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Field Safety Notice
AFX™ Endovascular AAA System: Suspension of CE Mark 29744/29731 and Patient Follow-up Advice

Type of Action: Customer Notification of CE Mark 29744/29731 Suspension
Product Codes: AFX® Endovascular AAA System

December 2016

Attention: Health Care Professionals

This letter is to inform you that GMED, the Notified Body for Endologix, has temporarily suspended the CE Mark certification for the AFX® Endovascular AAA System (AFX System) on December 13th, 2016. The suspension of the CE Mark is related to GMED's concerns about reports of Type III endoleak with a former version of the device. Endologix is currently collaborating with GMED to resolve this issue as quickly as possible. We are confident that we will be able to address G-MED's concerns through the device and labelling changes that have previously been implemented and are referenced in the attached background information. At the earliest possible date, any additional information regarding the status of the CE-certification will be communicated to health care professionals.

The AFX product is not currently available in the European Union and any product in your hospital inventory should be placed in quarantine until the suspension is lifted.

Part 1: Recommendations

1. Until the CE Mark suspension has been lifted, the AFX product should not be implanted in patients.

2. It is well documented that Type III endoleaks may cause increased pressure within the aneurysm sac that could increase the risk of aneurysm rupture and patient death.

   Therefore, at present, Endologix recommends that high-resolution CT scan (contrast-enhanced and non-contrast) imaging follow-up to be performed at one month, six months, one year, and annually thereafter for examination of:

   - Device integrity (e.g., absence of stent fracture or graft holes/tear);
   - Maintained overlap between bifurcated and extension stent grafts;
   - Absence of clinically relevant migration or lateral movement; and
   - Aneurysm enlargement, perigraft flow, loss of patency, increased tortuosity, or progressive disease.

3. If renal complications or other factors preclude the use of image contrast medium, abdominal radiographs and duplex ultrasound may provide similar information. Plain x-rays may provide information on stent integrity and maintained component overlap.

4. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms, changes in the structure or position of the endovascular graft, or reduced overlap of stent graft components) warrant a thorough clinical evaluation and assessment of further follow-up. If any evidence of therapy failure (i.e., enlarging aneurysm, Type I or III endoleak, or graft occlusion) is observed, the patient's condition and prognosis should be reassessed, along with potential re-intervention to reestablish aneurysm exclusion and/or graft patency.

Parts 2 and 3 of this letter (attached) provide further background information on our post-market surveillance program and important product and IFU changes that have been implemented that will help minimize the occurrence of Type III endoleaks.

Endologix, Inc. is deeply committed to patient safety and good clinical outcomes. As always, we will continue to provide clinical support and will actively monitor the clinical experience with the AFX System and all our other devices. Through our post-market surveillance and product development programs, we will continuously seek your feedback and update you with any important information to care for your patients. If you have any questions regarding the content of this notification, please contact your Endologix representative.

Yours Sincerely,
ENDOLOGIX

Shari O'Quinn
Vice President, Clinical & Regulatory Affairs

Field Safety Notice: AFX™ Endovascular AAA System: Type III Endoleaks

Part 2: Background to this field action:

For all products, Endologix has an active post-market surveillance program that has been monitoring and evaluating the performance of the AFX System since its introduction to the market in 2011. In January of 2013, an investigation into reports of Type IIIa endoleaks (separation of bifurcated and accessory stent grafts at the point of overlap), was initiated followed by an investigation into Type IIIb endoleaks (disruption of the stent graft material) in September of 2013. During this time, updates to the Instructions for Use (IFU) and modifications to the product were implemented, including introduction of a graft material processing improvement known as Duraply™, introduction of longer lengths of bifurcated devices to maximize component overlap, and most recently the introduction of the AFX®2 Bifurcated Endograft System (AFX2 System). A detailed discussion of the investigation of Type III endoleaks, along with the important product and IFU changes that have been implemented that may help prevent the occurrence of Type III endoleaks, is given in Part 3 of this Field Safety Notice.

Post-market surveillance evaluation since implementation of these IFU updates and device modifications has demonstrated a decrease in Type III endoleak rates. The cumulative Type IIIa endoleak rates for AFX System with Strata are 1.54%, AFX System with Duraply are 0.20%, and AFX2 System are 0.16%. The cumulative Type IIIb endoleak rates for AFX System with Strata are 1.34%, AFX System with Duraply are 0.19%, and AFX2 System are 0%. Additional details on the total number of events reported globally since introduction of each AFX product version is provided in **Table 1** below.

Table 1: Cumulative Events Rates by AFX Product Version

Event Type	AFX Product Version		
	AFX System + Strata Rate % (Total Events)	AFX System + Duraply Rate % (Total Events)	AFX2 System Rate % (Total Events)
Type IIIa Endoleak	1.54%	0.20%	0.16%
Type IIIb Endoleak	1.34%	0.19%	0%

The figures below demonstrate there has been a reduction in the incidence of Type IIIa (**Figure 1**) and Type IIIb (**Figure 2**) Endoleak reports at equivalent time points after introduction of the AFX with Duraply and the AFX2 System. However, the Type IIIb endoleak rates in implants with the AFX System with Strata have continued to increase.

Figure 1: Type IIIa Endoleak Complaint Trends by Product Type

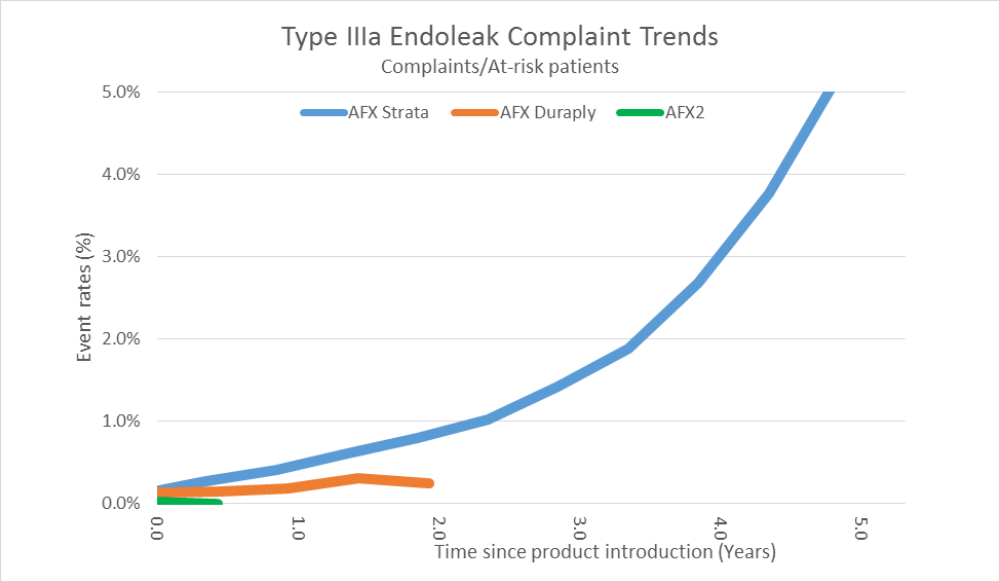
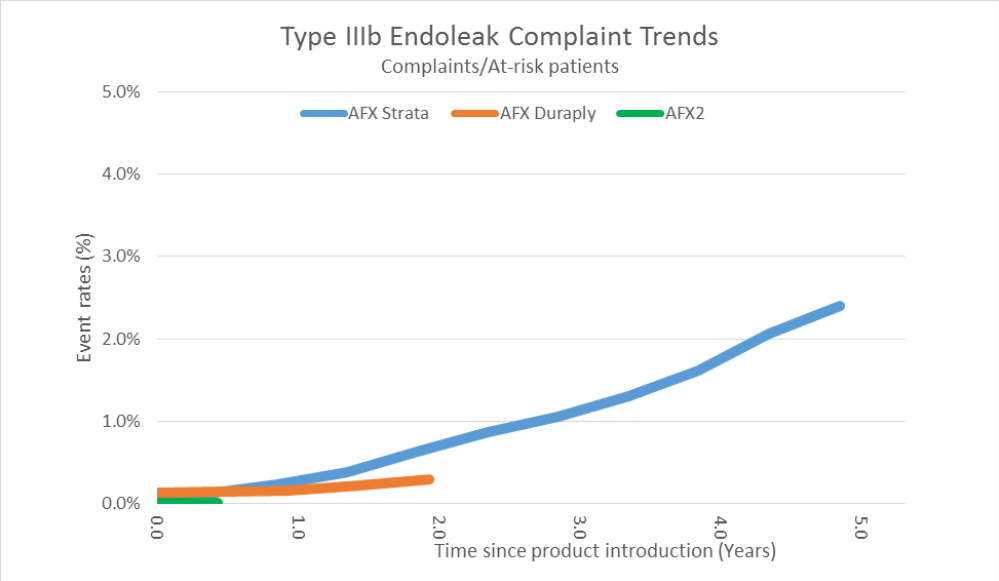


Figure 2: Type IIIb Endoleak Complaint Trends by Product Type



Post-market surveillance and review of the literature suggests that Type III endoleaks are most commonly treated with a secondary-intervention involving placement of an additional device

component.[1, 2] Endologix is collaborating with regulatory agencies on recommendations for treatment of patients presenting with a Type III endoleak in an AFX implant, and will provide additional information as soon as possible. If a secondary endovascular procedure is not appropriate, open surgical repair can be performed to correct a Type III endoleak, although it represents a significantly higher risk of morbidity and mortality.

Part 3: Summary Type III Endoleak Investigations and Associated Corrective Actions

Type IIIa Endoleaks

The investigations into Type IIIa endoleaks identified several contributing factors, including:

- Inadequate component overlap at the index procedure
- Lateral movement in large or tortuous aortas leading to reduction or loss of component overlap
- Use of an excessively oversized proximal extension relative to the bifurcated main body device

The following IFU updates may mitigate the identified contributing factors and help prevent the occurrence of Type IIIa endoleaks:

- Reinforce the importance of device selection with an emphasis on maximizing overlap between the bifurcated and extension components.
- Clarify important information related to anatomic considerations for patient selection, pre-procedure planning guidelines to maximize overlap with the primary bifurcated stent graft, and minimum post-operative follow-up imaging recommendations.
- Provide further guidance in the form of a simple sizing algorithm that can be applied to ensure maximum overlap and determine the need for an additional infrarenal extension.

Furthermore, Endologix commercialized longer bifurcated lengths to provide more device options to maximize component overlap.

Type IIIb Endoleaks

The investigations into Type IIIb endoleaks identified several contributing factors, including:

- Procedural factors such as guidewire/catheter manipulation or aggressive balloon molding
- Off-label use in highly calcified anatomy
- Lateral movement and changes in implant stability
- Implant of other manufacturer's devices as proximal extensions

[1] http://www.jvascsurg.org/article/S0741-5214(15)01021-6/abstract
[2] http://symposium.scvs.org/abstracts/2016/P105.cgi

The IFU updates associated with the clarification of existing cautions and warning statements related to over-inflation of a balloon (if used) beyond the nominal diameter of the stent graft, guidewire manipulation, and vessel calcification may mitigate the identified contributing factors and help prevent the occurrence of Type IIIb endoleaks.

Furthermore, in July 2014, Endologix developed and commercialized an improved ePTFE graft material processing, known as Duraply™. This improvement significantly increased the graft material strength compared to the previous Strata graft material while preserving the favorable biocompatibility profile, strength, and other conformability and mechanical characteristics.

Most recently in February 2016, Endologix introduced the AFX2 System. During the development of the AFX2 System, Endologix implemented manufacturing changes to reduce the potential for damage to the graft during loading onto the delivery system and an increase in the average thickness of the Duraply graft material by tightening of the manufacturing specifications.

The current IFU, inclusive of the changes outlined above is available in the Endologix Labeling Library at http://www.e-labeling.eu, as referenced in current product packaging