx™
Patient Information Booklet

The AneuRx™ Stent Graft System

A New Treatment
For
Abdominal Aortic Aneurysms

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This brochure is designed to provide important information regarding treatment for abdominal aortic aneurysms using a device known as the AneuRx™ Stent Graft System. Use of this medical device requires discussion with a qualified doctor. It is important that you read this booklet carefully and discuss its contents with your doctor.

TABLE OF CONTENTS

You are entitled to be informed about the proposed treatment, including the risks of the treatment and the alternatives to it. Please read this booklet and discuss its contents with your doctor so that all of your questions are answered to your satisfaction.

Introduction

This educational information is provided to help you make an informed decision about the AneuRx Stent Graft System as a method of treating your abdominal aortic aneurysm. Please read this material completely and discuss any questions with your doctor in order to decide if the AneuRx Stent Graft System is right for you. Only a doctor can determine whether you are a suitable candidate for the AneuRx Stent Graft Procedure.

What is an Aneurysm?

An aneurysm is a bulge or balloon that forms in the wall of a blood vessel. An aneurysm is most commonly a result of an accumulation of fatty deposits on the vessel wall, but may also relate to heredity, trauma or other disease that weakens the vessel wall. Over time, the vessel wall loses its elasticity and the force of normal blood pressure in the aneurysm can lead to the rupture of the vessel. If an aneurysm forms in the part of the aorta (one of the body's main blood vessels) that extends through the abdomen it is called an abdominal aortic aneurysm (see Figure 1).

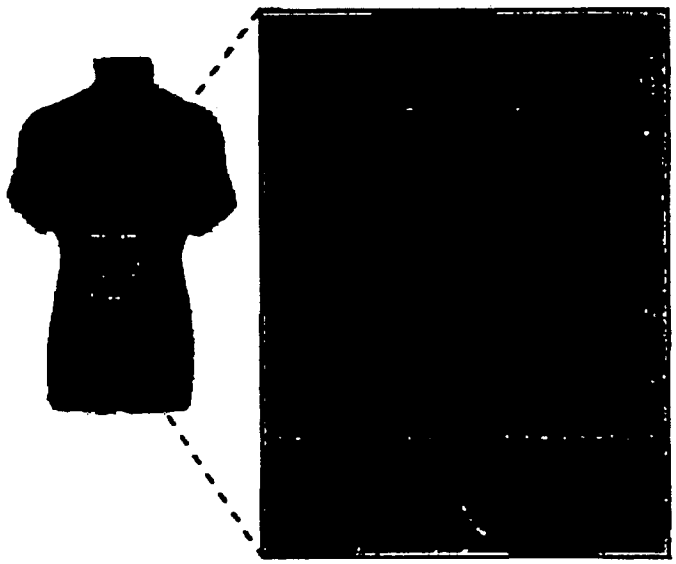

Figure 1. An aneurysm is a bulge or balloon that forms in the wall of the blood vessel.

What Symptoms Are Associated With Abdominal Aortic Aneurysms?

Most people do not experience any symptoms indicating that they may have an abdominal aortic aneurysm. During a routine physical examination, your doctor may notice or feel a throbbing tender mass in the middle or lower part of your abdomen. However, most aneurysms are identified when diagnostic imaging testing (such as x-ray) is performed for other reasons.

What is the Current Treatment Used for Repair of Abdominal Aortic Aneurysms?

An abdominal aortic aneurysm is treated if the doctor feels there is a risk that the aneurysm will burst. Currently, the standard treatment is conventional surgery. The

surgery is performed to replace the section of the vessel where the aneurysm has formed. The surgical procedure is performed under general anesthesia and takes about three to four hours to complete. The surgeon accesses the aneurysm through an incision in the abdomen. The aneurysmal portion of the vessel is excluded (shut-off from the main part) or sometimes replaced with a synthetic graft, which is sewn into place. Patients typically spend one night in an intensive care unit and remain in the hospital for an additional five to seven days.

Is There an Alternative Treatment to Conventional Surgery?

Yes, there is an alternative treatment known as "endovascular stent grafting." Endovascular stent grafting is a procedure in which a stent graft (a woven polyester tube covered by a tubular metal web) is placed inside of a diseased vessel without surgically opening the tissue surrounding the diseased vessel. This alternative treatment may be used for patients who are not good candidates or who prefer not to undergo open surgery.

The AneuRx Stent Graft System uses a stent graft (shown in Figure 2) to reinforce the weakened wall of the vessel to prevent rupture of the aneurysm. The stent graft is placed inside of the aneurysm using a delivery catheter (a long tube-like device that assists in the placement of the stent graft in the blood vessel).

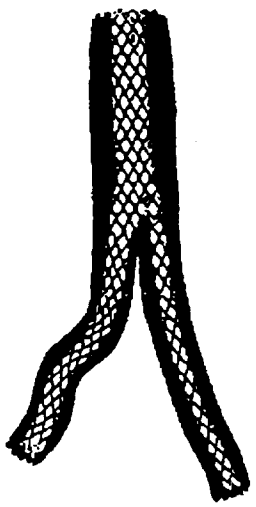

Figure 2. The AneuRx Stent Graft

Results Following the Procedure

In clinical trials conducted to evaluate the AneuRx Stent Graft System, the stent graft was successfully delivered and deployed in 97% of patients. The most common reason that the procedure was not successful was that the patient's blood vessels were too small or unhealthy to permit delivery of the Stent Graft.

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Are You a Good Candidate for the AneuRx Stent Graft Procedure?

Anyone who is considering the AneuRx Stent Graft procedure should:

- Be 18 years of age or older
- Not be pregnant
- Be sufficiently healthy to undergo a 2-4 hour implantation procedure
- Be available to attend regularly-scheduled office visits with a doctor following the procedure
- Be fully informed about the risks and benefits of the AneuRx Stent Graft Procedure as compared to open surgical repair.

Patients having very large aneurysms and/or aneurysms or vessels which are very angled may not be good candidates for treatment using the AneuRx Stent Graft. Since not all patients are good candidates for this type of treatment, it is very important that you speak to your doctor about your reasons for wanting to be treated with the AneuRx Stent Graft and ask if you would be a good candidate.

Please see Page 6 for a detailed safety summary the AneuRx Stent Graft procedure. It is important to discuss all possible risks and benefits with your doctor before deciding whether the AneuRx Stent Graft procedure is the appropriate treatment option for you.

How is the AneuRx Stent Graft Procedure Performed?

The AneuRx Stent Graft Procedure is performed using either regional or general anesthesia. Prior to the procedure, a number of diagnostic tests are performed. These diagnostic tests allow the doctor to visualize the aneurysm and the surrounding area. To prepare for the procedure, a small incision is made in each upper thigh area. Using fluoroscopy for visual guidance, the delivery catheter is advanced through the large vessel in your thigh to the aneurysm site in your abdomen (see Figure 3).

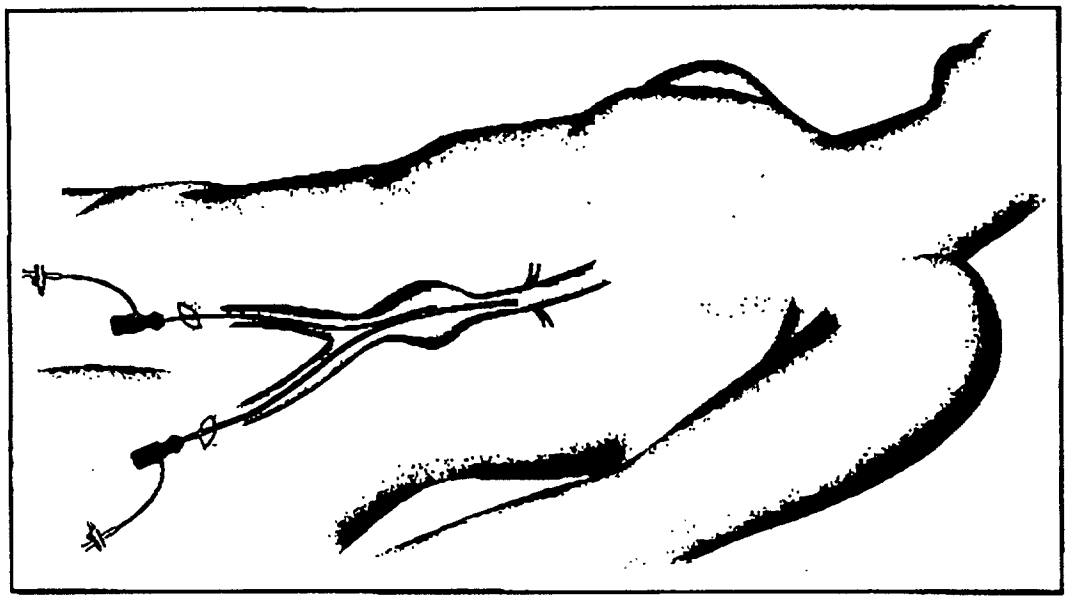

Figure 3. The delivery catheter is inserted through the vessel in your leg and into the aneurysm.

When the delivery catheter is properly positioned inside the aneurysm, the AneuRx Stent Graft is released from the delivery catheter into the blood vessel. When the Stent Graft comes into contact with blood, it expands to a preset size. After expansion of the Stent Graft, the delivery catheter is withdrawn and removed. Depending on the shape and size of your aneurysm, additional stent grafts may be placed to assure that the aneurysm is completely reinforced. X-rays and/or intravascular ultrasound imaging procedures are performed to allow the doctor to verify that the stent graft is properly placed within the aneurysm (see Figure 4). The procedure typically takes between two to four hours to complete.

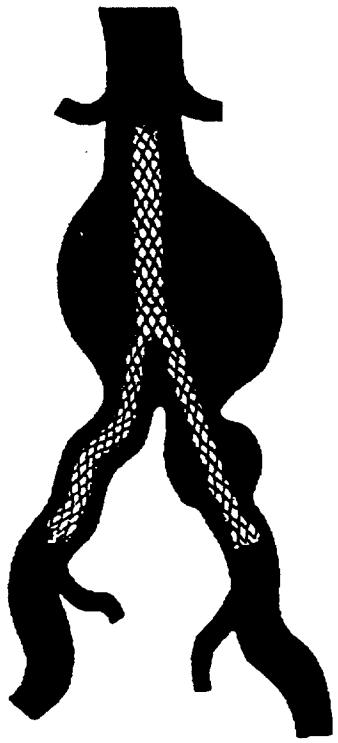

Figure 4. Placement of the AneuRx Stent Graft.

What Can I Expect After the AneuRx Stent Graft Procedure?

Patients have reported feeling discomfort for the first few days following the procedure. Immediately after recovery from the AneuRx Stent Graft procedure, your physician may require you to lay flat for 4-6 hours to allow the leg wounds to begin healing. You may experience side effects such as swelling of the upper thigh, numbness of the legs, nausea, vomiting, leg pain or throbbing, malaise, lack of appetite and/or absence of bowel movement for 1-3 days.

This section is not intended to be a substitute for a thorough discussion with your doctor about whether this treatment is right for you. Please read this section carefully, then talk to your doctor.

Safety Summary

Indications for Use

The AneuRx Stent Graft System is indicated for the endovascular treatment of infrarenal abdominal aortic or aorto-iliac aneurysms having:

- adequate iliac/femoral access;
- infrarenal non-aneurysmal neck length of at least 1 cm at the proximal and distal ends of the aneurysm and a vessel diameter 10-20% smaller than the labeled device diameter;
- morphology suitable for endovascular repair;
- one of the following:

  a diameter > 5 cm;

  a diameter of 4-5 cm and has increased in size by 0.5 cm in the last 6 months; or

  twice the diameter of the normal infrarenal aorta.

Contraindications for Use

There are no known contraindications currently associated with this device.

Warnings

- The long-term risks of prolonged fluoroscopy have not been established.
- Transluminal repair of aneurysms presents the potential for significant x-ray exposure because of beam intensity and duration of imaging. This can result in acute radiation injury as well as increased risk for somatic and genetic defects to patients and to clinical staff. Adequate attention must be given to the potential radiation exposure associated with these procedures, and steps should be taken to minimize and measure this exposure.
- Perforation and/or dissection of the vasculature are an inherent risk of any catheter-based procedure. These risks may be increased with the use of large sized catheters such as the Delivery Catheter or introducer sheath.
- The results of the clinical study indicate that women treated with this device may have a higher mortality rate as compared to their male counterparts.

Precautions

- The long-term safety and effectiveness of the AneuRx Stent Graft System has not yet been established.

Glossary

Abdominal Aortic Aneurysm – an aneurysm that forms in the part of the aorta that extends through the abdomen.

AneuRx Stent Graft – a woven polyester tube externally supported by a tubular metal web that expands to a pre-established diameter when placed in the artery.

Aneurysm – a bulging or "ballooning" of a weakened area of a blood vessel.

Aorta – the main trunk of the arterial system of the body.

CT Scan – a series of computerized x-rays that form a picture of your aneurysm and adjacent blood vessels.

Delivery Catheter – a long tube-like device that assists in the placement of the stent graft in the blood vessels.

Edema – a condition in which the body tissues contain an excessive amount of tissue fluid.

Endoleak – blood flow into the aneurysm after placement of a stent graft

Endovascular Stent Grafting – a procedure in which a stent graft is placed inside a diseased vessel without surgically opening the tissue surrounding the diseased vessel.

Excluded/Exclusion – shutting off or removing from the main part.

Fluoroscopy – a real-time X-ray image that is viewed on a monitor.

Intravascular Ultrasound – an image created on a monitor through the use of high frequency sound waves from inside the blood vessel (artery only).

Occlusion – the closure or state of being closed.

Perigraft Flow – blood flow through the material of the stent graft

Thrombus – a blood clot that obstructs a blood vessel or a cavity of the heart.

Thrombotic – related to, caused by or of the nature of a thrombus.

Ultrasound Imaging – an image created through the use of high frequency sound waves from outside the body.

This page is not intended to be a substitute for a thorough discussion with your doctor about whether this procedure is right for you.
Please read this page carefully and then talk to your doctor.

Possible Questions to Ask Your Doctor

- What are the other options for treatment of abdominal aortic aneurysms?
- Is the AneuRx Stent Graft System the only approved medical device for treatment of abdominal aortic aneurysms?
- Will my health insurance pay for part or all of the cost associated with this procedure?
- When was the first patient treated using the AneuRx Stent Graft System? To date, how many patients have been treated?
- What are the risks of rupture with a Stent Graft?
- Following the procedure, how often will I need to be seen by my doctor and what type of follow-up tests will need to be performed?
- Will I have to limit my activities after the treatment? If yes, for how long?
- How long can the Stent Graft remain implanted inside of my body?
- How many AneuRx Stent Graft procedures has this facility performed? What are the 6-month, 1-year and 2-year survival rates?

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