Consumer Information on: GORE TAG Thoracic Endoprosthesis - P040043/S040

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: GORE TAG Thoracic Endoprosthesis
Manufacturer: W.L. Gore & Associates, Inc.
Address: 3450 W. Kiltie Lane, Flagstaff, AZ 86001
Approval Date: January 13, 2012
Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf4/p040043s040a.pdf [1]

What is it? The GORE TAG Thoracic Endoprosthesis is an artificial endovascular stent graft and is used to treat isolated lesions, excluding dissections, of the descending thoracic aorta during endovascular repair. Some of the complex isolated lesions include aneurysms, transections, penetrating ulcers and intramural hematomas. An aneurysm is a diseased, bulging, weak section of an artery wall; in this case it's the aorta. A transection is a rupture or tear of the aortic wall, typically resulting from blunt force trauma.

The GORE TAG Thoracic Endoprosthesis is made of expanded polytetrafluoroethylene [2] (ePTFE), with an outer metallic support structure known as a stent. Each endovascular stent graft is compressed into the end of a long, thin, tube-like device called a delivery catheter

The GORE TAG Endoprosthesis is the first endovascular stent grafting system approved to treat transections of the thoracic aorta. Approval of the expanded indications was evaluated with clinical studies for aneurysms and transections.

How does it work? The delivery catheter containing the endovascular stent graft is inserted into the femoral artery in the groin through a small incision. It is carefully guided within the artery into the descending thoracic aorta to bridge the site of the

aneurysm or transection . The endovascular stent graft is then released (deployed) and the stent self-expands to the diameter of the aorta. The endovascular stent graft redirects blood flow away from the aneurysm or transection and it relines the artery wall. This can prevent further growth and possible rupture of the aneurysm, or prevent the severe bleeding from a transection.

When is it used? The GORE TAG Thoracic Endoprosthesis is used instead of an open (more invasive) surgery in patients who have lesions of the descending thoracic aorta, excluding dissections.

What will it accomplish? The GORE TAG Thoracic Endoprosthesis should benefit patients with an isolated lesion in the aorta in the chest by preventing further growth and rupture of the lesion. If the device doesn't completely seal off the lesion from pressurized blood flow, there is a chance that additional treatment may be needed to prevent these problems.

When should it not be used? The GORE TAG Thoracic Endoprosthesis 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 endovascular stent graft, and in patients who are sensitive to, or allergic to the device materials.

Additional information: The Summary of Safety and Effectiveness and labeling [3] are available online.

Other Resources:

- FDA News Release [4]
- Society for Vascular Surgery - Endovascular Stent Graft [5]

SOURCE [6]

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http://www.mdtmag.com/news/2012/01/consumer-information-gore-tag-thoracic-endoprosthesis-p040043/s040?qt-recent_content=0

Links:
[1] http://www.accessdata.fda.gov/cdrh_docs/pdf4/p040043s040a.pdf
[2] http://www.pslc.ws/macrog/ptfe.htm
[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p040043s040
[4] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm287698.htm
[5] http://www.vascularweb.org/vascularhealth/Pages/endovascular-stent-graft.aspx
[6] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceAppro

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