Update on Endologix AFX Endovascular AAA Graft Systems and Risk of Type III Endoleak: FDA Safety Communication

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The U.S. Food and Drug Administration (FDA) is updating our January 2022 safety communication (/medical-devices/safety-communications/update-risk-type-iii-endoleaks-use-endologix-afx-endovascular-aaa-graft-systems-fda-safety) on the use of Endologix AFX endovascular grafts used to treat patients with abdominal aortic aneurysm (AAA).

On December 6, 2022, the FDA approved new labeling for the currently available product, the AFX2 Endovascular AAA System (AFX2), that includes information to better inform patients and health care providers of the risk of Type III endoleaks.

In addition, the FDA is committed to evaluating the long-term safety of AFX2. The FDA is requiring that Endologix, the manufacturer, perform a postmarket study to continue to evaluate the benefits and risks of the AFX2, including the risk of Type III endoleaks. The study will compare outcomes for patients implanted with AFX2 to patients with other commercially available AAA endovascular grafts, using real world data through 10 years of follow-up.

The FDA continues to recommend that health care providers consider using available alternative treatment options for abdominal aortic aneurysm (AAA) patients rather than the AFX2 device. The recommendations for patients and health care providers below have been updated to include new, important information from the manufacturer's product labeling.

The FDA continues to emphasize to patients and health care providers the importance of at least yearly, lifelong follow-up for all patients who have any type of Endologix AFX endovascular graft (AFX with Strata, AFX with Duraply, or AFX2) in order to monitor for Type III endoleaks.

Recommendations for Patients Who Have or Are Considering an Endologix AFX Endovascular Graft System for Treatment of Abdominal Aortic Aneurysms (AAAs), including AFX with Strata, AFX with Duraply, or AFX2

- The FDA continues to recommend that before surgery, patients should discuss the benefits and risks of all available AAA treatment options with their health care provider.
    - Be aware that the FDA has approved endovascular grafts made by various manufacturers for the treatment of AAA, and each device has specific benefits

and risks.

- If your provider recommends AAA treatment with the AFX2 endovascular graft, ask the provider to explain why they believe it is an appropriate treatment option for you.

- The FDA also continues to recommend at least yearly, lifelong follow-up with a health care provider for all patients who have had their AAA treated with any AFX endovascular graft system (AFX with Strata, AFX with Duraply, or AFX) to monitor for Type III endoleaks.
  - If you have already had treatment of your AAA with an endovascular graft system, review the implant card you received at the time your AAA was treated to determine if you have any type of Endologix AFX endovascular graft implanted. If you do not know if you have an AFX endovascular graft or if you do not have your implant card, contact the health care provider who treated your AAA or the hospital where you were treated to find out.
  - If you have any type of Endologix AFX endovascular graft, contact the health care provider who treated your AAA or another vascular specialist about further care and to discuss continued follow-up.
  - If you have an AFX endovascular graft and are overdue for a follow-up, make an appointment with the health care provider who treated your AAA or another vascular specialist to get your device checked.

Updated Recommendation

Be aware of the following new information in the patient labeling for the AFX2 device:

- An increased rate of Type III endoleaks was detected with previous iterations of the AFX System.
- It is uncertain whether the increased rate of Type III endoleaks has been addressed by the AFX2 System because the risk of Type III endoleaks at 3 years and beyond is not yet established.

Recommendations for Health Care Providers who treat patients with Abdominal Aortic Aneurysms or follow patients with an Endologix AFX Endovascular Graft System (AFX with Strata, AFX with Duraply, or AFX2)

- Prior to surgery, discuss the risks and benefits of all available AAA treatment options with your patients.
- For AAA patients undergoing endovascular graft treatment, consider available alternative options to the AFX2 device.

- Closely monitor patients who have undergone implantation with any AFX endovascular graft (AFX with Strata, AFX with Duraply, or AFX2) and evaluate their risk profile for Type III endoleaks per the Instructions for Use (IFU).
    - Ensure at least yearly, lifelong imaging follow-up to monitor for the development of Type III endoleaks and aneurysm expansion for patients who have undergone implantation with any AFX endovascular graft.
    - Urgently evaluate patients with Type III endoleaks to assess the need for additional endovascular or surgical procedures.

Updated Recommendation

Read and follow the new Endologix AFX2 Endovascular AAA System Instructions for Use, which includes information about the risk of Type III endoleaks and recommendations for patient follow-up.

The Instructions for Use includes a new warning (below), as well as:

- A summary of postmarket Type III endoleak clinical data,
- A summary of other postmarket clinical outcomes data comparing AFX2 to other commercially available AAA endovascular grafts, and
- Information on AFX-in-AFX relining.

Review the new warning:

> The AFX System with Strata (a previous version of the AFX System) is associated with an increased risk of Type III endoleaks and AAA-related adverse events. The AFX System with Duraply (another previous version of the AFX System) may have an increased risk of Type III endoleaks and AAA-related adverse events. It is uncertain whether the increased risk of Type III endoleaks and AAA-related adverse events have been addressed by the AFX2 System (the currently marketed AFX System) because the risk of Type III endoleaks and AAA-related adverse events at 3 years and beyond is not yet established.

Device Description

An endovascular graft can be used to treat an abdominal aortic aneurysm (https://medlineplus.gov/ency/article/000162.htm) (AAA). Endovascular grafts are flexible fabric tubes supported by a metal frame either on the inside or outside of the fabric. The endovascular graft is permanently implanted inside a blood vessel (aorta) so that blood flows through the endovascular graft instead of into the aneurysm, reducing the risk of aneurysm growth or rupture. These devices are made by several manufacturers, and each device used to treat AAA has specific benefits and risks.

The AFX Endovascular AAA System (AFX), manufactured by Endologix, Inc., is an endovascular graft system intended to treat patients with AAA. The device has a unique design in which the metal frame is on the inside of the fabric. The AFX endovascular graft was approved by the FDA in 2011, and over time, the manufacturer has modified the device resulting in the following versions used in U.S. patients:

- **AFX with Strata graft material,** which was implanted in patients between 2011 and 2016 and is no longer available on the market after Endologix (https://endologix.com/wp-content/uploads/2016/12/12-30-Physician-Letter-AFX-TIII-Endoleak-FINAL.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) requested that all AFX with Strata devices be removed from hospital inventories because of an increase in the frequency of Type III endoleaks.
- **AFX with Duraply graft material** included a change in graft material from Strata to Duraply intended to help prevent Type III endoleaks. The device was implanted in patients between 2014 and 2018 but is no longer available on the market.
- **AFX2 (Duraply graft material) - currently available product,** which has been implanted in patients since 2016 with changes to the manufacturing of the Duraply graft material to increase the average thickness and intended to further help prevent Type III endoleaks.

In addition, the manufacturer over time has updated the instructions for use (IFU) for the device.

Type III Endoleak

Various types of endoleaks can occur after repair with any endovascular graft and typically do not result in symptoms. Therefore, patients who have been treated with **any** AAA endovascular graft require regular, lifelong follow-up imaging (for example, a CT scan with contrast (/radiation-emitting-products/medical-x-ray-imaging/computed-tomography-ct)) for the detection of endoleaks.

Type III endoleaks consist of blood flowing or leaking into the AAA either between endovascular graft segments that were joined together to treat the AAA at the time of implantation but have separated (Type IIIa) or through holes in the graft material (Type IIIb). Type III endoleaks may lead to expansion and rupture of the AAA, which can result in serious patient injury, including death. Imaging should be performed as part of routine lifelong patient follow-up to determine whether the device remains effective in excluding blood flow into the AAA sac and to be sure that the aneurysm is not enlarging over time.

Once diagnosed, Type III endoleaks require prompt treatment because of their life-threatening nature. Type IIIa endoleaks can generally be treated by placement of a covered stent across the gap between the separated endograft components. Type IIIb endoleaks may require either complete relining of the endograft with an endovascular procedure or open surgery.

November 2021 Advisory Committee Meeting (/media/154008/download)

On November 2, 2021, the FDA held a meeting (https://www.fda.gov/advisory-committees/advisory-committee-calendar/november-2-3-2021-circulatory-system-devices-panel-medical-devices-advisory-committee-meeting#event-materials) of the CDRH Circulatory System Devices Panel of the Medical Devices Advisory Committee to share information and perspectives on the benefits and risks of the Endologix AFX endovascular graft system focused on the risk of Type III endoleaks. The advisory committee determined that data were insufficient to show that the Type III endoleak risk associated with the AFX with Strata device has been adequately addressed by the currently available AFX product (the AFX2 device). Most committee members agreed that the benefits of the AFX2 device for routine AAA treatment did not outweigh the risks. The advisory committee recommended continued availability of the AFX2 device for use in selected patients, and in situations when alternative treatment options are insufficient or not available. The advisory committee expressed the need for additional clinical data and analysis to further evaluate long-term AFX endovascular graft system performance particularly for the currently marketed AFX2 device. Finally, the advisory committee emphasized that patients should be informed of the importance of annual clinical and imaging follow-up if they have been treated with any AFX endovascular graft.

FDA Actions

The FDA will continue to evaluate all available data on the risk of Type III endoleaks in patients who have undergone treatment with any Endologix AFX endovascular graft, including AFX with Strata, AFX with Duraply, or AFX2, and will consider additional steps as needed to address the issue.

As part of the FDA required postmarket study, the FDA will receive and assess more information to evaluate the long-term safety of AFX2.

In addition, the FDA is collaborating (/medical-devices/letters-health-care-providers/fda-advisory-panel-recommendations-lifelong-surveillance-and-long-term-postmarket-data-collection) with key stakeholders including patient representatives, professional societies, and industry to develop a real-world surveillance system to collect long-term data on the benefits and risks of AAA endovascular grafts as a device class.

The FDA will continue to keep the public informed if significant new information becomes available.

Reporting Problems with Your Device

If you think you had a problem with your device or a device your patient uses, we encourage you to report the problem through the MedWatch Voluntary Reporting Form (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home),

including, but not limited to, the following:

- Early or late device-related adverse events, such as Type III endoleaks.
- Adverse events related to secondary interventions to treat Type III endoleaks.

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Questions?

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV) or call 800-638-2041 or 301-796-7100.