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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Medtronic Exhibit 1019
Medtronic Corevalve v. Colibri Heart Valve
IPR2020-01454

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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.

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