



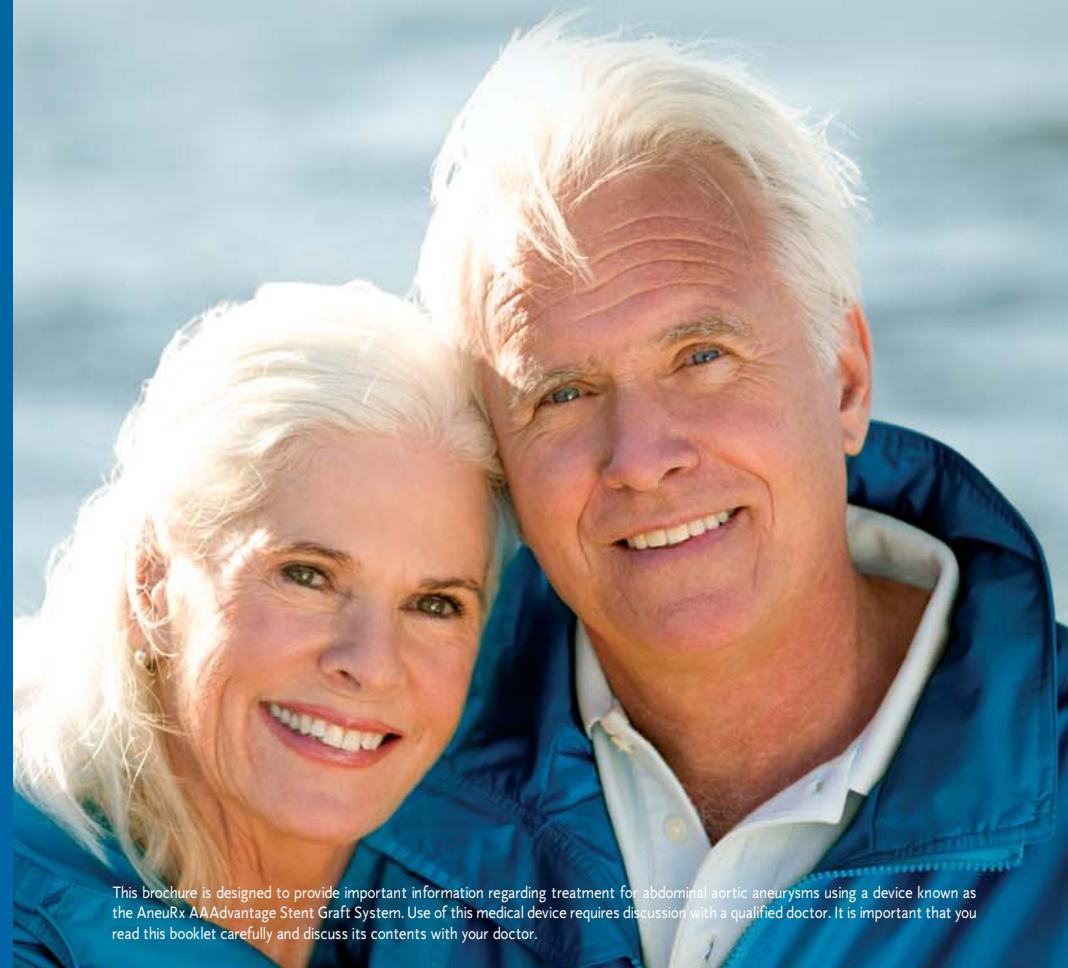
# *Patient Information Booklet*

The AneuRx AAAAdvantage Stent Graft System

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## ***Endovascular Stent Grafts:***

*A Treatment for Abdominal  
Aortic Aneurysms*



**Medtronic Vascular**  
3576 Unocal Place  
Santa Rosa, CA 95403  
Tel: 707.525.0111  
[Medtronic.com](http://Medtronic.com)

**Customer Service**  
Tel: (800) 961-9055  
Fax: (800) 929-2133

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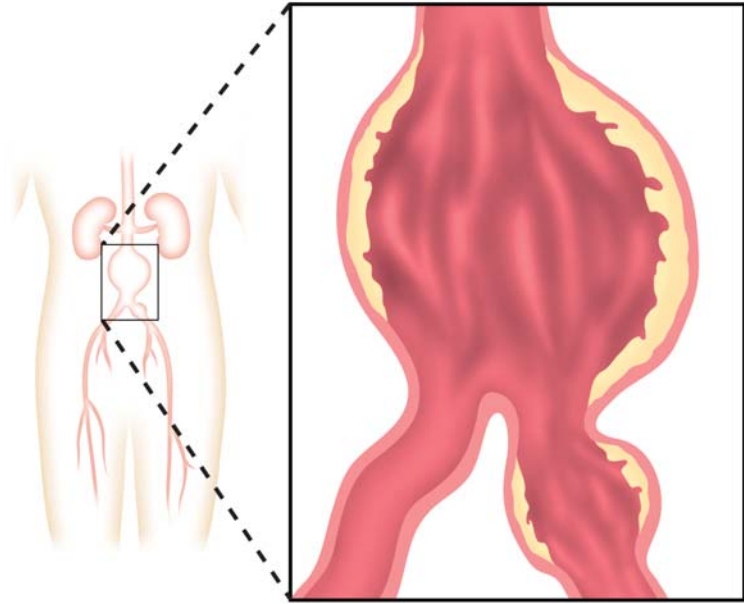
You are entitled to be informed about the proposed treatment, including the risks of the treatment and the alternatives to it. Please read this booklet and discuss its contents with your doctor so that all of your questions are answered to your satisfaction.

## Introduction



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

If you are unfamiliar with the terms used in this booklet, please refer to the Glossary at the back of this booklet.



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

### 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 bursting (also referred to as "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 Fig. 1).

### 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 (or rupture). Currently, the standard treatment is conventional surgery. The surgery is performed to replace the section of the vessel where the aneurysm has formed with a synthetic graft. 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?

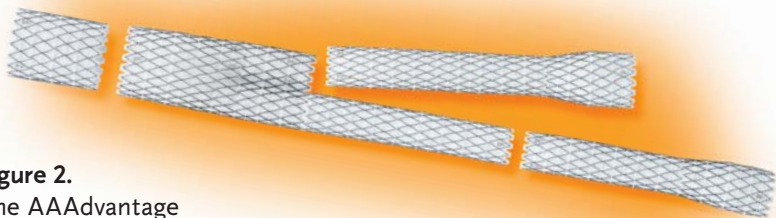
Yes, there is an alternative treatment known as "endovascular stent grafting." Endovascular stent grafting is a procedure where a stent graft, which is a woven polyester tube (graft) covered by a tubular metal web (stent), is placed inside of a diseased (aneurysmal) vessel without surgically opening the tissue surrounding the diseased vessel. The stent graft, therefore, excludes the aneurysm from the normal blood flow. However, since the diseased vessel is not actually replaced, there is a small but real risk of aneurysm rupture. Within 5 years after the procedure, the risk is about 1.5 percent compared to a low risk of rupture-type complications for surgical repair (less than 1 percent), where the diseased vessel is removed.

The long-term risks of the stent graft implant are not yet known, so you will have to be monitored at least once a year, for the duration of your life, with imaging devices such as computed tomography (also known as a CAT scan or CT). You may need to have more frequent exams and images taken if your physician feels that there is a problem with the implant. This frequency and type of monitoring is generally not required after open surgical repair.

There are also risks and benefits associated with conventional surgery. The AAA Advantage graft may benefit persons who are not good candidates for surgery or who prefer not to undergo open surgery. You should talk with your doctor about which option is best for you.

## How Does the Stent Graft Work?

The AAAdvantage Stent Graft System uses a stent graft (shown in Fig. 2) to exclude the aneurysm from the circulation and thus prevent continued pressurization and possible 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 within the blood vessel).



**Figure 2.**  
The AAAdvantage  
Stent Graft

## Results Following the Procedure

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



## Are You a Good Candidate for the AAAdvantage Stent Graft Procedure?

Anyone who is considering the AAAdvantage stent graft procedure should:

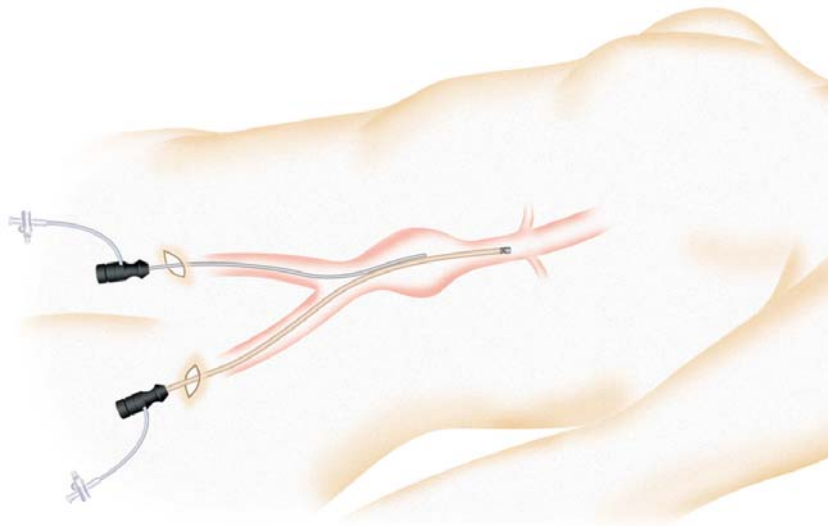
- Be 18 years of age or older.
- Not be pregnant.
- Be sufficiently healthy to undergo a 2–4 hour implantation procedure.
- Be available to attend regularly scheduled office visits with a doctor following the procedure, including radiographic imaging studies to evaluate the status of the graft and aneurysm. Imaging studies may be required as often as every three months or as infrequently as every 12 months, depending on the status of your aneurysm and graft.
- Be fully informed about the risks and benefits of the AAAdvantage Stent Graft procedure as compared to open surgical repair.

Patients having very large aneurysms and/or aneurysms or vessels that are very angled may not be good candidates for treatment using the AAAdvantage 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 AAAdvantage Stent Graft and ask if you would be a good candidate.

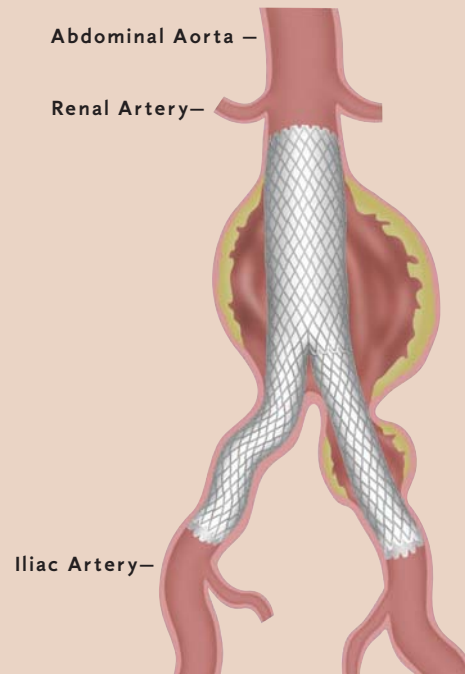
Please see Page 11 for a detailed safety summary about the AAAdvantage stent graft procedure. It is important to discuss all possible risks and benefits with your doctor before deciding whether the AAAdvantage stent graft procedure is the appropriate treatment option for you.

### How Is the AAAAdvantage Stent Graft Procedure Performed?

The AAAAdvantage 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 (X-rays) for visual guidance, the delivery catheter is advanced through the large vessel in your thigh (iliac vessel) to the aneurysm site in your abdomen (see Fig. 3).



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



**Figure 4.** Placement of the AAAAdvantage Stent Graft.

When the delivery catheter is properly positioned inside the aneurysm, the AAAAdvantage Stent Graft is slowly 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, leaving the stent graft within the vessel. Depending on the shape and size of your aneurysm, additional stent grafts may be placed to ensure that the aneurysm is completely excluded. 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 Fig. 4). The procedure typically takes between two to four hours to complete.

## What Can I Expect After the AAAAdvantage Stent Graft Procedure?

Immediately after recovery from the AAAAdvantage Stent Graft procedure, your physician may require you to lay flat for four to six hours to allow the leg wounds to begin healing. Patients have reported feeling discomfort for the first few days following the procedure. 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, fever, and/or absence of bowel movement for one to three days. Your stay in the hospital typically would be approximately two to four days.

## When Should I Call My Doctor?

If you experience any of the following symptoms, contact your doctor immediately:

- Pain, numbness, coldness or weakness in your legs or buttocks.
- Any back, chest, abdominal or groin pain.
- Dizziness, fainting, rapid heartbeat or sudden weakness.

You should also call your doctor if you are required to reschedule your follow-up visit for any reason

## Safety Summary

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 and then talk to your doctor.

## Indications for Use

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

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

## Contraindications for Use

There are no known contraindications currently associated with this device.

## Warnings and Precautions

The AneuRx Stent Graft system 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.

- 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 (ie, cardiac complications, fever, infection, musculoskeletal complications, neurological complications, pulmonary complications, vascular disease, vessel dissection, wound healing issues, and mortality).

## Glossary

**AAAdvantage Stent Graft:** a woven polyester tube externally supported by a tubular metal web that expands to a preestablished diameter when placed in the artery.

**Abdominal aortic aneurysm:** a bulging or “ballooning” of a weakened area of the abdominal aorta (main vessel of the arterial system of the body that extends through the abdomen). This term is often abbreviated to “AAA.”

**Aneurysm:** a bulging or “ballooning” of a weakened area of a blood vessel.

**Aneurysm rupture:** a tear in the vessel wall near or at the location of the bulging or “ballooning” of the weakened area of the blood vessel (abdominal aortic aneurysm).

**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 within the blood vessels.

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

**Endoleak:** blood flow into the aneurysm (bulge or “balloon” of the weakened area of the blood vessel) after placement of a stent graft.

**Endovascular stent grafting:** a procedure in which a tube-shaped device (see AAAdvantage stent graft above) 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 tube-shaped device (see AAAdvantage Stent Graft above).

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

**Ultrasound imaging:** an image created through the use of high-frequency sound waves.

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 AAAAdvantage 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 AAAAdvantage 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 AAAAdvantage Stent Graft procedures has this facility performed? What are the six-month, one-year and two-year survival rates?

