Endologix, Inc. Recalls AFX Endovascular AAA Systems Due to Risk of Type III Endoleaks

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product(s):

- Endologix AFX Endovascular AAA System
- Model/Item Numbers: See "**Full List of Affected Devices**"
- Lot Numbers: See "**Full List of Affected Devices**"
- Manufacturing Dates: March 2011 to Present
- Distribution Dates: August 2011 to Present
- Devices Recalled: 61,300

Device Use

The Endologix AFX Endovascular AAA System (AFX) is used to treat patients with a condition, called an abdominal aortic aneurysm (AAA), that occurs when the wall of the body's largest blood vessel (the aorta) becomes stretched and thin, causing the vessel to bulge or expand. The AFX is a thin polymer tube with a large metal stent on the inside. It is placed inside the aorta so that blood flows through the device instead of the weakened aneurysm. This helps to prevent the aneurysm from increasing in size and bursting (rupturing). The AFX is placed in a patient during a surgical procedure called endovascular aneurysm repair (EVAR).

Reason for Recall

Endologix is recalling its AFX Endovascular AAA Systems due to continued reports of Type IIIa and IIIb endoleaks. When a Type III endoleak occurs, blood continues to flow into the aneurysm, increasing the likelihood of a rupture. Left undetected and without treatment, a Type III endoleak may result in serious patient injury, such as an AAA rupture or death.

It is important to note that although this recall applies to all AFX Endovascular AAA Systems, most reports of endoleaks have concerned the AFX with Strata graft material. Endologix has not manufactured the AFX with Strata graft material since July 2014 and health care providers were advised to remove any remaining inventory from shelves in December 2016. However, the AFX with Duraply graft material and AFX2 devices have been distributed for a shorter time and it is unclear if these devices have fewer endoleaks or if they have not been implanted long enough for endoleaks to occur.

By issuing this recall, Endologix is updating their **December 2016 notification (https://endologix.com/wp-content/uploads/2016/12/12-30-Physician-Letter-AFX-TIII-Endoleak-FINAL.pdf)** and notifying physicians of new patient surveillance recommendations as well as general warnings about interventions to or through an existing AFX device.

Who May be Affected

- Patients who have been implanted with the AFX Endovascular AAA System.
- Health care providers who use the Endologix AFX Endovascular AAA System to treat patients diagnosed with an abdominal aortic aneurysm.

What to Do

Endologix, Inc. sent an **Urgent: Important Safety Update letter (https://endologix.com/wp-content/uploads/2018/07/AFX-Safety-Update-AFX-Users_July2018.pdf)** dated July 20, 2018, to inform physicians about the following with regards to the AFX Endovascular AAA System: 1) Type III endoleak rates, 2) refined patient-tailored surveillance recommendations, 3) sizing recommendations, and; 4) recommendations for catheter-based interventions through an existing AFX device or interventions to an existing AFX device.

The letter also provided updated information and revisions to the Instructions for Use to enhance patient safety. No product return is required.

Additionally, the letter instructed physicians to:

- Continue regular, lifelong follow-up of all patients treated with an Endologix AFX Endovascular AAA graft.
  - Revised product Instructions For Use can be provided by hard copy upon request to Endologix Customer Service for the U.S. at 800-983-2284 (5:00 AM - 6:00 PM Pacific Time) or through the Endologix Labeling Library accessible at **http://www.e-labeling.eu/ (http://www.e-labeling.eu/)** (KEY-CODES: ELX10022 and ELX10029).
- Report adverse reactions or quality problems with the use of this product to **MedWatch, the FDA's Safety Information and Adverse Event Reporting Program. (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)**
- Contact your Endologix Representative or the Endologix Customer Service Line at 800-983-2284 (5:00 AM - 6:00 PM Pacific Time) with any questions.

Contact Information

Customers who have questions or need additional information or support regarding this recall should contact Endologix's Customer Service line at 800-983-2284 (5:00 AM - 6:00 PM Pacific Time).

Date Recall Initiated

July 20, 2018

Full List of Affected Devices

- **Endologix AFX Endovascular AAA System (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/TextResults.cfm?uq=aaa%20endologix)** (8 entries)

Additional Resources

- **Endologix Urgent: Important Safety Update - Medical Device Correction for the AFX® Endovascular AAA System (July 20, 2018) (https://endologix.com/wp-content/uploads/2018/07/AFX-Safety-Update-AFX-Users_July2018.pdf)**
- **UPDATE on Type III Endoleaks Associated with Endovascular Graft Systems - Letter to Health Care Providers (June 19, 2018)**

(https://www.fda.gov/MedicalDevices/Safety/LetterstoHealthCareProviders/ucm611039.htm)

- Type III Endoleaks Associated with Endovascular Graft Systems - Letter to Health Care Providers (September 28, 2017) (https://www.fda.gov/MedicalDevices/Safety/LetterstoHealthCareProviders/ucm577859.htm)
- Endologix Important Safety Update: AFX™ Endovascular AAA System (December 30, 2016) (https://endologix.com/wp-content/uploads/2016/12/12-30-Physician-Letter-AFX-TIII-Endoleak-FINAL.pdf)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)**. Health care professionals employed by facilities that are subject to **FDA's user facility reporting requirements (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)** should follow the reporting procedures established by their facilities.

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2018 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm590900.htm)

2017 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)