Consumer Information on: OVATION Abdominal Stent Graft System - H100008

U.S. Food & Drug Administration

FDA approved this device under the Humanitarian Device Exemption (HDE) program *[1]. See the links below to the Summary of Safety and Probable Benefit (SSPB) and other sites for more complete information on this product, its indications for use, and the basis for FDA's approval.*

Product Name: OVATION Abdominal Stent Graft System
Manufacturer: Trivascular, Inc.
Address: 3910 Brickway Boulevard, Santa Rosa, CA 95403
Approval Date: November 1, 2011
Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf10/h100008a.pdf [2]

What is it? The OVATION abdominal stent graft system is used to treat abdominal aortic aneurysms [3] during endovascular repair (EVAR). An aneurysm is a diseased, bulging, weak section of an artery wall; in this case the aorta. The main portion of the OVATION abdominal stent graft is made of a plastic tube supported partially by polymer-filled rings and partially by a metallic stent. The OVATION abdominal stent graft 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 stent graft is inserted into the femoral artery in the groin through a small skin incision. It is carefully guided within the artery into the abdomen to bridge the site of the aneurysm in the aorta. The stent graft is then released (deployed) and the stent self-expands to the diameter of the aorta. Finally, the ring-shaped channels, which are filled with polymer, enable the stent graft to redirect the blood flow away from the aneurysm and reline the artery wall. This can prevent further growth and possible rupture of the aneurysm.

When is it used? The OVATION abdominal stent graft is used when patients with a small anatomy have an abdominal aortic aneurysm that can be treated using EVAR instead of the more invasive open surgery. This device is only used in patients with small access vessels and a small aortic anatomy.

What will it accomplish? Over time, the wall of the untreated aneurysm may weaken under the force of blood pressure, causing the aneurysm to rupture, which can be life-threatening. The OVATION abdominal stent graft should benefit patients with an abdominal aneurysm by preventing growth or rupture of the aneurysm.

When should it not be used? The OVATION abdominal stent graft should **not** be used in patients who are unable to undergo the necessary preoperative and

postoperative imaging and implantation studies, patients who have an infection that might threaten to infect the stent graft, and in patients who are sensitive to, or allergic to the device materials.

Additional information: The Summary of Safety and Probable Benefit Data and labeling [4] are available online.

Other Resources:

- NIH- MedlinePlus - Aortic Aneurysm Repair - Endovascular [5]

SOURCE [6]

Source URL (retrieved on *09/16/2014 - 9:35am*):
http://www.mdtmag.com/news/2012/03/consumer-information-ovation-abdominal-stent-graft-system-h100008?qt-most_popular=0

Links:
[1] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/default.htm
[2] http://www.accessdata.fda.gov/cdrh_docs/pdf10/h100008a.pdf
[3] http://www.nlm.nih.gov/medlineplus/aorticaneurysm.html
[4] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=h100008
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