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December 30, 2016

Important Safety Update
AFX™ Endovascular AAA System

Dear Physician,

This letter provides important information related to the AFX Endovascular AAA System (AFX System):

1. Updated information on the rates of Type III endoleaks and suggestions for patient surveillance and treatment.
2. Availability of AFX and AFX2 following the recently announced product hold, which is now being lifted except for the largest sizes of AFX2 Main Body (28 mm) and/or Iliac Limbs (20 mm).
3. Voluntary recall of (1) the small remaining quantity of original AFX with Strata graft material, and (2) the larger diameter sizes of AFX2.

Information and Guidance Regarding Type III Endoleaks and Voluntary Recall of Remaining Stents with Strata Graft Material

As 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, Endologix conducted an investigation into reports of Type IIIa endoleaks (separation of bifurcated and extension stent grafts at the point of overlap), which was followed by an investigation into Type IIIb endoleaks (disruption of the stent graft material) in September of 2013. During this time, a series of 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). At the time of the submission of these modifications to FDA, they were part of our ongoing product improvement efforts and not identified as measures intended to address Type III endoleaks. The ongoing Endologix investigation has determined that these changes may help prevent the occurrence of Type III endoleaks reported with the AFX device. Please reference *Attachment 1* for a detailed discussion of the investigation of Type III endoleaks.

It appears that the rate of Type III endoleaks may be decreasing since the 2014 introduction of the AFX with Duraply and AFX2 Systems. The time to event may exceed the amount of follow-up currently available; therefore, we do not have clinical data on the effectiveness of these changes longer term. In addition, the rates are calculated based on voluntary reporting and units sold instead of implanted, which may underestimate the true event rate occurring on a per-patient basis. This underestimate may be greater for the more recent versions (i.e., AFX with Duraply and AFX2 System), which may have a larger number of units sold with implants pending as compared to the AFX with Strata.

It is important to note that the Type IIIb endoleak rates in implants that occurred prior to these modifications increase over time. The increase in Type IIIb endoleaks may be associated with the Strata graft material, which has not been manufactured since July 2014. **Endologix wants to make sure there are no unused AFX devices with the Strata graft material remaining in hospital inventories. AFX devices with the Strata graft material can be identified by the product code starting with the letter F (i.e., FXXXXX or FXXXXX-XX). A comprehensive list of affected product codes is provided in *Attachment 2.* If you identify any AFX devices with the Strata graft material, please quarantine the devices and contact your Endologix Representative to arrange a return.**

Guidance for Patient Surveillance and Treatment

Type III endoleaks may cause increased pressure within the aneurysm sac that could increase the risk of aneurysm rupture and patient death. Therefore, at a minimum, 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);
- 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.

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. 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.

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.

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

Partial Lifting of Temporary Hold on AFX and AFX2 Shipments, and Voluntary Recall of Certain AFX2 Devices

Separately, on December 27, Endologix announced a temporary hold on shipments of its AFX and AFX2 Systems to complete an investigation of a manufacturing issue with some sizes of the device, which is related to **loading the stent graft onto the delivery system**. This manufacturing issue was identified through on-going product testing, and it is **not related to clinical experience**; to date, there have been no reported Type IIIb endoleaks and only one Type IIIa endoleak reported in the 4,143 units sold.

The company has lifted the hold on all AFX and AFX2 devices except for the largest sizes of Main Body (28 mm) and/or Iliac Limbs (20 mm). **Endologix wants to make sure there are no AFX2 devices in these sizes in hospital inventories. AFX2 devices with these sizes can be identified by the product code starting with the letter F (i.e., FXXXXX or FXXXXX-XX) and a comprehensive list of affected product codes is provided in *Attachment 3.* If you identify any AFX2 devices in these sizes (28 mm Main Body and/or 20 mm Iliac Limbs), please quarantine the devices and contact your Endologix Representative to arrange a return.**

Our Commitment to Safety and Excellent Clinical Outcomes

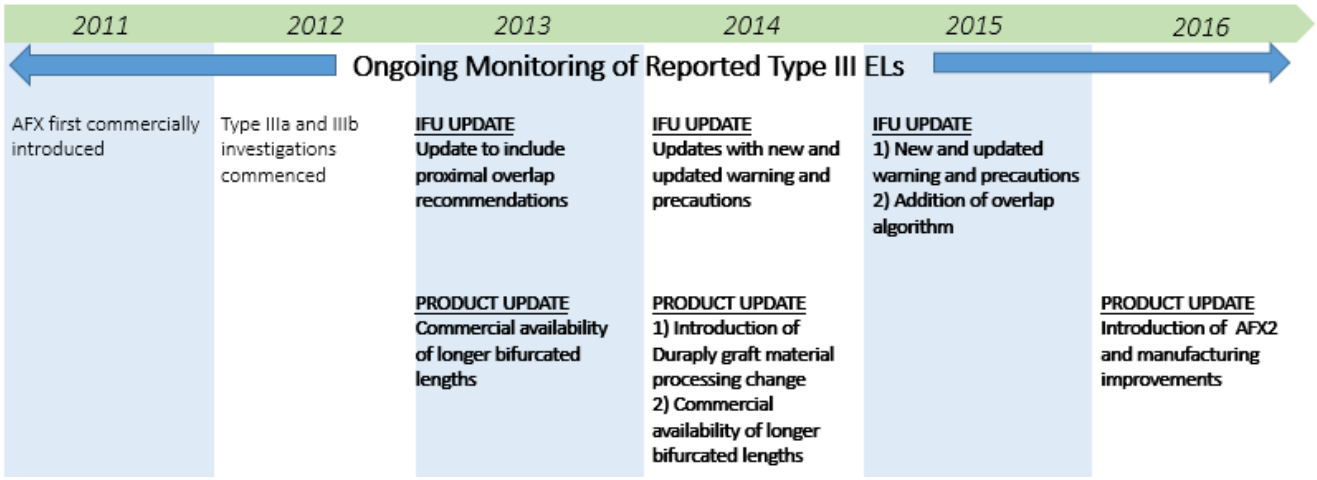
Endologix, Inc. is deeply committed to patient safety and excellent clinical outcomes. We will continue to develop, manufacture and test devices to the highest quality standards and provide experienced clinical support. Through our on-going clinical research and post-market surveillance programs, we will actively monitor the clinical experience with AFX and all our devices and provide 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

Attachment 1: Summary Type III Endoleak Investigations

In January of 2013, Endologix conducted an investigation into reports of Type IIIa endoleaks (separation of bifurcated and extension stent grafts at the point of overlap), followed by an investigation into Type IIIb endoleaks (disruption of the stent graft material) in September of 2013. During this time, multiple labeling, product, and manufacturing changes were implemented by Endologix. These include updates to the product Instructions for Use (IFU), implementation 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). At the time of the submission of these modifications to FDA, they were not identified as measures intended to address Type III endoleaks. The chart below outlines the monitoring activities associated with Type III endoleaks as well as various product and IFU updates with further discussion following.



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.

A comprehensive listing of the specific IFU changes that may help prevent Type IIIa endoleaks is provided Table 1 located in *Attachment 4* of this letter.

Furthermore, in January 2013 and November 2014, 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

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. A comprehensive listing of the specific IFU changes that may help prevent Type IIIb endoleaks is provided Table 2 located in *Attachment 4* of this letter.

Furthermore, in July 2014, Endologix developed and commercialized a modified ePTFE graft material processing, known as Duraply™. This modification increased the graft material strength compared to the previous Strata graft material while preserving biocompatibility, conformability, and other 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.

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Effectiveness of IFU and Product Updates

As discussed above, the Duraply graft material (commercialized in 2014), longer bifurcated lengths (commercialized in January 2013 and November 2014), and the AFX2 system (commercialized in 2016) were implemented since the AFX system was introduced into the U.S. market in 2011. Several IFU updates were also made in 2013, 2014, and 2015. We are actively monitoring the effectiveness of these changes through our post-market surveillance program. As reflected in Figure 1 and 2 below, it appears that the rate of Type IIIa and Type IIIb endoleaks may be decreasing since the introduction of the AFX with Duraply and AFX2 Systems, we do not have long term data on the effectiveness of these changes as the time to event may exceed the amount of follow-up currently available. In addition, the rates are calculated based on voluntary reporting and units sold, which may underestimate the true event rate occurring on a per patient basis. This underestimate may be greater for the more recent versions (i.e., AFX with Duraply and AFX2 System), which may have a larger hospital inventory as compared to the AFX with Strata.

Figure 1: Type IIIa Endoleak Complaint Trends by Product Type

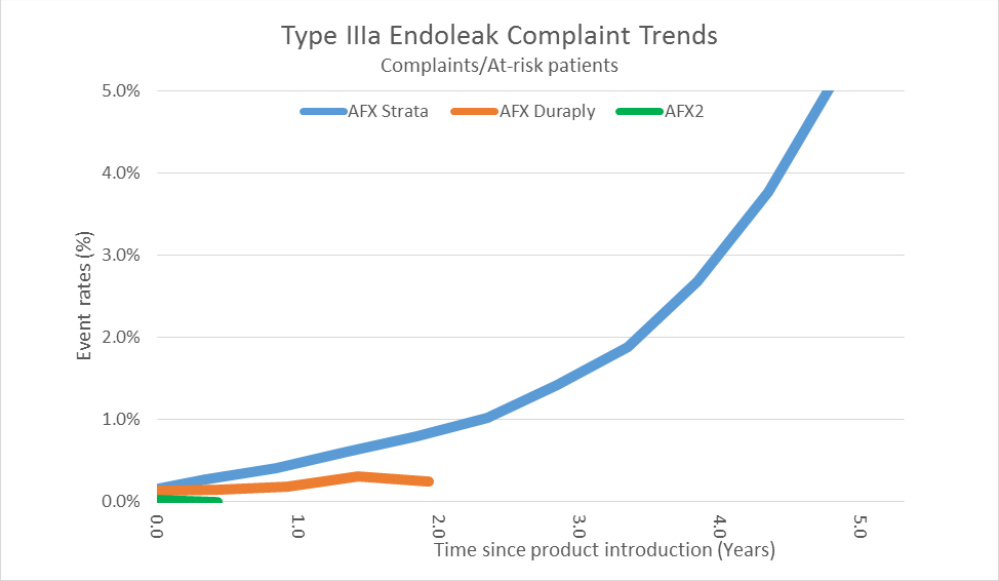
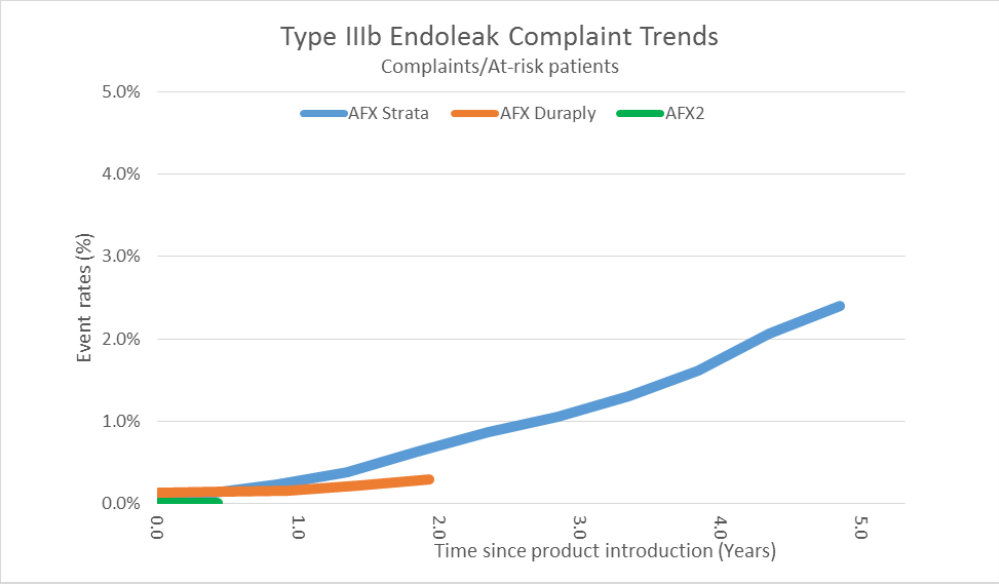


Figure 2: Type IIIb Endoleak Complaint Trends by Product Type



In addition to the complaint trends in the figures above, below is a table that reflects the cumulative reports of Type IIIa and Type IIIb endoleak by AFX product version. While the product changes appear to be reducing the occurrence of Type III endoleak rates, we do not have long-term data on the effectiveness of these changes and the time to event may exceed the amount of follow-up currently available.

Event Type	**AFX Product Version**		
	AFX System + Strata Rate*	**AFX System + Duraply** Rate*	**AFX2 System** Rate*
Type IIIa Endoleak	1.54% (366/23,828)	0.20% (34/17,139)	0.02% (1/4143)
Type IIIb Endoleak	1.34% (320/23,828)	0.19% (33/17,139)	0% (0/4143)

*Rate: Total Events Reported/Total Bifurcated Units Sold (1 required per case)

Attachment 2: AFX devices with Strata graft material

AFX STRATA F-Numbers

Model #	F #	Model #	F #	Model #	F #	Model #	F #
BA22-80/I20-40	F00627	BA28-120/I20-40	F00601	A22-22/C75-O20	F00392	A25-25/C75-O20V	F00726-05
BA22-100/I16-40	F00429	BA28-80/I20-40	F00663	A22-22/C95-O20	F00405	A25-25/C95-O20V	F00726-06
BA22-80/I16-40	F00424	BA28-120/I16-40	F00655	A25-25/C55-O20	F00388	A28-28/C55-O20V	F00726-07
BA22-60/I16-40	F00418	BA28-100/I16-40	F00431	A25-25/C75-O20	F00393	A28-28/C75-O20V	F00726-08
BA22-100/I13-40	F00412	BA28-80/I16-40	F00426	A25-25/C95-O20	F00395	A28-28/C95-O20V	F00726-09
BA22-80/I13-40	F00409	BA28-60/I16-40	F00420	A28-28/C55-O20	F00389	A31-31/C80-O20V	F00726-10
BA22-60/I13-40	F00406	BA28-100/I13-40	F00414	A28-28/C75-O20	F00394	A31-31/C100-O20V	F00726-11
BA22-40/I13-40	F00611	BA28-80/I13-40	F00411	A28-28/C95-O20	F00370	A34-34/C80-O20V	F00726-12
BA22-90/I20-30	F00623	BA28-60/I13-40	F00408	A31-31/C80-O20	F00398	A34-34/C100-O20V	F00726-13
BA22-70/I20-30	F00622	BA28-90/I20-30	F00659	A31-31/C100-O20	F00404	I16-16/C55	F00561
BA22-90/I16-30	F00421	BA28-70/I20-30	F00658	A34-34/C80-O20	F00400	I16-16/C55F	F00371
BA22-70/I16-30	F00415	BA28-90/I16-30	F00423	A34-34/C100-O20	F00369	I16-16/C88	F00373
BA25-120/I20-40	F00600	BA28-70/I16-30	F00417	A22-22/C55V	F00703-01	I20-13/C70F	F00566
BA25-80/I20-40	F00645	BA28-100/I16-55	F00368	A22-22/C75V	F00703-02	I20-13/C88F	F00567
BA25-120/I16-40	F00637	BA28-80/I16-55	F00428	A22-22/C95V	F00703-03	I20-20/C55	F00564
BA25-100/I16-40	F00430	A22-22/C55	F00381	A25-25/C55V	F00703-04	I20-20/C55F	F00375
BA25-80/I16-40	F00425	A22-22/C75	F00384	A25-25/C75V	F00703-05	IS20-25/C55	F00378
BA25-60/I16-40	F00419	A22-22/C95	F00442	A25-25/C95V	F00703-06	IF20-25/C65	F00379
BA25-100/I13-40	F00413	A25-25/C55	F00382	A28-28/C55V	F00703-07	IS20-25/C65	F00380
BA25-80/I13-40	F00410	A25-25/C75	F00385	A28-28/C75V	F00703-08	I16-16/C55 SA	F00551
BA25-60/I13-40	F00407	A25-25/C95	F00390	A28-28/C95V	F00703-09	I16-16/C55F SA	F00553
BA25-110/I20-30	F00642	A28-28/C55	F00383	A31-31/C80V	F00703-10	I16-16/C88 SA	F00552
BA25-90/I20-30	F00641	A28-28/C75	F00386	A31-31/C100V	F00703-11	I20-13/C70F SA	F00556
BA25-70/I20-30	F00640	A28-28/C95	F00391	A34-34/C80V	F00703-12	I20-13/C88F SA	F00557
BA25-110/I16-30	F00635	A31-31/C80	F00396	A34-34/C100V	F00703-13	I20-20/C55 SA	F00554
BA25-90/I16-30	F00422	A31-31/C100	F00443	A22-22/C55-O20V	F00726-01	I20-20/C55F SA	F00555
BA25-70/I16-30	F00416	A34-34/C80	F00397	A22-22/C75-O20V	F00726-02	IS20-25/C55 SA	F00558
BA25-100/I16-55	F00432	A34-34/C100	F00399	A22-22/C95-O20V	F00726-03	IF20-25/C65 SA	F00560
BA25-80/I16-55	F00427	A22-22/C55-O20	F00387	A25-25/C55-O20V	F00726-04	IS20-25/C65 SA	F00559

Attachment 3: AFX2 devices in 28 mm Main Body and/or 20 mm Iliac Limbs

AFX2 28 mm Main Body and/or 20 mm Iliac Limbs F-Numbers

Generic Model Code	$X^1X^2X^3$-X^4/X^5X^6-X^7						
Example	BEA22-60/I20-40						
Parameter	X^1	X^2	X^3	X^4	X^5	X^6	X^7
Interpretation	B	EA	22	60	I	20	40

X^2 = EA	X^3 = 28mm (Aortic Body Stent Graft Diameter)		X^3 = 25mm (Aortic Body Stent Graft Diameter)		X^3 = 22mm (Aortic Body Stent Graft Diameter)	
	Model #	F #	Model #	F #	Model #	F #
X^6 = 20mm (Iliac Stent Graft Diameter)	BEA28-120/I20-40	F00820-01	BEA25-120/I20-40	F00820-28	BEA22-120/I20-40	F00820-55
	BEA28-100/I20-40	F00820-02	BEA25-100/I20-40	F00820-29	BEA22-100/I20-40	F00820-56
	BEA28-80/I20-40	F00820-03	BEA25-80/I20-40	F00820-30	BEA22-80/I20-40	F00820-57
	BEA28-60/I20-40	F00820-04	BEA25-60/I20-40	F00820-31	BEA22-60/I20-40	F00820-58
	BEA28-40/I20-40	F00820-05	BEA25-40/I20-40	F00820-32	BEA22-40/I20-40	F00820-59
	BEA28-110/I20-30	F00820-16	BEA25-110/I20-30	F00820-43	BEA22-110/I20-30	F00820-70
	BEA28-90/I20-30	F00820-17	BEA25-90/I20-30	F00820-44	BEA22-90/I20-30	F00820-71
	BEA28-70/I20-30	F00820-18	BEA25-70/I20-30	F00820-45	BEA22-70/I20-30	F00820-72
	BEA28-50/I20-30	F00820-19	BEA25-50/I20-30	F00820-46	BEA22-50/I20-30	F00820-73
	BEA28-100/I20-55	F00820-24	BEA25-100/I20-55	F00820-51	BEA22-100/I20-55	F00820-78
	BEA28-80/I20-55	F00820-25	BEA25-80/I20-55	F00820-52	BEA22-80/I20-55	F00820-79
X^6 = 16mm (Iliac Stent Graft Diameter)	BEA28-120/I16-40	F00820-06				
	BEA28-100/I16-40	F00820-07				
	BEA28-80/I16-40	F00820-08				
	BEA28-60/I16-40	F00820-09				
	BEA28-40/I16-40	F00820-10				
	BEA28-110/I16-30	F00820-20				
	BEA28-90/I16-30	F00820-21				
	BEA28-70/I16-30	F00820-22				
	BEA28-50/I16-30	F00820-23				
	BEA28-100/I16-55	F00820-26				
	BEA28-80/I16-55	F00820-27				

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Attachment 4: IFU Updates Addressing Type III Endoleaks

Table 1: IFU Updates Addressing Type IIIa Endoleaks

Date of Introduction	Purpose of Update	Specific IFU Change (changes noted in bold)
2013	Reinforce the importance of device selection with an emphasis on maximizing overlap between the bifurcated and extension components.	*Section 2.0; Indications for Use* Extension stent grafts must have the ability to overlap the bifurcated stent graft by at least **30 to 40 mm proximally** and 15 to 20 mm **distally**. *Section 4.3; Implant Procedure* When placing an extension stent graft, the extension stent graft must overlap the bifurcated stent graft by **at least 30 to 40mm proximally and** at least 15 to 20mm **distally.** Section 7.1; *Patient Selection and Treatment* The length of the extension stent graft should extend from the lowest renal artery or the inside of the limb to achieve **at least 30 to 40 mm (proximally) and** at least 15 to 20 mm (distally) overlap inside the chosen bifurcated stent graft model.
2015	Clarify important information related to patient selection, procedure planning and post-operative follow-up imaging.	*Section 4.3; Implant Procedure* When placing an extension stent graft, the extension stent graft must overlap the bifurcated stent graft by at least 30 to 40mm proximally and at least 15 to 20mm distally. **Care should be taken to maximize overlap. Placement of an additional infrarenal extension to overlap this junction should be considered in patients with an angulated aortic neck, tortuous aorta, large diameter aneurysm (>7cm), long renal to bifurcation length, or as deemed appropriate by the treating physician.** When placing an extension stent graft, care should be taken during initiation of and through deployment to visualize positioning and proper location. **Care should be taken to ensure the bare segment of the suprarenal extension is placed over the renal arteries, and the graft covered segment is below the most caudal renal artery. Placement of the suprarenal segment in short aortic necks (< 15mm) may lead to device damage, endoleak, or patient injury.** *Section 7.1; Individualization of Treatment* **Select the bifurcated device with the longest body length suitable for the patient's anatomy without compromising luminal blood flow. Pre-procedure planning and device selection should aim to maximize overlap with the primary bifurcated stent graft;** the length of the extension stent graft should extend from the lowest renal artery or the inside of the limb

		to achieve at least 30 to 40 mm (proximally) and at least 15 to 20 mm (distally) overlap inside the chosen bifurcated stent graft model. **Care should be taken to maximize overlap. Placement of an additional infrarenal extension to overlap this junction should be considered in patients with an angulated aortic neck, tortuous aorta, large diameter aneurysm (>7cm), long renal to bifurcation length, or as deemed appropriate by the treating physician.** The following determinants should be considered in selecting devices during pre-implant planning: • Angulation of aortic neck, aneurysm and iliac arteries. • Quality of the aortic neck. • Diameter of the infrarenal aortic neck • **Diameter of the aneurysm and aortic tortuosity** • Length from the **most caudal renal artery** to the aortic bifurcation. • Length from the aortic bifurcation to the distal seal zone and/or internal iliac arteries • Aneurysm(s) extending into the iliac arteries may require special consideration in selecting a suitable graft/artery interface site • Diameter of the external and common iliac arteries • Pre-dilation of the iliac arteries may ease deployment procedure *Section 12.0; Imaging Guidelines and Post-Operative Follow-Up:* Physicians should evaluate patients on an individual basis and prescribe their follow-up relative to the needs and circumstances of each individual patient. A suggested imaging schedule is presented in Table 47 (on page 49); alternatives to this schedule may be made by the physician per medical judgment. This physician defined schedule for patient follow-up should be maintained even in the absence of clinical symptoms (e.g., pain, numbness, weakness). Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the stent graft including reduced overlap of stent graft components) should receive follow-up at more frequent intervals. **At a minimum, 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 extensions stent grafts;** • **Absence of clinically relevant migration or lateral movement;** • **Aneurysm enlargement, perigraft flow, loss of patency, increased tortuosity, or progressive disease.**

		Annual imaging may include one or more of the following per physician medical judgment and patient-specific factors: contrast and/or non-contrast CT scans; duplex ultrasound; magnetic resonance imaging. The combination of contrast and non-contrast CT imaging provides information on aneurysm diameter change, endoleak, patency, tortuosity, progressive disease, fixation length, and other morphological changes. Duplex ultrasound imaging may provide information on aneurysm diameter change, endoleak, patency, tortuosity and progressive disease. **Plain x-rays may provide information on stent integrity and maintained component overlap.**
2015	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. Clarified the device sizing guidelines when using proximal extensions with bifurcated stent grafts.	*Section 7.1; Individualization of Treatment* Select the bifurcated and proximal endograft components to maximize overlap (OL) as follows: • Measure and record aneurysm length(AL) and maximum aneurysm diameter (AD) • **Select Endograft components so that the overlap (OL) is greater than the aneurysm radius (AR = AD ÷2) plus 20 mm (OL ≥AR + 20 mm)** **Note: If the recommended overlap (OL) cannot be achieved, or if AD > AL, use an infrarenal Endograft component of similar covered length and diameter to bridge to achieve the necessary overlap (OL).** *Section 10.4; Device Diameter Sizing Guidelines* **Refer to Tables 43-45 (pp. 49-50) for sizing of stent graft components. When selecting a 22, 25, or 28 mm proximal extension, a diameter one size larger than the main body of the bifurcated stent graft is recommended. When selecting a 31 or 34 mm proximal extension, use only a bifurcated stent graft having a 28 mm diameter body.** Under sizing or over sizing may result in incomplete sealing or compromised flow.

Table 2: IFU Updates Addressing Type IIIb Endoleaks

Date of Introduction	Purpose of Update	Specific IFU Change (changes noted in bold)
2014	Provide further 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.	*Section 4.2; Patient Selection, Treatment and Follow-Up* Irregular calcification and/or plaque may compromise **graft integrity** or the fixation and sealing of the implantation sites. *Section 4.3; Implant Procedure* • The AFX Endovascular AAA System was evaluated using Endologix components. The safety and effectiveness of other stent or stent graft devices used in conjunction with the AFX System have not been established. • Over-inflation **beyond the nominal diameter of the stent graft** may result in damage to the vessel wall and/or vessel rupture, or damage to the stent graft. *Section 11.5; Procedure – Bifurcated Stent Graft Delivery* **WARNING: Care should be taken during guidewire or catheter manipulation. Excessive manipulation may cause damage to the endoprosthesis** CAUTION: Take care during manipulation of catheters, wires and sheaths within an aneurysm. Significant disturbances may dislodge fragments of thrombus, which can cause distal embolization, **or damage the graft material, leading to endoleaks.** **CAUTION: Calcification or other disturbances along the vessel wall interacting with the graft may increase the risk of damage to the graft, which may cause endoleaks.** **WARNING: Do not exceed the manufacturer's recommended maximum inflation diameter. Rupture of the balloon may occur. Adhere to balloon inflation parameters as described in this booklet. Over-inflation beyond the nominal diameter of the stent graft may result in damage to the vessel wall and/or vessel rupture, or damage to the stent graft.** *Section 11.6; Procedure – Accessory Extension Stent Graft Delivery* WARNING: Care should be taken to verify that the delivery system handle is fully locked into the hemostasis valve of the introducer sheath.

		Incomplete connection may prevent stent graft advancement and deployment. • Advance the core assembly of the delivery system to move the extension stent graft through the introducer sheath until it stops (and the bottom of the radiopaque tip is aligned with the radiopaque marker on the introducer sheath). • Ensure the significant component overlap (minimum 30 to 40mm) is achieved. WARNING: Inaccurate placement, inadequate component overlap, inadequate fixation and/or incomplete sealing of the AFX stent graft within the vessel may result in increased risk of endoleak, migration or inadvertent occlusion of the renal arteries. Renal artery patency must be maintained to prevent/reduce the risk of renal failure and subsequent complications. Incorrect deployment or migration of the stent graft may require additional endovascular treatment or surgical intervention. WARNING: Do not exceed the manufacturer's recommended maximum inflation diameter. Rupture of the balloon may occur. Adhere to balloon inflation parameters as described in this booklet. Over-inflation beyond the nominal diameter of the stent graft may result in damage to the vessel wall and/or vessel rupture, or damage to the stent graft.