

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 nonaneurysmal neck length of greater than 1 cm at the proximal and distal ends of the aneurysm and an inner vessel diameter approximately 10–20% smaller than the labeled device diameter
- Morphology suitable for endovascular repair
- One of the following:
 - Aneurysm diameter of >5 cm
 - Aneurysm diameter of 4–5 cm which has also increased in size by 0.5 cm in the last 6 months
 - Aneurysm which is twice the diameter of the normal infrarenal aorta.

Contraindications

There are no known contraindications currently associated with this device.

Warnings and Precautions

FDA approval of the AneuRx device on September, 28, 1999 was based upon one-year follow-up data.

The clinical information in this Brief Statement has been updated from the information originally submitted to the FDA for approval to include updated clinical information available to Medtronic as of August 1, 2003 (the clinical data freeze date for the 2003 PMA Annual Report).

The AneuRx Stent Graft is intended to prevent rupture of abdominal aortic aneurysms. However, this risk is not completely eliminated. Based on reports received for patients enrolled in all phases of the clinical study, through August 1, 2003, ruptures have occurred in 2/1193 (0.167%) patients during the operative period; in 3/1193 (0.251%) patients within 30 days of treatment; and in 15/1193 (1.257%) patients greater than 30 days after treatment. The one-year freedom from rupture rate for patients enrolled in all phases of the clinical study is 99.5%; the two-year freedom from rupture rate is 98.6%; the three-year freedom from rupture rate is 98.5%; the four-year freedom from rupture rate is 97.2%; and the five-year freedom from rupture rate is 97.2%.

The long-term safety and effectiveness of this implant have not been established. All patients with endovascular aneurysm repair must undergo periodic imaging to evaluate the stent graft, aneurysm size, and occlusion of vessels in the treatment area. Significant aneurysm enlargement (>5 mm), the

appearance of a new endoleak, evidence of perigraft flow, change in aneurysm pulsatility, or migration resulting in an inadequate seal zone should prompt further investigation and may indicate the need for additional intervention or surgical conversion.

Exercise care in the handling and delivery technique to aid in the prevention of vessel rupture. If an AneuRx Stent Graft is placed with less than one centimeter length of nonaneurysmal tissue at the proximal or distal end attachment sites, there is potential for leaking or migration due to inadequate apposition of the stent graft.

- Inappropriate patient selection may contribute to poor device performance. Preliminary data indicate that patients with an aortic neck angle >45 degrees may have a higher likelihood of suboptimal outcomes compared to patients with an aortic neck angle <45 degrees. The same data indicate that patients with an aortic seal length of <15 mm and an iliac seal length of <25 mm may also have a higher likelihood of sub-optimal outcomes.
- This device should only be used by physicians and teams trained in vascular interventional techniques, including training in the use of the device.
- Do not use the AneuRx Stent Graft in patients unable to undergo the necessary preoperative and postoperative imaging and implantation studies.
- 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).
- The safety and effectiveness of the AneuRx Stent Graft System for the treatment of abdominal aortic aneurysms have 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 thoracoabdominal 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.

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: polyether block amide (PEBA); polyether block amide (PEBA) with tungsten filler; polyether block amide (PEBA) with barium sulfate filler; acrylonitrile-butadiene-styrene (ABS) copolymer; glass-filled acrylonitrile-butadiene-styrene (ABS) copolymer; polyetheretheretherketone (PEEK); polyvinyl chloride (PVC); stainless steel; ethylene propylene rubber; Nylon; silicone; polycarbonate; cyanoacrylate; nickel/titanium (nitinol); tantalum; and polyester. The AneuRx Stent Graft with Xcelerant Delivery System is latex-free.
 - 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 lb (150 kg) or whose weight may impede accurate fluoroscopic imaging.
 - Regular follow-up including imaging of the device should be performed every 3 to 6 months for patients in the enhanced surveillance group and at least every 6 to 12 months for patients in the routine surveillance group (see IFU for patient follow-up recommendations). During the recommended follow-up imaging schedule, patients should be monitored for aneurysm size, occlusion of vessels, change in pulsatility, migration, leaks, and device integrity.
 - Additional treatment including endovascular treatment or surgical conversion should be strongly considered in the following cases:
 - Aneurysm growth >5 mm (with or without leak) since last follow-up
 - Change in aneurysm pulsatility (with or without growth or leak)
 - Persistent endoleak with or without aneurysm growth
 - Stent graft migration resulting in an inadequate seal zone
- 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.
 - Non-clinical testing has demonstrated that the AneuRx Stent Graft is MR Conditional. It can be scanned safely under the following conditions:
 - Static magnetic field of 3-Tesla or less
 - Spatial gradient field of 720 Gauss/cm or less
 - Maximum whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning.

Adverse Events

Death, AAA rupture, bleeding, cardiac failure/infarction, edema, wound healing complications, impotence, pulmonary complications, renal failure, gastrointestinal complications, arterial vascular occlusion, and venous vascular occlusion.

Potential adverse events include: arterial and venous occlusion (includes thrombosis and thromboembolism), arterial trauma/dissection/perforation, bleeding, cardiac failure/infarction, central or peripheral nervous system impairment, coagulopathy, death, edema, endoleak, erosion with fistula or pseudo-aneurysm, gastro-intestinal complications, graft dilatation, graft migration, graft occlusion, impotence, infection, loss of device integrity: stent fractures, graft wear holes, suture breaks, pulmonary/respiratory complications, renal insufficiency/failure, ruptured vessel/aneurysm, and wound healing complications.

Please reference appropriate product *Instructions for Use* for a more detailed list of indications, warnings, precautions and potential adverse events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.



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