Consumer Information on: Endurant Stent Graft System - P100021

U.S. Food & Drug Administration

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: Endurant Stent Graft System
Manufacturer: Medtronic Vascular
Address: 3576 Unocal Place, Santa Rosa, CA 95403
Approval Date: December 16, 2010
Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100021a.pdf [1]

What is it? The Endurant Stent Graft System is used to repair aneurysms of the aorta [2] in the abdomen. An aneurysm is a diseased, weakened and bulging section of an artery wall. The Endurant Stent Graft System is made of a fabric tube supported by a metal framework. Each endovascular stent graft [3]is compressed into the end of a long, thin, tube-like device called a delivery catheter.

How does it work? The delivery catheter containing the endovascular stent graft is inserted into an artery in the groin through a small incision (cut). It is carefully guided within the artery into the abdomen to contain the blood flow of the aneurysm in the aorta. The endovascular stent graft is then released in the aorta where it self-expands to the diameter of the aorta to seal off the aneurysm and reline the artery wall. This endovascular stent graft goes from the aorta to the arteries that supply blood to one leg. Another delivery catheter containing an endovascular stent graft is inserted through a small skin incision on the other side of the groin. This endovascular stent graft connects the first endovascular stent graft with the arteries that go to the other leg.

When is it used? The Endurant Stent Graft System is used instead of more

invasive (open) surgery in patients who have an abdominal aortic aneurysm.

What will it accomplish? The Endurant Stent Graft System should benefit patients with an abdominal aortic aneurysm by preventing further growth and rupture of the aneurysm.

When should it not be used? The Endurant Stent Graft should not be used in patients who have a condition that threatens to infect the graft or in patients with sensitivities or allergies to the device materials. In addition, the device should not be used in patients who are unable to undergo the necessary preoperative and postoperative imaging [4] and follow-up examinations.

Additional information : The Summary of Safety and Effectiveness and Labeling [5] will be available online.

Other Resources:

- NIH MedlinePlus – Aneurysms [6]
- NIH MedlinePlus - Aortic Aneurysm Repair - Endovascular [7]
- NIH MedlinePlus Tutorial – Abdominal Aortic Aneurysm [8]

SOURCE [9]

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Links:
[1] http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100021a.pdf
[2] http://www.nlm.nih.gov/medlineplus/aorticaneurysm.html
[3] https://www.vascularweb.org/vascularhealth/Pages/endovascular-stent-graft.aspx
[4] http://www.nlm.nih.gov/medlineplus/diagnosticimaging.html
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