OVERVIEW

This annual clinical update provides a review of the ongoing experience with the AFX2 Endovascular AAA System (AFX2 System) intended for the endovascular repair of abdominal aortic or aorto-iliac aneurysms. The data presented in this annual clinical update includes post-market clinical experience with the AFX2 System through February 29, 2024.

The US Food and Drug Administration (FDA) issued premarket approval of the first generation of the device, the Powerlink System, in 2004. The AFX System, the next generation of the Powerlink System, received FDA approval in 2011. Initially, the implantable components of the device were manufactured with what was known as Strata ePTFE, but this was subsequently changed to Duraply ePTFE due to an increase of Type III Endoleaks observed in Strata devices. This incidence of Type III Endoleaks also led to updates to the IFU and the removal of Strata devices from hospital inventory. (Please refer to the sections WORLDWIDE RECALLS, SAFETY COMMUNICATIONS & FIELD SAFETY NOTICES and TYPE III ENDOLEAKS below for additional information regarding Type III Endoleaks with the legacy AFX System devices.) In 2016, FDA approval was issued for delivery system modifications resulting in the AFX2 Bifurcated device. Prior to launch, 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. After multiple product iterations involving updates to the manufacturing, labeling, and design, the resulting, currently marketed device is the AFX2 System. The currently marketed AFX2 System consists of the AFX2 Bifurcated device as well as proximal and limb extension devices, all of which are manufactured with Duraply ePTFE.

Links to Source Information	
PMA Approval Letter Order	https://www.accessdata.fda.gov/cdrh_docs/pdf4/P040002A.pdf
SSED	https://www.accessdata.fda.gov/cdrh_docs/pdf4/P040002B.pdf
Instructions for Use (IFU)	www.e-labeling.eu/ELX10022
2016 – 2019 AFX Clinical Update	https://endologix.com/wp-content/uploads/2022/09/MM2165-ALL-Rev-03.pdf
2023 AFX Clinical Update	https://endologix.com/wp-content/uploads/2024/05/AFX2-Clinical-Updates-2023-MM2813-ALL-Rev-01.pdf

Note: Refer to the ***2016 – 2019 AFX Clinical Update*** for additional details and information from previous reporting periods for previous generations of the device.

CLINICAL EVALUATIONS

COMPLETED CLINICAL EVALUATIONS

Endologix has completed five US pivotal clinical studies of the Powerlink System, the predecessor of the AFX System, for endovascular abdominal aortic aneurysm (AAA) repair that were the basis for determination of reasonable assurances of safety and effectiveness by the US Food and Drug Administration. Additional details are provided in the ***2016 – 2019 AFX Clinical Update***.

Link to Summary Information for the Pivotal Studies	
Protocol TP00-005 (Infrarenal Bifurcated Study) (original)	https://endologix.com/wpcontent/uploads/2019/10/MM2165-Rev-01Endologix-2016-2019-AFX-Clinical-Update.pdf
Protocol TP00-006 (Suprarenal Bifurcated Study) (S018)	
Protocol CP03-023 (34mm Proximal Extension Study) (S019)	
Protocol CP04-022 (25/28mm Suprarenal Proximal Extension Study) (S022)	
Protocol CP-0001 (PEVAR Trial) (S039)	

The clinical data encompasses the legacy Powerlink System device; however, it remains relevant and can, in part, be extrapolated to the AFX2 System. Although the Powerlink System and the AFX2 System delivery systems have a number of differences, the only difference between the stent grafts is the ePTFE graft processing method: the Powerlink System grafts were tube extruded and the AFX2 System grafts are sheet extruded. This difference in processing method ultimately resulted in a different ePTFE graft wall thickness for the current ePTFE grafts, which allows the ePTFE graft to better respond to a pressure difference between the stent graft lumen and the aneurysm sac. Referred to as

"ActiveSeal," this allows the AFX2 System ePTFE graft to readily conform to and press against the flow lumen of the aorta. Additionally, the current ePTFE has some different graft properties compared to Powerlink, including improved suture retention and tear resistance.

LEOPARD TRIAL

The LEOPARD (**L**ooking at **E**VAR **O**utcomes by **P**rimary **A**nalysis of **R**andomized **D**ata) Trial is an Endologix-initiated, multicenter, prospective, randomized trial of endovascular abdominal aortic aneurysm repair (EVAR) in the US. The trial was initiated to obtain Level I evidence for the purpose of comparing outcomes in a contemporary, real-world EVAR patient population. LEOPARD is the first trial designed to directly compare endograft outcomes using the methodology of a randomized controlled trial. LEOPARD utilized CoreLab findings in addition to site-reported findings and utilized CT imaging based on physician discretion as per the guidelines of the Society of Vascular Surgery (SVS). In addition, an independent physician adjudicator evaluated adverse events based upon all clinical information available. NOTE: The trial was not designed to fulfill any FDA post-market requirements and the protocol was not reviewed by the FDA prior to trial initiation.

The LEOPARD Trial compared the anatomically fixated AFX with Duraply/AFX2 System to a reference group of proximally fixated EVAR devices (Cook Zenith, Gore Excluder, and Medtronic Endurant). Subjects were randomized between these two groups at a ratio of 1:1. The comparator device was selected by each investigator prior to enrolling the first subject, and this device served as the comparator device for that investigator throughout the course of enrollment. Thus, randomization was between the AFX with Duraply/AFX2 System devices and one selected proximally fixated device, specific for each investigator. The protocol-specified primary endpoint in the LEOPARD Trial was one-year survival in the absence of Aneurysm-Related Complications (ARC), which was a composite of relevant EVAR-related outcomes, including perioperative death (≤ 30 days), aneurysm rupture, conversion to open surgical repair, post-operative endoleaks, endograft migration (≥ 10mm), aneurysm enlargement (≥ 5mm), endograft occlusion, and any reinterventions for device- or aneurysm-related complications. Using ARC, the trial was designed to sequentially evaluate non-inferiority and superiority hypotheses, with comparisons between the AFX System with Duraply/AFX2 System and the proximally fixated endografts. This Endologix-initiated trial started enrollment in 2015, with the intention to enroll up to 800 subjects. However, in August 2017, Endologix made a voluntary decision to halt further randomization into the study, capping the trial at 455 subjects.

Links to Source Information	
ClinicalTrials.gov	https://www.clinicaltrials.gov/ct2/show/NCT02407457?term=leopard&cond=AAA&draw=2&rank=1
Published LEOPARD Trial	https://pubmed.ncbi.nlm.nih.gov/37068528/

WORLDWIDE RECALLS, SAFETY COMMUNICATIONS & FIELD SAFETY NOTICES

Since the introduction of the original AFX System in 2011, the following worldwide recalls, safety communications, and field safety notices occurred:

December 2022: FDA Safety Communication

- On December 6, 2022, FDA published an update to the January 2022 field safety communication to inform health care providers that FDA approved new labeling for the currently available product, the AFX2 Endovascular AAA System (AFX2 System), that includes information to better inform patients and health care providers of the risk of Type III Endoleaks with previous iterations of the AFX System and acknowledges the limited clinical follow-up on the current AFX2 System. It was further discussed that Endologix will perform a post-market study to compare outcomes for patients implanted with the AFX2 System to patients with other commercially available AAA endovascular grafts, using real world data.
  Safety Communication Link: https://www.fda.gov/medical-devices/safety-communications/update-endologix-afx-endovascular-aaa-graft-systems-and-risk-type-iii-endoleak-fda-safety
  Post-Market Study Link: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=758886&c_id=7231
- Note: FDA published an update in May 2023 to add recent published research that compares safety outcomes for Endologix AFX endovascular grafts to other endovascular grafts. There were no changes to FDA's previous recommendations.

January 2022: FDA Safety Communication

- On January 13, 2022, FDA published a field safety communication to inform patients and health care providers that FDA recommends health care providers consider using available alternative treatment options for AAA patients rather than the AFX2 device. It was further communicated that FDA would taking additional steps to address Type III Endoleak risks associated with AFX endovascular grafts, including working with Endologix to identify patients who may benefit from treatment with the AFX2 device, update the device labeling, and collect and evaluate additional data to assess the long-term safety of AFX endovascular grafts. https://www.fda.gov/medical-devices/safety-communications/update-risk-type-iii-endoleaks-use-endologix-afx-endovascular-aaa-graft-systems-fda-safety-0

November 2021: FDA Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting

- On November 2, 2021, FDA convened an advisory committee meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee to further discuss the totality of data available regarding Type III Endoleak risk for the AFX/AFX2 System and how it relates to the overall safety profile of the currently marketed AFX2 System. Based on the analysis of the currently available data, FDA concluded there appears to be a higher-than-expected rate of Type III Endoleaks with the AFX System, regardless of the device iteration. Because of the limitations with data sources, there was uncertainty regarding whether the mitigation measures implemented by Endologix adequately addressed Type III Endoleak concerns for the currently marketed AFX2 device. https://www.fda.gov/advisory-committees/advisory-committee-calendar/november-2-3-2021-circulatory-system-devices-panel-medical-devices-advisory-committee-meeting
- Endologix believes it is important to distinguish the safety and effectiveness data on the currently marketed AFX2 from previous versions of the device. With respect to the AFX2 device, Endologix presented a compendium of clinical evidence at the Advisory Committee meeting supporting its safety and effectiveness. A summary of the information presented by clinical research groups at the Advisory Committee meeting is included in Section 6 of the IFU and is also available on the FDA website linked above.

December 2020: FDA Safety Communication & Endologix Response

- On December 4, 2020, FDA published a field safety communication to inform patients and health care providers that FDA recommendations had not changed from the October 2019 Safety Communication, and that the FDA will convene an advisory committee meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee in 2021 to discuss the Type III Endoleak risk for the AFX/AFX2 System, the Type III Endoleak treatment options for patients who are implanted with the AFX/AFX2 devices, as well as future post-market surveillance strategies for all endovascular grafts used for the treatment of AAA. https://www.fda.gov/medical-devices/safety-communications/update-fda-reminds-patients-and-health-care-providers-importance-least-yearly-lifelong-follow-use

October 2019: FDA Safety Communication & Endologix Response

- On October 28, 2019, FDA published a safety communication to inform patients and health care providers that data published in a recent conference abstract (Rothenberg et al.) suggest there may be a higher than expected risk of Type III Endoleaks occurring with the use of AFX with Duraply and AFX2 endovascular grafts. https://www.fda.gov/medical-devices/safety-communications/update-risk-type-iii-endoleaks-use-endologix-afx-endovascular-aaa-graft-systems-fda-safety
- In response, Endologix issued a response on October 30, 2019 to provide clarification to health care providers as well as the company's perspective on the totality of data on the AFX/AFX2 System with respect to Type III Endoleaks. https://endologix.com/wpcontent/uploads/2019/10/Endologix-Response-to-FDA-Communication-AFX-Oct30_2019.pdf

October 2018: FDA Class I Recall of Endologix Safety Update (July 2018) & Endologix Response

- On October 15, 2018, FDA issued a Class I recall notifying patients and health care providers about the risk of Type III Endoleaks with use of the AFX System. Although the recall applied to all AFX devices, most reports of endoleaks have concerned the AFX System with Strata devices, which had been removed from the field. However, the AFX with Duraply graft material and AFX2 devices have been distributed for a shorter time. Therefore, Endologix continues to monitor the performance of these devices. https://www.fda.gov/medical-devices/letters-health-care-providers/update-type-iii-endoleaks-associated-endovascular-graft-systems-letter-health-care-providers#:~:text=October%2015%2C%202018%20%2D%20The%20FDA,Endologix%20AFX%20Endovascular%20AAA%20System.
- In response, Endologix issued a response on October 19, 2018 to provide clarification to health care providers and an update to the Type III Endoleak complaint trending previously provided in the July 2018 Endologix Safety Update. https://endologix.com/wpcontent/uploads/2018/10/Endologix_Comment_Oct-2018.pdf

July 2018: Endologix Safety Update

- On July 20, 2018, Endologix issued a field safety notice to provide physicians with updated information to the December 2016 update, as well as revisions to the IFU to enhance patient safety. The notification provided an update on Type III Endoleak rates, refined patient-tailored surveillance recommendations, sizing recommendations for the AFX System with Duraply (which aligned with the AFX2 IFU), and recommendations for intervening through an AFX device or re-intervening on an AFX device.
  - AFX Users: https://endologix.com/wp-content/uploads/2018/07/AFX-Safety-Update-AFX-Users_July2018.pdf
  - Non-AFX Users: https://endologix.com/wp-content/uploads/2018/07/AFX-Safety-Update-Non-AFX-Users_July2018.pdf

December 2016: Endologix Safety Update

- On December 30, 2016, Endologix issued a field safety notice to provide updated information on the rates of Type III Endoleaks, along with suggestions for patient surveillance and treatment as well as the voluntary recall of the small remaining quantity of the original AFX System with Strata due to elevated Type III Endoleak rates. This field safety notice also included the voluntary recall of the larger diameter sizes of AFX2 (28mm main body and 20mm iliac limbs), which was taken as a precautionary measure while additional investigation was ongoing. https://endologix.com/wp-content/uploads/2016/12/12-30-Physician-Letter-AFX-TIII-Endoleak-FINAL.pdf

WORLDWIDE COMMERCIAL EXPERIENCE

DEVICE DISTRIBUTION

Table 1 provides a summary of the AFX with Duraply System and the AFX2 System devices that were sold in the US, EU, and ROW through February 28, 2023, and **Table 2** provides a summary of the AFX with Duraply System and the AFX2 System devices that were sold in the US, EU, and ROW within the reporting period (March 1, 2023 – February 29, 2024). As noted above, Endologix released the AFX2 Bifurcated device in 2016. Since then, the AFX Bifurcated device was gradually phased out and remained on the market while global approvals were pending. Distribution of the AFX Bifurcated device ceased within the US in August 2018 and globally in July 2020.

Note: *The US data depicts the number of devices sold through direct sales. The OUS data depicts the number of devices sold through both direct sales and distributor sales. Therefore, the data presented provides the largest number of devices that may have been implanted in each region. ROW is defined as "Rest of World".*

Table 1. Devices Sold Worldwide - Lifetime

Product Type	AFX System with Duraply / AFX2 System			
	US	EU	ROW	Total
Bifurcated	36,023	13,248	29,163	78,434
AFX Bifurcated (01 JUL 2014 – 31 MAY 2020)	10,833	3,881	7,982	22,696
AFX2 Bifurcated (01 FEB 2016 – 29 FEB 2024)	25,190	9,367	21,181	55,738
Extensions	36,142	10,621	28,828	75,591
Proximal Extensions *(01 JUL 2014 – 29 FEB 2024)*	30,090	8,648	23,072	61,810
Infrarenal Extensions	6,404	3,630	6,699	16,733
Suprarenal Extensions	23,686	5,018	16,373	45,077
Limb Extensions *(01 JUL 2014 – 29 FEB 2024)*	6,052	1,973	5,756	13,781

Table 2. Devices Sold Worldwide – Reporting Period (MAR 1, 2023 – FEB 29, 2024)

Product Type	AFX System with Duraply / AFX2 System			
	US	EU	ROW	Total
Bifurcated	1,992	1,649	2,918	6,559
AFX Bifurcated	0	0	*-1**	*-1**
AFX2 Bifurcated	1,992	1,649	2,919	6,560
Extensions	1,432	1,076	2,451	4,959
Proximal Extensions	1,314	858	2,159	4,331
Infrarenal Extensions	325	329	705	1,359
Suprarenal Extensions	989	529	1,454	2,972
Limb Extensions	118	218	292	628

*The AFX Bifurcated devices sold for ROW was reduced by one (1) due to a return from Japan.

REPORTED ADVERSE EVENTS[1]

As of February 28, 2024, the current AFX2 System devices demonstrate low incident counts for adverse events when compared to 55,738 total AFX2 Bifurcated implants sold globally. The events and occurrence rate percentages (calculated using the number of lifetime total of events as the numerator and the total AFX2 Bifurcated implants sold as the denominator) are as follows: aneurysm-related mortality (65 lifetime events, 0.12%), aneurysm rupture (post-implant) (116 lifetime events, 0.21%), surgical conversion (98 lifetime events, 0.18%), device migration (57 lifetime events, 0.10%), and stent graft integrity events (163 lifetime events, 0.29%). The highest incident counts reported are Type III Endoleaks, but the occurrence rate remains acceptable (0.36% and 0.43% for Type IIIa and Type IIIb Endoleaks, respectively).

The total adverse events for the reporting period (March 1, 2023 – February 29, 2024) are as follows: aneurysm-related mortality (6 events), aneurysm rupture (post-implant) (17 events), surgical conversion (18 events), device migration (9 events), stent graft integrity events (11 events), Type IIIa Endoleaks (36 events), and Type IIIb Endoleaks (55 events).

[1] As complaints can have multiple causative types attributed to a given event, the values listed are for the total number of reported adverse events rather than the total number of complaints.

NOTE: Sales data by year is not interpretable when evaluating adverse events. This is because most adverse event types for EVAR devices are delayed and occur years after implantation. As an example, a Type III Endoleak event reported during this reporting period could be the result of a case whose sale and implantation was performed in a previous reporting period. For this reason, looking at lifetime total of events against total sales is the most clinically meaningful when evaluating adverse event occurrence rates.

The commercial experience analysis has limitations. End users may fail to report all adverse events, reducing the accuracy of rate estimates. Additionally, total unit sales are used as a surrogate for total implanted devices. Though a denominator of the total implanted devices would provide more accurate rate estimates, implant data outside of the US is unknown as there is no device tracking requirement in those regions. Additionally, the majority of Endologix's sales outside of the US and outside of the EU are through a third-party distributor, which handles sales with the hospitals directly. Therefore, total AFX2 Bifurcated implants sold is the best option.

EXPLANT ANALYSIS

Over the lifetime of the AFX2 System, there have been a total of thirty-one (31) devices returned to Endologix for explant evaluation (February 2016 – February 2024). Of the devices that were returned for explant evaluation, the leading reason for device explanation with AFX2 System grafts were attributed to acute factors such as implantation difficulties, infection, or intra-operative complications (totaling 9 events) with the second leading causative event for AFX2 System explants being a Type IIIb Endoleak (9 events). The results of the explant evaluation found that the majority of the device explant cases with the AFX2 System grafts were attributed to patient anatomy and involved patients whose devices were implanted outside of the IFU recommendations/requirements (18 events). It is important to highlight that 100% of all AFX/AFX2 System subjects in the LEOPARD Trial data are free from surgical conversion (and subsequently device explantation) at 5 years.

TYPE III ENDOLEAKS

Endologix has an active post-market surveillance program that has been monitoring and evaluating the performance of the AFX/AFX2 System since its introduction to the market. Through this monitoring, an increased rate of Type III Endoleaks with the first AFX iteration, the AFX System with Strata, was detected. In response, Endologix has made corrective actions to address Type III Endoleaks. Specifically, Endologix implemented various product changes including: commercialization of the Duraply graft material (2014), longer bifurcated lengths (January 2013 and November 2014), and the AFX2 Bifurcated device (2016). Additionally, several IFU updates were made between 2013 and 2018. These corrective actions were made to address Type III Endoleaks, however, it is still uncertain whether the increased risk of Type III Endoleaks and AAA-related adverse events have been addressed with the currently marketed AFX System as the risk of Type III Endoleaks and AAA-related adverse events at three (3) years and beyond is not yet established. There are limited datasets which evaluate Type III endoleaks for the currently marketed AFX2 System, which are included in Section 6.3 of the IFU. Additionally, Endologix monitors the overall device performance of the AFX2 System compared to other EVAR devices on the market, which are included in Section 6.4 of the IFU. As discussed above, Endologix has initiated a postmarket study to compare outcomes for patients implanted with the AFX2 System to patients with other commercially available AAA endovascular grafts, using real world data.

LITERATURE REVIEW

A literature review of the publications for the AFX/Powerlink Systems in the reporting period since the last PMA Annual Clinical Update (2023), through April 10, 2024, includes five (5) articles pertaining to the AFX/AFX2 System in elective endovascular aortic repair. Brief summaries are provided below.

1. Nishijima, Efficacy of Sac Coil Embolization in Endovascular Aortic Repair for Sac Shrinkage in Patients at a High Risk of Type II Endoleak from Lumbar Arteries. Annals of Vascular Surgery (2024) 103 (122-132). Date of Publication: 1 Jun 2024.

   Nishijima retrospectively evaluated 76 patients that underwent elective EVAR repair with 4 or more patent lumbar arteries (LA). Their sample included 11 AFX cases, none of which had coil embolization of the lumber arteries, and 6 having embolization of the IMA. Cox regression analysis showed potentially higher rate of sac shrinkage (HR=2.24) among AFX patients, but did not reach statistical

significance (p-value = 0.12). Sac embolization of LAs was shown to have a statistically higher rate of sac shrinkage compared to occlusion of the IMA (p=0.039) or no occlusion at all (p=0.024). The authors concluded that non-selective sac embolization is effective for sac shrinkage when patients are at high-risk for type II endoleaks.

2. Shirasu T. et al. Midterm outcomes of side branch embolization and endovascular abdominal aortic aneurysm repair. Journal of Vascular Surgery (2024) 79:4 (784-792.e2). Date of Publication: 1 Apr 2024.

   Shirasu retrospectively compared 223 patients with no embolization, 228 with IMA embolization, and 164 with IMA+LA embolization, among a cohort of EVAR patients initially treated between 2013 and 2021 at a single center. Among these, AFX cases were included in the "other device" category (n=28). Results for AFX cohort alone were not provided. However, the authors concluded that embolization in general reduced the incidence of type II endoleaks and intervention, and promoted sac shrinkage through 3 years of follow-up.

3. Ueda, et al. Impact of the Lumbar Arteries on Aneurysm Diameter and Type 2 Endoleak after Endovascular Aneurysm Repair. Annals of Vascular Surgery (2024) 100 (138-147). Date of Publication: 1 Mar 2024.

   Ueda evaluated risk factors for sac enlargement, sac shrinkage, and type II endoleaks among 57 patients enrolled between January 2012 and September 2022 at a single center. AFX represented a small proportion of the total (n=2), and were used in patients with a small terminal aorta. AFX was not independently associated with sac shrinkage in a univariate model, though power was limited due to the small sample size. The AFX cohort showed no type II endoleaks compared to a 77% and 23% rate in the other tested devices. Type of stent graft was not found to be a predictor of type II endoleaks in the multivariate analysis. Diabetes and number of patent LAs were a risk factor for type II endoleaks (HR 95%CI: 1.81- 62.8, and HR 95% CI: 1.54-12.7). The number of patent LAs was also a risk factor for sac enlargement (adjusted HR: 3.15, 95% CI: 1.43-6.96) and negatively associated with sac shrinkage (adjusted HR: 0.63, 95% CI: 0.43-0.91). The authors concluded that the number of patent LAs had a significant impact on sac sizes.

4. Çetinkaya F., et al. Predictive Parameters of Type 1A Endoleak for Elective Endovascular Aortic Repair: A Single-Center Experience. Annals of Vascular Surgery (2024) 98 (108-114). Date of Publication: 1 Jan 2024.

   Çetinkaya evaluated 180 patients who underwent elective EVAR at a single center between July 2016 and January 2021 for predictive risk factors of type IA endoleaks. AFX cases constituted 6.6% of the cohort. While results for AFX were not presented independently, neck lengths shorter than 15mm carried a 10.4-fold higher risk for type IA endoleaks (p<0.001). Neck diameters > 28 mm carried a 21.9-fold higher risk (p=0.04). Neck calcification increased the risk 4-fold (p=0.04). The authors conclude that short and wide necks are the most important factors that increase risk of type IA endoleaks.

5. Ide. T, et al. Impact of Patent Lumbar Arteries on Aneurysm Sac Enlargement with Type II Endoleak after Endovascular Aneurysm Repair European Journal of Vascular and Endovascular Surgery (2023) 66:4 (513-520). Date of Publication: 1 Oct 2023.

   Ide retrospectively investigated the relationship between number of patent LAs and sac enlargement in a cohort of 336 patients treated by EVAR in a single center between January 2006 and December 2019. Patients with type I or type III endoleaks were excluded from the analysis. Among the 336 patients, 87 were treated with AFX or Powerlink. It was found that the AFX and Powerlink devices have a lower incidence of T2EL than the other three devices evaluated in this study. In addition, the Zenith, Powerlink, and AFX devices had a lower incidence of sac enlargement than the other two devices. Among patients with a patent IMA, a high number of patent LAs was a significant risk factor for type II endoleaks (adjusted HR 2.7, 95% CI: 1.5, 4.9). In contrast, a high number of patent LAs in the setting of an occluded IMA was a more clinically significant risk factor for type II endoleaks (adjusted HR 11.3, 95% CI: 2.8, 45.5). Among patients with a patent IMA, a high number of patent LAs was a significant risk factor for sac expansion (adjusted HR 2.8, 95% CI:1.6, 4.9). The authors conclude that in the setting of pre-operatively patent IMA, a high number of patent LAs have a significant role in sac enlargement. Conversely, in the setting of a pre-operatively occluded IMA, a high number of patent LAs has limited influence.

NOTES TO CLINICIANS

ADVERSE REPORTING

Any adverse event (i.e., clinical incidents) involving an Endologix device should be reported to Endologix LLC immediately or to the FDA (MedWatch Form 3500). To report an incident, call the Customer Service Department at 800-983-2284 (24-hour message service). Outside the US, contact your local Endologix representative.

PATIENT FOLLOW-UP AND SELECTION

Continued monitoring and follow-up of patients treated with the AFX2 System devices is essential. All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and the performance of their endovascular graft is a critical part of ensuring the ongoing safety and effectiveness of endovascular treatment of AAAs. Patients should be counseled on the importance of adhering to the follow-up schedule during the first year and at yearly intervals thereafter, and that subsequent reintervention including catheter based and open surgical conversion are possible following endograft placement.

Physicians should evaluate patients on an individual basis and prescribe their follow-up relative to the needs and circumstances of each individual patient. 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 extension stent grafts;
- Absence of clinically relevant migration or lateral movement;
- Aneurysm enlargement, perigraft flow, loss of patency, increased tortuosity, or progressive disease.

Refer to the ***Instructions for Use*** for detailed patient selection and follow-up recommendations.