

Consumer Information on: OVATION Abdominal Stent Graft System - P120006

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: OVATION Abdominal Stent Graft System

PMA Applicant: Trivascular, Inc.

Address: 3910 Brickway Blvd., Santa Rosa, CA 95403

Approval Date: October 5, 2012

Approval Letter: will be available soon

What is it? The OVATION Abdominal Stent Graft System is used to treat abdominal [aortic aneurysms](#) [1] 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 aortic aneurysm. The stent graft is then released and it self-expands to the diameter of the aorta. The polymer-filled rings enable the stent graft to conform to the vessel wall. The stent graft then redirects the blood flow away from the aneurysm and it relines the artery wall. This can prevent further growth and possible rupture of the aneurysm.

When is it used? The OVATION Abdominal Stent Graft System is used instead of a

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

What will it accomplish? Over time, the wall of an 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 System should benefit patients with an abdominal aneurysm by redirecting blood flow, preventing growth or rupture of the aneurysm.

When should it not be used? The OVATION Abdominal Stent Graft System should not be used in patients who:

- are unable to undergo the necessary preoperative and postoperative imaging and implantation studies.
- have an infection that might threaten to infect the stent graft.
- are sensitive to, or allergic to the device materials.

Additional information:

The Summary of Safety and Effectiveness Data and labeling will be available soon.

Other Resources:

- [NIH - MedlinePlus - Aortic Aneurysm Repair - Endovascular](#) [2]

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<http://www.mdtmag.com/news/2012/10/consumer-information-ovation-abdominal-stent-graft-system-p120006>

Links:

[1] <http://www.nlm.nih.gov/medlineplus/aorticaneurysm.html>

[2] <http://www.nlm.nih.gov/medlineplus/ency/article/007391.htm>