



## FDA Classifies Previous Endologix AFX Safety Notice as Class I Recall

October 5, 2018

IRVINE, Calif.--(BUSINESS WIRE)--Oct. 5, 2018-- Endologix® Inc. (Nasdaq: ELGX), a developer and marketer of innovative treatments for aortic disorders, announced today that it has received notice that the U.S. Food and Drug Administration (FDA) has classified a voluntary recall action that Endologix took in July of this year as a Class I recall. The July recall involved Endologix's issuance of a Safety Notice to healthcare professionals (HCPs) using the AFX® Endovascular AAA System.

The Safety Notice, dated 20 July 2018, provided updated information on comparative AFX Type III endoleak rates, patient-tailored surveillance recommendations, and recommendations for intervening through an AFX device or re-intervening on an AFX device. No product was removed from the field as part of this recall.

The July 2018 Safety Notice followed several earlier communications. Safety Notices from Endologix issued in late 2016 and early 2017 requested that all remaining AFX Strata devices be returned from the field and emphasized that Endologix had not manufactured AFX Strata grafts since 2014. On September 28, 2017, the FDA issued a letter to HCPs to raise awareness of an increased occurrence of Type III endoleaks after endovascular aneurysm repair (EVAR). On June 19, 2018, the FDA issued an updated letter to HCPs indicating the increased risk for Type III endoleak appears to be specific to one device at this time, the AFX with Strata device. (<https://www.fda.gov/MedicalDevices/Safety/LetterstoHealthCareProviders/ucm611039.htm>)

"As outlined at our Investor Day on October 2, 2018, the AFX Strata product was removed from global inventory in the first half of 2017. Our current commercially available versions of the AFX system, the AFX Duraply™ and AFX2™ products, are manufactured using a different ePTFE processing methodology and include additional product improvements," noted John Onopchenko, Chief Executive Officer of Endologix. "These AFX Duraply and AFX2 products, while part of the July 2018 Safety Notice providing updated recommendations to HCPs on how to re-intervene on or through these products, were not the subject of the voluntary product removal actions in December 2016/January 2017. Furthermore, AFX Duraply and AFX2 products were not the subject of the June 19, 2018 FDA letter to HCPs. Through our comprehensive system of post-market surveillance, anonymized registry data, and the only randomized trial to compare EVAR systems (the LEOPARD trial), we have a strong and growing evidence base that supports the use of the AFX Duraply and AFX2 systems for patients with AAA. We are proud of, and committed to, advancing our collaborative work with the FDA on behalf of our patients, customers, and the broader clinical community."

### About Endologix

Endologix, Inc. develops and manufactures minimally invasive treatments for aortic disorders. The Company's focus is endovascular stent grafts for the treatment of abdominal aortic aneurysms (AAA). AAA is a weakening of the wall of the aorta, the largest artery in the body, resulting in a balloon-like enlargement. Once AAA develops, it continues to enlarge and, if left untreated, becomes increasingly susceptible to rupture. The overall patient mortality rate for ruptured AAA is approximately 80%, making it a leading cause of death in the United States. For more information, visit [www.endologix.com](http://www.endologix.com).

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