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Irvine, CA 92618
949 595 7200
endologix.com

July 20, 2018

Urgent: Important Safety Update
Medical Device Correction for the AFX® Endovascular AAA System

Dear Physician,

This letter provides important information related to the AFX Endovascular AAA System (AFX System) which is intended for the endovascular treatment of patients with abdominal aortic aneurysms (AAA). This information has been directly shared with current and historical AFX System users; however, Endologix recognizes there are situations in which a non-AFX System user may be monitoring or treating a patient with an AFX device (e.g., obtaining access for a coronary catheter procedure, transfer of care). Therefore, in the interest of patient safety, Endologix believes it is important the following information is shared with non-AFX System users:

1) Regarding the monitoring of patients with an AFX device, information on Type III endoleak rates (Appendix 1) and patient-tailored surveillance recommendations (Appendix 3); and
2) Recommendations for intervening through an AFX device or re-intervening on an AFX device (Appendices 4 and 5, respectively).

Please note this notice provides updated information and revisions to the Instructions for Use (IFU) to enhance patient safety. No product return is required.

Information Regarding Type III Endoleak Rates

The AFX System was originally introduced in 2011 and was manufactured with a graft material referred to as Strata (AFX System with Strata). Since it was initially commercialized, Endologix has been monitoring and evaluating the performance of the device via the company's complaint monitoring program. As a result of this monitoring, Endologix has conducted investigations into reports of Type III endoleaks which may cause increased pressure within the aneurysm sac that could increase the risk of aneurysm rupture and patient death. These investigations identified the following associations:

- Inadequate component overlap at the index procedure
- Lateral movement in large or tortuous aortas leading to reduction or loss of component overlap and/or implant stability
- Use of an excessively oversized proximal extension relative to the bifurcated main body device
- Procedural factors such as extensive guidewire/catheter manipulation or aggressive balloon molding
- Off-label use (especially in highly calcified anatomy)
- Implant of other manufacturer's devices as proximal extensions

In consideration of these factors, Endologix has taken a number of actions in recent years to address Type III endoleaks with the AFX System. These have included changes to the system's Instructions for Use (IFU) as well as product modifications intended to help prevent the occurrence of Type III endoleaks. Endologix has been monitoring the effectiveness of these changes through its complaint monitoring system and, as shown in Appendix 1, the reported Type IIIa and IIIb endoleak estimated complaint rates at equivalent time points past 1-year have been lower for the AFX System with Duraply and AFX2 Systems with Duraply compared to the AFX System with Strata, which has been discontinued and was removed from the field in December 2016. Note that the estimated complaint rates are calculated based on voluntary complaint reporting and units sold, which may underestimate the true event rate on a per patient basis.

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 Appendix 2 in order to assist you in determining if your patient is implanted with an AFX device with the Strata graft material.

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Irvine, CA 92618
949 595 7200
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You may also request details on any patients that have been implanted with the AFX STRATA system by sending requests directly to device.tracking@endologix.com. Physicians may also contact their Endologix representative to request the data or may contact Endologix's medical affairs office at medicalaffairs@endologix.com with questions.

Patient-Tailored Surveillance Recommendations

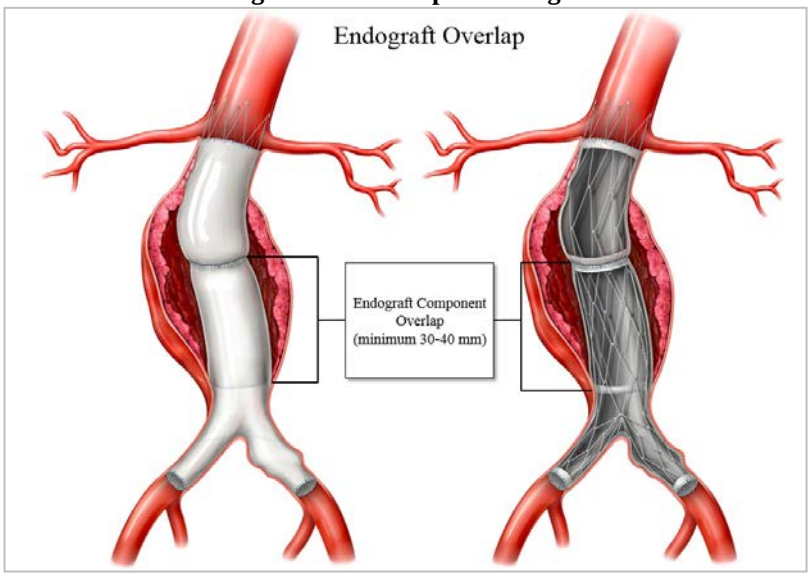
All AFX patients require life-long, regular follow-up to assess the performance of their endovascular implant. Therefore, at a minimum, Endologix recommends that high- resolution CT scan imaging (contrast-enhanced and non-contrast) be performed at one month, six months, one year, and annually thereafter.

In addition to these general surveillance recommendations, and in line with the clinical practice guidelines published by the Society of Vascular Surgeons (SVS) and the European Society of Vascular Surgeons (ESVS) recommending personalized surveillance regimens[1, 2], Endologix is providing information to assist physicians in tailoring follow-up for patients. These recommendations are provided in Appendix 3.

Guidelines on Intervention Through or Re-intervention On an AFX Device

Endologix recognizes there may be a clinical need to either perform an intervention through a previously implanted AFX device (e.g., to gain vascular access for a coronary procedure), or a re-intervention on such a device (e.g., for treatment of a Type III endoleak). As illustrated in **Figure 1**, the AFX implant has a unique endoskeleton design where the ePTFE is only attached to the most proximal and distal stent apices of the implant. The ePTFE is not attached to the stent cage throughout its entire length.

Figure 1: AFX Implant Design



**Note: Figure 1 above corresponds to Figure 16 of the IFU*

Based on this unique design, Endologix has developed guidelines that should be considered in intervention/re-intervention situations to ensure that devices can be tracked through the previously implanted AFX device without damage. This includes step-by-step instructions on how to best navigate the endoskeleton design of the existing AFX device in order to obtain and confirm proper wire access. These guidelines are intended to help guide the physicians and do not take the place of physician judgement. Refer to Appendix 4 and Appendix 5 for an outline of the complete intervention and re-intervention guidelines, respectively.

[1] Chaikof, Elliot L., et al. "The Society for Vascular Surgery Practice Guidelines on the Care of Patients with an Abdominal Aortic Aneurysm." Journal of Vascular Surgery, vol. 67, no. 1, Jan. 2018, pp. 2–77.e2.
[2] Moll, F.l., et al. "Management of Abdominal Aortic Aneurysms Clinical Practice Guidelines of the European Society for Vascular Surgery." European Journal of Vascular and Endovascular Surgery, vol. 41, 2011, pp. S1–S58.

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The information described has also been included in the revised product IFUs, which can be provided via hard copy upon request to Endologix Customer Service for the U.S. at 800-983-2284 (5:00 A.M. - 6:00 P.M. Pacific Time). Alternatively, Endologix Customer Service can provide instructions for obtaining a copy of the IFU via the online e-labeling website.

Endologix will continue to monitor the clinical experience with the AFX System, listen to physician feedback, and provide updates regarding important information collected through complaint monitoring. Endologix appreciates your review of this notification and requests that you share it within your organization as appropriate. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax, and to Endologix, at fieldassurance@endologix.com. If you have any questions regarding the content of this notification, please contact your Endologix representative or Endologix Customer service for the U.S. at 800.983.2284 (5.00 A.M. – 6:00P.M. Pacific Time).

Yours Sincerely,

Matt Thompson, MD
Chief Medical Officer

2 Musick
Irvine, CA 92618
949 595 7200
endologix.com

Appendix 1: Type III Endoleak Update

As explained above, Endologix has completed a number of product modifications to address Type III endoleaks, including the introduction of longer lengths of bifurcated devices to maximize component overlap, changing from the original graft material processing referred to as Strata (AFX System with Strata) to an improved process known as Duraply™ (AFX System with Duraply™), and introduction of the AFX®2 Bifurcated Endograft System manufactured with Duraply (AFX2 System with Duraply). Endologix has been monitoring the effectiveness of these changes through its complaint monitoring system. **Table 1** and **Table 2** below provide the number of Type IIIa and IIIb events reported to have been observed within the respective durations of implantation. Follow up continues to accrue with events reported across all time points.

Figure 2 and **Figure 3** below display the Type IIIa and Type IIIb endoleak complaint trends for AFX with Strata, AFX System with Duraply, and AFX2 System with Duraply. As shown in these figures, the reported Type IIIa and IIIb endoleak complaint rates have been lower for the AFX System with Duraply and AFX2 System with Duraply compared to the AFX System with Strata, at equivalent time points past 1-year. Additionally, it appears the Type IIIa endoleak rate for the AFX System with Strata continues to increase. Therefore, continued vigilance in patient surveillance and re-intervention in the case of loss of component overlap remains important. Note that the estimated complaint rates are calculated based on voluntary complaint reporting and units sold, which may underestimate the true event rate on a per patient basis. This underestimate may be greater for the more recent versions (i.e., AFX System with Duraply and AFX2 System with Duraply), which may have a larger hospital inventory as compared to the AFX System with Strata, which is no longer available. In particular, as there are only an estimated 285 patients at risk at 2-years for the AFX2 System, these particular data should be interpreted with caution.

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949 595 7200
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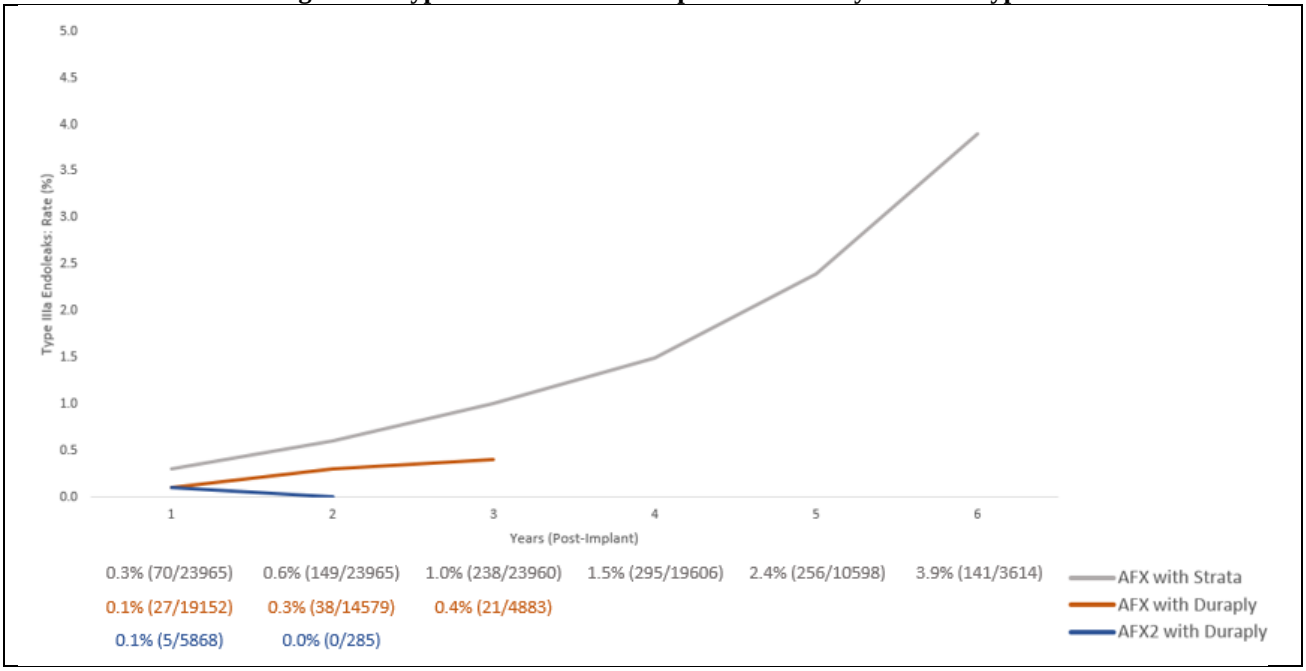
Figure 2: Type IIIa Endoleak Complaint Trends by Product Type



**NOTE: Complaint rates are calculated based on voluntary complaint reporting and units sold, which may underestimate the true event rate on a per patient basis. This underestimate may be greater for the more recent versions (i.e. AFX System with Duraply and AFX2 System with Duraply), which may have a larger hospital inventory as compared to the AFX System with Strata, which is no longer available.*

*** NOTE: Rates are generated by first summing all patients that have the minimum designated length of follow-up, based on the bifurcated implant sales. Then, all events that occur within the designated period among that same group of patients are summed together. The cumulative rate for each period is found by dividing the event sum by the number of at-risk patients. This approach provides cumulative complaint rates across a range of follow-up periods. Note that events known to have occurred within the designated length of follow-up, but occur in patients who have not yet reached the minimum required follow-up, are not included.*

Table 1: Number of Reported Type IIIa Endoleaks by Duration of Implantation

	≤30 days	> 30 days & ≤ 1 year	>1 year & ≤ 2 years	>2 years & ≤ 3 years	>3 years & ≤ 4 years	>4 years & ≤ 5 years	>5 years & ≤ 6 years	>6 years & ≤ 7 years
AFX with Strata	28	44	80	90	95	65	35	4
AFX with Duraply	13	16	14	21	7	-	-	-
AFX2 with Duraply	1	9	0	0	-	-	-	-

The time to event above is calculated as the difference between the implantation date and event date. Note that this calculation differs from the assessment of **Figure 2.*

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Irvine, CA 92618
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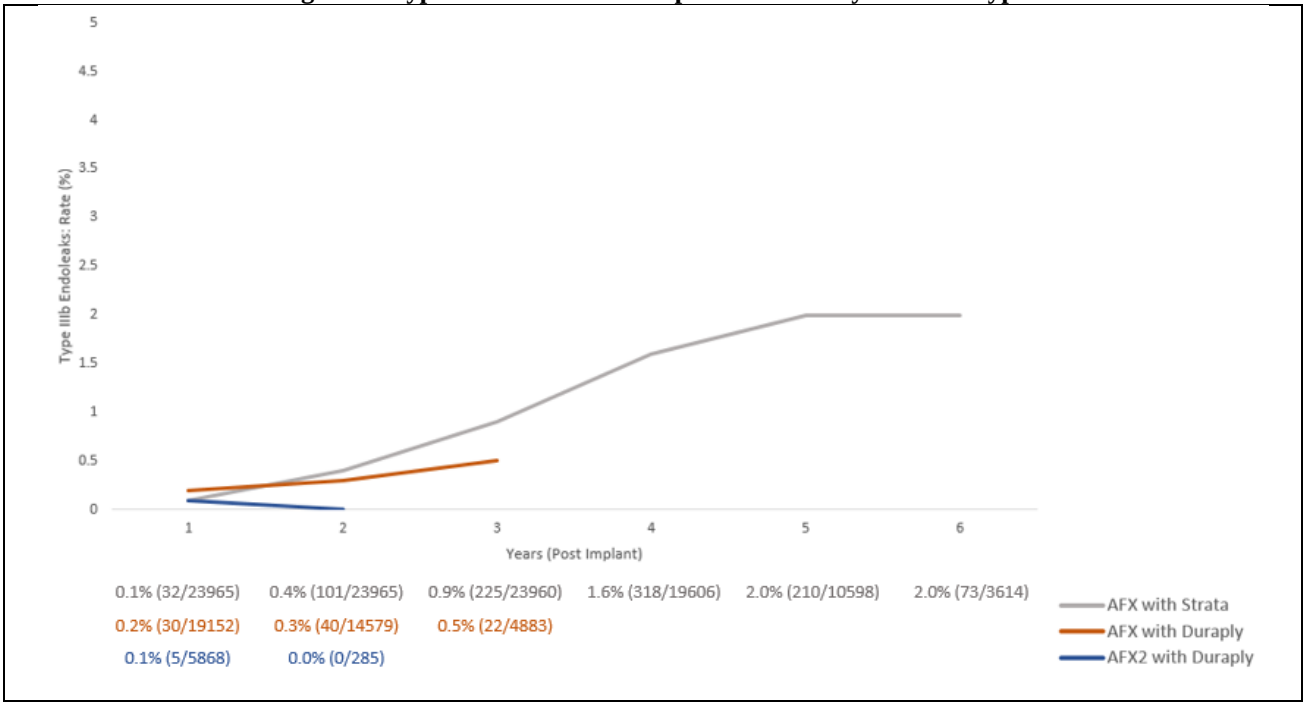
Figure 3: Type IIIb Endoleak Complaint Trends by Product Type



**NOTE: Complaint rates are calculated based on voluntary complaint reporting and units sold, which may underestimate the true event rate on a per patient basis. This underestimate may be greater for the more recent versions (i.e. AFX System with Duraply and AFX2 System with Duraply), which may have a larger hospital inventory as compared to the AFX System with Strata, which is no longer available.*

*** NOTE: Rates are generated by first summing all patients that have the minimum designated length of follow-up, based on the bifurcated implant sales. Then, all events that occur within the designated period among that same group of patients are summed together. The cumulative rate for each period is found by dividing the event sum by the number of at-risk patients. This approach provides cumulative complaint rates across a range of follow-up periods. Note that events known to have occurred within the designated length of follow-up, but occur in patients who have not yet reached the minimum required follow-up, are not included.*

Table 2: Number of Reported Type IIIb Endoleaks by Duration of Implantation

	≤30 days	> 30 days & ≤ 1 year	>1 year & ≤ 2 years	>2 years & ≤ 3 years	>3 years & ≤ 4 years	>4 years & ≤ 5 years	>5 years & ≤ 6 years	>6 years & ≤ 7 years
AFX with Strata	13	21	70	123	174	106	32	2
AFX with Duraply	20	13	21	22	1	-	-	-
AFX2 with Duraply	2	7	3	0	-	-	-	-

The time to event above is calculated as the difference between the implantation date and event date. Note that this calculation differs from the assessment of **Figure 3.*

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Irvine, CA 92618
949 595 7200
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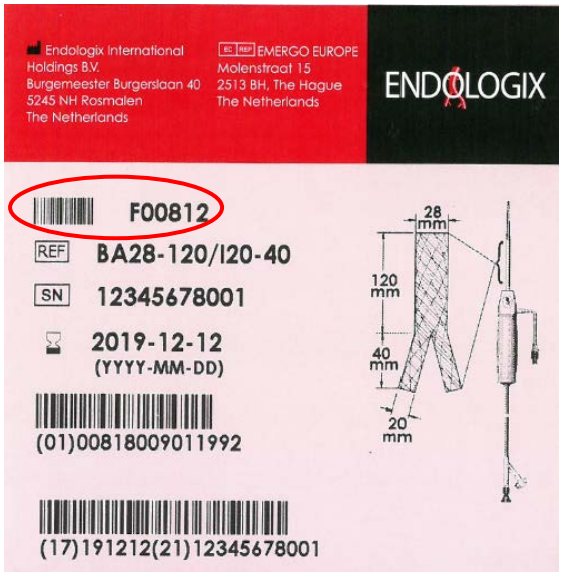
Appendix 2: AFX Devices with Strata Graft Material

Model #	F #	Model #	F #	Model #	F #	Model #	F #
BA22-80/I20-40	F00627	BA28-80/I20-40	F00663	A22-22/C95-O20	F00405	A25-25/C95-O20V	F00726-06
BA22-100/I16-40	F00429	BA28-120/I16-40	F00655	A25-25/C55-O20	F00388	A28-28/C55-O20V	F00726-07
BA22-80/I16-40	F00424	BA28-100/I16-40	F00431	A25-25/C75-O20	F00393	A28-28/C75-O20V	F00726-08
BA22-60/I16-40	F00418	BA28-80/I16-40	F00426	A25-25/C95-O20	F00395	A28-28/C95-O20V	F00726-09
BA22-100/I13-40	F00412	BA28-60/I16-40	F00420	A28-28/C55-O20	F00389	A31-31/C80-O20V	F00726-10
BA22-80/I13-40	F00409	BA28-100/I13-40	F00414	A28-28/C75-O20	F00394	A31-31/C100-O20V	F00726-11
BA22-60/I13-40	F00406	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
BA28-120/I20-40	F00601	A22-22/C75-O20	F00392	A25-25/C75-O20V	F00726-05		

Example:



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949 595 7200
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Appendix 3: Patient-Tailored Surveillance Recommendations

New IFU Section	Content
Section 12.2: Patient-Tailored Surveillance	Physicians should evaluate patients on an individual basis and prescribe their follow-up relative to the needs and circumstances of each individual patient. This is in line with personalized surveillance regimens discussed in the clinical practice guidelines published by the Society of Vascular Surgeons (SVS) and the European Society of Vascular Surgeons (ESVS).[1,2] 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 than described in Section 12.1 General. In addition, enhanced surveillance should be considered for patients at higher risk of graft related complications (e.g., treated off-label, with a short seal zone, with clinical risk factors associated with Type III endoleaks). Investigations into Type III endoleaks have identified the following associations: • Inadequate component overlap at the index procedure • Lateral movement in large or tortuous aortas leading to reduction or loss of component overlap and/or implant stability • Use of an excessively oversized proximal extension relative to the bifurcated main body device • Procedural factors such as extensive guidewire/catheter manipulation or aggressive balloon molding • Off-label use (especially in highly calcified anatomy) • Implant of other manufacturer's devices as proximal extensions 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. Endovascular or open re-intervention to reestablish aneurysm exclusion and/or graft patency should be considered. _____ [1] Chaikof, Elliot L., et al. "The Society for Vascular Surgery Practice Guidelines on the Care of Patients with an Abdominal Aortic Aneurysm." Journal of Vascular Surgery, vol. 67, no. 1, Jan. 2018, pp. 2–77.e2. [2] Moll, F.l., et al. "Management of Abdominal Aortic Aneurysms Clinical Practice Guidelines of the European Society for Vascular Surgery." European Journal of Vascular and Endovascular Surgery, vol. 41, 2011, pp. S1–S58.

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Irvine, CA 92618
949 595 7200
endologix.com

Appendix 4: Intervention Guidelines

New IFU Section	Content
13.0: Intervention Guidelines (i.e., catheter-based procedures through an existing AFX device)	Prior to performing an intervention that requires a catheter to track through an existing AFX device, review this *Instructions for Use* booklet. The following instructions embody basic guidelines to consider when performing a catheter-based procedure on a patient implanted with the AFX Endovascular AAA System. These instructions are intended to help guide the physician and do not take the place of physician judgment.
13.1: General Use Information	Due to its unique endoskeleton design and because the ePTFE is not attached to the stent cage throughout its entire length (**Figure 1**), the techniques described in the sections below should be employed during an intervention that may be traversing/crossing/transferring through the AFX Endovascular AAA System. ***CAUTION:*** ***Systemic anticoagulation should be used during the intervention procedure based on hospital and physician preferred protocols. If Heparin is contraindicated, an alternative anticoagulant should be considered.*** ***CAUTION:*** ***The ePTFE graft is not attached to the stent throughout its entire length and could give the appearance of a properly placed wire or accessory, when the wire may be inadvertently placed behind a stent strut.*** ***WARNING:*** ***Excessive movement during catheter advancement may lead to cephalad movement of the existing AFX device(s), which may result in inadvertent visceral coverage.*** ***WARNING:*** ***Excessive manipulation during catheter advancement may lead to damage of the existing AFX device, which may result in a Type IIIb endoleak.***
13.2: Pre-Procedure Planning	As part of pre-procedure planning, verify that an appropriately-sized catheter or accessory device (e.g., balloons, flexible "J-tip" guidewires, pigtail catheters) have been selected to track through the previously implanted AFX Endovascular AAA System without damage. Determinants include: 1. The number of modular AFX components currently implanted may impact the flow lumen and/or endoskeleton diameter and should be considered when planning an intervention that requires transferring through the existing AFX device. NOTE: The information provided in the subsequent sections is intended to assist physicians in tracking through the existing AFX device. Follow the manufacturer's instructions for use for additional pre-procedure planning.

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949 595 7200
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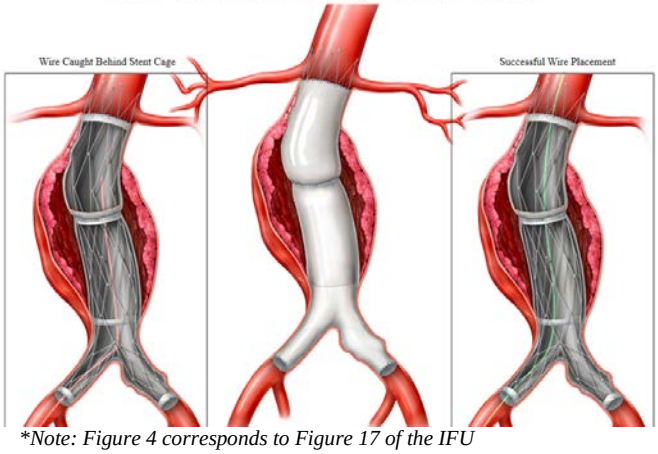
New IFU Section	Content
13.3: Patient Preparation/ Arterial Access	1. Refer to institutional protocols relating to anesthesia, anticoagulation and monitoring of vital signs. 2. Position patient on imaging table allowing fluoroscopic visualization from the aortic arch to the femoral bifurcations. 3. Gain luminal access through the femoral arteries. 4. Establish adequate proximal and distal vascular control of the surgically exposed femoral artery, as needed. 5. Following the manufacturer's instructions for use, advance a flexible "J-tip" guidewire, pigtail catheter, or acceptable equivalent, into the vasculature under fluoroscopy. • NOTE: Proper device choice may limit the likelihood of tracking behind a stent strut. Reference **Figure 4**. **Figure 4: Ensure Guidewire Is Not Caught Behind Stent Strut** Ensure Guidewire is Not Caught Behind Stent Strut  **Note: Figure 4 corresponds to Figure 17 of the IFU* ***CAUTION:*** ***Tortuosity and angulation may impact the morphology of the endoskeleton within the vasculature. Use caution when tracking devices through the existing AFX device.*** 6. Once the flexible "J-tip" guidewire or pigtail catheter reaches above the existing AFX device, slowly advance an occlusion balloon or PTA balloon over the wire and under fluoroscopy. Slowly inflate, per the manufacturer's instructions, until the balloon has been fully shaped or formed. It is recommended to use a 12mm diameter PTA balloon or an occlusion balloon that is partially inflated to ensure devices are not behind a stent strut. • Advance and retract the balloon catheter up and down the entire length of the existing AFX device to ensure there is proper luminal wire access. o NOTE: Balloon kinking during inflation or enlargement of a section of the stent cage may be a signal of a potential wire placed behind a stent strut. Reference **Figure 5**.

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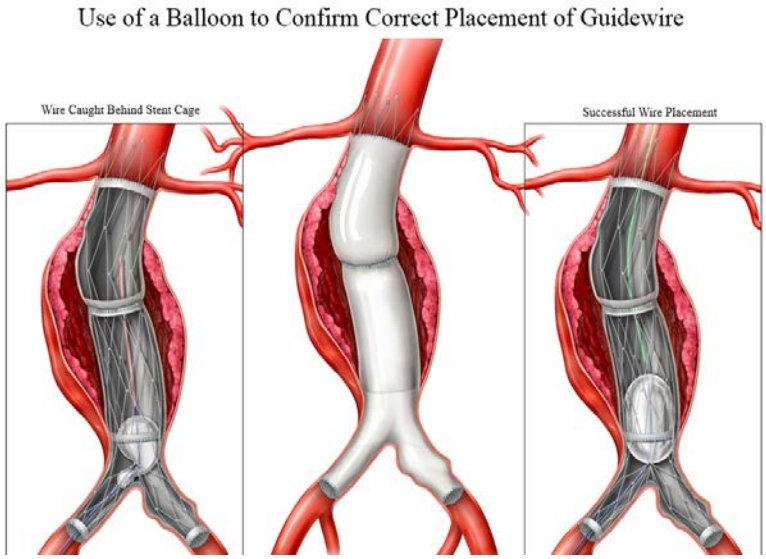
Irvine, CA 92618
949 595 7200
endologix.com

New IFU Section	Content
	Figure 5: Use of a Balloon to Confirm Correct Placement of Guidewire  **Note: Figure 5 corresponds to Figure 18 of the IFU* ***CAUTION:*** ***Balloon inflation and advancement should be performed slowly so as not to damage or dislodge the existing AFX device.*** ***WARNING:*** ***Overinflation of the balloon to ensure luminal access may create the false appearance of a wire placed behind a stent strut or may shift the main body cephalad.*** 7. During inflation and while tracking through the aortic lumen, fluoroscopic imaging in multiple planes should be used to verify that no accessory devices are behind a stent strut. 8. After verifying correct wire placement fluoroscopically, the balloon should be removed and use of alternative techniques (e.g., intravascular ultrasound) may be helpful to confirm correct wire placement. 9. Should incorrect wire placement behind a stent strut be observed, remove wire and re-advance guidewire/pigtail catheter, as described above. 10. Repeat Steps 5-8 for contralateral access, if appropriate.
13.4: Procedure – Device Advancement	1. While using continuous fluoroscopy and visualizing the entire existing AFX device, advance sheaths slowly up the ipsilateral and/or contralateral access points, as needed, and remove dilators. ***CAUTION:*** ***If the existing AFX device is at risk of being displaced cephalad while advancing devices (e.g., existing device is in severely angulated or tortuous anatomy), use of an appropriately-sized balloon on the contralateral (opposite) side may help to stabilize the existing AFX device.*** 2. Following the manufacturer's instructions for use, prepare and advance any devices necessary to complete a procedure. Once a catheter has been passed through the existing AFX device and does not lie behind a stent strut, then standard wire exchange techniques can be utilized to place a wire of appropriate diameter for the procedure. Continue to visualize the entire existing AFX device under fluoroscopy when manipulating any devices through the existing AFX device.

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Irvine, CA 92618
949 595 7200
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New IFU Section	Content
	CAUTION: ***Observe any cephalad movement of the existing AFX device as this may obstruct visceral vessels above the covered portion of the stent cage.*** ***CAUTION:*** ***Care should be taken when tracking accessory devices through an existing AFX device to ensure the ePTFE graft and endoskeleton is not inadvertently punctured or damaged.*** ***WARNING:*** ***Failure to visualize the entire existing AFX device when manipulating devices through the existing AFX device(s) may result in deformation.*** ***WARNING:*** ***Excessive movement when positioning devices may lead to cephalad movement, which may result in inadvertent visceral or internal iliac artery coverage.*** ***CAUTION:*** ***If the existing AFX device is displaced cephalad while advancing the device (e.g., catheter, endovascular devices), use of an appropriately-sized balloon on the contralateral (opposite) side may help to stabilize the existing AFX graft and mitigate further displacement.***
13.5: Imaging Guidelines and Post-Operative Follow-up	Procedurally, fluoroscopic imaging in multiple planes should be used to verify that no accessory devices are placed behind a stent strut. Imaging should also be used after device advancement and/or placement to ensure the existing AFX device has not been damaged or moved and that a new endoleak is not present. Upon confirmation of no negative effect to the existing AFX device, Endologix recommends that patients continue on their current imaging surveillance. Refer to Section 12 for additional imaging and post-operative follow-up guidelines.

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Irvine, CA 92618
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Appendix 5: Re-intervention Guidelines

New IFU Section	Content
14.0: Secondary Intervention Guidelines (i.e., endovascular procedures to correct an existing AFX device)	Prior to performing a secondary intervention, review this *Instructions for Use* booklet, including the Intervention Guidelines in Section 13 above. The following additional warning and precautions embody basic guidelines to consider when conducting a secondary intervention on a patient implanted with the AFX Endovascular AAA System. These additional warnings and precautions are intended to help guide the physician and do not take the place of physician judgment.
14.1: General Warnings and Precautions	***WARNING:*** ***Due to the unique design of the existing AFX device, it may be difficult to achieve adequate seal for a Type III endoleak by only utilizing aortic cuffs or extensions. Specifically, the ePTFE is not attached to the stent cage throughout its entire length, thus preventing the newly placed endograft from properly sealing through its entire length.*** ***WARNING:*** ***Due to the unique design of the AFX device, only utilizing an aortic cuff or extension for the treatment of Type IIIa endoleaks may lead to a Type IIIb endoleak over time. Specifically, the aortic cuff or extension has the potential to puncture the ePTFE graft of the existing AFX device if either end interacts with the existing AFX graft material.*** ***CAUTION:*** ***Self-expanding and balloon expandable endografts used within the existing AFX device have the potential to puncture the ePTFE graft if either end interacts with the AFX graft material.*** ***CAUTION:*** ***Barbs, hooks, or anchors in the new implant may tear the existing graft material or lead to progressive tears throughout the existing AFX device. Any re-intervention should aim to prevent placement of barbs, hooks, or anchors adjacent to or within the ePTFE graft.*** ***CAUTION:*** ***The guidewire should remain in the lumen of the stent frame rather than behind the endoskeleton for the entire procedure and must be in the suprarenal aorta before any devices can be advanced and implanted within the existing endoskeleton. Care should be taken to prevent guidewire passage behind a stent strut.***
14.2: Imaging Guidelines and Post-Operative Follow Up	Procedurally, fluoroscopic imaging in multiple planes should be used to verify that no accessory devices are placed behind a stent strut (Reference **Figure 4**). Imaging should also be used after device placement to ensure the existing AFX device has not been damaged and to ensure that the reason for the re-intervention has been addressed. Assuming no additional concerns have been identified, Endologix recommends, at a minimum, 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 following any re-intervention. Alternative imaging modalities such as magnetic resonance imaging, plain X-Ray or duplex ultrasound may be used in patients with impaired renal function or intolerance to contrast media. Determination of imaging techniques should be based on the physician's clinical assessment of the patient and stent graft implant, including any adjunct procedures that may have been performed in conjunction with the endovascular stent graft procedure.

2 Musick
Irvine, CA 92618
949 595 7200
endologix.com

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	Note: Additional radiological imaging may be necessary to further evaluate the stent graft in situ based on findings revealed by one of the surveillance programs. The following recommendations may be considered: • If there is evidence of poor or irregular position of the stent graft, severe angulation, kinking or migration of the stent graft on abdominal X-rays, a spiral CT or duplex ultrasound may be considered to assess aneurysm size and the presence or absence of an endoleak. • If a new endoleak or increase in AAA size is observed by spiral CT, adjunctive studies such as 3-D reconstruction or angiographic assessment of the stent graft and native vasculature may be helpful in further evaluating any changes of the stent graft or aneurysm. Spiral CT without contrast or MRI may be considered in select patients who cannot tolerate contrast media or who have renal function impairment. For centers with appropriate expertise, gadolinium or CO2 angiography may be considered in patients with renal function impairment requiring angiographic assessment. Refer to Section 12 for additional imaging and post-operative follow-up guidelines.