Consumer Information on: Aorfix Flexible Stent Graft System - P110032

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: Aorfix Flexible Stent Graft System (a prosthetic endovascular graft)
PMA Applicant: Lombard Medical Inc.
Address: 195 Worcester St. Suite 202 Wellesley Hill, MA 02481
Framingham, MA 01701
Approval Date: February 14, 2013
Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf11/p110032a.pdf [1]

What is it? The Aorfix Flexible Stent Graft System is an endovascular stent graft [2] used to repair abdominal aortic aneurysms [3] (AAA).

An abdominal aortic aneurysm is a diseased, weakened, and bulging section of the wall of the aorta, the body's largest vessel. A synthetic tube-like device (a stent graft) is used within the blood vessel (endovascular) to treat the AAA by sealing it off.

The Aorfix Flexible Stent Graft System is made of a fabric tube supported by a metal framework. This framework supports the graft and holds it open within the blood vessel. Each endovascular 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 endovascular graft is inserted into an artery in the groin through a small skin incision. It is carefully guided by a type of x-ray (called fluoroscopy [4]) within the artery into the abdomen to bridge the site of the aneurysm in the aorta. The endovascular graft is then released in the aorta where it expands to the diameter of the aorta to seal off the aneurysm and relines the artery wall. This endovascular graft goes from the aorta to the arteries that supply blood to one leg.

When is it used? The Aorfix Flexible Stent Graft System is used instead of more invasive open surgery in patients who have an abdominal aortic aneurysm.

What will it accomplish? The Aorfix Flexible 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 Aorfix Flexible Stent Graft System 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.

Additional information: The Summary of Safety and Effectiveness Data and labeling [5] are available online.

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Links:
[1] http://www.accessdata.fda.gov/cdrh_docs/pdf11/p110032a.pdf
[2] http://www.vascularweb.org/vascularhealth/Pages/endovascular-stent-graft.aspx
[3] http://www.nlm.nih.gov/medlineplus/aorticaneurysm.html
[4] http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm115354.htm
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