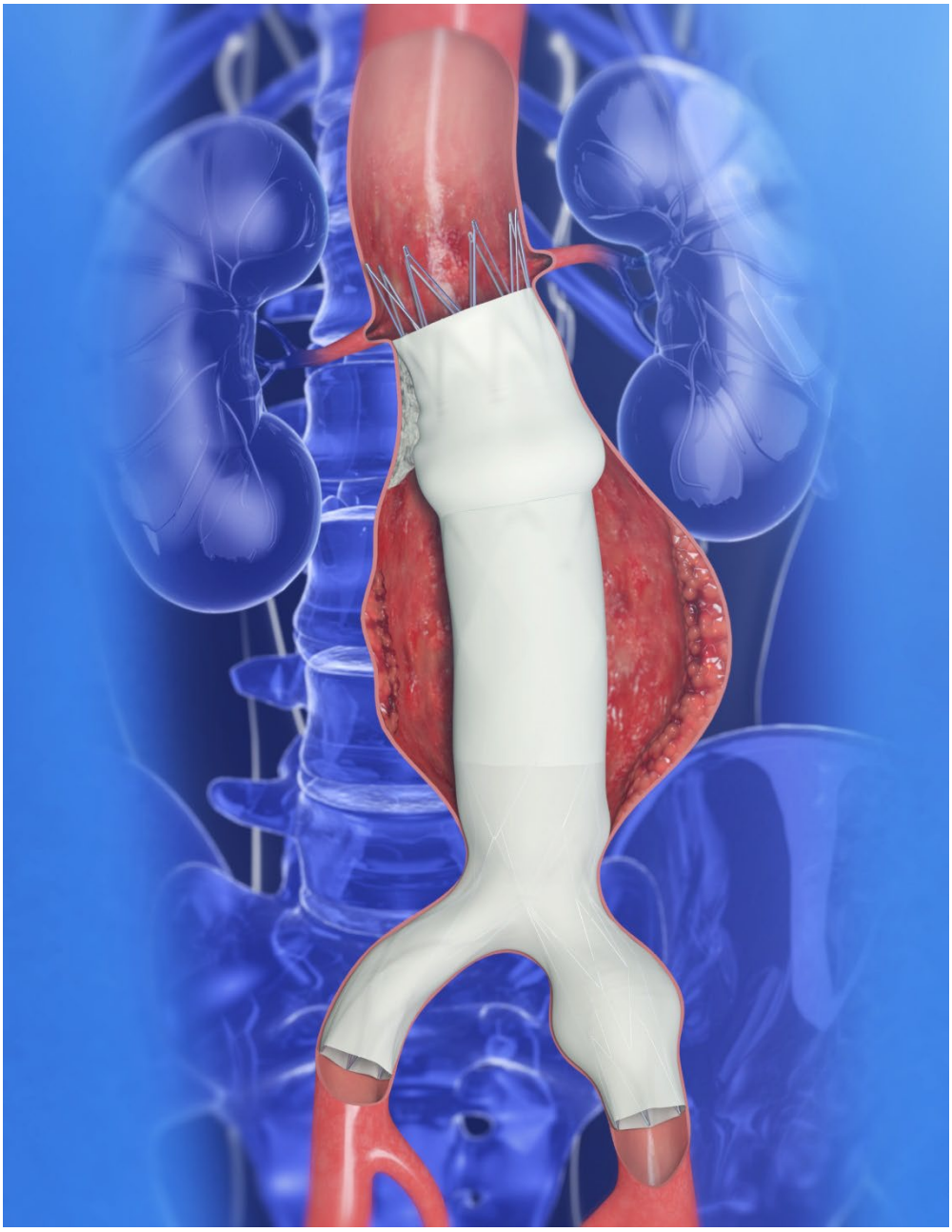
2016-2019 Clinical Update

AFX® Endovascular AAA System



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ABSTRACT

This 2016-2019 Clinical Update report provides a current summary of the long-term clinical experience for Endologix's AFX Endovascular AAA System (AFX System). The data presented in this Clinical Update includes the AFX System (with the DURAPLY ePTFE graft) as well its predecessors, the Powerlink System and the AFX System with STRATA, which are no longer marketed. As outlined below, the data presented in this update includes summaries of the clinical studies (Powerlink System), post-market clinical experience (AFX System with the DURAPLY ePTFE graft), and the commercial experience data (AFX System) to date.

Clinical Studies (page 11)

Endologix was the sponsor for five pivotal US clinical studies of the Powerlink System, including TP00-005 for the infrarenal system, TP00-006 for the suprarenal system, CP03-023 and CP04-002 for the proximal extension devices, and CP-0001 for the evaluation of percutaneous access. All five studies were completed through the primary endpoints and final follow-ups. The data presented within this section has been updated from that provided in the previous Clinical Update in order to better align with and present data which had been included in the final study reports. This updated section now ensures consistent data reporting across studies so that appropriate comparisons and conclusions can be drawn. Refer to Section 1 for additional details.

Post-Market Clinical Experience (page 33)

In 2015, Endologix self-initiated the first multicenter, prospective, randomized trial of endovascular abdominal aortic aneurysm repair (EVAR) in the US that is being conducted exclusively for the purpose of comparing outcomes in a contemporary, real-world EVAR patient population. This trial was initiated by Endologix for the purpose of comparing the anatomically stabilized AFX System (i.e., the currently marketed AFX with DURAPLY and AFX2 Bifurcated Systems) to a reference group of proximally fixated EVAR devices: the Cook Zenith, the Gore Excluder and the Medtronic Endurant devices. The trial methodology was not designed to fulfill any FDA post-market requirements and therefore was not reviewed by FDA. Randomization in the trial was completed in August 2017 with 455 subjects implanted in the study. All subjects will be followed for the planned 5 years.

Commercial Experience (page 49) and Type III Endoleaks (page 79)

As of March 31, 2019, more than 69,000 patients have been treated with the AFX System globally. The commercial experience is consistent with the clinical outcomes reported in the clinical studies, with the exception of an observed higher Type III endoleak incidence rate for the earlier AFX System with STRATA in comparison to the legacy Powerlink device clinical study data. In response to these data, which were accumulated from Endologix's post-market surveillance program, an investigation was initiated to further evaluate the root cause of the Type III endoleaks. As a result of these investigations, several updates were made to the device which primarily included, but were not limited to, updates to the IFU for additional emphasis on patient selection and maximizing component overlap, availability of longer bifurcated lengths to optimize component overlap, development of new ePTFE graft technology, DURAPLY (along with discontinuation of the previous ePTFE graft technology, STRATA), and commercial launch of the modified delivery system, the AFX2 Bifurcated System.

The highest rate of Type III endoleaks to date is associated with devices constructed with the STRATA graft material, with post-market clinical data out to 36 months suggesting the rates for AFX with DURAPLY and AFX2 with DURAPLY are lower (refer to page 33 for additional details). Endologix is continuing to monitor the Type III endoleak rates for the AFX System and will continue to report out on the data in forthcoming Clinical Updates. To identify if your patient has been implanted with the AFX with STRATA graft material, please refer to **Appendix C** (page 104) for a complete list of AFX with STRATA device identifiers. Refer to Section 4, Recommendations for Type III Endoleaks (page 81), on how to contact Endologix for device tracking information on patients that have been implanted with the AFX with STRATA.

Summary

Endologix is providing the information in this report in order to help physicians make informed decisions regarding patients with abdominal aortic aneurysms (AAA) or aortoiliac aneurysms who have or may be considering the AFX System as their endovascular treatment option. As can be seen from the results published in this report, the AFX with DURAPLY and AFX2 with DURAPLY stent graft systems provide a safe and effective treatment option for appropriately selected patients.

READER'S GUIDE

Endologix, Inc. has prepared this clinical update to provide current information to physician users on the worldwide experience of the AFX System to date. Data and information on the final follow-up on the test patients implanted with the Powerlink System during the original clinical studies and on surgical control patients is detailed, including patient accountability, adverse events, incidence of endoleak, and aneurysm sac diameter regression. In addition, information on the LEOPARD Trial outcomes and worldwide post-market information pertaining to product use, safety, and performance of the AFX System are discussed. A brief summary of the stent graft and delivery system design and construction as well as the history of the different device iterations is provided below. The remainder of this section provides an overview of the contents of this report.

Device Description

The AFX System is a family of abdominal aneurysm endoluminal prostheses and delivery catheters intended for the endovascular repair of abdominal aortic or aorto-iliac aneurysms. All AFX System stent graft prostheses consist of a self-expanding cobalt chromium alloy wire stent cage covered with expanded polytetrafluoroethylene (ePTFE) graft material. As part of its unique design, the implantable, self-expanding unibody stent cage design does not utilize mechanical attachment (e.g., hooks, barbs) and relies on anatomical fixation. Refer to the Instructions for Use for all indications, contraindications, warnings, precautions, and details for proper use of the device.

The primary device is the unibody, infrarenal bifurcated stent graft, which has a main body with two attached limbs. The accessory devices, which are utilized to customize the AFX System to the patient anatomy, are comprised of infrarenal and suprarenal proximal extensions as well as limb extensions in straight, tapered, flared, and stepped configurations. The bifurcated and proximal extension stent graft configurations are depicted in **Figure 1**. The limb extension stent graft configurations are shown in **Figure 2**.

Figure 1. Bifurcated and Proximal Extension Stent Graft Configurations

Bifurcated Stent Graft *Infrarenal Proximal Stent Graft* *Suprarenal Proximal Stent Graft*

Figure 2. Limb Extension Stent Graft Configurations

Straight and Tapered Limb Extension Stent Grafts *Flared and Stepped Limb Extension Stent Grafts*

The AFX System is used with a separate 17Fr AFX Introducer System (19Fr outside diameter). All AFX System

stent graft delivery systems are compatible with the AFX Introducer System. There are four types of stent graft delivery systems in the AFX System that require delivery through the AFX Introducer: the AFX Bifurcated Delivery System, the AFX2 Bifurcated Delivery System, the AFX Vela Delivery System and the standard AFX Accessory Delivery System. The fifth delivery system, referred to as the AFX Stand Alone Delivery System, is a lower profile limb extension delivery system (14Fr or 16Fr) that may be used alone or in conjunction with the AFX Introducer. Only one femoral access site compatible with the 17Fr introducer sheath is required for ipsilateral deployment; contralateral access is compatible with standard percutaneous 9Fr introducers for the current AFX Bifurcated Delivery System and reduces to 7Fr with the latest addition to the portfolio, the AFX2 Bifurcated Delivery System.

ePTFE Graft Variations

There were four (4) separate ePTFE graft variations, or iterations, commercialized under P040002 that are referenced in subsequent sections of this Clinical Update.

1. The first of these grafts was utilized for the Powerlink System, which was in commercial distribution in select countries outside of the US beginning in 2000 and in the US since FDA approval in October 2004. This graft was discontinued globally in January 2016 as a business decision to migrate customers to the AFX System, its next generation product.

2. The second graft variation/iteration was branded as STRATA and was utilized for the first generation AFX System, which was introduced in the US in August 2011 and in Europe in late 2011. The Powerlink and AFX System with STRATA had identical stent cage designs. The only difference between the Powerlink and AFX System with STRATA stent grafts is the graft processing method used, which resulted in a reduction in nominal wall thickness for the AFX System ePTFE graft in comparison to the Powerlink graft. Despite this reduction in the graft wall thickness, the STRATA graft was shown to meet all the established mechanical and strength specifications of its predecessor. Even so, the STRATA process did not incorporate material tear resistance in the transverse (or circumferential) direction. This, combined with the serial wrapped layers, introduced directionality into the STRATA ePTFE graft, which meant that it was less resistant to transverse propagation for a disruption in the graft material. Endologix discontinued production of the STRATA ePTFE graft in mid-2014, following commercialization of the DURAPLY ePTFE graft, its next generation product. Distribution of the AFX Bifurcated devices manufactured with the STRATA ePTFE graft ceased globally in June 2015 and distribution of the AFX accessory devices manufactured with the STRATA ePTFE graft ceased globally in November 2016. Following discussions with FDA regarding elevated Type III endoleak rates with the AFX devices manufactured with STRATA, all remaining STRATA devices were recalled from the field in December 2016. Refer to page 79 for additional details.

3. In 2014, Endologix implemented a graft material processing improvement known as DURAPLY (3rd iteration) commercialized under P040002. In comparison to the original STRATA ePTFE graft, the DURAPLY technique, which introduced alternating helically-wrapped ePTFE layers into the manufacturing process, improved the material tear propagation resistance in the transverse direction, not just perpendicular to the direction of expansion as STRATA. With higher tear resistance in both the transverse and longitudinal directions, the DURAPLY graft is a stronger ePTFE graft than its STRATA counterpart. Based on these material properties, disruptions in the DURAPLY graft would be more resistant to propagation in comparison to STRATA. Because of this, DURAPLY replaced STRATA on all AFX System grafts in mid-2014, following necessary regulatory approvals.

4. The fourth and most recent graft variation/iteration was the AFX2 Bifurcated system, which was released in February 2016 with the DURAPLY ePTFE graft. While the design intent was to improve usability, various manufacturing changes were also implemented in the AFX2 System, which reduced the potential for damage to the graft during loading onto the delivery system. Additionally, Endologix implemented tighter manufacturing specifications on the ePTFE graft during the implementation of AFX2, which

resulted in an increase in the average thickness of the DURAPLY graft material. NOTE: The tightened average thickness of the DURAPLY graft material was also carried over to the remainder of the AFX System in early 2016.

Currently, the AFX System is only commercialized with the DURAPLY graft*. Both bifurcated endograft systems (AFX Bifurcated and AFX2 Bifurcated) consist of identical implantable stent grafts, which are manufactured in various diameters and lengths in a unibody bifurcated design. The only difference between the two bifurcated endograft systems is that AFX2 Bifurcated consists of an improved delivery catheter and is, hence, considered the next-generation bifurcated endograft system in the AFX System portfolio. While both the Powerlink System and the AFX System with STRATA are discontinued and no longer commercially available, the data are relevant since the Powerlink and AFX System stent grafts incorporate the same anatomical fixation mechanism.

* Endologix discontinued sales of the AFX with DURAPLY bifurcated device in the US and in some other markets across the globe following the full product roll-out of the AFX2 Bifurcated device. NOTE: Endologix currently maintains approval for the AFX with DURAPLY bifurcated device, despite discontinuing sales in the US, as this iteration is still distributed in some regions of the globe where the AFX2 Bifurcated device is pending regulatory approval.

Introduction

Endologix is dedicated to putting patients first in all we do as a company. Central to this core value is our commitment to provide updated and emerging data and information on our products and their safety and performance profiles to the physicians who care for our patients. This 2016-2019 update marks the 14-year anniversary of the initial US Food and Drug Administration (FDA) premarket approval of the Powerlink System, which was available internationally in various countries until it was discontinued in January 2016. The AFX System has been available in the US since FDA approval in 2011. It was introduced in Europe shortly after the US introduction and is available in various countries outside the US.

Section 1 (page 11) presents the long-term, final follow-up results from the five US pivotal clinical studies conducted with the Powerlink stent graft: the Infrarenal Bifurcated Study, the Suprarenal Bifurcated Study, the 34mm Proximal Extension Study, the 25/28mm Suprarenal Proximal Extension Study, and the PEVAR (completely percutaneous EVAR) Study. At this time, the clinical study results for the Powerlink device can only be extrapolated to the AFX with DURAPLY and AFX2 with DURAPLY devices, which are commercially available. Specifically, these clinical study results cannot be extrapolated to the AFX with STRATA devices as they were found to have a higher Type III endoleak rate in comparison to its Powerlink counterpart. Refer to page 79 for additional information.

Safety results presented in this Clinical Update include the incidence of major adverse events as prospectively defined in the study protocols. Kaplan-Meier estimates for freedom from major adverse events, freedom from all-cause mortality, and freedom from aneurysm-related mortality are presented. Effectiveness results include primary performance measures, and Core Laboratory reported aneurysm morphology evaluations, migration, endoleak incidence, secondary interventions, and stent graft performance measures including device patency, stent fracture, and graft integrity.

In the Infrarenal and Suprarenal Bifurcated studies, results within one year demonstrate reduced incidence of major adverse events compared to the surgical control group. Continued follow-up through five years found no significant differences between groups. Among all test subjects, no aneurysm rupture was observed. Kaplan-Meier estimates for Infrarenal and Suprarenal test subjects, respectively, include freedom from major adverse events (47%, 53%); freedom from all-cause mortality (77%, 77%); and freedom from aneurysm- related mortality (98%, 98%) at 5 years. Aneurysm size is stable or decreased in the majority of subjects, and mean sac diameter continued to decrease over time in the test groups. Secondary interventions within five years were performed primarily for Type II endoleak, with relatively low rates of device-related interventions for endoleak or limb occlusion. No aneurysm rupture, stent fracture, graft failure, or other significant device integrity loss was

observed through the five-year follow-up.

In the proximal extension studies, no aneurysm-related mortality was observed, which prospectively studied the anatomical fixation technique of the Powerlink System endografts. Unique to this platform, the bifurcated device was placed at the aortoiliac bifurcation with the long main body across the aneurysm; a proximal extension of suitable diameter was then placed to achieve both significant overlap with the bifurcated device body and proximal seal in the infrarenal neck. Aneurysm size was stable or decreased in the majority of subjects. Secondary interventions within five years were performed primarily for Type II endoleak, with low rates of device-related interventions for endoleak or limb occlusion. No aneurysm rupture, stent fracture, graft failure, or other significant device integrity loss was observed through final five-year follow-up.

No aneurysm-related deaths were observed in the PEVAR Trial among 100 subjects randomized to either completely percutaneous access (PEVAR) or standard femoral exposure and endovascular repair (SEVAR) using the Powerlink endografts. Treatment Success at one month, defined as procedural technical success per randomized assignment and absence of major adverse event or vascular event, was 88% and 78% in the PEVAR/ProGlide and SEVAR groups, respectively. No aneurysm rupture, stent fracture, graft failure, or other significant device integrity loss was observed through final six-month follow-up.

Section 2 (page 33) presents the interim results of Endologix's ongoing, self-initiated LEOPARD (**L**ooking at **E**VAR **O**utcomes by **P**rimary **A**nalysis of **R**andomized **D**ata) Trial. As of August 9, 2017, Endologix has completed randomization in the trial and the trial formally enrolled 455 subjects. This study randomized the AFX/AFX2 to marketed devices with mechanical fixation. Based on the similarity in Aneurysm-Related Complication (ARC) outcomes through available 3-Year follow-up, the LEOPARD Trial data set provides objective, clinical evidence that the performance of the AFX/AFX2 Bifurcated devices with the DURAPLY ePTFE graft perform equivalent to contemporary EVAR devices. Furthermore, the LEOPARD Trial data shows 99.0% of AFX/AFX2 subjects being free from Type III endoleaks at 3-Years. This provides objective, clinical evidence that the corrective actions for both Type IIIa and Type IIIb endoleaks appear to be effective in reducing the rate of Type III endoleaks as compared to the AFX with STRATA device through 3-Years. Endologix will continue to monitor the longer-term effectiveness of these corrective actions through final 5-Year follow-up.

Section 3 (page 49) presents the worldwide post-marketing experience for the AFX System. A total of 69,519 bifurcated devices have been distributed globally since initial marketing through March 31, 2019. Endologix maintains an active system for collection, monitoring, and handling of customer experience reports (complaints) for its devices marketed worldwide. Integral to this system is the reporting of events in accordance with US regulations under 21 CFR 803 (Medical Device Reporting) and international Vigilance reporting requirements.

Section 4 (page 79) continues by providing an additional summary regarding investigations into both Type IIIa and Type IIIb endoleaks, including several improvements to the AFX stent graft family that were made in response to investigations into both Type IIIa and Type IIIb endoleaks. Additional information for physicians who have implanted patients with the AFX with STRATA system (page 81) is included.

Section 5 (page 83) provides a summary of all explant analyses from commercial experience. Analyses included evaluation of the explanted stent graft using standard techniques. Histopathological analyses were conducted by an independent, qualified laboratory.

Section 6 (page 87) provides notes to clinicians on the AFX System and summarizes important information on patient selection, device selection, and patient follow-up recommendations, including imaging assessments.

Section 7 (page 90) provides a brief summary of the product indications, contraindications, warnings, and precautions; it also provides information on the peer-reviewed published literature of the Powerlink and AFX Systems' outcomes to further inform physician decision making in caring for patients with AAA.

SECTION 1: US Pivotal Clinical Studies

Endologix has completed five US pivotal clinical studies of the Powerlink System for endovascular AAA repair that were the basis for determinations of reasonable assurances of safety and effectiveness by the US Food and Drug Administration:[1]

- ***Protocol TP00-005 (Infrarenal Bifurcated Study)***: The Infrarenal Bifurcated Study was a prospective, multicenter, nonrandomized, concurrent surgically-controlled design conducted at 15 investigational sites. It was designed to compare standard risk endovascular subjects having anatomy suitable for the Powerlink infrarenal stent graft to a concurrent control group comprised of standard risk surgical subjects. A total of 192 test subjects and 66 control subjects (treated with open surgery) were enrolled between July 2000 and March 2003. Clinical follow-up and diagnostic test evaluations were scheduled pre-discharge, at one month, six months, one year and annually thereafter through five years. An independent core laboratory evaluated CT scans and abdominal x-rays to assess aneurysm changes, endoleaks, device position and integrity. Safety was monitored by an independent data safety monitoring board (DSMB). The study primary safety endpoint was the incidence of major adverse events at one year; the primary effectiveness endpoint was all-cause mortality rate at one year. These results were submitted to the US FDA, with initial approval of the premarket approval application (PMA) in October 2004. The complete five-year follow-up study report was submitted to and approved by the US FDA in 2008 and 2009, respectively.

  The devices under investigation in this study were the 25mm and 28mm diameter infrarenal bifurcated Powerlink stent grafts. NOTE: the 25mm and 28mm diameter infrarenal/suprarenal Powerlink proximal extension stent grafts as well as the 16mm and 20mm diameter Powerlink limb extension stent grafts were included as part of the "Powerlink System." Of the 188 subjects who were successfully implanted with the infrarenal bifurcated Powerlink stent grafts, 66 received a 25mm device and 122 received a 28mm device.

Figure 4. Infrarenal Bifurcated Stent Graft

- ***Protocol TP00-006 (Suprarenal Bifurcated Study)***: The Suprarenal Bifurcated Study was a prospective, multicenter, nonrandomized, historically surgically-controlled design conducted at 17 investigational sites. It was designed to compare standard risk endovascular subjects having anatomy suitable for the Powerlink suprarenal stent graft to the historical infrarenal stent graft and surgical control group (TP00-005). A total of 153 test subjects were enrolled between October 2001 and November 2007. Clinical follow-up and diagnostic test evaluations were scheduled pre-discharge, at one month, six months, one year and annually thereafter through five years. An independent core laboratory evaluated CT scans and abdominal x-rays to assess aneurysm changes, endoleaks, device position and integrity. Safety was monitored by an independent data safety monitoring board (DSMB). The study primary safety endpoint was the incidence of major adverse events at one year; the primary effectiveness endpoint was all-cause mortality rate at one year. These results were submitted to the US FDA, with approval of the PMA supplement in October 2008. The complete five-year follow-up study report was submitted to and approved by the US FDA in 2014.

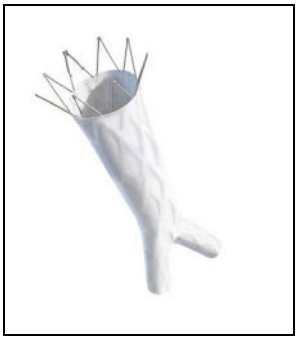

Figure 3. Suprarenal Bifurcated Stent Graft

  The devices under investigation in this study were the 25mm, 28mm and 34mm diameter suprarenal bifurcated Powerlink stent grafts. NOTE: the 25mm, 28mm and 34mm diameter infrarenal/suprarenal Powerlink proximal extension stent grafts as well as the 16mm and 20mm diameter

[1] Please refer to the approved Summary of Safety and Effectiveness Data under P040002: Infrarenal Bifurcated Study (original); Suprarenal Bifurcated Study (S018); XL Aortic Extension Study (S019); Suprarenal Aortic Extension Study (S022); PEVAR Trial (S039).

Powerlink limb extension stent grafts were included as part of the "Powerlink System". Of the 150 subjects who were successfully implanted with the suprarenal bifurcated Powerlink stent grafts, 34 received a 25mm device, 73 received a 28mm device and 43 received a 34mm device.

- ***Protocol CP03-023 (34mm Proximal Extension Study)***: The 34mm Proximal Extension Study was a prospective, multicenter, nonrandomized design conducted at 10 investigational sites. It was designed to evaluate the performance of the 34mm infrarenal Powerlink proximal extension stent graft to (1) treat subjects with larger aortic neck anatomy and (2) obtain an effective seal to prevent/repair Type Ia endoleak during the implant procedure. A total of 60 test subjects were enrolled between September 2005 and July 2007. Clinical follow-up and diagnostic test evaluations were scheduled pre-discharge, at one month, six months, one year and annually thereafter through five years. An independent core laboratory evaluated CT scans and abdominal x-rays to assess aneurysm changes, endoleaks, device position and integrity. Safety was monitored by an independent data safety monitoring board (DSMB). The study primary endpoint was the absence of Type Ia endoleaks at one year. These results were submitted to the US FDA, with approval of the PMA supplement in November 2008. The complete five-year follow-up study report was submitted to and approved by the US FDA in 2014 and 2015, respectively.

  The device under investigation in this study was the 34mm diameter infrarenal Powerlink proximal extension stent graft. All 60 subjects were successfully implanted with both a commercially available 28mm infrarenal bifurcated Powerlink stent graft and a 34mm infrarenal Powerlink proximal extension stent graft.

Figure 5. Infrarenal Proximal Stent Graft

- ***Protocol CP04-002 (25/28mm Suprarenal Proximal Extension Study)*** : The 25/28mm Suprarenal Proximal Extension Study was a prospective, multicenter, nonrandomized design conducted at 8 investigational sites. It was designed to evaluate the performance of the 25/28mm suprarenal Powerlink proximal extension stent graft to (1) extend the primary bifurcated stent grafts to accommodate the subject's anatomy and (2) obtain an effective seal to prevent/repair Type Ia endoleak during the implant procedure. A total of 44 test subjects were enrolled between May 2006 and July 2008. Clinical follow-up and diagnostic test evaluations were scheduled pre-discharge, at one month, six months, one year and annually thereafter through five years. An independent core laboratory evaluated CT scans and abdominal x-rays to assess aneurysm changes, endoleaks, device position and integrity. Safety was monitored by an independent data safety monitoring board (DSMB). The study primary endpoint was the absence of Type Ia endoleaks at one month. These results were submitted to the US FDA, with approval of the PMA supplement in April 2009. The complete five-year follow-up study report was submitted to and approved by the US FDA in 2014.

  The devices under investigation in this study were the 25mm and 28mm diameter suprarenal Powerlink proximal extension stent grafts. All 44 subjects were successfully implanted with a commercially available 25mm or 28mm infrarenal bifurcated Powerlink stent graft as well as a 25mm or 28mm suprarenal Powerlink proximal extension stent graft.

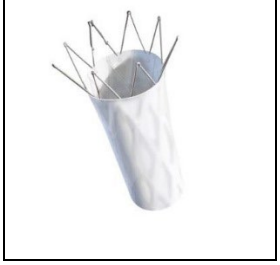

Figure 6. Suprarenal Proximal Stent Graft

- ***Protocol CP-0001 (PEVAR Trial)***: The PEVAR Trial was a prospective, multicenter, randomized design (2:1, test:control) conducted at 18 investigational sites. It was designed to evaluate the safety and effectiveness of totally percutaneous endovascular AAA repair (PEVAR) compared to standard endovascular AAA repair (SEVAR) using a Powerlink delivery system with a maximum sheath size of 21Fr. A total of 151 subjects were enrolled between July 2010 and February 2012 (51 PEVAR/Prostar XL test subjects, 50 PEVAR/ProGlide test subjects, and 50 SEVAR control subjects). Clinical follow-up and

diagnostic test evaluations were scheduled pre-discharge, at one month and at six months (follow-up commitment). An independent assessor and clinical events committee evaluated CT scans and femoral ultrasounds to identify and adjudicate adverse events. Safety was monitored by an independent data safety monitoring board (DSMB). The study primary endpoint was treatment success at one month, which was a composite of procedural success as well as the absence of major adverse events and vascular events. The results of the PEVAR/ProGlide arm were submitted to the US FDA, with approval of the PMA supplement in April 2013. Final six-month follow-up for the entire trial is complete. The complete six-month follow-up study reports for both PEVAR arms were submitted to and approved by the US FDA in 2014.

Final safety and effectiveness results for each of the Powerlink clinical studies are included in this section. Specifically, the data presented is based on the primary endpoints as well as other secondary endpoint data that was collected. These data have been presented in prior annual reports. A summary of all studies is presented as follows:

Table 1. Summary of Clinical Study Data[€]

	TP00-005 (Infrarenal Bifurcated Study)	***TP00-006 (Suprarenal Bifurcated Study)***	***CP03-023 (34mm Proximal Extension Study)***	***CP04-002 (25/28mm Suprarenal Proximal Extension Study)***	***CP-0001 (PEVAR Trial)***
Primary Endpoint Data					
Major Adverse Events (MAEs)	X	X	-	-	-
All-Cause Mortality (ACM)	X	X	-	-	-
Absence of Type Ia Endoleaks	-	-	X	X	-
Treatment Success	-	-	-	-	X
Study Outcome Data					
Subject Status and Accountability	X	X	X	X	X
All-Cause Mortality (ACM)[∞]	X (with KM curve)	X (with KM curve)	X	X	X
Aneurysm-Related Mortality (ARM)[∞]	X (with KM curve)	X (with KM curve)	X	X	X
Major Adverse Events (MAEs)[∞]	X (with KM curve)	X (with KM curve)	X	X	X
Vascular Events[¥]	-	-	-	-	X
Treatment Success[±]	X	X	-	-	X
Aneurysm Sac Diameter[β]	X	X	X	X	-
Device Integrity and Performance	X	X	X	X	X
Device Migration	X	X	X	X	X
Endoleaks	X	X	X	X	X
Secondary Procedures	X	X	X	X	X

[€]The clinical study data presented throughout this section aligns with the final clinical study reports that were submitted to and approved by the FDA, as indicated in the study summaries above.
[∞]KM curves are presented for ACM, ARM, and MAEs for the Infrarenal/Suprarenal Bifurcated Studies (TP00-005, TP00-006) in order to serve as a graphical representation of the data in comparison to the surgical control group, for which the endpoint comparisons are based.
[¥]Vascular Events data was collected for the PEVAR Trial (CP-0001) as part of the primary endpoint. This data was not collected in the other studies.
[±]Treatment Success data was collected for the PEVAR Trial (CP-0001) as part of the primary endpoint and was collected for the Infrarenal/Suprarenal Bifurcated Studies (TP00-005, TP00-006) as part of a secondary outcome. This data was not collected in the other studies.
[β]Aneurysm Sac Diameter was recorded for all studies that had long-term subject follow-up through 5 years. As the PEVAR Trial (CP-0001) only had a 6-month follow-up commitment, this data was not collected.

NOTE: While the clinical data was collected on the Powerlink stent grafts, as described above, the data can be applied in part to the AFX System as the stent grafts under clinical evaluation are analogous to the currently marketed AFX ePTFE grafts. As summarized above (page 8), both the Powerlink and AFX System stent grafts had identical stent cage designs, with the only difference between the stent grafts used being the graft processing methods which resulted in different ePTFE graft wall thicknesses and properties. As an important point of note, the AFX Vela stent grafts have one additional difference from the proximal extension stent grafts included in the studies. Specifically, the AFX Vela stent grafts contain an additional platinum/tungsten (Pt/W) radiopaque coil marker, which is embedded inside the hem of the proximal end of the endograft. This coil is visible under fluoroscopy and is used to help physicians identify the proximal edge of the graft material during the placement of the endograft.

NOTE: The suprarenal bifurcated grafts (evaluated in TP00-006) were discontinued with all other Powerlink System devices and were not carried over to the AFX System's family of endografts. While this design is no longer in commercial distribution, the clinical data remains relevant as the stent graft design below the uncovered proximal stent portion of the suprarenal bifurcated stent graft is comparable to the infrarenal bifurcated graft (evaluated in TP00-005). Refer to **Figure 4** and **Figure 3** for a visual comparison of the two bifurcated stent graft designs.

Primary Endpoint Results

Infrarenal Bifurcated Study (TP00-005) and Suprarenal Bifurcated Study (TP00-006)

As noted in the summary above, the protocol-specified primary safety endpoint in the Infrarenal and Suprarenal Bifurcated studies was the proportion of subjects with MAE within one year compared to the surgical control group. As shown in the subsequent data below, subjects treated with the Powerlink System stent graft in both studies experienced fewer MAEs compared with control subjects treated with open surgery both within 30 days and within one year. Refer to page 23 for additional details.

Additionally, the primary effectiveness endpoint in both the Infrarenal and Suprarenal Bifurcated studies was the rate of all-cause mortality at one year compared to the surgical control group. Comparing the Infrarenal Bifurcated Test Group (TP00-005) and Suprarenal Bifurcated Test Group (TP00-006) to the Surgical Control Group (TP00-005), the KM curves show that survival rates at one year (as well as at all data points through five years) are similar to one another and better than the surgical control group. Refer to page 19 for additional details.

34mm Proximal Extension Study (CP03-023) and 25/28mm Suprarenal Proximal Extension Study (CP04-002)

As noted in the summary above, the protocol-specified primary endpoint in the 34mm and in the 25/28mm Proximal Extension Studies was the absence of Type Ia endoleaks at one year and at one month, respectively. Study success was to be demonstrated when Type I proximal endoleak was not observed in at least in 92.2% of the study patients. As shown in the subsequent data below, subjects treated with the Powerlink System proximal extension stent grafts had a Type Ia endoleak rate of 2.0% and 4.8% at the respective one year and one month endpoints. Refer to page 30 for additional details.

PEVAR Trial (CP-0001)

As noted in the summary above, the protocol-specified primary endpoint was treatment success at one month, which was a composite of procedural success as well as the absence of major adverse events and vascular events.

- *PEVAR/ProGlide*
  The treatment success rate supports the safety and effectiveness of the 'pre-close' technique facilitated with the ProGlide closure system using a Powerlink delivery system with a maximum sheath size of 21Fr (88% vs. 78%, PEVAR vs. SEVAR, p=0.0036). Follow-up to six months is consistent with an overall treatment success rate of 82% vs. 72% (PEVAR vs. SEVAR, p=0.008). Refer to page 27 for additional details.

- *PEVAR/ProStar XL*
  The treatment success rate of the 'pre-close' technique facilitated with the ProStar XL closure system using a Powerlink delivery system with a maximum sheath size of 21Fr was found to not be statistically non-inferior to the rate for SEVAR (78% vs. 78%, p=0.102). Follow-up to six months was consistent with an overall treatment success rate of 73% vs. 72%, PEVAR vs. SEVAR (p=0.118). NOTE: While these results were clinically comparable, Endologix did not pursue approval for a percutaneous indication using the ProStar XL. As such, this data is not included in the subsequent section.

Study Outcome Data

Subject Status and Accountability

Subject status and accountability from the time of enrollment through final follow-up are presented in **Table 2** (TP00-005, Infrarenal Bifurcated Test Group); **Table 3** (TP00-005, Infrarenal Bifurcated Control Group); **Table 4** (TP00-006, Suprarenal Bifurcated Test Group); **Table 5** (CP03-023, 34mm Proximal Extension Test Group); **Table 6** (CP04-002, 25/28mm Suprarenal Proximal Extension Test Group) and **Table 7** (CP-0001, PEVAR Trial allocated groups).

Table 2. Subject and Imaging Accountability – TP00-005, Infrarenal Bifurcated Study (Test Group)

Interval	Subject Follow-up n (% of eligible)			Pts. with Imaging n (% of eligible)			Pts. with Adequate Imaging to Assess Parameter -- n (% of eligible)					Events Occurring Before Next Visit			
	Eligible	Clinical Follow-up	Imaging Follow-up	CT Scan	Duplex Ultrasoun	KUB Imaging	Aneurysm Size	Aneurysm Size Change	Endoleak	Migration	Integrity	Technical Failure	Conversion	Death	Withdrawn / Lost
Originally Enrolled [1, 2]	192														
Implant and <1Mo Events												4	3	2	0
1 Month (±2 weeks)	190	186 (98%)	174 (92%)	174 (92%)	---	129 (68%)	101 (54%)	---	152 (80%)	163 (86%)	164 (86%)				
Events >1Mo and <6Mo												---	0	6	3
6 Months (±1 month)	181	171 (94%)	171 (94%)	171 (94%)	---	118 (65%)	161 (89%)	161 (89%)	147 (82%)	153 (85%)	162 (90%)				
Events >6Mo and <1Yr												---	0	5	2
1 Year (±2 months)	174	157 (90%)	156 (90%)	144 (83%)	---	146 (84%)	156 (90%)	156 (90%)	138 (79%)	147 (84%)	151 (87%)				
Events >1Yr and <2Yrs												---	1	7	4
2 Years (±3 months)	162	152 (94%)	145 (90%)	145 (90%)	---	135 (83%)	145 (90%)	145 (90%)	119 (73%)	133 (82%)	135 (83%)				
Events >2Yrs and <3Yrs												---	0	3	8
3 Years (±3 months)	151	147 (97%)	130 (86%)	130 (86%)	---	119 (79%)	130 (86%)	130 (86%)	103 (68%)	122 (81%)	119 (79%)				
Events >3Yrs and <4Yrs												---	0	9	6
4 Years (±3 months)	136	132 (97%)	121 (89%)	121 (89%)	---	113 (83%)	121 (89%)	121 (89%)	97 (71%)	120 (88%)	113 (83%)				
Events >4Yrs and <5Yrs												---	0	11	9
5 Years (±3 months)	116	108 (93%)	107 (92%)	107 (92%)	---	101 (87%)	107 (92%)	107 (92%)	87 (75%)	104 (90%)	101 (87%)				

[1]Data analysis sample size variability is due to subject availability for follow-up, as well as, quantity and quality of images available from specific timepoints for analysis.

[2]Of the 192 subjects enrolled, four are considered technical failures due to: intraoperative conversion to open repair [n=3]; implant of a non-study device due to access issues [n=1]. Subjects continued to return for follow-up.

In cases where imaging data at a timepoint were not available, subsequent timepoint imaging data were used.
Note: The number of subjects who did not withdraw from the study but who missed clinical or imaging visits are: 1Yr (17); 2 Yrs (10); 3 Yrs (4); 4Yrs (4); 5Yrs (4).

Table 3. Subject Accountability – TP00-005, Infrarenal Bifurcated Study (Surgical Control Group)

Interval	Subject Follow-up: n (% of eligible)		Events Occurring Before Next	
	Eligible	Clinical Follow-up	Death	Withdrawn/Lost
Originally Enrolled	66			
Events after surgery but before 1-month visit			4	0
1 Month (±2 weeks)	62	59 (95%)		
Events >1Mo and <6Mo			1	2
6 Month s (±1 month)	59	54 (92%)		

Events >6 Months and <1 Yr			4	5
1 Year (±2 months)	50	46 (92%)		
Events >1Yr and <2 Yrs			1	6
2 Years (±3 months)	43	37 (86%)		
Events >2Yr and <3 Yrs			3	2
3 Years (±3 months)	38	34 (89%)		
Events >3Yrs and <4 Yrs			1	6
4 Years (±3 months)	31	30 (97%)		
Events >4Yr and <5 Yrs			1	3
5 Years (±3 months)	27	26 (96%)		

Table 4. Subject and Imaging Accountability – TP00-006, Suprarenal Bifurcated Study (Test Group)

Interval	Subject Follow-up n (% of eligible)			Pts. with Imaging n (% of eligible)			Pts. with Adequate Imaging to Assess Parameter -- n (%of eligible)					Events Occurring Before Next Visit			
	Eligible	Clinical Follow-up	Imaging Follow-up	CT Scan (Core	Duplex Ultrasoun	KUB Imaging	Aneurysm Size	Aneurysm Size Change	Endoleak	Migration	Integrity	Technical Failure	Conversion	Death	Withdrawn / Lost
Originally Enrolled [1, 2]	153														
Events after Implant and <1Mo												3	1	0	2
1 Month (±2 weeks)	150	141 (94%)	138 (92%)	138 (92%)	2 (1.3%)	131 (87%)	136 (91%)	136 (91%	138 (93%)	134 (89%)	135 (90%)				
Events >1Mo and <6Mo												---	0	2	0
6 Months (±1 month)	148	122 (82%)	115 (78%)	115 (78%)	3 (2.0%)	124 (90%)	115 (78%)	115 (78%	115 (78%)	113 (76%)	113 (76%)				
Events >6Mo and <1Yr												---	2	7	3
1 Year (±2 months)	136	125 (92%)	111 (82%)	114 (84%)	4 (2.9%)	121 (89%)	113 (83%)	113 (83%	114 (84%)	111 (82%)	111 (82%)				
Events >1Yr and <2Yrs												---	0	1	4
2 Years (±3 months)	131	104 (79%)	89 (68%)	89 (68%)	4 (3.1%)	81 (62%)	89 (68%)	89 (68%)	89 (68%)	89 (68%)	89 (68%)				
Events >2Yrs and <3Yrs												---	1	7	5
3 Years (±3 months)	118	84 (71%)	74 (63%)	74 (63%)	7 (5.9%)	57 (48%)	74 (63%)	74 (63%)	74 (63%)	74 (63%)	74 (63%)				
Events >3Yrs and <4Yrs												---	1	4	9
4 Years (±3 months)	104	72 (69%)	54 (52%)	54 (52%)	5 (4.8%)	48 (46%)	54 (52%)	54 (52%)	54 (52%)	54 (52%)	54 (52%)				
Events >4Yrs and <5Yrs												---	0	8	17
5 Years (±3 months)	79	63 (80%)	50 (63%)	50 (63%)	7 (8.9%)	45 (57%)	50 (63%)	50 (63%)	50 (63%)	50 (63%)	50 (63%)				

[1]Data analysis sample size variability is due to subject availability for follow-up and quantity and quality of images available from specific timepoints for evaluation.
[2]Of the 153 subjects enrolled, three are considered technical failures due to: intraoperative conversion to open repair [n=1]; implant of a non-study device due to access issues [n=1]; and intraoperative death [n=1]. Two of these subjects withdrew at 1Mo.
In cases where imaging data at a timepoint were not available, subsequent timepoint imaging data were used.
Note: The number of subjects who did not withdraw from the study but who missed a visit are: 1Mo (9); 6Mo (24): 1Yr (11); 2 Yrs (27); 3 Yrs (34); 4Yrs (32); 5Yrs (16).

Table 5. Subject and Imaging Accountability – CP03-023, 34mm Proximal Extension Study

Interval	Subject Follow-up n (% of eligible)			Pts. with Imaging n (% of eligible)			Pts. with Adequate Imaging to Assess Parameter: n (% of eligible)					Events Occurring Before Next Visit			
	Eligible	Clinical Follow-up	Imaging Follow-up	CT Scan (Core Lab)	Duplex Ultrasound	KUB Imaging	Aneurysm Size	Aneurysm Size Change	Endoleak	Migration	Integrity	Technical Failure	Conversion	Death	Withdrawn/ Lost
Originally Enrolled [1, 2]	60														
Events after Implant and <1Mo												1	0	0	0
1 Month (±2 weeks)	60	60 (100%)	59 (98%)	59 (98%)	---	53 (88%)	56 (93%)	---	59 (98%)	59 (98%)	59 (98%)				
Events >1Mo and <6Mo													0	2	0
6 Months (±1 month)	58	58 (100%)	55 (95%)	55 (95%)	---	53 (91%)	55 (95%)	55 (95%)	55 (95%)	55 (95%)	54 (93%)				
Events >6Mo and <1Yr													0	3	0
1 Year (±2 months)	55	51 (93%)	50 (91%)	50 (91%)	---	46 (84%)	50 (91%)	50 (91%)	50 (91%)	50 (91%)	50 (91%)				
Events >1Yr and <2Yrs												---	1	4	1
2 Years (±3 months)	50	48 (96%)	46 (92%)	43 (86%)	3 (6.0%)	34 (68%)	43 (86%)	43 (86%)	43 (86%)	43 (86%)	43 (86%)				
Events >2Yrs and <3Yrs												---	0	5	4
3 Years (±3 months)	41	32 (78%)	31 (76%)	29 (71%)	1 (2.4%)	25 (61%)	29 (71%)	29 (71%)	29 (71%)	29 (71%)	29 (71%)				
Events >3Yrs and <4Yrs												---	0	2	4
4 Years (±3 months)	36	30 (83%)	29 (81%)	27 (75%)	2 (5.6%)	23 (64%)	27 (75%)	27 (75%)	27 (75%)	27 (75%)	27 (75%)				
Events >4Yrs and <5Yrs												---	0	2	7
5 Years (±3 months)	26	21 (81%)	21 (81%)	20 (77%)	3 (12%)	14 (54%)	20 (77%)	20 (77%)	20 (77%)	20 (77%)	20 (77%)				

[1]Data analysis sample size variability is due to subject availability for follow-up and quantity and quality of images available from specific timepoints for evaluation. In cases where imaging data at a timepoint were not available, subsequent timepoint imaging data were used.

Note: The number of subjects who did not withdraw from the study but who missed specific visits are as follows: 1Yr (4); 2 Yrs (2); 3 Yrs (9); 4Yrs (6); 5Yrs (5).

Table 6. Subject and Imaging Accountability – CP04-002, 25/28mm Suprarenal Proximal Extension Study

Interval	Subject Follow-up n (% of eligible)			Pts. with Imaging n (% of eligible)			Pts. with Adequate Imaging to Assess Parameter: n (% of eligible)					Events Occurring Before Next Visit			
	Eligible	Clinical Follow-up	Imaging Follow-up	CT Scan (Core	Duplex Ultrasoun	KUB Imaging	Aneurysm Size	Aneurysm Size Change	Endoleak	Migration	Integrity	Technical	Conversion	Death	Withdrawn / Lost
Originally Enrolled [1, 2]	44														
Events after Implant and <1Mo												0	0	0	2
1 Month (±2 weeks)	42	42 (100%)	42 (100%)	41 (98%)	1 (2%)	38 (90%)	41 (98%)	41 (98%)	42 (100%)	41 (98%)	41 (98%)				
Events >1Mo and <6Mo													0	3	0
6 Months (±1 month)	39	36 (92%)	36 (92%)	30 (77%)	---	23 (59%)	30 (77%)	30 (77%)	30 (77%)	26 (67%)	26 (67%)				
Events >6Mo and <1Yr													0	1	5
1 Year (±2 months)	33	30 (91%)	29 (88%)	29 (88%)	---	22 (67%)	24 (73%)	24 (73%)	24 (73%)	29 (88%)	24 (73%)				
Events >1Yr and <2Yrs												-	0	2	3
2 Years (±3 months)	28	26 (93%)	20 (71%)	20 (71%)	---	17 (61%)	20 (71%)	20 (71%)	20 (71%)	20 (71%)	20 (71%)				
Events >2Yrs and <3Yrs												-	0	0	8
3 Years (±3 months)	20	18 (90%)	16 (80%)	16 (80%)	---	17 (75%)	16 (80%)	16 (80%)	16 (80%)	16 (80%)	16 (80%)				
Events >3Yrs and <4Yrs												-	0	1	5
4 Years (±3 months)	14	13 (93%)	7 (50%)	7 (50%)	---	4 (29%)	7 (50%)	7 (50%)	7 (50%)	7 (50%)	7 (50%)				
Events >4Yrs and <5Yrs												-	0	2	4
5 Years (±3 months)	8	8 (100%)	4 (50%)	4 (50%)	---	3 (38%)	4 (50%)	4 (50%)	4 (50%)	4 (50%)	4 (50%)				

[1]Data analysis sample size variability is due to subject availability for follow-up and quantity and quality of images available from specific timepoints for evaluation. In cases where imaging data at a timepoint were not available, subsequent timepoint imaging data were used.

Table 7. Subject and Imaging Accountability – CP-0001, PEVAR Trial

Interval	Subject Follow-up n (% of eligible)			Pts. with Imaging n (% of eligible)			Pts. with Adequate Imaging to Assess Parameter: n (% of eligible)					Events Occurring Before Next Visit			
	Eligible	Clinical Follow-up	Imaging Follow-up	CT Scan	Femoral Ultrasoun	KUB Imaging	Aneurysm Size	Aneurysm Size Change	Endoleak	Migration	Integrity	Technical Failure	Conversion	Death	Withdrawn/ Lost
PEVAR/ProGlide Group (N=50 Originally Enrolled)															
Events after Implant and <1Mo												0	0	0	0
1 Month (±2 weeks)	50	50 (100%)	50 (100%)	50 (100%)	---	---	50 (100%	50 (100%)	50 (100%)	50 (100%)	50 (100%)				
Events >1Mo and <6Mo												---	0	0	2
6 Months (±1 month)	48	47 (98%)	48 (100%)	---	48 (100%)	---	---	---	---	---	---				
Femoral Exposure/Standard EVAR (SEVAR) Group (N=50 Originally Enrolled)															
Events after Implant and <1Mo												1	0	0	0
1 Month (±2 weeks)	50	50 (100%)	50 (100%)	50 (100%)	---	---	50 (100%	50 (100%)	50 (100%)	50 (100%)	50 (100%)				
Events >1Mo and <6Mo												---	0	1	5
6 Months (±1 month)	44	43 (98%)	42 (95%)	---	42 (95%)	---	---	---	---	---	---				

All-Cause Mortality

Table 8 provides a summary of all deaths reported through final follow-up in the test group and in the surgical control group for each study, organized by probable body system. Aneurysm-related deaths, including those that occurred within 30 days are detailed below in **Table 10**. Among the study groups, the largest causative categories are cancer-related, cardiac-related, and pulmonary-related. Please note that final follow-up for the PEVAR Trial (CP-0001) was at six months.

Table 8. All-Cause Mortality by Relationship to Body System

Category/Body System Relatedness	**TP00-005** ***Surgical Control*** **[N=66]*** **n (%)**	**TP00-005** ***Infrarenal Bifurcated Study*** **[N=192]** **n (%)**	**TP00-006** ***Suprarenal Bifurcated Study*** **[N=153]** **n (%)**	**CP03-023** ***34 mm Proximal Extension Study*** **[N=60]** **n (%)**	**CP04-002** ***25, 28 mm Suprarenal Proximal Extension Study*** **[N=44]** **n (%)**	**CP-0001** ***PEVAR Trial*** **[N=100]** **n (%)**
Aneurysm-Related	4 (6.1%)	4 (2.1%)	3 (2.0%)	-	-	-
Cancer-Related	5 (7.6%)	14 (7.3%)	2 (1.3%)	6 (10%)	1 (2.3%)	1 (1.0%)
Cardiac-Related	3 (4.5%)	8 (4.2%)	11 (7.2%)	3 (5.0%)	-	-
Cerebrovascular-Related	1 (1.5%)	3 (1.6%)	2 (1.3%)	2 (3.3%)	2 (4.6%)	-
Gastrointestinal-Related	-	1 (0.5%)	-	-	1 (2.3%)	-
Pulmonary-Related	2 (3.0%)	8 (4.2%)	10 (6.5%)	3 (5.0%)	4 (9.1%)	-
Other†	2 (3.0%)	5 (2.6%)	4 (2.6%)	4 (6.7%)	1 (2.3%)	-

†Other includes: Liver cirrhosis, multiorgan failure, kidney failure, sepsis, and natural causes (Infrarenal Bifurcated test group); sepsis; asphyxial suicide, unknown, and natural causes (Suprarenal Bifurcated test group); multiorgan failure; unknown (Surgical Control group); dementia and malnutrition, multiorgan failure, pneumonia, thrombocytopenia (34 mm Proximal Extension test group)
*Deaths reported to Endologix that occurred after the five-year follow-up are included (cancer [1]; cardiac [1]).

Table 9 and **Figure 7** show that survival rates at five years are similar (p=0.69, log rank test) when comparing the Infrarenal Bifurcated Test Group (TP00-005) and Suprarenal Bifurcated Test Group (TP00-006) to the Surgical Control Group (TP00-005).

Table 9. Freedom from All-Cause Mortality

Time Point	Powerlink Infrarenal (TP00-005)			Powerlink Suprarenal (TP00-006)			Surgical Control (TP00-005)		
	# At Risk	Survival	95% CI	# At Risk	Survival	95% CI	# At Risk	Survival	95% CI
1 Month	190	0.99	0.98, 1.00	151	0.99	0.97, 1.00	62	0.94	0.88, 1.00
6 Months	180	0.96	0.93, 1.00	146	0.97	0.95, 1.00	59	0.92	0.86, 1.00
1 Year	175	0.94	0.91, 1.00	137	0.93	0.89, 1.00	53	0.88	0.79, 1.00
2 Years	164	0.90	0.86, 1.00	122	0.88	0.83, 1.00	43	0.84	0.75, 1.00
3 Years	148	0.88	0.83, 1.00	112	0.87	0.81, 1.00	39	0.78	0.67, 1.00
4 Years	129	0.82	0.76, 1.00	88	0.79	0.73, 1.00	33	0.76	0.65, 1.00
5 Years	77	0.77	0.71, 1.00	62	0.77	0.69, 1.00	17	0.73	0.60, 1.00

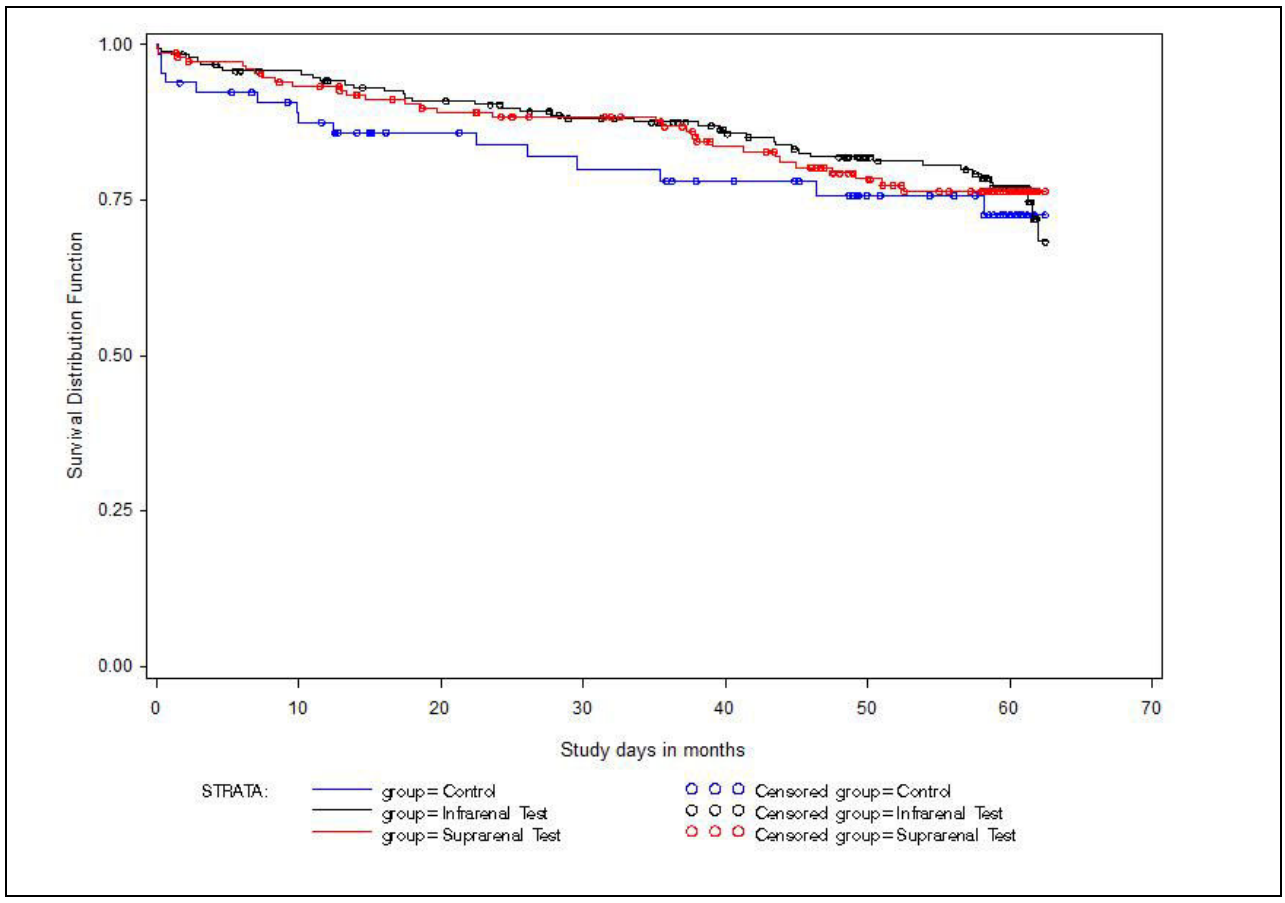

Figure 7. Freedom from All-Cause Mortality

Aneurysm-Related Mortality

Aneurysm-related mortality was defined as any death within 30 days of implantation, regardless of cause; and any death after 30 days due to aneurysm rupture, a primary or secondary procedure, or surgical conversion. **Table 10** summarizes the aneurysm-related deaths in the Powerlink Study test groups and in the original open surgery control group.

Table 10. Aneurysm-Related Death Summaries By Study Group

Days Post-Op	Subject Age	Subject Gender	Summary
TP00-005 (Infrarenal Bifurcated Study) Surgical Control Group			
3	69	M	Metabolic acidosis
9	79	F	Pulmonary embolism
10	77	F	Cardiopulmonary arrest
18	81	F	Acute respiratory distress syndrome
TP00-005 (Infrarenal Bifurcated Study) Test Group			
1	83	M	Cardiac arrest
9	80	F	Myocardial infarction after attempted thoracic repair with Talent endograft
33	76	M	Ischemic heart disease
403	73	F	Death during conversion to open repair after iliac artery rupture during attempted secondary endovascular intervention for Type Ia endoleak.
TP00-006 (Suprarenal Bifurcated Study) Test Group			
0	82	M	Cardiopulmonary arrest secondary to iliac artery rupture/hemorrhage
3	83	M	Macroembolization involving the bowel and intraabdominal organs
43	78	M	Multi-organ failure
CP03-023 (34mm Proximal Extension Study) Test Group			
None	---	---	None
CP04-002 (25/28 mm Suprarenal Proximal Extension Study) Test Group			
None	---	---	None
CP-0001 (PEVAR Trial) Test Group			
None	---	---	None

Table 11 and **Figure 8** show that survival rates at five years are similar (p=0.17, log rank test) when comparing the Infrarenal Bifurcated Test Group (TP00-005) and Suprarenal Bifurcated Test Group (TP00-006) to the Surgical Control Group (TP00-005).

Table 11. Freedom from Aneurysm-Related Mortality

Time Point	Powerlink Infrarenal (TP00-005)			Powerlink Suprarenal (TP00-006)			Surgical Control (TP00-005)		
	# At Risk	Survival	95% CI	# At Risk	Survival	95% CI	# At Risk	Survival	95% CI
1 Month	190	0.99	0.98, 1.00	151	0.99	0.97, 1.00	62	0.94	0.88, 1.00
6 Months	180	0.98	0.97, 1.00	146	0.98	0.96, 1.00	59	0.94	0.88, 1.00
1 Year	175	0.98	0.97, 1.00	137	0.98	0.96, 1.00	53	0.94	0.88, 1.00
2 Years	164	0.98	0.96, 1.00	122	0.98	0.96, 1.00	43	0.94	0.88, 1.00
3 Years	148	0.98	0.96, 1.00	112	0.98	0.96, 1.00	39	0.94	0.88, 1.00
4 Years	129	0.98	0.96, 1.00	88	0.98	0.96, 1.00	33	0.94	0.88, 1.00
5 Years	77	0.98	0.96, 1.00	62	0.98	0.96, 1.00	17	0.94	0.88, 1.00

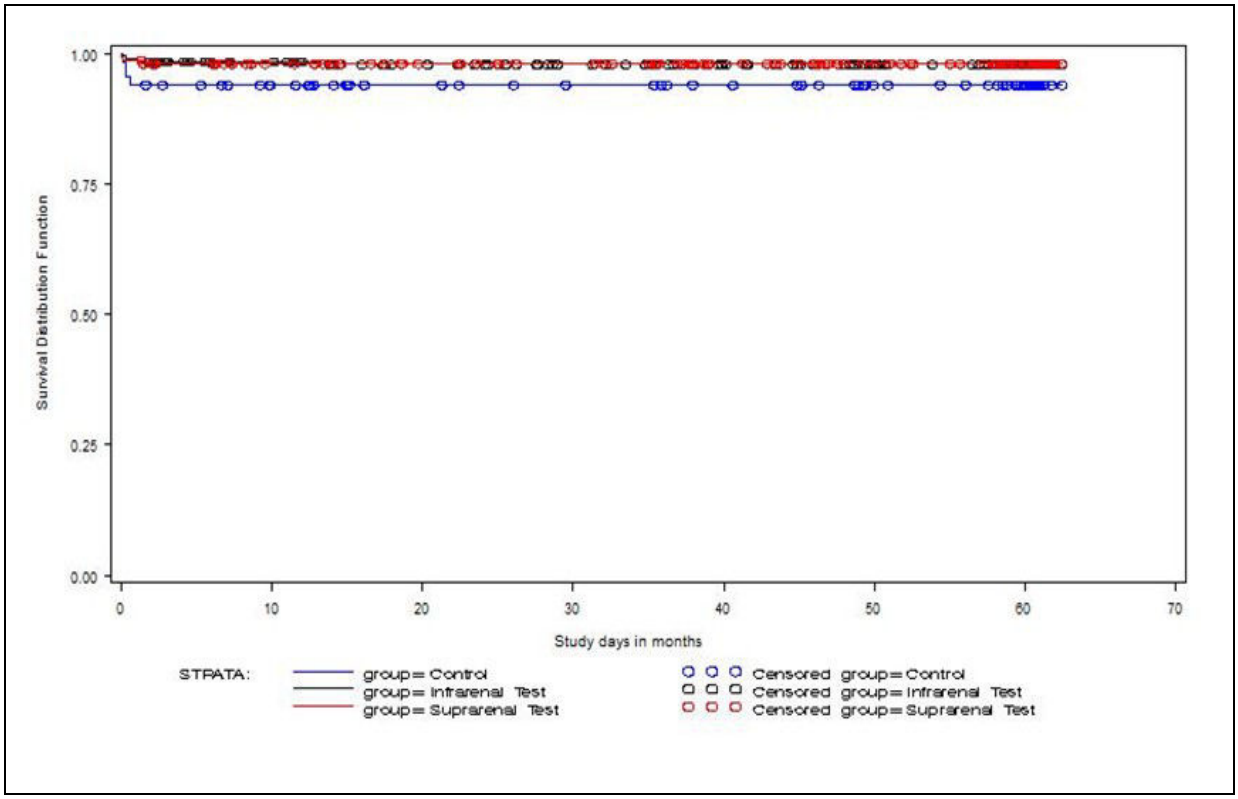

Figure 8. Freedom from Aneurysm-Related Mortality

Major Adverse Events (MAEs)

Infrarenal Bifurcated Study (TP00-005) and Suprarenal Bifurcated Study (TP00-006)

MAEs reported from the time of enrollment through one year (0 Days – 1 Year), and after one year through current follow-up to five years (>1 year through 5 years) are presented in **Table 12**. Longer term results are consistent with results within one year, supporting the continued safety and effectiveness of the Powerlink System for endovascular repair of AAA.

Within one year, fewer subjects treated with the Endologix stent graft experienced an MAE compared with subjects treated with open surgery. Longer-term follow-up of subjects in the test group included clinical visits as well as Core Laboratory evaluated diagnostic imaging results (i.e., CT scans, x-rays). Longer term follow up in control group subjects who remained in the study was primarily through telephone communication.

Notably, no aneurysm rupture was observed through five-year follow-up in any study. Further details on secondary procedures are provided in the Treatment Effectiveness subpart of this Section. Additional details on explants are provided in Section 3.

Table 12. MAE Composite and Individual Components: Endovascular vs. Surgical Controls

Parameter	0 Days-1 Year[†]			>1 Year-5 Years[†]		
	TP00-005 ***Infrarenal Bifurcated Study*** **[N=192] n (%)**	**TP00-006** ***Suprarenal Bifurcated Study*** **[N=153] n (%)**	**TP00-005** ***Surgical Control*** **[N=66] n (%)**	**TP00-005** ***Infrarenal Bifurcated Study*** **[N=192] n (%)**	**TP00-006** ***Suprarenal Bifurcated Study*** **[N=153] n (%)**	**TP00-005** ***Surgical Control*** **[N=66] n (%)**
Subjects with ≥1 MAE	46 (24%)	32 (21%)	22 (33%)	64 (37%)	16 (10.5%)	8 (16%)
All-Cause Mortality[‡]	13 (6.8%)	12 (7.8%)	9 (14%)	30 (17%)	25 (16.3%)	6 (12%)
AAA Rupture	--	--	---	--	--	---
Conversion/Explant	4 (2.1%)	2 (1.3%)	---	--	3 (2.2%)	---
Coronary Intervention	3 (1.6%)	5 (3.3%)	--	22 (13%)	11 (7.2%)	2 (4.0%)
Myocardial Infarction	7 (3.7%)	1 (0.7%)	6 (9.1%)	11 (6.5%)	3 (2.0%)	1 (2.0%)
Renal Failure	6 (3.1%)	4 (2.6%)	7 (11%)	1 (0.6%)	4 (2.6%)	--
Respiratory Failure	4 (2.1%)	4 (2.6%)	5 (7.6%)	2 (1.2%)	2 (1.3%)	--
Secondary Procedure	20 (10%)	12 (7.8%)	2 (3.0%)	11 (6.5%)	22 (14.4%)	--
Stroke	5 (2.6%)	1 (0.7%)	2 (3.0%)	10 (5.8%)	3 (2.0%)	--

[*]Enrolled subjects: Infrarenal Bifurcated Test: N=192; Suprarenal Bifurcated Test: N=153; Control: N=66. Results (n) shown as number of subjects with at least one event (% of subjects available in group). Some subjects experienced more than one event.
[†]The events in the grouping 0 Days-1 year includes all events occurring up to 14 months post-procedurally. The events in the grouping >1 Year-5 Years include all events after 14 months and up to 62 months post-procedurally.
[‡]All deaths within 30 days are considered AAA and procedure related. Of the late Powerlink deaths, one occurring at approximately one year was considered AAA and procedure related.

Figure 9 presents the Kaplan-Meier analysis of major adverse events in the Infrarenal Bifurcated Test Group (TP00-005), Suprarenal Bifurcated Test Group (TP00-006), and the Surgical Control Group (TP00-005). As shown in **Table 13** and **Figure 9** below, results through five years are similar (p=0.69, log rank).

Table 13. Freedom from MAE through 5 Years: Endovascular vs. Surgical Controls

Time Point	Powerlink Infrarenal (TP00-005)			Powerlink Suprarenal (TP00-006)			Surgical Control (TP00-005)		
	# At Risk	Survival	95% CI	# At Risk	Survival	95% CI	# At Risk	Survival	95% CI
1 Month	182	0.95	0.92, 0.98	144	0.94	0.90, 0.98	51	0.77	0.67, 0.87
6 Months	162	0.85	0.80, 0.90	133	0.87	0.82, 0.92	49	0.76	0.65, 0.86
1 Year	150	0.80	0.74, 0.86	120	0.80	0.74, 0.86	42	0.69	0.58, 0.81
2 Years	128	0.70	0.64, 0.77	102	0.70	0.62, 0.77	37	0.66	0.54, 0.78
3 Years	113	0.66	0.59, 0.73	88	0.65	0.58, 0.73	33	0.61	0.49, 0.73
4 Years	91	0.56	0.48, 0.63	68	0.59	0.51, 0.67	30	0.61	0.49, 0.73
5 Years	53	0.47	0.40, 0.55	44	0.53	0.44, 0.61	18	0.58	0.46, 0.71

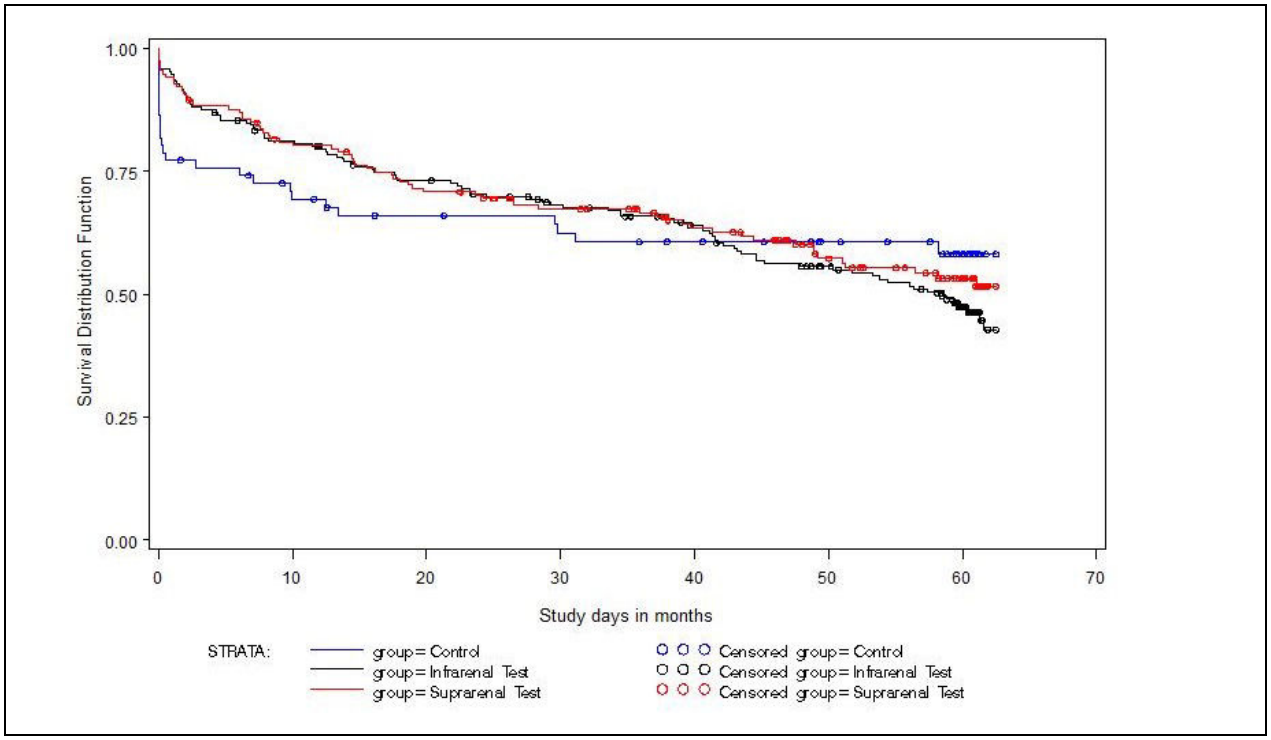

Figure 9. Freedom from Major Adverse Events to 5 Years

34mm Proximal Extension Study (CP03-023) and 25/28mm Suprarenal Proximal Extension Study (CP04-002)

MAEs reported in CP03-023 and CP04-002 (34mm Proximal Extension and 25/28mm Suprarenal Proximal Extension studies, respectively) through the final five year follow-up are provided in **Table 14**. Results are consistent with the Infrarenal and Suprarenal Bifurcated studies (TP00-005 and TP00-006, respectively), and with the natural history of this elderly subject population. No aneurysm rupture has been observed through 5-year follow-up. One conversion to open repair was performed in one CP03-023 (34mm Proximal Extension Study) subject in conjunction with a total open repair of a thoracic aortic aneurysm.

Table 14. MAEs, Aortic Extension Test Groups*

Parameter	0-30 Days		0 Days-1 Year †		>1 Year to 5 Years	
	CP03-023 ***34 mm Proximal Extension Study*** **[N=60] n (%)**	**CP04-002** ***25, 28 mm Suprarenal Proximal Extension Study*** **[N=44] n (%)**	**CP03-023** ***34 mm Proximal Extension Study*** **[N=55] n (%)**	**CP04-002** ***25, 28 mm Suprarenal Proximal Extension Study*** **[N=33] n (%)**	**CP03-023** ***34 mm Proximal Extension Study*** **[N=50] n (%)**	**CP04-002** ***25, 28 mm Suprarenal Proximal Extension Study*** **[N=28] n (%)**
Subjects with ≥1 MAE	1 (1.7%)	1 (2.3%)	10 (18%)	9 (27%)	30 (60%)	10 (36%)
All-Cause Death‡	--	--	5 (9.1%)	4 (12%)	13 (26%)	5 (18%)
AAA Rupture	--	--	--	--	--	--
Conversion/Explant	--	--	--	--	1 (1.7%)	--
Coronary Intervention	--	--	--	--	5 (8.3%)	1 (3.6%)
Myocardial Infarction	--	--	1 (1.8%)	1 (3.0%)	3 (5.0%)	--
Renal Failure	--	1 (2.3%)	3 (5.4%)	2 (6.0%)	3 (5.0%)	2 (7.2%)
Respiratory Failure	1 (1.7%)	1 (2.3%)	2 (3.6%)	2 (6.0%)	3 (5.0%)	1 (3.6%)
Secondary Procedure	--	--	1 (1.8%)	5 (15%)	5 (10%)	2 (7.2%)
Stroke	--	--	3 (5.4%)	--	2 (3.3%)	--

*CP03-023: N=60; CP04-002: N=44. Results (n) shown as number of subjects with at least one event (% of subjects available in group). Some subjects may experience more than one event.

†The events in the grouping 0-30 days include all events procedurally and up to and including exactly 30 days post-procedurally. The events in the grouping 0 Days-1 Year include all events procedurally and up to 14 months post-procedurally.

‡Deaths within 30 days are considered AAA and procedure related. Of the late Powerlink deaths (>30 days), none was considered AAA and procedure related.

PEVAR Trial (CP-0001)

MAEs reported in CP-0001 through final six-month follow-up are provided in **Table 15**. Comparisons for the proportion of subjects identified with one or more MAE for each time point shows no significant difference between the PEVAR and SEVAR groups (p=0.436 for 0-30 days, p=0.338 for 31 days-6 months, and p=0.200 total).

Table 15. MAEs, PEVAR Trial

Parameter	0 to 30 Days		31 Days to 6 Months*		Total to 6 Months	
	PEVAR Test Group [N=50] n (%)±	SEVAR Control Group [N=50] n (%)	PEVAR Test Group [N=50] n (%)	SEVAR Control Group [N=50] n (%)	PEVAR Test Group [N=50] n (%)	SEVAR Control Group [N=50] n (%)
Subjects with ≥1 MAE	**3 (4.0%)**	**7 (10%)**	**1 (2.3%)**	**3 (7.7%)**	**3 (6.0%)**	**8 (16%)**
All-Cause Death	--	--	--	1 (2.0%)	--	1 (2.0%)
AAA Rupture	--	--	--	--	--	--
Conversion to Open Repair	--	--	--	--	--	--
Bowel Ischemia	--	--	--	--	--	--
Cardiac Morbidity	--	--	--	--	--	--
Neurological Complication	--	3 (6.0%)	--	--	--	3 (6.0%)
Renal Failure	2 (4.0%)	1 (2.0%)	1 (2.0%)	--	3 (6.0%)	1 (2.0%)
Respiratory Failure	1 (2.0%)	1 (2.0%)	--	--	1 (2.0%)	1 (2.0%)
Secondary Procedure	--	2 (4.0%)	--	2 (4.0%)	--	4 (8.0%)

*The events in the grouping 0-30 days include all events procedurally and up to and including exactly 30 days post-procedurally. Per the protocol, six months was defined as 183 days. Because some subjects had their follow-up visit after this, the presentation shown here includes events to 210 days.
± n is defined as the number of events, with the exception of the first row of data, for which n represents the number of subjects.

Vascular Events

PEVAR Trial (CP-0001)

Vascular Events reported in CP-0001 through final six-month follow-up are provided in **Table 16**. Comparisons for the proportion of subjects identified with one or more vascular event for each time point shows no significant difference between the PEVAR and SEVAR groups (p=0.364 for 0-30 days, p=1.000 for 31 days – 6 months, and p=0.744 total).

Table 16. Vascular Events, PEVAR Trial

Parameter	0 to 30 Days		31 Days to 6 Months*		Total to 6 Months	
	PEVAR Test Group [N=50] n (%)±	SEVAR Control Group [N=50] n (%)	PEVAR Test Group [N=50] n (%)	SEVAR Control Group [N=50] n (%)	PEVAR Test Group [N=50] n (%)	SEVAR Control Group [N=50] n (%)
Subjects with ≥1 Vascular Event	**5 (8.0%)**	**11 (16%)**	**2 (4.0%)**	**1 (2.0%)**	**6 (12.0%)**	**8 (16.0%)**
Arteriovenous Fistula	--	--	--	--	--	--
Femoral Neuropathy	--	1 (2.0%)	--	--	--	1 (2.0%)
Hematoma	--	--	--	--	--	--
Hemorrhage	1 (2.0%)	3 (6.0%)	--	--	1 (2.0%)	3 (6.0%)
Infection	--	--	--	--	--	--
Lymphocele	--	1 (2.0%)	--	1 (2.0%)	--	2 (4.0%)
Thrombosis/Occlusion	2 (4.0%)	3 (6.0%)	--	--	2 (4.0%)	3 (6.0%)
Vascular Injury	1 (2.0%)	1 (2.0%)	2 (4.0%)	--	3 (6.0%)	1 (2.0%)

*The events in the grouping 0-30 days include all events procedurally and up to and including exactly 30 days post-procedurally. Per the protocol, six months was defined as 183 days. Because some subjects had their follow-up visit after this, the presentation shown here includes events to 210 days.
± n is defined as the number of events, with the exception of the first row of data, for which n represents the number of subjects.

Treatment Success

Infrarenal Bifurcated Study (TP00-005) and Suprarenal Bifurcated Study (TP00-006)

Successful aneurysm treatment at one year was defined as the composite of subjects in whom technical success was achieved (successful delivery and deployment of the Powerlink stent graft at the initial procedure), stent graft patency was maintained, and who were free from: aneurysm rupture; conversion to open repair; stent or attachment site fracture; migration; post-operative Type Ia/b endoleak beyond 30 days, Type III endoleak; or post-operative intervention for aneurysm enlargement.

The infrarenal bifurcated Powerlink stent graft achieved a successful aneurysm treatment rate of 92.7% (178/192). As shown in **Table 17**, 14 subjects did not have treatment success at one year. The suprarenal bifurcated Powerlink stent graft achieved a successful aneurysm treatment rate of 92.2% (141/153). As shown in **Table 17**, 12 subjects did not have treatment success at one year.

Table 17. Treatment Success at One Year, TP00-005 and TP00-006

	Powerlink Infrarenal (TP00-005) % (n/N)	**Powerlink Suprarenal (TP00-006) % (n/N)**
Unsuccessful (Failure) Aneurysm Treatment	**7.3% (14/192)**	**7.8% (12/153)**
Technical Failure*	2.1% (4/192)	2.0% (3/153)
Stent graft not patent	--	--
Aneurysm rupture	--	--
Conversion to open repair	2.1% (4/192)	1.3% (2/153)
Stent or attachment site fractures	--	--
Migration >10mm	1.6% (3/192)	--
Type Ib Endoleak >30 days	1.0% (2/192)	2.6% (4/153)
Type Ia Endoleak >30 days	2.1% (4/192)	2.6% (4/153)
Type III Endoleak	--	--

*Technical failure defined as unsuccessful delivery and deployment of the Powerlink stent graft at the initial procedure

PEVAR Trial (CP-0001)

The Primary Endpoint (Treatment Success) at 30-Days was defined as the composite of subjects in whom technical success was achieved (successful vascular access and delivery/deployment/removal of the Intuitrak delivery system at the initial procedure), and the absence of vascular exposure in the PEVAR group. The composite and component results in the PEVAR Trial (CP-0001) test group among the PEVAR/ProGlide and SEVAR (femoral exposure) groups are provided in **Table 18**. The results show that the non-inferiority hypothesis test retains significance through six months (p=0.008), demonstrating sustained non-inferiority of PEVAR (82%) to SEVAR (72%) with respect to Treatment Success rate at six months within a margin of 10%.

Table 18. Treatment Success, PEVAR Trial (CP-0001)

Outcome	**0 to 30 Days**		**31 Days to 6 Months**		**Total to 6 Months**	
	PEVAR Test Group [N=50]	**SEVAR Control Group [N=50]**	**PEVAR Test Group [N=50]**	**SEVAR Control Group [N=50]**	**PEVAR Test Group [N=50]**	**SEVAR Control Group [N=50]**
Pts with Treatment Success [%]	**44 (88%)**	**39 (78%)**	**47 (94%)**	**46 (92%)**	**41 (82%)**	**36 (72%)**
Unsuccessful (Failure) Treatment*	6 (12%)	11 (22%)	3 (6.0%)	4 (8.0%)	9 (18%)	14 (28%)
Procedural Technical Failure	3 (6.0%)	1 (2.0%)	---	---	1 (2.0%)	3 (6.0%)
Pre-Close Failure	3 (6.0%)	--	---	---	3 (6.0%)	--
Endovascular Failure	--	1 (2.0%)	---	---	--	1 (2.0%)
Major Adverse Event (MAE)†	2 (4.0%)	5 (10%)	1 (2.0%)	3 (6.0%)	3 (6.0%)	8 (16%)
Vascular Event‡	4 (8.0%)	8 (16%)	2 (4.0%)	1 (2.0%)	6 (12%)	8 (16%)

*Results shown as n (% of total subjects in group). Subjects may have experienced more than one type of failure.
†Defined as death, conversion to open repair, aneurysm rupture, bowel ischemia, cardiac morbidity, neurological complication, renal failure, respiratory failure, secondary procedure for Type I or III endoleak.
‡Defined as A-V fistula, hematoma, hemorrhage, infection, lymphocele, neuropathy, occlusion/thrombosis/stenosis, and vascular access injury

Aneurysm Sac Diameter

The Core Laboratory assessed CT scans to determine the effectiveness of aneurysm sac exclusion, as measured by maximum diameter changes over time in the first four studies (TP00-005, TP00-006, CP03-023, and CP04-002). Aneurysm sac diameter decrease or increase was defined as a change of >5 mm compared to baseline. A summary of the results to five years for these four studies is presented in **Table 19**.

No aneurysm rupture occurred in any subject. At five years, the large majority of subjects in each study were observed with stable or decreased aneurysm sac diameter. These long-term data are consistent in demonstrating effective aneurysm sac exclusion. Since the ePTFE grafts used in all of the clinical studies are identical in size, design, and processing, a similar rate of sac increase was anticipated in the absence of other variables. Slightly higher rates of increased aneurysm sac diameter reported in the Suprarenal Bifurcated Study (TP00-006), 34mm Proximal Extension Study (CP03-023), and the 25/28mm Suprarenal Proximal Extension Study (CP04-002) compared to the Infrarenal Bifurcated Study (TP00-005). These higher rates were attributed to Type II endoleaks in the majority of subjects (Type I endoleak was causal in six subjects).

Core laboratory comparison of the Type II endoleak rates among the Infrarenal Bifurcated Study (TP00-005) and the Suprarenal Bifurcated Study (TP00-006) demonstrates a substantial disparity in the prevalence of Type II endoleaks (23% Suprarenal vs. 15% Infrarenal) categorized as moderate to severe due to a patent IMA or multiple lumbar arteries (60% Suprarenal vs. 42% Infrarenal). As reported in the literature, the incidence of Type II endoleak varies in the endovascularly-treated population from 8% to 32%. It is therefore plausible that the difference in aneurysm sac enlargement in the 34mm Proximal Extension Study (CP03-023) and the 25/28mm Suprarenal Proximal Extension Study (CP04-002) is also due to differences in the prevalence and severity of Type II endoleak, which was shown to more prevalent in the 34mm Proximal Extension Study (CP03-023) at the 3-, 4-, and 5-year time points (**Table 20**).

Table 19. Aneurysm Sac Diameter Change Over Time

Change*	1 Year % (n/N)	2 Years % (n/N)	3 Years % (n/N)	4 Years % (n/N)	5 Years % (n/N)
TP00-005 (*Infrarenal Bifurcated Study*) Test Group					
No Growth	99% (154/156)	97% (141/145)	96% (125/130)	96% (116/121)	92% (98/107)
Decreased	37% (57/156)	54% (78/145)	60% (78/130)	66% (80/121)	71% (76/107)
Stable	62% (97/156)	43% (63/145)	36% (47/130)	30% (36/121)	21% (22/107)
Increased	1.3% (2/156)	2.8% (4/145)	3.8% (5/130)	4.1% (5/121)	8.4% (9/107)
TP00-006 (*Suprarenal Bifurcated Study*) Test Group					
No Growth	90% (106/113)	87% (77/89)	86% (64/74)	89% (48/54)	84% (42/50)
Decreased	24% (27/113)	36% (32/89)	49% (36/74)	59% (32/54)	48% (24/50)
Stable	66% (75/113)	51% (45/89)	38% (28/74)	30% (16/54)	36% (18/50)
Increased	9.4% (11/113)	8.9% (8/89)	14% (10/74)	11% (6/54)	14% (7/50)
CP03-023 (*34 mm Proximal Extension Study*) Test Group					
No Growth	98% (50/51)	93% (42/45)	76% (22/29)	67% (18/27)	75% (15/20)
Decreased	27% (14/51)	51% (23/45)	52% (15/29)	52% (14/27)	65% (13/20)
Stable	71% (36/51)	44% (19/45)	24% (7/29)	15% (4/27)	10% (2/20)
Increased	2.0% (1/51)	7.0% (3/45)	24% (7/29)	33% (9/27)	25% (5/20)
CP04-002 (*25, 28 mm Suprarenal Proximal Extension Study*) Test Group					
No Growth	88% (21/24)	100% (20/20)	88% (14/16)	86% (6/7)	100% (4/4)
Decreased	38% (9/24)	45% (9/20)	50% (8/16)	43% (3/7)	75% (3/4)
Stable	50% (12/24)	55% (11/20)	38% (6/16)	43% (3/7)	25% (1/4)
Increased	12% (3/24)	-- (0/20)	12% (2/16)	14% (1/7)	-- (0/4)

Includes evaluable CTs received and reviewed by the Core Laboratory.
*No Growth: Decreased + Stable; Decreased: >5 mm reduction; Stable: 5 mm or less change; Increased: >5 mm increase. Among subjects identified with a sac diameter increase, all but one was attributed to a Type II endoleak.

Device Integrity and Performance

Stent Graft Integrity

The Core Laboratory evaluated abdominal radiographs for stent fracture and CT scans for stent graft patency and integrity, including stent fracture, graft fatigue, an obstruction of any kind, or a device kink or alignment observation. No subject was identified with a stent fracture, a graft hole, or fatigue at any follow-up in any of the five clinical studies.

Device Migration

The Core Laboratory assessed CT scans to determine distal device movement relevant to the initial implant location (baseline CT scan) at each follow-up for each of the five clinical studies. Migration was defined as device movement of >10 mm relative to the original implant location.

In the Infrarenal Bifurcated Study (TP00-005), a total of eight subjects (4.2%) were observed with distal migration over five years. Two (2) subjects first presented with migration at 6 months, one (1) subject at 1 year, three (3) subjects at 4 years, one (1) subject at 4.5 years, and one (1) subject at 5 years. A proximal extension was implanted in the subject that presented at 4.5 years to address distal migration (with no observable endoleak prior to or following the re-intervention). In the Suprarenal Bifurcated Study (TP00-006), a total of three subjects (2.0%) have been observed with distal migration: one (1) subject first presented with migration at 17 months, one (1) subject at 2 years, and one (1) subject at 3 years. The subject that presented with migration at 2 years underwent an intervention in which one proximal extension was placed.

In the 34mm Proximal Extension Study (CP03-023), two (2) subjects presented with migration. One (1) subject presented with migration of the proximal cuff at 60 months. The second subject presented with a rapidly enlarging thoracic aortic aneurysm, underwent resection and graft replacement of his ascending thoracic aorta at 18 months and, at 20 months, presented with migration of the infrarenal graft. The patient underwent resection and graft replacement of thoracoabdominal aortic aneurysm and resection of abdominal aortic and bilateral iliac artery stents at 22 months.

No migrations were reported through final follow-up in either the 25/28mm Suprarenal Proximal Extension Study (CP04-002) or in the PEVAR Trial (CP-0001).

Endoleaks

The Core Laboratory assessed CT scans to determine the presence of endoleak at each follow-up. Available results to five years for the four long-term studies are presented in **Table 20**. The majority of endoleaks are Type II (collateral vessel-related). Moreover, there have been no Type III or IV endoleaks reported by the Core Laboratory at any time point. Secondary interventions completed to address endoleak are described on page 31.

Table 20. Core Laboratory Reported Endoleaks TP00-005, TP00-006, CP03-023, CP04-002*[α]

Endoleak Type	1 Month % (n/N)	1 Year % (n/N)	2 Years % (n/N)	3 Years % (n/N)	4 Years % (n/N)	5 Years % (n/N)
Type Ia Endoleak						
TP00-005	2.0% (3/152)	0.7% (1/138)	0.8% (1/119)	-- (0/103)	-- (0/97)	-- (0/87)
TP00-006	4.6% (6/130)	2.8% (3/105)	2.4% (2/85)	1.4% (1/74)	1.9% (1/54)	2.0% (1/50)
CP03-023	-- (0/59)	2.0% (1/50)	-- (0/43)	3.6% (1/28)	11% (3/27)	5.0% (1/20)
CP04-002	4.8% (2/41)	-- (0/24)	-- (0/20)	13% (2/15)	-- (0/7)	-- (0/3)
Type Ib Endoleak						
TP00-005	-- (0/152)	-- (0/138)	-- (0/119)	-- (0/103)	-- (0/97)	-- (0/87)
TP00-006	0.8% (1/130)	2.8% (3/105)	-- (0/85)	-- (0/74)	-- (0/54)	-- (0/50)
CP03-023	-- (0/59)	-- (0/50)	-- (0/43)	-- (0/28)	-- (0/27)	-- (0/20)
CP04-002	-- (0/41)	4.2% (1/24)	-- (0/20)	-- (0/15)	-- (0/7)	-- (0/3)
Type II Endoleak						
TP00-005	19% (29/152)	12% (17/138)	9.2% (11/119)	5.8% (6/103)	10% (10/97)	11% (10/87)
TP00-006	37% (48/130)	27% (28/105)	19% (16/85)	22% (16/74)	13% (7/54)	12% (6/50)
CP03-023	22% (13/59)	16% (8/50)	14% (6/43)	11% (3/28)	11% (3/27)	5.0% (1/20)
CP04-002	15% (6/41)	21% (5/24)	15% (3/20)	6.6% (1/15)	-- (0/7)	-- (0/3)

*Endoleaks reported are not cumulative but are those identified at each time point. Note: at both one month and one year, one Infrarenal subject and four Suprarenal subjects have more than one type of endoleak and are included in multiple rows.
[α]TP00-005 = Infrarenal Bifurcated Study; TP00-006 = Suprarenal Bifurcated Study; CP03-23 = 34mm Proximal Extension Study; CP02-002 = 25/28mm Suprarenal Proximal Extension Study.

Table 21. Endoleaks, PEVAR Trial (CP-0001)

Outcome	0 to 30 Days		31 Days to 6 Months*		Total to 6 Months	
	PEVAR Test Group [N=50] n (%)[±]	SEVAR Control Group [N=50] n (%)	PEVAR Test Group [N=50] n (%)	SEVAR Control Group [N=50] n (%)	PEVAR Test Group [N=50] n (%)	SEVAR Control Group [N=50] n (%)
Subjects with Endoleak [%]	**1 (2.0%)**	**2 (4.0%)**	**5 (10.0%)**	**6 (12.0%)**	**6 (12.0%)**	**8 (16.0%)**
Type Ia Endoleak	--	1 (2.0%)	--	2 (4.0%)	--	3 (6.0%)
Type Ib Endoleak	--	--	--	--	--	--
Type II Endoleak	1 (2.0%)	1 (2.0%)	5 (10.0%)	4 (8.0%)	6 (12.0%)	5 (10.0%)
Type III Endoleak	--	--	--	--	--	--
Type IV Endoleak	--	--	--	--	--	--

*The events in the grouping 0-30 days include all events procedurally and up to and including exactly 30 days post-procedurally. Per the protocol, six months was defined as 183 days. Because some subjects had their follow-up visit after this, the presentation shown here includes events to 210 days.
[±] n is defined as the number of events, with the exception of the first row of data, for which n represents the number of subjects.

Secondary Interventions

Secondary interventions following the index procedure to repair an endoleak, stent graft occlusion, or for other reasons are summarized in this section. No interventions for Type III or IV endoleak were completed in any study.

- *Infrarenal Bifurcated Study (TP00-005):* Through five years, a total of 25 subjects (13%) underwent 33 secondary procedures. The majority of interventions were for Type II endoleak. Within one year, secondary interventions were performed for Type II endoleak (6), limb occlusion (6), Type Ia endoleak (4), Type Ib endoleak (2), or for sac fluid aspiration (1). After one year, secondary interventions were performed for Type II endoleak (10), Type Ib/indeterminate endoleak (2), limb occlusion (1), or migration in the absence of endoleak (2). Secondary interventions for surgically placed graft-related concerns were reported in 3.0% of control subjects.

- *Suprarenal Bifurcated Study (TP00-006):* Through five years, a total of 26 subjects (17%) underwent 39 secondary procedures. The majority of interventions were for Type II endoleak. Within one year, secondary interventions were performed for Type II endoleak (7), limb occlusion (3), Type Ib endoleak (3), Type Ia endoleak (2), lymph leak (1), or limb alignment (1). After one year, secondary interventions were performed for Type II endoleak (12), Type Ia endoleak (4), Type Ib endoleak (4), limb occlusion (1), or migration (1).

- *34 mm Proximal Extension Study (CP03-023):* Through five years, a total of six subjects (10%) underwent nine secondary procedures. Within one year, secondary interventions were performed for Type II endoleak (3) or Type Ib endoleak (1). After one year, secondary interventions were performed for Type Ia endoleak (3), Type II endoleak (1) and one endoleak of unknown origin.

- *25, 28 mm Suprarenal Proximal Extension Study (CP04-002):* Through five years, a total of five subjects (11%) underwent six secondary procedures. Within one year, secondary interventions were performed for Type Ia endoleak (1), Type Ib endoleak (1), and limb occlusion (1). After one year, secondary interventions were performed for Type II endoleak (2) and Type Ib endoleak (1).

- *PEVAR Trial (CP-0001):* Through six months, a total of one PEVAR (2.0%) and four SEVAR subjects (8.0%) underwent a secondary procedure. In the PEVAR group, one subject underwent ballooning at the index procedure to resolve an intraoperative Type I endoleak. In the SEVAR group, one subject was implanted with a Cook Renu extension at the index procedure to resolve an intraoperative Type I endoleak. Another subject underwent angiography to rule out a suspected Type I endoleak, with no other intervention performed. The remaining two secondary interventions were to treat Type Ia endoleaks.

Summary

Among the five pivotal studies of the Powerlink System stent graft, primary safety and effectiveness analyses that served as the basis for regulatory approval met the prospectively defined acceptance criteria. Subjects who received the Powerlink Infrarenal and Suprarenal Bifurcated stent graft (TP00-005 and TP00-006, respectively) experienced fewer major adverse events, mortality, and aneurysm-related mortality than subjects treated with open surgery. In the multicenter, prospective, randomized study of totally percutaneous EVAR facilitated using the ProGlide closure, a 94% technical success rate was observed.

Available data beyond the pivotal analysis time points also continue to support device safety and effectiveness. Longer term follow-up shows similar rates of mortality and major adverse events among test groups and the surgical control group. No stent fractures or graft disruptions were observed in independent Core Laboratory evaluations. The majority of test subjects did not experience an endoleak. Of those that did, most were Type II, with a low number of Type I and no Type III or IV endoleaks observed by the Core Laboratory or the independent assessor/clinical events committee (for the PEVAR Trial). One hundred percent (100%) freedom from aneurysm rupture was observed.

The clinical data encompasses the legacy Powerlink System devices; however, it remains relevant and can, in part, be extrapolated to the AFX System[2]. The only difference between the Powerlink and AFX System stent grafts is the ePTFE graft processing method, which ultimately results in a different graft wall thickness and some graft properties, including tear propagation resistance. Based on these differences and real-world clinical evidence, the clinical data from the Powerlink System clinical studies may not be appropriately extrapolated to the earlier AFX System with STRATA graft material, in particular due to the Type III endoleaks and the subsequent clinical harms. However, as detailed in the data below (page 79), the reported Type IIIa and IIIb endoleak estimated complaint rates at equivalent time points have been lower for the AFX with DURAPLY and AFX2 with DURAPLY stent grafts compared to the AFX with STRATA stent grafts.

[2] Both the STRATA and DURAPLY ePTFE grafts utilized in the AFX System had a nominal wall thickness that was approximately half the wall thickness of the legacy Powerlink ePTFE graft. Due to this reduction in the wall thickness specification, paired with the introduction of a stand-alone introducer sheath system and other modifications to the stent graft delivery system, the AFX System reduced the overall profile by 2 Fr.

SECTION 2: Post-Market Clinical Experience

Leopard Trial Overview

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 only trial designed to directly compare endograft outcomes using the methodology of a randomized controlled trial. The trial methodology was designed as a site-reported, post-market study. The trial was not designed to fulfill any FDA post-market requirements and therefore was not reviewed by FDA. LEOPARD employed a Risk Based Monitoring (RBM) approach in alignment with the current FDA Guidance, *Oversight of Clinical Investigations, A Risk Based Approach to Monitoring (August 2013)*, in order to ensure adequate protection of subjects enrolled in the study and to ensure the quality and integrity of clinical study data. Overall, the trial has ~50% source documentation validation.

The LEOPARD Trial compares the anatomically stabilized AFX System (AFX with DURAPLY and AFX2) to a reference group of proximally fixated EVAR devices: the Cook Zenith, the Gore Excluder and the Medtronic Endurant devices. 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/AFX2 Bifurcated devices and one selected proximally-fixated device (i.e., Zenith, Excluder, Endurant), 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. Using ARC, the trial was designed to sequentially evaluate non-inferiority and superiority hypotheses, with comparisons between the AFX System and the proximally-fixated endografts. This Endologix-initiated trial started enrollment in 2015, with the intention to enroll up to 800 subjects.

In December 2016, Endologix issued a recall for all AFX with STRATA devices as well as the larger sizes of AFX2 (reference Section 4, page 79, for additional details). In order to support subsequent submissions with FDA and Endologix's notified body (LNE/G-MED), Endologix made the decision to review all available site-reported data collected through LEOPARD in March 2017 in order to understand how both AFX with DURAPLY and AFX2 were performing with respect to Type III endoleaks. This initial review of Type III endoleak data in March 2017 found that no Type IIIa or Type IIIb endoleaks had been reported from the subjects in either the AFX/AFX2 or the proximally-fixated treatment groups.

Based on the reporting of these data during periodic updates on the AFX2 Recall, Endologix began to receive additional queries from the field regarding the complete safety profile of AFX with DURAPLY and AFX2. Based on these requests, Endologix made a decision on August 2, 2017 to complete a descriptive analysis on the 246 subjects who had completed their 1-year follow-up (pre-specified primary endpoint timing). This descriptive analysis showed that freedom from ARC with the AFX/AFX2 Bifurcated device were similar to the three proximally-fixated comparator devices at one-year. Since the current trend suggested that the primary endpoint of non-inferiority was achievable and continued enrollment for superiority was futile, Endologix made a voluntary decision to halt further randomization into the study in August 2017, capping the trial at 455 subjects.

Leopard Trial Outcome Data

As summarized above, 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 the most relevant EVAR-related outcomes. This included: peri-operative death (≤30 days), aneurysm rupture, conversion to open surgical repair, post-operative endoleaks, endograft migration (≥10mm), aneurysm enlargement (≥5mm compared to 1-month CT), endograft occlusion, and any reinterventions for device- or aneurysm-related complications. As shown in the subsequent data below, freedom from ARC with the AFX/AFX2 Bifurcated device were similar to the three proximally-fixated comparator devices at one-year and continue to trend similarly out to 3-years. Below is a side-by-side comparison of those aneurysm-related complications reported in the LEOPARD Trial through May 2019, followed by Kaplan-Meier estimates for the most relevant EVAR-related outcomes. Additional event summaries are provided in the text that follows, as appropriate. These summaries detail the device type, time to event, and the on/off label status (if known, which is limited to adherence to the anatomical neck criteria).

Aneurysm-Related Complications

ARC events for the LEOPARD Trial reported from the time of enrollment through the primary endpoint (0 Days – 1-Year), and after 30-Days through 5-Year follow-up are being collected under CP-0011. Available, site reported follow-up data through May 6, 2019 are presented in **Table 22**. As shown in the table below, the incidence of ARC events across the two cohorts remains similar through 3-Years of follow-up, thus providing objective clinical evidence that the performance of the AFX/AFX2 Bifurcated devices with the DURAPLY ePTFE graft perform equivalent to contemporary EVAR devices.

Table 22. Aneurysm-Related Complications (ARC) Summary, LEOPARD Trial

Aneurysm-Related Complications (ARC) Through May 6, 2019	**Anatomically-Fixated Grafts (AFX/AFX2 with DURAPLY) N=235**	**Proximally-Fixated Grafts (Comparators)* N=220**
Aneurysm-Related Mortality (ARM)	4	2
Peri-Operative Mortality	*3*	-
ARM ≥30 Days	*1*[*∞]	*2*
Aneurysm Rupture	1*[∞]	-
Conversion to Open Surgical Repair	-	4
Type Ia Endoleak	3[∞]*	1
Type Ib Endoleak	4	3
Type II Endoleak	22[¥]	24
Type IIIa Endoleak	1[β]	-
Type IIIb Endoleak	1[∞]	-
Migration >10mm	-	-
Aneurysm Enlargement >5mm	1	3
Device Occlusion	1	8
Device/AAA-Related Re-intervention	14	16
Number Subjects[Σ]	**38**	**40**

*The following adverse events were likely attributed to the off-label condition of the AFX System graft: one (1) aneurysm rupture/death and one (1) Type Ia Endoleak. No adverse events were likely attributed to the off-label condition of the proximally-fixated grafts.
∞Pt. 105-005 was reported with an endoleak that was reported as either a Type Ia or Type IIIb endoleak. The subject is considered off-label as they did not meet the minimum neck-length requirements in the AFX System IFU (subject had a neck length of 6mm, which failed to meet the minimum requirement of a ≥15mm neck). This case is under adjudication as the post-op CT image provided to Endologix is in an unsupported format; therefore, the endoleak type cannot be confirmed at this time.
¥Pt. 144-004 was reported with Aneurysm Enlargement due to a possible Type II endoleak. The subject subsequently underwent a re-intervention to add a right iliac extension. This case is under adjudication to verify the endoleak type.
βPt. 100-019 was reported as a Type IIIa Endoleak; however, Endologix was unable to confirm a Type IIIa Endoleak from the imaging provided. Endologix was also unable to confirm whether the subject met the eligibility requirements in the AFX System IFU. Based on the imaging, Endologix's complaint investigation has concluded this to be an indeterminate endoleak; however, as the site reported a Type IIIa Endoleak, the ARC results include the site reported event (per protocol).
ΣEach reported adverse event is not mutually exclusive and a given subject may have had multiple adverse events.

Figure 10 and **Figure 11** detail the Kaplan-Meier estimates of aneurysm-related complications (ARC) for subjects in the LEOPARD Trial with and without Type II endoleak, respectively. As shown in the data below, the long-term performance of the AFX/AFX2 Bifurcated (with the DURAPLY ePTFE graft) is supported with 82.6% of subjects being free from ARC at 3-Years (inclusive of Type II endoleaks) and 91.6% of subjects being free from ARC at 3-Years (exclusive of Type II endoleaks). This is compared to the comparator group results of 79.8% and 89.7%, respectively.

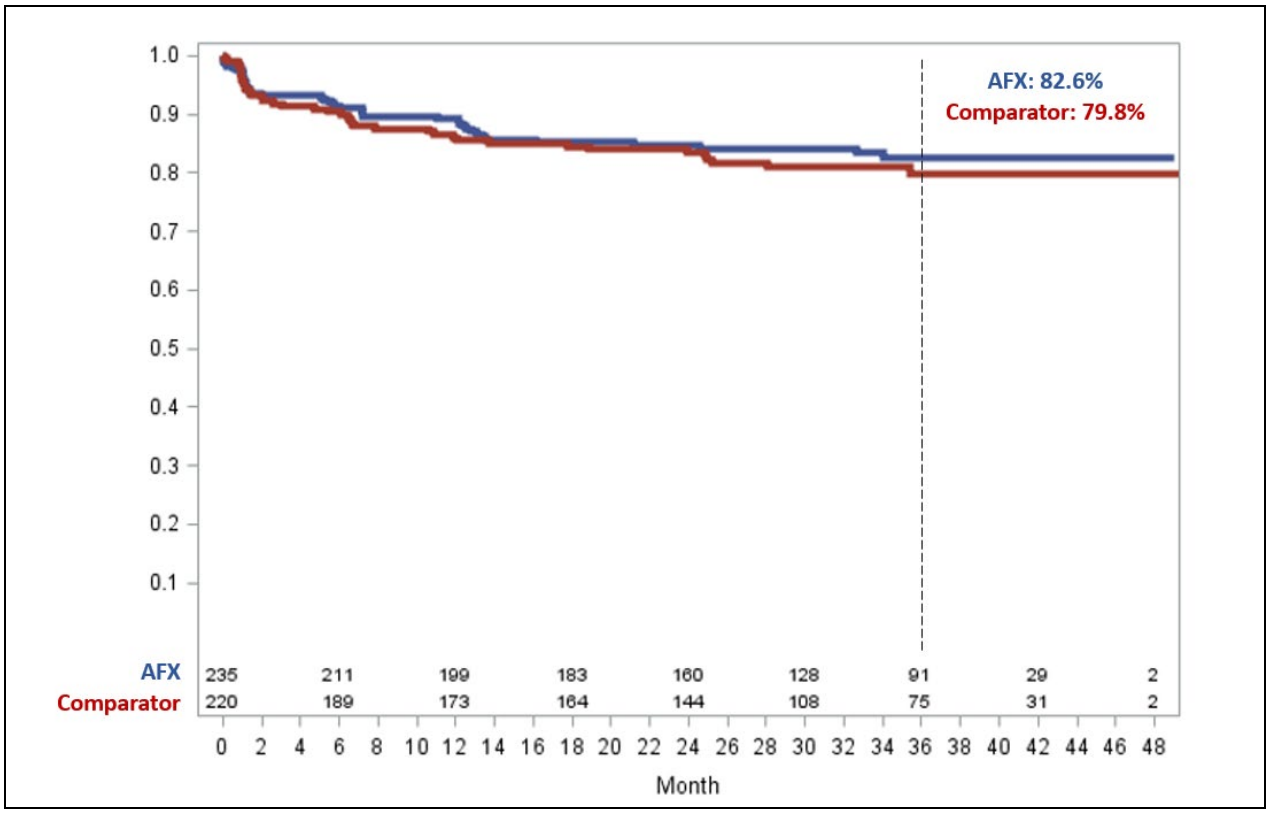

Figure 10. Freedom from Aneurysm-Related Complications (ARC), including Type II Endoleaks LEOPARD Trial

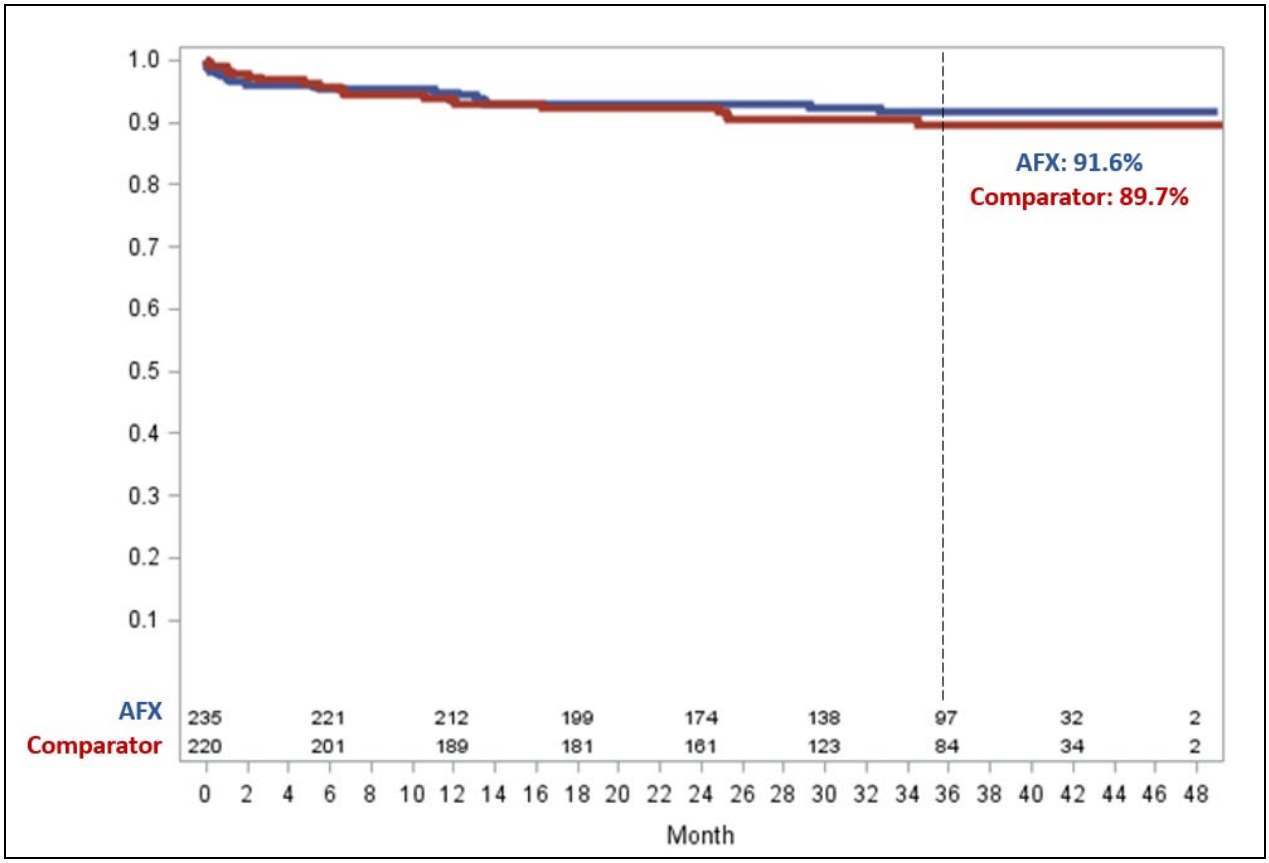

Figure 11. Freedom from Aneurysm-Related Complications (ARC), excluding Type II Endoleaks LEOPARD Trial

All-Cause Mortality

Figure 12 details the Kaplan-Meier estimates of all-cause mortality (ACM) for subjects in the LEOPARD Trial. As shown in the data below, the long-term performance of the AFX/AFX2 Bifurcated (with the DURAPLY ePTFE graft) is supported with 86.7% of subjects being free from ACM at 3-Years. This is compared to the comparator group results of 83.0%.

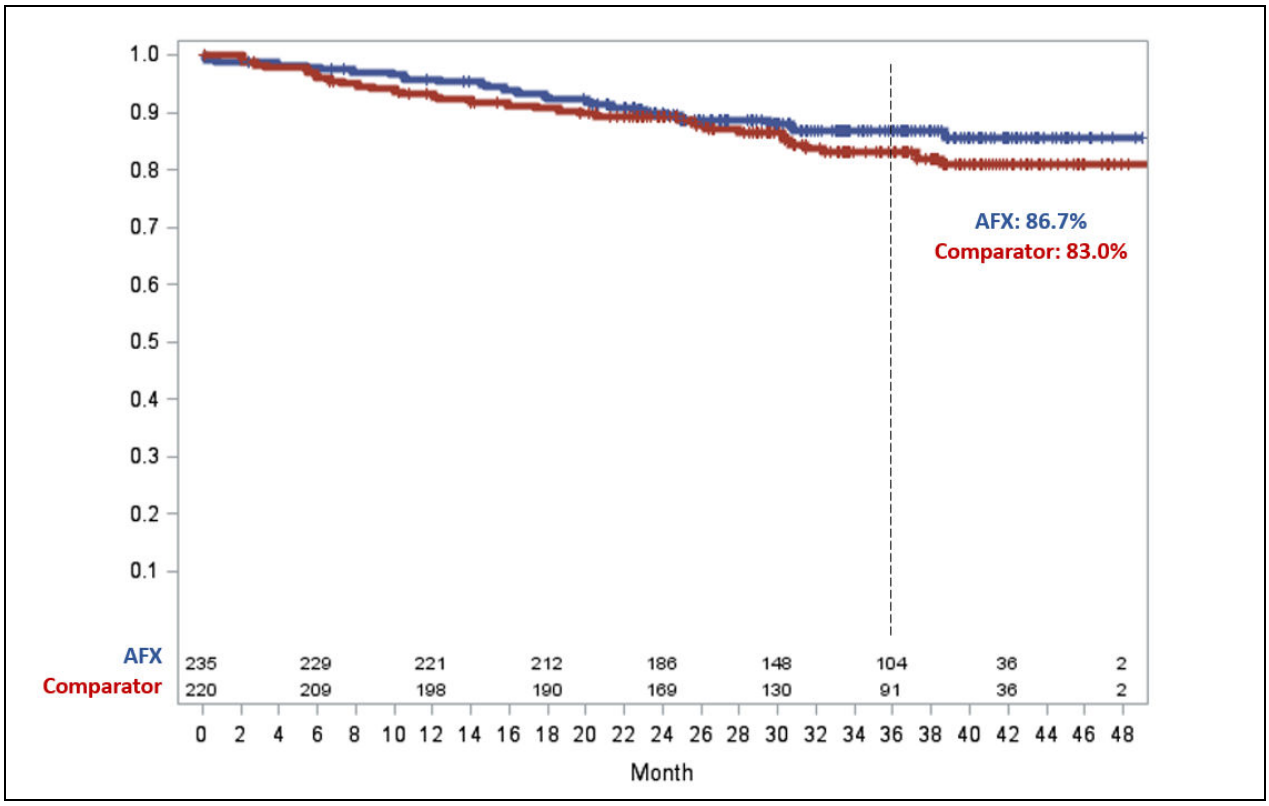

Figure 12. Freedom from All-Cause Mortality (ACM), LEOPARD Trial

Aneurysm-Related Mortality

Figure 13 details the Kaplan-Meier estimates of aneurysm-related mortality (ARM) for subjects in the LEOPARD Trial. As shown in the data below, the long-term performance of the AFX/AFX2 Bifurcated (with the DURAPLY ePTFE graft) is supported with 98.2% of subjects being free from ARM at 3-Years. This is compared to the comparator group results of 98.9%. Additional event summaries are provided in the text that follows.

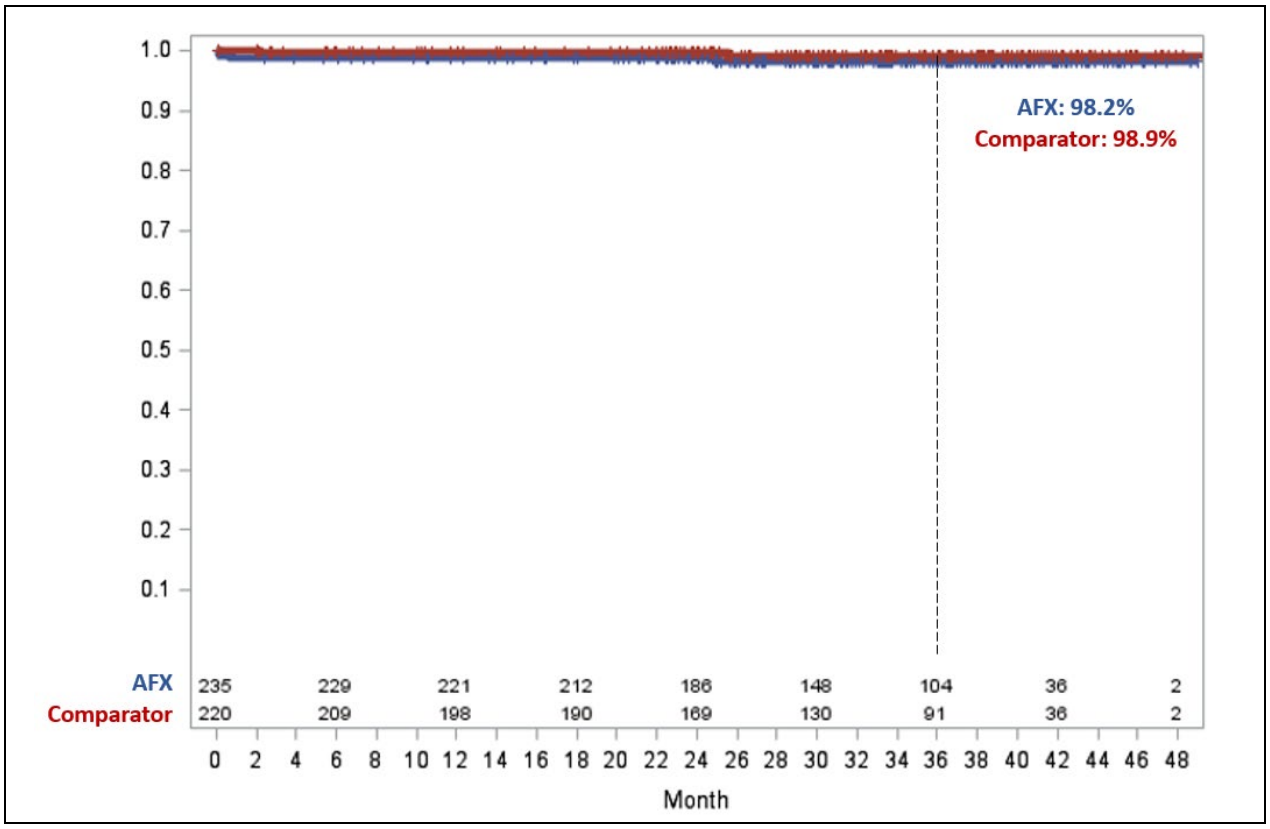

Figure 13. Freedom from Aneurysm-Related Mortality (ARM), LEOPARD Trial

Peri-Operative Mortality

As of the May 2019 data cut, three (3) peri-operative deaths have been reported in the anatomically-fixated group and zero (0) peri-operative deaths have been reported in the proximally-fixated group:

- Pt. 111-014 was implanted with an anatomically-fixated graft (AFX/AFX2 with DURAPLY). The subject was considered off-label as they exceeded the upper-bound of the proximal aortic neck diameter (subject had a proximal diameter of 33mm, which failed to meet the defined range 18 mm ≤ x ≤ 32 mm). Following the index procedure, the subject suffered acute limb ischemia, requiring immediate re-intervention. The subject died following the re-intervention due to multi-system organ failure. The death occurred 6 days post-op from the index.
- Pt. 126-009 was implanted with an anatomically-fixated graft (AFX/AFX2 with DURAPLY). The subject was considered on-label per the neck requirements in the IFU. At 24-days post-op, the site reported that the subject had died. No post-op CT or additional case details are available at this time.
- Pt. 159-007 was implanted with an anatomically-fixated graft (AFX/AFX2 with DURAPLY). The subject is considered off-label as they did not meet the minimum neck-length requirements in the IFU (subject had a neck length of 9mm, which failed to meet the minimum requirement of a ≥15mm neck). At 4-days post-op, the subject died following abdominal surgery for an ischemic bowel.

Aneurysm-Related Mortality (ARM) ≥ 30 Days

As of the May 2019 data cut, one (1) ARM event ≥30 Days has been reported in the anatomically-fixated group and two (2) ARM events ≥30 Days has been reported in the proximally-fixated group:

- Pt. 105-005 was implanted with an anatomically-fixated graft (AFX/AFX2 with DURAPLY). The subject is considered off-label as they did not meet the minimum neck-length requirements in the IFU (subject had a neck length of 6mm, which failed to meet the minimum requirement of a ≥15mm neck). At 760-days post-op, the subject presented to an outside hospital with an aneurysm rupture. No post-op CT was provided and the outside hospital reported the rupture as being caused by either a Type Ia or Type IIIb endoleak. The subject underwent a secondary intervention with a proximally-fixated device and subsequently withdrew from the trial. The subject was reported to have died on post-op day 760. NOTE: The post-op CT image provided to Endologix is in an unsupported format; therefore, the endoleak type cannot be confirmed at this time. This case is under adjudication.
- Pt. 133-010 was implanted with a proximally-fixated graft (Comparator). The subject was considered on-label per the neck requirements in the IFU. At 62-days post-op, Pt. 133-010 was reported with device occlusion and subsequently underwent re-intervention. The subject experienced complications from the re-intervention and died.
- Pt. 133-008 was implanted with a proximally-fixated graft (Comparator). The subject was considered on-label per the neck requirements in the IFU. At 767-days post-op, Pt. 133-008 presented with a Type Ia endoleak and subsequently underwent re-intervention. Five (5) days following the re-intervention, the subject experienced sepsis in the setting of pneumonia and end stage renal disease. The subject died four (4) days later (776 days post-op).

Conversions to Open Surgical Repair

Figure 14 details the Kaplan-Meier estimates of conversions for subjects in the LEOPARD Trial. As shown in the data below, the long-term performance of the AFX/AFX2 Bifurcated (with the DURAPLY ePTFE graft) is supported with 100.0% of subjects being free from conversions at 3-Years. This is compared to the comparator group results of 98.1%. Additional event summaries are provided in the text that follows.

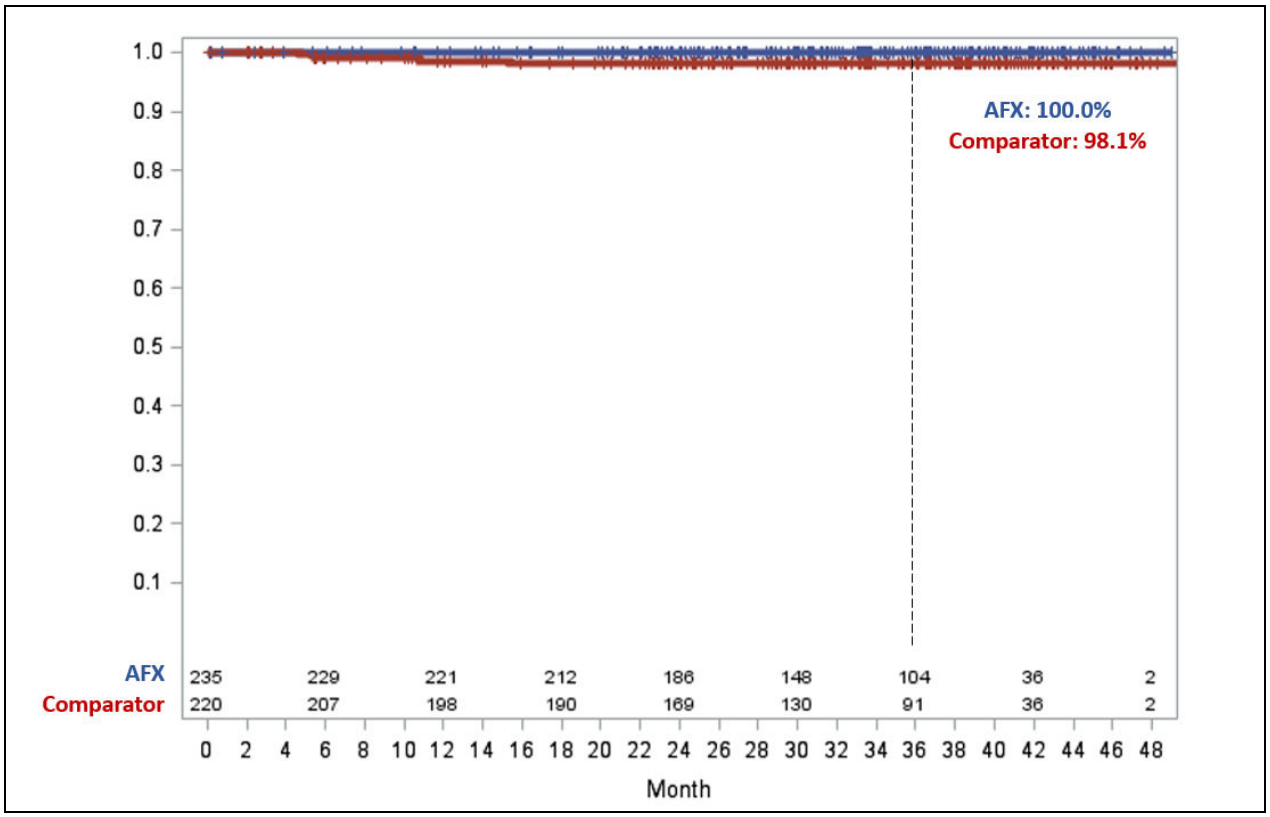

Figure 14. Freedom from Conversions, LEOPARD Trial

As of the May 2019 data cut, zero (0) conversions have been reported in the anatomically-fixated group and four (4) conversions have been reported in the proximally-fixated group:

- Pts. 117-007, 156-005, 166-005, and 960-006 were implanted with a proximally-fixated graft (Comparator). All four subjects were considered on-label per the neck requirements in the IFU. At 144-days post-op, Pt. 117-007 was reported with an aorto-enteric fistula and subsequently underwent conversion to open repair. At 78-days post-op, Pt. 156-005 was reported with multiple (left) iliac limb occlusions and an iliac artery dissection. The subject subsequently underwent conversion to open repair. At 38-days post-op, Pt. 166-005 was reported with Aneurysm Enlargement due to a Type II Endoleak and underwent conversion to open repair. At 322-days post-op, Pt. 960-006 was reported with a stent graft infection and underwent conversion to open repair.

Endoleak

Figure 15, **Figure 16**, and **Figure 17** detail the Kaplan-Meier estimates of Type I, Type II, and Type III endoleaks for subjects in the LEOPARD Trial. As shown in the data below, the long-term performance of the AFX/AFX2 Bifurcated (with the DURAPLY ePTFE graft) is supported with 96.8% of subjects being free from Type I endoleaks at 3-Years, 87.7% of subjects being free from Type II endoleaks at 3-Years, and 99.0% of subjects being free from Type III endoleaks at 3-Years. This is compared to the comparator group results of 97.9%, 82.5%, and 100.0%, respectively. Additional event summaries for the Type I and Type III endoleak events are provided in the text that follows.

As outlined in Section 4 (page 79), Type IIIa endoleaks were an early failure mode of the AFX System of devices due to inadequate overlap instructions in the IFU. Additionally, Type IIIb endoleaks were a known failure mode of the now-discontinued STRATA ePTFE material. These failure modes ultimately resulted in Endologix implementing a number of IFU and product changes since 2013 and removing all STRATA devices from the field. Based on the data available in the LEOPARD Trial to date, the corrective actions for both Type IIIa and Type IIIb endoleaks appear to be effective in reducing the rate of Type III endoleaks through 3-Years. Endologix will continue to monitor the longer-term effectiveness of these corrective actions through final 5-Year follow-up.

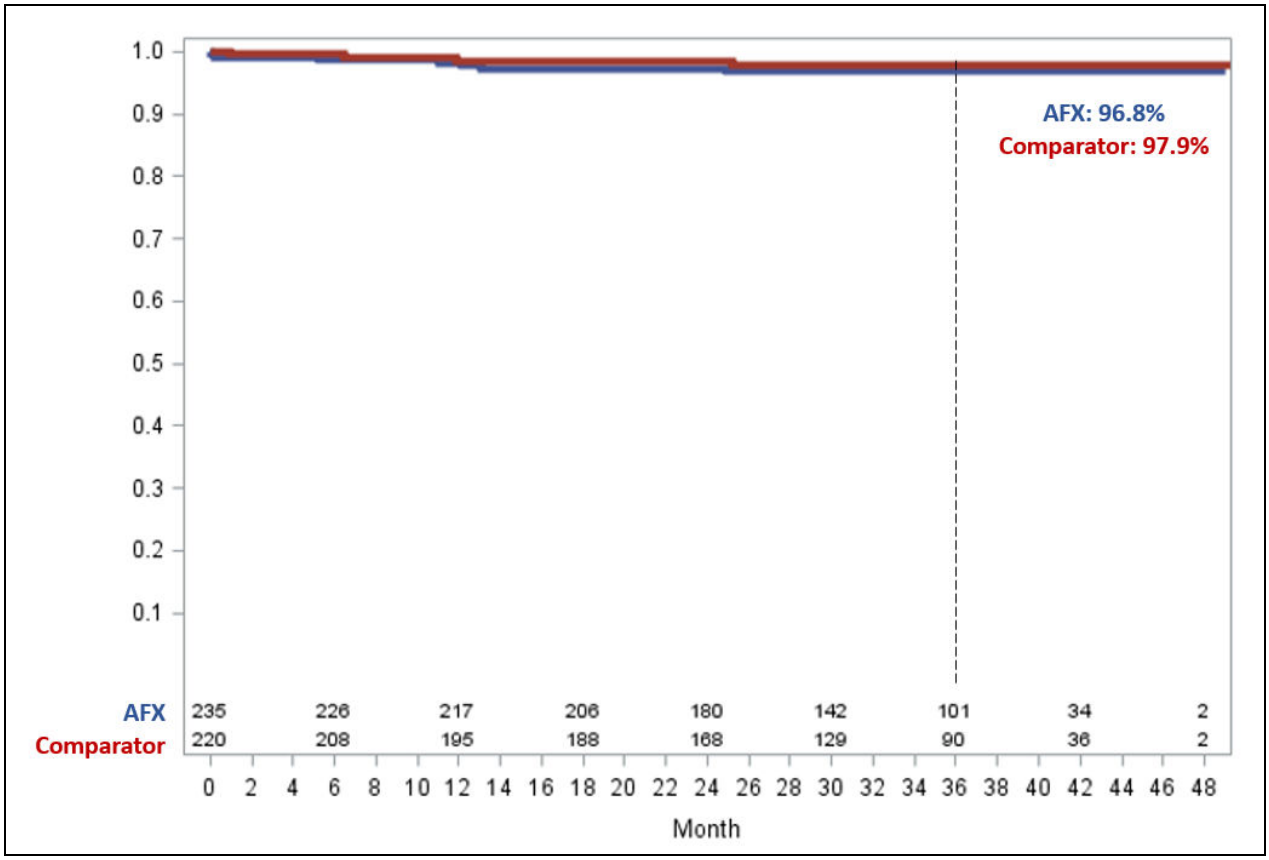

Figure 15. Freedom from Type I Endoleak, LEOPARD Trial

As of the May 2019 data cut, three (3) Type Ia Endoleaks have been reported in the anatomically-fixated group and one (1) Type Ia Endoleak has been reported in the proximally-fixated group. See page 39 for additional details on Pt. 105-005 and Pt. 133-008. The other two event summaries are included below.

- Pt. 144-017 was implanted with an anatomically-fixated graft (AFX/AFX2 with DURAPLY). The subject is considered off-label as they did not meet the minimum neck-length requirements in the IFU (subject had a neck length of 11mm, which failed to meet the minimum requirement of a ≥15mm neck). At 370-days post-op, the subject presented with a Type Ia Endoleak. No secondary intervention was performed.
- Pt. 120-016 was implanted with an anatomically-fixated graft (AFX/AFX2 with DURAPLY). The subject was considered on-label per the neck requirements in the IFU. At 5-days post-op, the subject presented with a Type Ia Endoleak and subsequently underwent a re-intervention.

As of the May 2019 data cut, four (4) Type Ib Endoleaks have been reported in the anatomically-fixated group and three (3) Type Ib Endoleaks have been reported in the proximally-fixated group:

- Pts. 108-001 and 144-004 were implanted with an anatomically-fixated graft (AFX/AFX2 with DURAPLY). The subjects were considered on-label per the neck requirements in the IFU. At 397-days post-op, Pt. 108-001 presented with a Type Ib Endoleak and subsequently underwent a re-intervention to place an additional iliac extension. The re-intervention was not successful and Pt. 108-001 underwent a complete reline of the index AFX devices, which resolved the endoleak. Pt. 144-004 was reported to have a Type Ib during the index procedure. The subject did not immediately undergo a re-intervention. Pt. 144-004 was implanted with a right iliac limb extension 1-Year after the index procedure, which was reported to have corrected the Type Ib Endoleak.
- Pts. 128-005 and 113-007 were implanted with an anatomically-fixated graft (AFX/AFX2 with DURAPLY). No pre-op CT was provided for either subject; therefore, Endologix was unable to confirm whether the subjects met the eligibility requirements in the IFU. At 336-days post-op, Pt. 128-005 presented with a Type Ib Endoleak. No secondary intervention was performed. At 160-days post-op, Pt. 113-007 presented with a Type Ib Endoleak and subsequently underwent a re-intervention.
- Pt. 127-005 was implanted with a proximally-fixated graft (Comparator). The subject was considered on-label per the neck requirements in the IFU. At 196-days post-op, the subject presented with a Type Ib Endoleak and subsequently underwent a re-intervention.
- Pts. 119-030 and 121-001 were implanted with a proximally-fixated graft (Comparator). No pre-op CT was provided for either subject; therefore, Endologix was unable to confirm whether the subjects met the eligibility requirements in the IFU. At 360-days post-op, Pt. 119-030 presented with a Type Ib Endoleak. No secondary intervention was performed. At 27-days post-op, Pt. 121-001 presented with a Type Ib Endoleak and subsequently underwent a re-intervention.

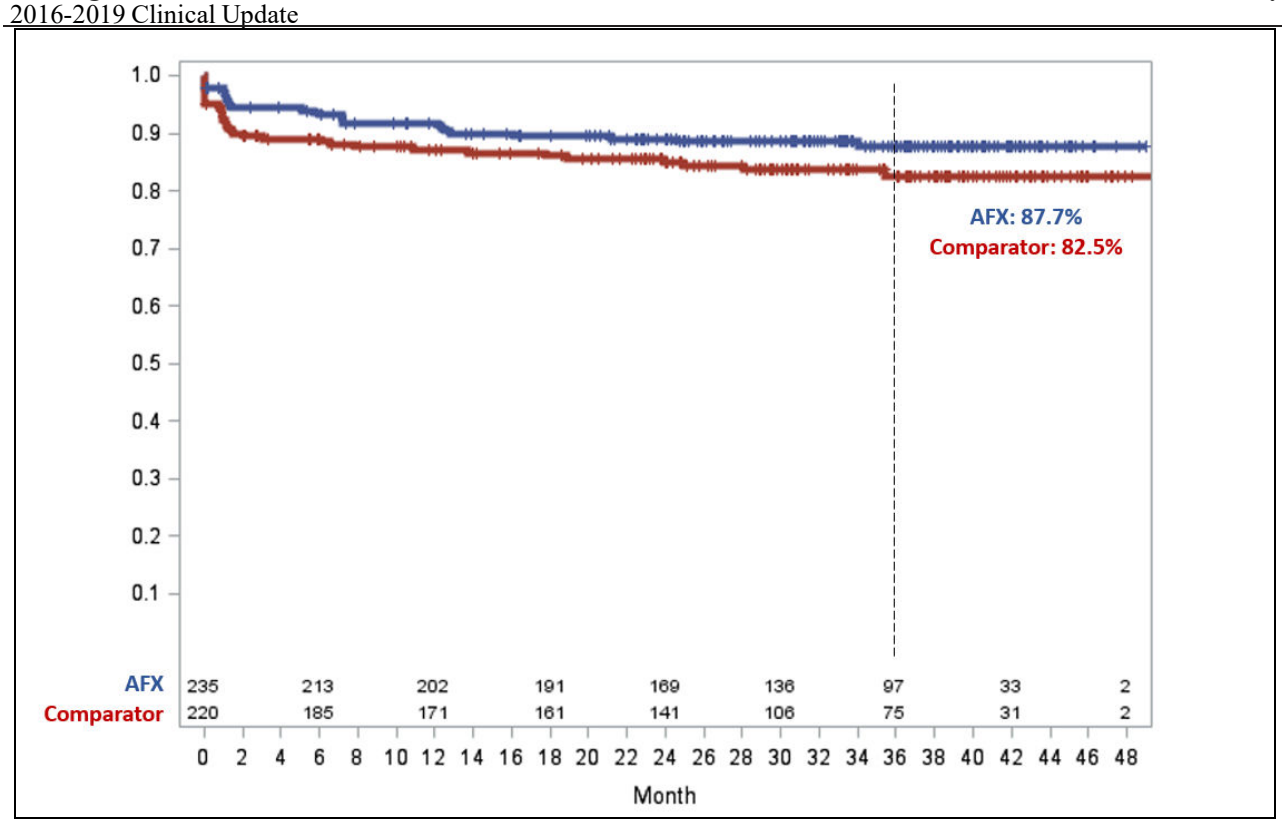

Figure 16. Freedom from Type II Endoleak, LEOPARD Trial

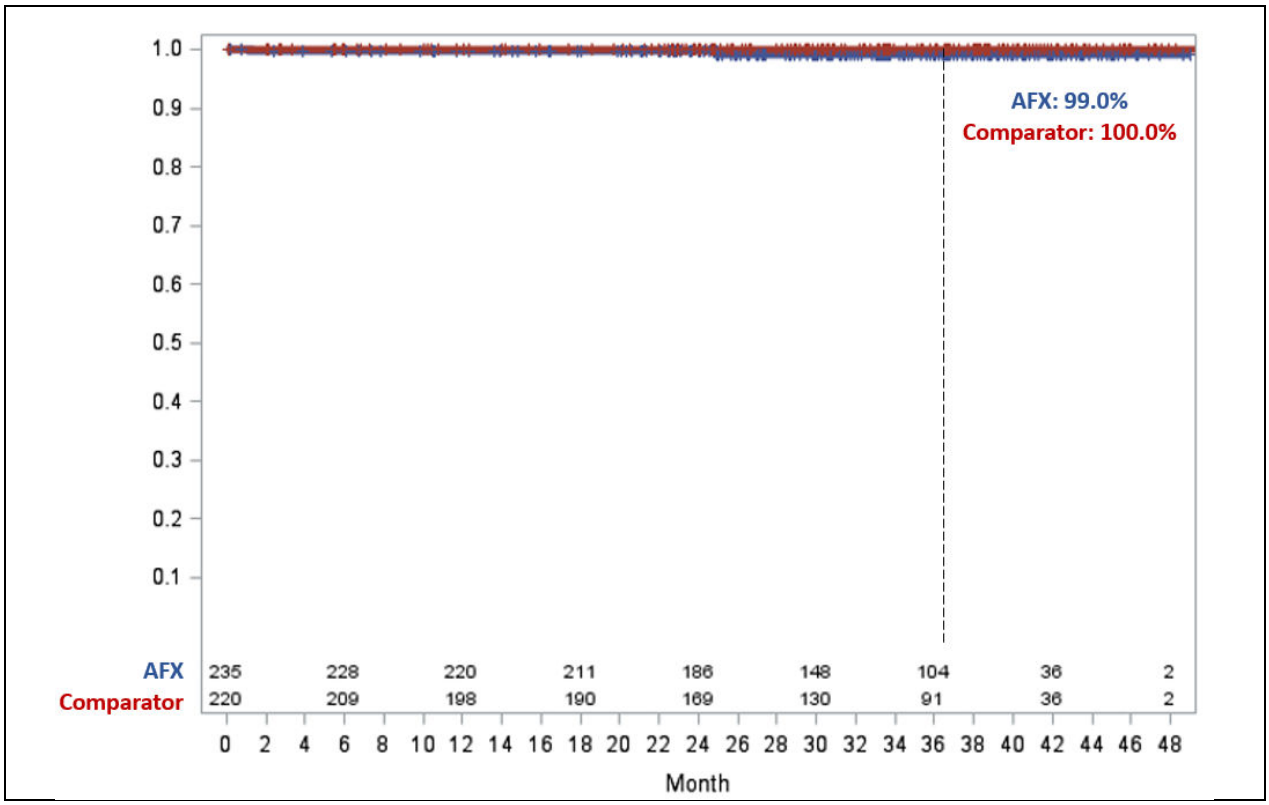

Figure 17. Freedom from Type III Endoleak, LEOPARD Trial

As of the May 2019 data cut, one (1) Type IIIa Endoleak has been reported in the anatomically-fixated group and zero (0) Type IIIa Endoleaks have been reported in the proximally-fixated group:

- Pt. 100-019 was implanted with an anatomically-fixated graft (AFX/AFX2 with DURAPLY). No pre-op CT was provided; therefore, Endologix was unable to confirm whether the subject met the eligibility requirements in the IFU. At 36-days post-op, the subject presented with a Type IIIa Endoleak. No secondary intervention was performed. Endologix cannot confirm a Type IIIa Endoleak from the imaging provided. As no secondary intervention has been performed, this case is under adjudication.

As of the May 2019 data cut, one (1) Type IIIb Endoleak has been reported in the anatomically-fixated group and zero (0) Type IIIb Endoleaks have been reported in the proximally-fixated group. This patient summary was originally presented on page 39 above and is copied below for reference:

- Pt. 105-005 was implanted with an anatomically-fixated graft (AFX/AFX2 with DURAPLY). The subject is considered off-label as they did not meet the minimum neck-length requirements in the IFU (subject had a neck length of 6mm, which failed to meet the minimum requirement of a ≥15mm neck). At 760-days post-op, the subject presented to an outside hospital with an aneurysm rupture. No post-op CT was provided and the outside hospital reported the rupture as being caused by either a Type Ia or Type IIIb endoleak. The subject underwent a secondary intervention with a proximally-fixated device and subsequently withdrew from the trial. The subject was reported to have died on post-op day 760. NOTE: The post-op CT image provided to Endologix is in an unsupported format; therefore, the endoleak type cannot be confirmed at this time. This case is under adjudication.

Rupture

Figure 18 details the Kaplan-Meier estimates of aneurysm rupture for subjects in the LEOPARD Trial. As shown in the data below, the long-term performance of the AFX/AFX2 Bifurcated (with the DURAPLY ePTFE graft) is supported with 99.4% of subjects being free from aneurysm rupture at 3-Years. This is compared to the comparator group results of 100.0%. Additional event summaries are provided in the text that follows.

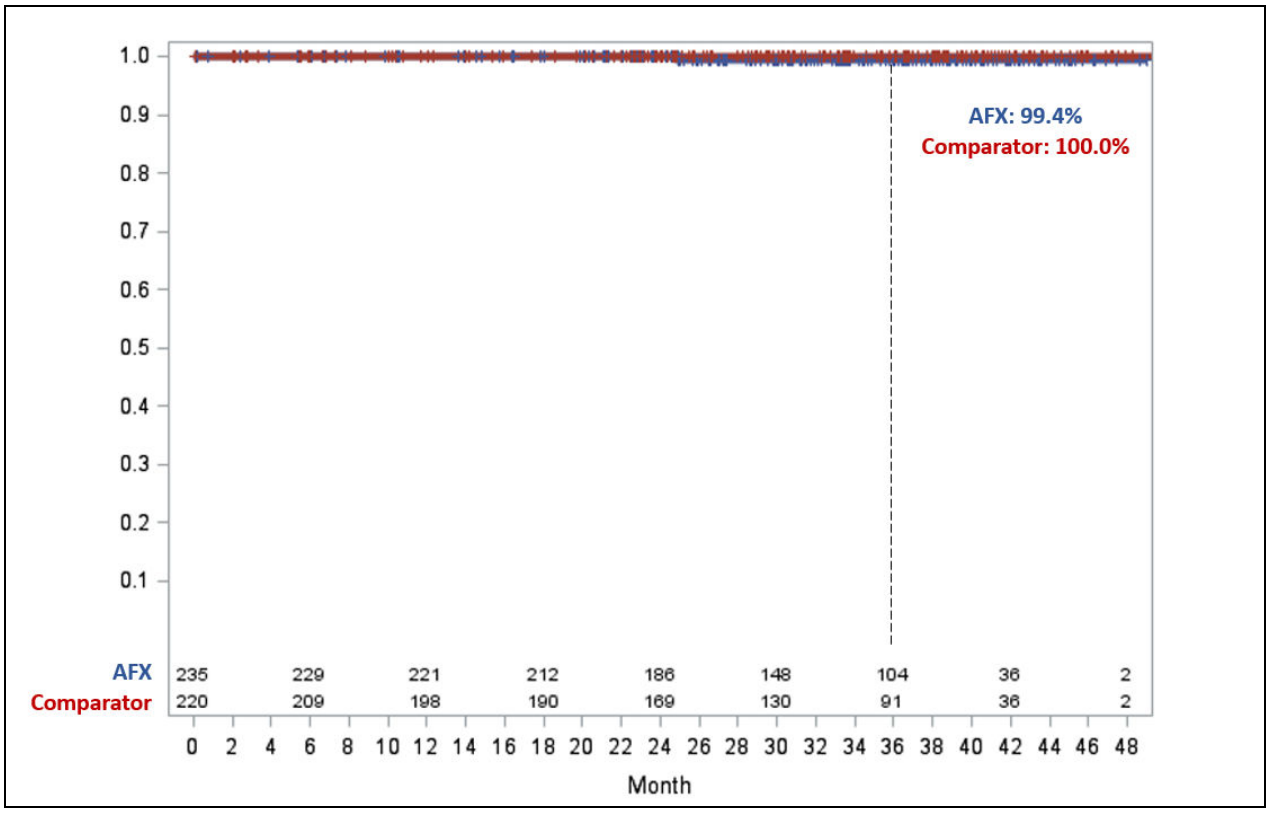

Figure 18. Freedom from Aneurysm Rupture, LEOPARD Trial

As of the May 2019 data cut, one (1) rupture has been reported in the anatomically-fixated group and zero (0) ruptures have been reported in the proximally-fixated group. See page 39 for additional details on Pt. 105-005.

Secondary Interventions

Figure 19 details the Kaplan-Meier estimates of secondary interventions for subjects in the LEOPARD Trial. As shown in the data below, the long-term performance of the AFX/AFX2 Bifurcated (with the DURAPLY ePTFE graft) is supported with 93.2% of subjects being free from secondary interventions at 3-Years. This is compared to the comparator group results of 92.1%. Additional event summaries for any re-interventions related to other ARC events summarized within this Clinical Update are included in the respective sections, as applicable.

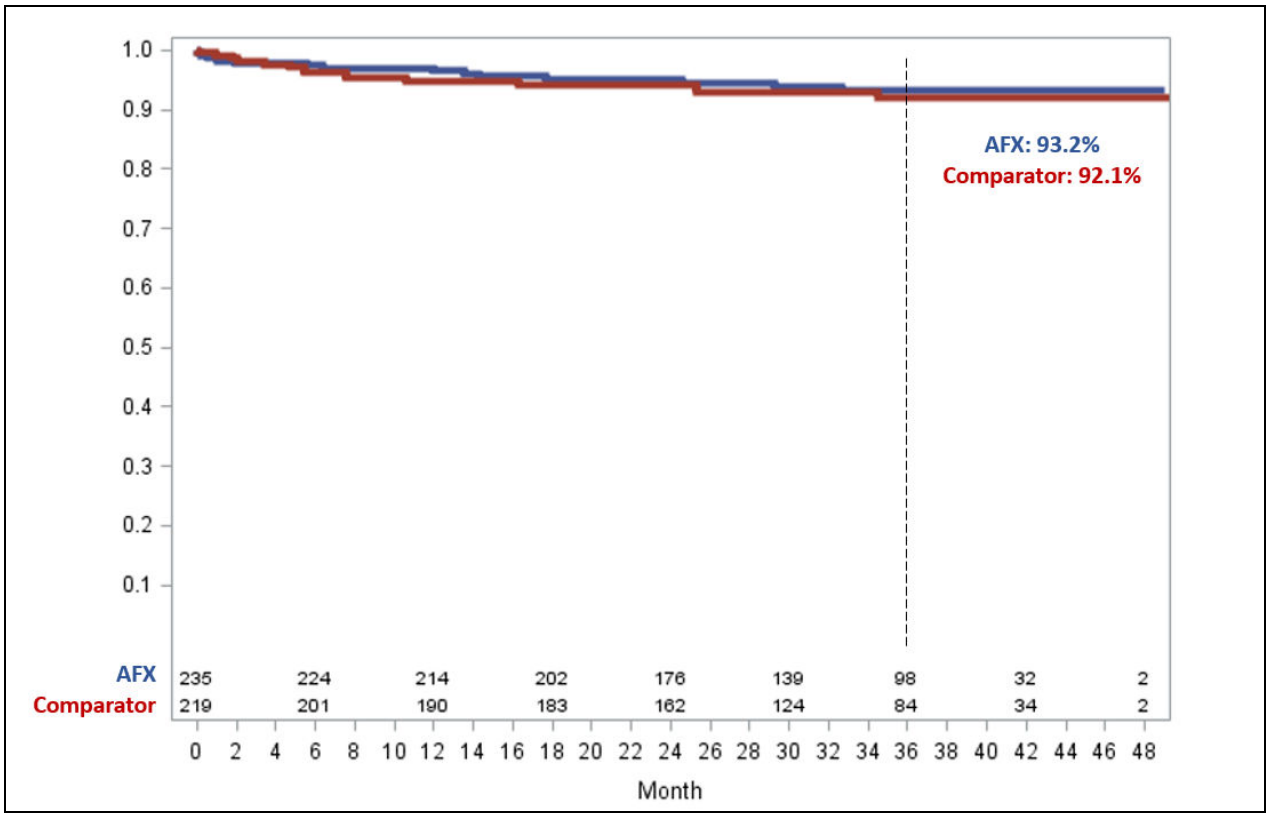

Figure 19. Freedom from Secondary Interventions, LEOPARD Trial

Device Occlusions

Figure 20 details the Kaplan-Meier estimates of device occlusions for subjects in the LEOPARD Trial. As shown in the data below, the long-term performance of the AFX/AFX2 Bifurcated (with the DURAPLY ePTFE graft) is supported with 99.6% of subjects being free from device occlusion at 3-Years. This is compared to the comparator group results of 96.1%. Additional event summaries are provided in the text that follows.

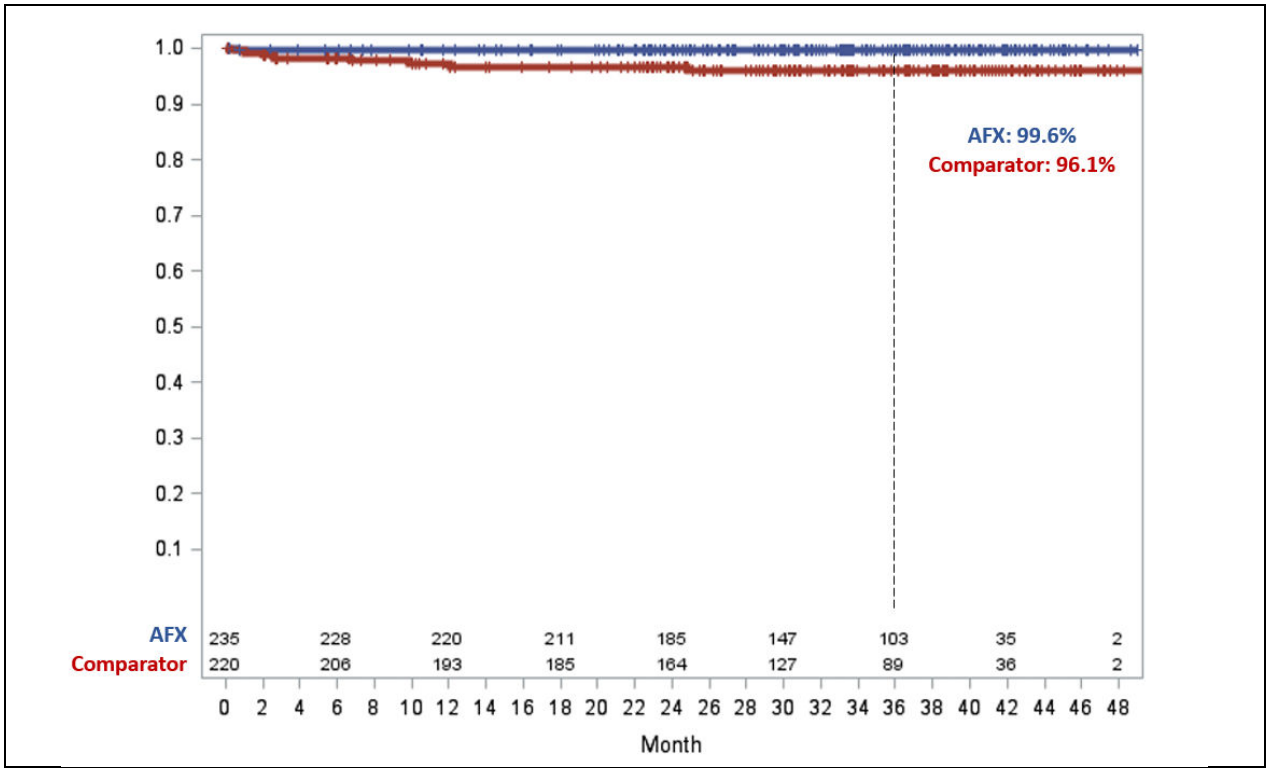

Figure 20. Freedom from Device Occlusions, LEOPARD Trial

As of the May 2019 data cut, one (1) device occlusion has been reported in the anatomically-fixated group and eight (8) device occlusions have been reported in the proximally-fixated group. See page 39 for additional details on Pt. 133-010 and see page 40 for additional details on Pt. 156-005. The other seven (7) event summaries are included below.

- Pt. 126-008 was implanted with an anatomically-fixated graft (AFX/AFX2 with DURAPLY). No pre-op CT was provided; therefore, Endologix was unable to confirm whether the subject met the eligibility requirements in the IFU. At 16-days post-op, the subject presented with a device occlusion and subsequently underwent a re-intervention.
- Pts. 101-006, 115-007, 120-005, and 132-028 were implanted with a proximally-fixated graft (Comparator). These subjects were all considered on-label per the neck requirements in the IFU. During the index procedure, Pt. 101-006 was reported with device occlusion and subsequently underwent re-intervention. At 366-days post-op, Pt. 115-007 was reported with 100% occlusion of the left limb. The thrombotic occlusion had not resolved when the subject returned for follow-up at 709-days post-op. No secondary intervention has been performed. At 5-days post-op, Pt. 120-005 was reported with device occlusion. No secondary intervention was performed. At 205-days post-op, Pt. 132-028 was reported with device occlusion and subsequently underwent re-intervention.
- Pt. 129-001 was implanted with a proximally-fixated graft (Comparator). The subject is considered off-label as they did not meet the minimum neck-length requirements in the IFU. At 757-days post-op, the subject was reported with device occlusion and subsequently underwent re-intervention.

- Pt. 119-015 was implanted with a proximally-fixated graft (Comparator). No pre-op CT was provided; therefore, Endologix was unable to confirm whether the subject met the eligibility requirements in the Medtronic IFU. At 32-days post-op, the subject was reported with device occlusion and subsequently underwent re-intervention.

Discussion and Conclusions: Leopard Trial

Endologix initiated the LEOPARD Trial in 2015 in order to collect Level I clinical evidence on the AFX/AFX2 Bifurcated devices with the DURAPLY ePTFE graft in direct contemporaneous comparison with other commercially-available EVAR devices, using the methodology of a randomized controlled clinical trial. A total of 455 subjects were enrolled in the LEOPARD Trial (with 124 AFX with DURAPLY, 111 AFX2, and 220 comparator grafts). As of this clinical update, all subjects have reached the 1-Year primary endpoint and there are more than 100 subjects in the AFX/AFX2 cohort out to 36 months. Freedom from ARC is similar between the AFX/AFX2 Bifurcated devices to 36 months. Specifically, the data show 82.6% of AFX/AFX2 subjects are free from ARC at 3-Years (inclusive of Type II endoleaks) and 91.6% of AFX/AFX2 subjects being free from ARC at 3-Years (exclusive of Type II endoleaks). This is compared to the comparator group results of 79.8% and 89.7%, respectively. Based on these outcomes, the LEOPARD Trial data provide objective, directly comparative, clinical evidence that the performance of the AFX/AFX2 Bifurcated devices with the DURAPLY ePTFE graft perform at an equivalent level to contemporary EVAR devices in terms of relevant patient outcomes out to 36 months.

SECTION 3: Commercial Experience

Endologix maintains an active customer experience reporting system to collect, evaluate, and report complaints and adverse events in compliance with US and international requirements. This section details the commercial experience for the AFX System. Information on the worldwide commercial experience with the Powerlink System is presented separately in **Appendix A**. The information on the Powerlink System devices continues to be relevant with respect to reliance on anatomical stabilization rather than proximal fixation. Other attributes of this earlier generation device have limited applicability to the more contemporary device designs.

The information in this section is stratified by the different graft variations/iterations of the AFX System that have been commercialized under P040002 (AFX with STRATA, AFX with DURAPLY, and AFX2)[3]. The AFX System is currently only commercialized with the DURAPLY graft, which includes both AFX and AFX2. As outlined in Section 4 (page 42), the AFX System with STRATA was discontinued in 2015 (and recalled in 2016). Similar to the Powerlink System devices, the commercial experience data for the STRATA ePTFE graft continues to be relevant with respect to reliance on anatomical stabilization rather than proximal fixation; however, other attributes of this earlier generation device limit the applicability to the more contemporary device designs.

Additionally, Endologix discontinued sales of the AFX with DURAPLY bifurcated device in the US and in some other markets across the globe following the full product roll-out of the AFX2 Bifurcated device. NOTE: Endologix currently maintains approval for the AFX with DURAPLY bifurcated device, despite discontinuing sales in the US, as this iteration is still distributed in some regions of the globe where the AFX2 Bifurcated device is pending regulatory approval.

Market Status and Approvals

In addition to the US, the AFX System is currently commercialized in the EU and in other parts of the world. **Table 23** illustrates the marketing approvals for the bifurcated systems for each of the ePTFE graft variations/iterations described above (page 8) which were ultimately commercialized. Accessory endograft systems, including AFX Vela, are registered on a country-by-country basis in regions with approval of one or more of the bifurcated systems. Not all model numbers are registered in the regions listed.

Table 23. AFX System Market Approvals (August 2011 – March 2019)

Region or Country	AFX Bifurcated		AFX2 Bifurcated
	STRATA	DURAPLY	
United States	May 2011	June 2014	October 2015
EU (CE Mark)	November 2011	August 2014	November 2015
Rest Of World (ROW)			
Argentina	May 2012		February 2017
Australia	--	May 2014	December 2016
Brazil	July 2012		--
Chile*	N/A	N/A	N/A
Colombia	September 2012		April 2016
Ecuador	October 2014		--
El Salvador	--	--	November 2017
Hong Kong	--	--	March 2017
Japan	--	December 2015	February 2017
Malaysia †	--	--	December 2017
Mexico Ø	October 2012		--
New Zealand	October 2014	--	July 2016
Panama	June 2013	May 2017	--
Peru ø	May 2015		--
Philippines	--	--	June 2017

[3] NOTE: Complaint data is reported based on "Original Closed Date."

Table 23. AFX System Market Approvals (August 2011 – March 2019)

Region or Country	AFX Bifurcated		AFX2 Bifurcated
	STRATA	DURAPLY	
Singapore †	--	N/A	N/A
South Korea	--	--	March 2017
Thailand	--	--	October 2016

*Chile has no in-country regulatory approval requirements.
†Singapore does not have the AFX System commercially approved; however, submissions currently being reviewed and units are being distributed per in-country allowances. ᴼAFX Bifurcated is no longer approved in Mexico or Peru.

Devices Sold Worldwide

Table 24 provides a summary of the AFX System devices sold worldwide for each of the ePTFE graft variations/iterations described above (page 8). NOTE: Despite earlier regulatory approvals, AFX with STRATA was first commercialized in August 2011, AFX with DURAPLY was first commercialized in July 2014 and AFX2 was first commercialized in February 2016.

Table 24. Devices Sold ¥ Worldwide

Product Type	AFX System with STRATA (Aug. 1, 2011 – May 31, 2016*)				AFX/AFX2 with DURAPLY± AFX: (July 1, 2014 – March 31, 2019) AFX2: (Feb. 1, 2016 – March 31, 2019)			
	US	EU	ROWα	Total	US	EU	ROWα	Total
Bifurcated	**18,920**	**3,021**	**2,568**	**24,515≠**	**25,319** *(11,611 AFX) (13,708 AFX2)*	**5,817** *(3,170 AFX) (2,647 AFX2)*	**13,874** *(7,483 AFX) (6,391 AFX2)*	**45,010** *(22,264 AFX) (22,746 AFX2)*
Extensions	**27,818**	**4,114**	**4,186**	**36,118**	**27,526**	**5,385**	**14,510**	**47,421**
Proximal Extensions	20,655	3,113	2,953	26,721	22,027	4,349	10,787	37,163
Infrarenal Extensions	*6,882*	*1,252*	*423*	*8,557*	*4,429*	*2,181*	*3,048*	*9,658*
Suprarenal Extensions	*13,773*	*1,861*	*2,530*	*18,164*	*17,598*	*2,168*	*7,739*	*27,505*
Limb Extensions	7,163	1,001	1,233	9,397	5,499	1,036	3,723	10,258

¥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.
± The AFX System (bifurcated device and endograft extensions) consists of two separate bifurcated endograft systems: AFX Bifurcated and AFX2 Bifurcated. These endograft systems consist of identical implantable stent grafts, which are manufactured in various diameters and lengths in a unibody bifurcated design. Because the stent grafts are identical, the DURAPLY data is presented as a total of both the AFX Bifurcated and AFX2 Bifurcated device. This shows the overall data for the DURAPLY ePTFE graft. However, as noted in §4, specific manufacturing changes and IFU updates were implemented during development of the AFX2 Bifurcated device. Additionally, the commercialization of AFX2 also aligns with the increase in the average graft thickness as noted above. For this reason, the data is also presented to show the difference between the two bifurcated systems.
≠There were six (6) STRATA bifurcated implants for which a region is not known.
** Distribution of the AFX System with STRATA ceased globally in May 2016.*
α ROW is defined as "Rest of World".

Reported Adverse Events (Lifetime)

Table 25 and **Table 26** summarize adverse events reported for the AFX System device iterations from its commercial release through March 31, 2019. **Table 27** and **Table 28** summarize adverse events reported for the AFX System device iterations during the most recent four reporting periods.

Table 25. Summary of Performance (Worldwide Data, Cumulative) – AFX System Bifurcated Devices

Event Type (August 2011 – March 2019)	AFX with STRATA			AFX with DURAPLY			AFX2		
	US	EU	ROW[α]	US	EU	ROW[α]	US	EU	ROW[α]
Aneurysm-Related Mortality	59	3	2	23	4	1	19	-	3
Aneurysm Rupture (post-implant)	132	6	2	39	2	4	19	-	3
Surgical Conversion	174	18	4	52	6	8	25	-	3
Device Migration	57	-	-	8	-	-	1	-	-
Type IIIa Endoleak	265	16	-	63	5	5	23	-	2
Type IIIb Endoleak	597	30	3	95	4	4	30	-	7
Other Stent Graft Integrity Events*	119	2	1	46	4	5	52	3	3
Total Complaints‡	**913**	**51**	**6**	**213**	**15**	**21**	**121**	**3**	**17**

‡Represents total number of complaints reported for those adverse events listed. Multiple event types (harm and device) may be attributed to each complaint
[α] ROW is defined as "Rest of World".
*Other Stent Graft Integrity Events are defined as device buckling/kinking, device fracture, device occlusion, and stent graft patency.

Table 26. Summary of Performance (Worldwide Data, Cumulative) – AFX System Extension Devices

Event Type (August 2011 – March 2019)	STRATA			DURAPLY			UNKNOWN GRAFT TYPE[×]		
	US	EU	ROW[α]	US	EU	ROW[α]	US	EU	ROW[α]
Aneurysm-Related Mortality	37	4	-	12	-	1	3	1	-
Aneurysm Rupture (post-implant)	76	3	-	26	-	1	7	1	-
Surgical Conversion	81	6	-	30	1	1	5	5	-
Device Migration	73	5	-	34	2	-	-	1	-
Type IIIa Endoleak	268	11	2	18	2	2	1	12	4
Type IIIb Endoleak	130	16	1	12	-	1	20	5	1
Other Stent Graft Integrity Events*	84	6	-	35	3	10	2	2	1
Total Complaints‡	**484**	**31**	**2**	**102**	**5**	**14**	**36**	**13**	**2**

‡ Represents total number of complaints reported for those adverse events listed. Multiple event types (harm and device) may be attributed to each complaint
[α] ROW is defined as "Rest of World".
*Other Stent Graft Integrity Events are defined as device buckling/kinking, device fracture, device occlusion, and stent graft patency.
[×] "Unknown Graft Type" is listed for any event in which the graft type could not be identified due to insufficient medical records.

Table 27. Summary of Performance (Worldwide Data, by Reporting Period) – AFX System Bifurcated Devices

Event Type	AFX with STRATA	AFX with DURAPLY	AFX2
2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016			
Aneurysm-Related Mortality	10	12	2
Aneurysm Rupture (post-implant)	20	6	1
Surgical Conversion	51	19	6
Device Migration	10	2	-
Type IIIa Endoleak	62	10	-
Type IIIb Endoleak	101	12	-
Other Stent Graft Integrity Events*	3	5	2
2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017			
Aneurysm-Related Mortality	11	4	7
Aneurysm Rupture (post-implant)	29	10	3
Surgical Conversion	43	12	9
Device Migration	13	2	1
Type IIIa Endoleak	75	15	4
Type IIIb Endoleak	145	24	3
Other Stent Graft Integrity Events*	8	5	6
2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018			
Aneurysm-Related Mortality	8	3	3
Aneurysm Rupture (post-implant)	14	6	1
Surgical Conversion	14	12	1
Device Migration	9	2	-
Type IIIa Endoleak	29	12	1
Type IIIb Endoleak	74	16	3
Other Stent Graft Integrity Events*	5	4	7
2019 Reporting Period: Apr. 1, 2018 –Mar. 31, 2019			
Aneurysm-Related Mortality	6	5	10
Aneurysm Rupture (post-implant)	19	14	16
Surgical Conversion	25	13	12
Device Migration	16	2	-
Type IIIa Endoleak	87	34	20
Type IIIb Endoleak	203	42	31
Other Stent Graft Integrity Events*	15	9	27

‡Multiple event types (harm and device) may be attributed to each complaint
*Other Stent Graft Integrity Events are defined as device buckling/kinking, device fracture, device occlusion, and stent graft patency.

Table 28. Summary of Performance (Worldwide Data, by Reporting Period) – AFX System Extension Devices

Event Type	STRATA	DURAPLY	UNKNOWN GRAFT TYPE×
2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016			
Aneurysm-Related Mortality	3	2	-
Aneurysm Rupture (post-implant)	9	3	-
Surgical Conversion	16	9	2
Device Migration	14	5	1
Type IIIa Endoleak	37	6	7
Type IIIb Endoleak	21	2	5
Other Stent Graft Integrity Events*	1	2	-
2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017			
Aneurysm-Related Mortality	5	3	1
Aneurysm Rupture (post-implant)	11	7	1
Surgical Conversion	11	8	3
Device Migration	12	7	-
Type IIIa Endoleak	19	4	1
Type IIIb Endoleak	40	2	5
Other Stent Graft Integrity Events*	5	-	-
2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018			
Aneurysm-Related Mortality	2	2	1
Aneurysm Rupture (post-implant)	3	5	1
Surgical Conversion	6	3	1
Device Migration	11	5	-
Type IIIa Endoleak	15	1	-
Type IIIb Endoleak	16	4	3
Other Stent Graft Integrity Events*	1	6	-
2019 Reporting Period: Apr. 1, 2018 –Mar. 31, 2019			
Aneurysm-Related Mortality	1	3	2
Aneurysm Rupture (post-implant)	8	7	6
Surgical Conversion	3	4	4
Device Migration	8	15	-
Type IIIa Endoleak	20	8	9
Type IIIb Endoleak	40	4	13
Other Stent Graft Integrity Events*	10	13	3

‡Multiple event types (harm and device) may be attributed to each complaint
*Other Stent Graft Integrity Events are defined as device buckling/kinking, device fracture, device occlusion, and stent graft patency.
× "Unknown Graft Type" is listed for any event in which the graft type could not be identified due to insufficient medical records.

Commercial Experience Data Summary

Aneurysm-Related Mortality

Fifty-six (56) aneurysm-related deaths have been reported worldwide in patients treated with the DURAPLY ePTFE grafts (AFX Bifurcated with DURAPLY, AFX2 Bifurcated, and the AFX DURAPLY extensions) between November 1, 2015 and March 31, 2019. Over this same time period, forty-six (46) aneurysm-related deaths have been reported worldwide in patients treated with the STRATA ePTFE grafts (AFX Bifurcated with STRATA and the AFX STRATA extensions). An additional four (4) aneurysm-related deaths related to AFX System extensions have been reported worldwide during this same time period, for which the ePTFE graft type is unknown.

As outlined in **Table 29** and **Table 30** below, the majority of aneurysm-related deaths involved patients that had procedural and/or peri-operative complications as well as patients whose devices were implanted outside of the IFU recommendations or requirements. It is important to highlight that this non-recommended use was found to lead to secondary events that resulted in an aneurysm-related death. As with all EVAR devices, it is important to adhere to the approved instructions for use. Please refer to Section 6 (page 87) for patient and device selection recommendations. Of those aneurysm-related deaths for which adequate information was received to determine a cause, only nine (9) and fourteen (14) events resulted from aneurysm rupture for the DURAPLY and STRATA ePTFE grafts, respectively, during the 3.5-year period.

Table 29. Primary Causes of Aneurysm-Related Mortality – AFX System Bifurcated Devices

Cause of Aneurysm-Related Mortality‡µ	AFX with STRATA	AFX with DURAPLY	AFX2
2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016			
Procedural and/or Peri-Operative Complications	10	9	1
Abnormal Blood Loss	*3*	*2*	-
Conversion to Open Repair (EVAR Attempted)	*2*	*1*	-
Conversion to Open Repair (EVAR Not Attempted)	*1*	*1*	-
Intraoperative	*1*	-	*1*
Procedure-Related (Post-Op, ≤30 days)	*3*	*5*	-
Usage Outside of IFU Recommendations/Requirements	2	2	2
Cautionary Product Use	*1*	*1*	*1*
Off-IFU	*1*	*1*	*1*
Pre-Existing Conditions	1	-	1
Rupture	2	2	-
Indeterminate	3	2	1
2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017			
Procedural and/or Peri-Operative Complications	10	3	1
Abnormal Blood Loss	*1*	*1*	-
Conversion to Open Repair (EVAR Attempted)	*2*	-	*1*
Intraoperative	*3*	*1*	-
Procedure-Related (Post-Op, ≤30 days)	*4*	*1*	-
Usage Outside of IFU Recommendations/Requirements	4	1	6
Cautionary Product Use	*2*	*1*	*3*
Off-IFU	*2*	-	*3*
Pre-Existing Conditions	-	-	1
Rupture	5	1	-
Indeterminate	2	3	3
2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018			
Procedural and/or Peri-Operative Complications	5	1	2
Conversion to Open Repair (EVAR Not Attempted)	*2*	-	-
Intraoperative	*2*	*1*	*1*
Procedure-Related (Post-Op, ≤30 days)	*1*	-	*1*
Usage Outside of IFU Recommendations/Requirements	-	1	1
Off-IFU	-	*1*	*1*
Rupture	2	1	-
Indeterminate	1	1	-
2019 Reporting Period: Apr. 1, 2018 –Mar. 31, 2019			
Procedural and/or Peri-Operative Complications	5	-	4
Abnormal Blood Loss	-	-	*1*
Conversion to Open Repair (EVAR Attempted)	*1*	-	-
Intraoperative	*2*	-	*1*
Perforation	*1*	-	-
Procedure-Related (Peri-Operative)	*1*	-	*2*
Usage Outside of IFU Recommendations/Requirements	-	-	3
Off-IFU	-	-	*3*
Rupture	2	1	-
Indeterminate	3	4	3
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**35**	**24**	**22**

‡19 complaints had multiple causative types attributed to a given event.

µ "Cautionary Product Use" is defined as non-recommended product usage that is warned or cautioned against in the IFU. "Off-IFU" is defined as product usage against the product indications or contraindications in the IFU. "Indeterminate" is defined as an event for which the failure and/or cause could not be confirmed due to insufficient imaging or medical records.

Table 30. Primary Causes of Aneurysm-Related Mortality – AFX System Extension Devices

Cause of Aneurysm-Related Mortality‡µ	STRATA	DURAPLY	UNKNOWN GRAFT TYPE×
2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016			
Procedural and/or Peri-Operative Complications	2	4	-
Abnormal Blood Loss	-	*1*	-
Conversion to Open Repair (EVAR Attempted)	-	*1*	-
Intraoperative	-	*1*	-
Procedure-Related (Peri-Operative)	*2*	*1*	-
Usage Outside of IFU Recommendations/Requirements	-	1	-
Off-IFU	-	*1*	-
Rupture	1	1	-
2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017			
Procedural and/or Peri-Operative Complications	4	1	-
Abnormal Blood Loss	*1*	-	-
Conversion to Open Repair (EVAR Attempted)	-	*1*	-
Perforation	*1*	-	-
Procedure-Related (Peri-Operative)	*2*	-	-
Usage Outside of IFU Recommendations/Requirements	3	4	-
Cautionary Product Use	*1*	*2*	-
Off-IFU	*2*	*2*	-
Pre-Existing Conditions	1	1	-
Rupture	2	1	-
Indeterminate	-	-	1
2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018			
Procedural and/or Peri-Operative Complications	2	-	-
Procedure-Related (Peri-Operative)	*2*	-	-
Rupture	-	2	-
Indeterminate	-	-	1
2019 Reporting Period: Apr. 1, 2018 –Mar. 31, 2019			
Procedural and/or Peri-Operative Complications	1	2	2
Abnormal Blood Loss	*1*	-	-
Intraoperative	-	-	*1*
Procedure-Related (Peri-Operative)	-	*2*	*1*
Indeterminate	-	1	1
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**11**	**10**	**4**

‡6 complaints had multiple causative types attributed to a given event.

µ "Cautionary Product Use" is defined as non-recommended product usage that is warned or cautioned against in the IFU. "Off-IFU" is defined as product usage against the product indications or contraindications in the IFU. "Indeterminate" is defined as an event for which the failure and/or cause could not be confirmed due to insufficient imaging or medical records.

× "Unknown Graft Type" is listed for any event in which the graft type could not be identified due to insufficient medical records.

Aneurysm Rupture (post-implant)

Seventy-nine (79) aneurysm ruptures have been reported worldwide in patients treated with the DURAPLY ePTFE grafts (AFX Bifurcated with DURAPLY, AFX2 Bifurcated, and the AFX DURAPLY extensions) between November 1, 2015 and March 31, 2019. Over this same time period, one-hundred and thirteen (113) aneurysm ruptures have been reported worldwide in patients treated with the STRATA ePTFE grafts (AFX Bifurcated with STRATA and the AFX STRATA extensions). An additional eight (8) aneurysm ruptures related to AFX System extensions have been reported worldwide during this same time period, for which the ePTFE graft type is unknown.

As outlined in **Table 31** and **Table 32** below, the majority of aneurysm ruptures for both the DURAPLY and STRATA ePTFE grafts involved patients whose devices were implanted outside of the IFU recommendations/requirements and this non-recommended use was found to lead to secondary events that resulted in rupture. As with all EVAR devices, it is important to adhere to the approved instructions for use. Please refer to Section 6 (page 87) for patient and device selection recommendations.

Other than usage outside of the IFU recommendations/requirements, the leading causative event for ruptures with the STRATA ePTFE grafts were patients that experienced a Type IIIa or Type IIIb endoleak. Of those aneurysm ruptures for which adequate information was received to determine a cause, there were forty-eight (48) and thirty-five (35) rupture events that resulted from a Type IIIb and Type IIIa endoleak, respectively, during the 3.5-year period. As outlined in Section 4 (page 79), Type III endoleaks are a known failure mode of the now-discontinued STRATA ePTFE material. This failure mode ultimately resulted in the removal of all STRATA devices from the field in December 2016. Refer to page 81 for recommendations regarding Type III endoleaks and Section 7 (page 90) for patient tailored surveillance recommendations for patients implanted with a STRATA ePTFE graft.

The leading causative event for ruptures with the DURAPLY ePTFE graft (other than usage outside of the IFU recommendations/requirements) were Type IIIa endoleaks, with eleven (11) total events reported during the 3.5-year period. As outlined in Section 4 (page 79), Type IIIa endoleaks were an early failure mode of the AFX System of devices due to inadequate overlap instructions in the IFU. The Instructions for Use were updated in June 2015 to provide oversizing and patient selection recommendations, which was approximately one year after DURAPLY was first commercialized. Available data out to 54 months, inclusive of LEOPARD data that has more than 100 subjects out to 36 months, suggests that this IFU update has been effective at reducing the occurrence of Type IIIa endoleaks. Endologix is continuing to monitor the Type III endoleak rates for the AFX System and will continue to report out on this data in forthcoming Clinical Updates.

Further, data provided in the table below shows that all rupture events caused by Type IIIa endoleaks have been reported on the AFX Bifurcated device and its extensions. There were no ruptures caused by a Type IIIa endoleak for the AFX2 Bifurcated device during the reporting period, which had incorporated these updated instructions prior to commercialization in February 2016. This also suggests that the IFU updates have been effective at reducing the occurrence of Type IIIa endoleaks. Endologix is continuing to monitor the Type III endoleak rates for the AFX System and will continue to report out on this data in forthcoming Clinical Updates.

Table 31. Primary Causes of Post-Implant Aneurysm Rupture – AFX System Bifurcated Devices

Cause of Aneurysm Rupture‡µ*	AFX with STRATA	AFX with DURAPLY	AFX2
2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016			
Endoleak Type Ia	3	1	-
Endoleak Type II	1	-	-
Endoleak Type IIIa	6	-	-
Endoleak Type IIIb	8	1	-
Endoleak (Indeterminate Origin)	-	1	-
Migration	2	-	-
Usage Outside of IFU Recommendations/Requirements	14	3	-
Cautionary Product Use	*5*	*1*	-
Off-IFU	*9*	*2*	-
Indeterminate	3	1	1
2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017			
Endoleak Type Ia	6	1	-
Endoleak Type Ib	2	1	-
Endoleak Type II	4	1	-
Endoleak Type IIIa	8	3	-
Endoleak Type IIIb	18	1	-
Endoleak (Indeterminate Origin)	2	-	-
Kinking	-	1	-
Migration	1	-	-
Usage Outside of IFU Recommendations/Requirements	24	2	2
Cautionary Product Use	*9*	-	*1*
Off-IFU	*15*	*2*	*1*
Indeterminate	2	4	1
2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018			
Endoleak Type Ia	1	-	-
Endoleak Type II	1	1	-
Endoleak Type IIIa	2	3	-
Endoleak Type IIIb	6	1	-
Endoleak (Indeterminate Origin)	1	-	-
Usage Outside of IFU Recommendations/Requirements	-	1	1
Off-IFU	-	*1*	*1*
Indeterminate	3	-	-
2019 Reporting Period: Apr. 1, 2018 –Mar. 31, 2019			
Endoleak Type Ia	1	-	-
Endoleak Type Ib	1	-	-
Endoleak Type II	1	-	-
Endoleak Type IIIa	6	2	-
Endoleak Type IIIb	9	3	1
Kinking	1	-	-
Migration	1	-	-
Usage Outside of IFU Recommendations/Requirements	5	-	5
Cautionary Product Use	*1*	-	*1*
Off-IFU	*4*	-	*4*
Indeterminate	6	8	10
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**82**	**36**	**21**

‡39 complaints had multiple causative types attributed to a given event.

µ "Cautionary Product Use" is defined as non-recommended product usage that is warned or cautioned against in the IFU. "Off-IFU" is defined as product usage against the product indications or contraindications in the IFU. "Indeterminate" is defined as an event for which the failure and/or cause could not be confirmed due to insufficient imaging or medical records.

**Aneurysm Sac Enlargement is not included as a causative event if the sac growth was attributed to an endoleak.*

Table 32. Primary Causes of Post-Implant Aneurysm Rupture – AFX System Extension Devices

Cause of Aneurysm Rupture‡µ*	STRATA	DURAPLY	UNKNOWN GRAFT TYPE×
2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016			
Endoleak Type Ia	-	1	-
Endoleak Type Ib	1	-	-
Endoleak Type II	2	-	-
Endoleak Type IIIa	6	1	-
Usage Outside of IFU Recommendations/Requirements	5	1	-
Cautionary Product Use	*2*	-	-
Off-IFU	*3*	*1*	-
2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017			
Endoleak Type Ia	3	1	-
Endoleak Type Ib	1	-	-
Endoleak Type II	1	1	-
Endoleak Type IIIa	5	1	-
Endoleak Type IIIb	1	-	-
Migration	1	-	-
Usage Outside of IFU Recommendations/Requirements	8	5	-
Cautionary Product Use	*3*	*1*	-
Off-IFU	*5*	*4*	-
Indeterminate	-	1	1
2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018			
Endoleak Type Ia	-	3	-
Endoleak Type IIIb	1	-	-
Usage Outside of IFU Recommendations/Requirements	1	2	-
Off-IFU	*1*	*2*	-
Indeterminate	1	-	1
2019 Reporting Period: Apr. 1, 2018 –Mar. 31, 2019			
Endoleak Type Ia	2	1	-
Endoleak Type IIIa	2	1	1
Endoleak Type IIIb	5	1	-
Migration	1	1	-
Usage Outside of IFU Recommendations/Requirements	1	1	-
Off-IFU	*1*	*1*	-
Indeterminate	-	3	5
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**31**	**22**	**8**

‡12 complaints had multiple causative types attributed to a given event.

µ "Cautionary Product Use" is defined as non-recommended product usage that is warned or cautioned against in the IFU. "Off-IFU" is defined as product usage against the product indications or contraindications in the IFU. "Indeterminate" is defined as an event for which the failure and/or cause could not be confirmed due to insufficient imaging or medical records.

**Aneurysm Sac Enlargement is not included as a causative event if the sac growth was attributed to an endoleak.*

× "Unknown Graft Type" is listed for any event in which the graft type could not be identified due to insufficient medical records.

As outlined in **Table 33** and **Table 34** below, the time to event for the ruptures reported between November 1, 2015 and March 31, 2019 trends differently for each of the different device types:

As noted above, the leading causative event for ruptures with the STRATA ePTFE grafts were patients that experienced a Type IIIa or Type IIIb endoleak. The majority of these ruptures occurred between 3- to 5-Years post-implantation. Again, please refer to page 81 for recommendations regarding Type III endoleaks and Section 7 (page 90) for patient tailored surveillance recommendations for patients implanted with a STRATA ePTFE graft.

Similarly, as detailed above, the leading causative event for ruptures with the DURAPLY ePTFE graft (other than usage outside of the IFU recommendations/requirements were Type IIIa endoleaks) were Type IIIa endoleaks, with eleven (11) total events reported during the 3.5-year period. The majority of these ruptures occurred between 2- and 3-Years post-implantation. This trend, however, does not carry over to the AFX2 Bifurcated with DURAPLY grafts as there were no reported ruptures caused by a Type IIIa endoleak (which would result in a delayed failure mode). Instead, the majority of AFX2 ruptures reported occurred peri-operatively.

Table 33. Time to Event for Post-Implant Aneurysm Rupture – AFX System Bifurcated Devices

Time to Event for Aneurysm Rupture	AFX with STRATA	AFX with DURAPLY	AFX2
≤30 days	1	5	14
>30 days, ≤6 mo.	0	4	1
>6 mo., ≤1 year	1	1	2
>1 year, ≤2 year	2	7	2
>2 year, ≤3 year	12	13	1
>3 year, ≤4 year	25	5	0
>4 year, ≤5 year	25	0	-
>5 year, ≤6 year	9	-	-
>6 year, ≤7 year	4	-	-
>7 year, ≤8 year	0	-	-
Unknown	3	1	1
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**82**	**36**	**21**

NOTE: Within this table, dashes are used to denote timeframes for which follow-up does not exist, based on product introduction to the market.

Table 34. Time to Event for Post-Implant Aneurysm Rupture – AFX System Extension Devices

Time to Event for Aneurysm Rupture	STRATA	DURAPLY	UNKNOWN GRAFT TYPE
≤30 days	0	5	1
>30 days, ≤6 mo.	0	3	0
>6 mo., ≤1 year	0	2	0
>1 year, ≤2 year	6	5	0
>2 year, ≤3 year	6	6	0
>3 year, ≤4 year	6	1	0
>4 year, ≤5 year	6	0	0
>5 year, ≤6 year	5	-	-
>6 year, ≤7 year	2	-	-
>7 year, ≤8 year	0	-	-
Unknown	0	0	7
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**31**	**22**	**8**

NOTE: Within this table, dashes are used to denote timeframes for which follow-up does not exist, based on product introduction to the market.

Surgical Conversion

One hundred and eight (108) surgical conversions have been reported worldwide in patients treated with the DURAPLY ePTFE grafts (AFX Bifurcated with DURAPLY, AFX2 Bifurcated, and the AFX DURAPLY extensions) between November 1, 2015 and March 31, 2019. Over this same time period, one-hundred and seventy (170) surgical conversions have been reported worldwide in patients treated with the STRATA ePTFE grafts (AFX Bifurcated with STRATA and the AFX STRATA extensions). An additional ten(10) surgical conversions related to AFX System extensions have been reported worldwide during this same time period, for which the ePTFE graft type is unknown.

As outlined in **Table 35** and **Table 36** below, the majority of surgical conversions for both the DURAPLY and STRATA ePTFE grafts were attributed to patients that experienced aneurysm expansion:

Of those aneurysm expansions with the STRATA ePTFE grafts for which adequate information was received to determine a cause, there were forty (40) and sixty-seven (67) aneurysm expansion events that resulted from a Type IIIa and Type IIIb endoleaks, respectively, and resulted in surgical conversion during the 3.5-year period. As outlined in Section 4 (page 79), Type III endoleaks are a known failure mode of the now-discontinued STRATA ePTFE material. These failure modes ultimately resulted in various updates to the IFU since 2013 as well as the removal of all STRATA devices from the field in December 2016. Refer to page 81 for recommendations regarding Type III endoleaks and Section 7 (page 90) for patient tailored surveillance recommendations for patients implanted with a STRATA ePTFE graft.

Of those aneurysm expansions with the DURAPLY ePTFE grafts for which adequate information was received to determine a cause, there were twelve (12) and fourteen (14) aneurysm expansion events that resulted from a Type IIIa and Type IIIb endoleaks, respectively, and resulted in surgical conversion during the 3.5-year period. As outlined in Section 4 (page 79), Type IIIa and Type IIIb endoleaks were an early failure mode of the AFX System of devices due to inadequate overlap instructions in the IFU as well as the Strata ePTFE material which introduced directionality into the ePTFE graft. The Instructions for Use were updated in June 2015 to provide oversizing and patient selection recommendations, which was approximately one year after DURAPLY was first commercialized. Available data out to 54 months, inclusive of LEOPARD data that has more than 100 subjects out to 36 months, suggests that the implementation of the DURAPLY material in conjunction with the IFU Updates have been effective at reducing the occurrence of Type IIIa and Type IIIb endoleaks. Endologix is continuing to monitor the Type III endoleak rates for the AFX System and will continue to report out on this data in forthcoming Clinical Updates.

Further, data provided in the table below shows a low number of surgical conversions resulting from Type IIIa or Type IIIb endoleaks with the DURAPLY graft during the past 3.5-year period, which encompasses the majority of the commercialization of the DURAPLY ePTFE graft. Furthermore, there were zero (0) and two (2) surgical conversions that resulted from a Type IIIa or Type IIIb endoleak, respectively, for the AFX2 Bifurcated device during the reporting period, which encompasses the entire lifetime of the AFX2 Bifurcated device. This also suggests that the implementation of the DURAPLY material in conjunction with the IFU Updates have been effective at reducing the occurrence of Type IIIa and Type IIIb endoleaks. Endologix is continuing to monitor the Type III endoleak rates for the AFX System and will continue to report out on this data in forthcoming Clinical Updates.

As outlined in **Table 35** and **Table 36** below, the second leading cause of surgical conversions for the DURAPLY ePTFE grafts was attributed to patient anatomy and involved patients whose devices were implanted outside of the IFU recommendations/requirements, with forty (40) total surgical conversions during the 3.5-year period. It is important to highlight that 100% of all AFX System subjects in the LEOPARD Trial data (page 34) are free from surgical conversion at 3-Years. As with all EVAR devices, it is important to adhere to the approved instructions for use. Please refer to Section 6 (page 87) for patient and device selection recommendations.

Table 35. Primary Causes of Surgical Conversion – AFX System Bifurcated Devices

Cause of Surgical Conversion[‡µ]	AFX with STRATA	AFX with DURAPLY	AFX2
2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016			
Implantation Difficulties	2	3	1
Patient Anatomy	25	10	5
Cautionary Product Use	*10*	*6*	*1*
Off-IFU	*12*	*4*	*3*
Indeterminate	*3*	-	*1*
Occlusion	6	8	1
Aneurysm Expansion	40	8	2
Endoleak Type Ia	*3*	*1*	-
Endoleak Type Ib	*1*	*1*	-
Endoleak Type II	*2*	*1*	-
Endoleak Type IIIa	*12*	-	-
Endoleak Type IIIb	*15*	*2*	-
Endoleak (Indeterminate Origin)	*4*	*2*	-
Indeterminate	*3*	*1*	*2*
User Error	4	2	1
2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017			
Implantation Difficulties	1	3	3
Patient Anatomy	15	8	8
Cautionary Product Use	*3*	*3*	*4*
Off-IFU	*8*	*3*	*4*
Indeterminate	*4*	*2*	-
Occlusion	4	2	3
Aneurysm Expansion	46	6	1
Endoleak Type Ia	*5*	-	-
Endoleak Type Ib	*1*	-	-
Endoleak Type II	*4*	-	-
Endoleak Type IIIa	*8*	*3*	-
Endoleak Type IIIb	*20*	*2*	-
Endoleak Type V	*1*	-	-
Endoleak (Indeterminate Origin)	*4*	-	-
Indeterminate	*3*	*1*	*1*
User Error	2	3	2
2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018			
Implantation Difficulties	-	2	1
Patient Anatomy	-	1	-
Cautionary Product Use	-	*1*	-
Occlusion	1	1	-
Aneurysm Expansion	16	9	-
Endoleak Type Ia	*2*	*1*	-
Endoleak Type Ib	*1*	*2*	-
Endoleak Type II	-	*2*	-
Endoleak Type IIIa	*3*	*2*	-
Endoleak Type IIIb	*9*	*2*	-
Endoleak (Indeterminate Origin)	*1*	-	-
User Error	5	1	-
2019 Reporting Period: Apr. 1, 2018 –Mar. 31, 2019			
Implantation Difficulties	1	-	-
Infection	-	1	3
Patient Anatomy	1	-	-
Indeterminate	*1*	-	-
Occlusion	1	1	3
Aneurysm Expansion	32	15	6
Endoleak Type Ia	*7*	-	*1*
Endoleak Type Ib	-	*1*	-
Endoleak Type II	*1*	*3*	-
Endoleak Type IIIa	*9*	*4*	-

Table 35. Primary Causes of Surgical Conversion – AFX System Bifurcated Devices

Cause of Surgical Conversion[‡μ]	AFX with STRATA	AFX with DURAPLY	AFX2
Endoleak Type IIIb	*12*	*5*	*2*
Endoleak (Indeterminate Origin)	*1*	*1*	*2*
Indeterminate	*2*	*1*	*1*
User Error	5	-	2
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**133**	**56**	**28**

‡Complaints had multiple causative types attributed to a given event.

μ "Cautionary Product Use" is defined as non-recommended product usage that is warned or cautioned against in the IFU. "Off-IFU" is defined as product usage against the product indications or contraindications in the IFU. "Indeterminate" is defined as an event for which the failure and/or cause could not be confirmed due to insufficient imaging or medical records.

Table 36. Primary Causes of Surgical Conversion – AFX System Extension Devices

Cause of Surgical Conversion[‡µ]	STRATA	DURAPLY	UNKNOWN GRAFT TYPE[×]
2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016			
Implantation Difficulties	-	2	-
Patient Anatomy	4	5	-
Cautionary Product Use	*1*	*1*	-
Off-IFU	*2*	*2*	-
Indeterminate	*1*	*2*	-
Occlusion	2	1	-
Aneurysm Expansion	9	5	3
Endoleak Type Ia	*1*	*3*	-
Endoleak Type Ib	-	*1*	-
Endoleak Type IIIa	*3*	*1*	*1*
Endoleak Type IIIb	*3*	-	*1*
Indeterminate	*2*	-	*1*
User Error	-	2	-
2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017			
Implantation Difficulties	1	1	-
Patient Anatomy	6	2	2
Cautionary Product Use	*3*	*1*	-
Off-IFU	*3*	*1*	-
Indeterminate	-	-	*2*
Occlusion	1	1	-
Aneurysm Expansion	12	7	2
Endoleak Type Ia	*2*	*3*	-
Endoleak Type II	*1*	*2*	-
Endoleak Type IIIa	*3*	*2*	-
Endoleak Type IIIb	*5*	-	*1*
Indeterminate	*1*	-	*1*
User Error	1	-	-
2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018			
Occlusion	-	2	-
Aneurysm Expansion	9	1	-
Endoleak Type Ia	*4*	*1*	-
Endoleak Type II	*1*	-	-
Endoleak Type IIIa	*1*	-	-
Endoleak Type IIIb	*3*	-	-
User Error	3	2	-
2019 Reporting Period: Apr. 1, 2018 –Mar. 31, 2019			
Implantation Difficulties	1	-	-
Patient Anatomy	1	1	-
Off-IFU	*1*	*1*	-
Occlusion	-	1	1
Aneurysm Expansion	3	2	3
Endoleak Type Ia	*2*	*1*	-
Endoleak Type II	-	-	*1*
Endoleak Type IIIa	*1*	-	-
Endoleak Type IIIb	-	*1*	*1*
Endoleak (Indeterminate Origin)	-	-	*1*
User Error	2	-	-
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**37**	**24**	**10**

‡ Complaints had multiple causative types attributed to a given event.

µ "Cautionary Product Use" is defined as non-recommended product usage that is warned or cautioned against in the IFU. "Off-IFU" is defined as product usage against the product indications or contraindications in the IFU. "Indeterminate" is defined as an event for which the failure and/or cause could not be confirmed due to insufficient imaging or medical records.

× "Unknown Graft Type" is listed for any event in which the graft type could not be identified due to insufficient medical records.

As outlined in **Table 37** and **Table 38** below, the time to event for the surgical conversions reported between November 1, 2015 and March 31, 2019 trends differently for each of the different device types:

As noted above, one of the leading causative events for surgical conversions with the DURAPLY ePTFE grafts were attributed to patient anatomy and involved patients whose devices were implanted outside of the IFU recommendations/requirements. Based on this cause, it follows that the majority of surgical conversions for the DURAPLY ePTFE grafts occur peri-operatively as implanting the AFX System devices outside of the anatomical requirements/recommendations in the IFU would lead to difficulties in excluding the aneurysm and achieving adequate seal. As detailed on page 34 above, there have been zero (0) surgical conversions reported in the AFX System subjects in the LEOPARD Trial through May 6, 2019. As of this data cut, there were 104 evaluable subjects that had reached 36 months of follow-up. As with all EVAR devices, it is important to adhere to the approved instructions for use. Please refer to Section 6 (page 87) for patient and device selection recommendations.

As noted above, one of the leading causative events for surgical conversions with the STRATA ePTFE grafts were patients that experienced a Type IIIa or Type IIIb endoleak. The majority of these conversions occurred between 2- to 5-Year post-implantation. Again, please refer to page 81 for recommendations regarding Type III endoleaks and Section 7 (page 90) for patient tailored surveillance recommendations for patients implanted with a STRATA ePTFE graft.

Table 37. Time to Event for Surgical Conversion – AFX System Bifurcated Devices

Time to Event for Surgical Conversion	AFX with STRATA	AFX with DURAPLY	AFX2
≤30 days	2	17	18
>30 days, ≤6 mo.	0	7	5
>6 mo., ≤1 year	2	6	2
>1 year, ≤2 year	8	10	2
>2 year, ≤3 year	31	9	1
>3 year, ≤4 year	43	5	0
>4 year, ≤5 year	26	1	-
>5 year, ≤6 year	12	-	-
>6 year, ≤7 year	6	-	-
>7 year, ≤8 year	0	-	-
Unknown	3	1	0
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**133**	**56**	**28**

NOTE: Within this table, dashes are used to denote timeframes for which follow-up does not exist, based on product introduction to the market.

Table 38. Time to Event for Surgical Conversion – AFX System Extension Devices

Time to Event for Surgical Conversion	STRATA	DURAPLY	UNKNOWN GRAFT TYPE
≤30 days	1	7	1
>30 days, ≤6 mo.	0	5	0
>6 mo., ≤1 year	0	4	0
>1 year, ≤2 year	7	3	0
>2 year, ≤3 year	10	3	0
>3 year, ≤4 year	2	2	0
>4 year, ≤5 year	9	0	0
>5 year, ≤6 year	4	-	-
>6 year, ≤7 year	0	-	-
>7 year, ≤8 year	0	-	-
Unknown	4	0	9
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**37**	**24**	**10**

NOTE: Within this table, dashes are used to denote timeframes for which follow-up does not exist, based on product introduction to the market.

Device Migration

Forty-one (41) post-implant migrations have been reported worldwide in patients treated with the DURAPLY ePTFE grafts (AFX Bifurcated with DURAPLY, AFX2 Bifurcated, and the AFX DURAPLY extensions) between November 1, 2015 and March 31, 2019. Over this same time period, ninety-three (93) post-implant migrations have been reported worldwide in patients treated with the STRATA ePTFE grafts (AFX Bifurcated with STRATA and the AFX STRATA extensions). An additional one (1) post-implant migration related to an AFX System extension has been reported worldwide during this same time period, for which the ePTFE graft type is unknown. NOTE: The majority of migrations with the AFX System are caudal migrations of the proximal extension component (as the bifurcated device rests on the native aortic bifurcation). Even so, complaints for a migration are often reported on the bifurcated device as that is often considered the primary component of the implanted system.

As outlined in **Table 39** and **Table 40** below, the majority of post-implant migrations for both the DURAPLY and STRATA ePTFE grafts involved patients whose devices were implanted outside of the IFU recommendations/requirements and this non-recommended use was found to lead to implant migration. This would include, but is not limited to, patients that had anatomy outside of the IFU indications or patients that had been implanted with a device not meeting the revised overlap requirements in the IFU. As detailed on page 34 above, there have been zero (0) migration events reported in the AFX System subjects in the LEOPARD Trial through May 6, 2019. As with all EVAR devices, it is important to adhere to the approved instructions for use. Please refer to Section 6 (page 87) for patient and device selection recommendations.

Table 39. Primary Causes of Post-Implant Migration – AFX System Bifurcated Devices

Cause of Migration‡µ	AFX with STRATA	AFX with DURAPLY	AFX2
2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016			
Intraoperative	2	1	-
Disease Progression	-	-	-
Usage Outside of IFU Recommendations/Requirements	9	1	-
Cautionary Product Use	*3*	-	-
Off-IFU	*6*	*1*	-
Indeterminate	3	-	-
2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017			
Intraoperative	1	-	-
Disease Progression	3	-	-
Usage Outside of IFU Recommendations/Requirements	13	2	2
Cautionary Product Use	*3*	-	*1*
Off-IFU	*10*	*2*	*1*
Indeterminate	-	-	-
2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018			
Intraoperative	-	-	-
Disease Progression	1	-	-
Usage Outside of IFU Recommendations/Requirements	6	1	-
Cautionary Product Use	*2*	*1*	-
Off-IFU	*4*	-	-
Indeterminate	2	1	-
2019 Reporting Period: Apr. 1, 2018 –Mar. 31, 2019			
Intraoperative	-	-	-
Disease Progression	3	-	-
Usage Outside of IFU Recommendations/Requirements	5	1	-
Cautionary Product Use	*1*	-	-
Off-IFU	*4*	*1*	-
Indeterminate	9	1	-
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**48**	**8**	**1**

‡36 complaints had multiple causative types attributed to a given event.

µ "Cautionary Product Use" is defined as non-recommended product usage that is warned or cautioned against in the IFU. "Off-IFU" is defined as product usage against the product indications or contraindications in the IFU. "Indeterminate" is defined as an event for which the failure and/or cause could not be confirmed due to insufficient imaging or medical records.

Table 40. Primary Causes of Post-Implant Migration – AFX System Extension Devices

Cause of Migration‡µ	STRATA	DURAPLY	UNKNOWN GRAFT TYPE×
2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016			
Intraoperative	1	2	-
Disease Progression	2	-	-
Usage Outside of IFU Recommendations/Requirements	13	3	1
Cautionary Product Use	*8*	*1*	*1*
Off-IFU	*5*	*2*	-
Indeterminate	2	-	-
2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017			
Intraoperative	2	1	-
Disease Progression	5	1	-
Usage Outside of IFU Recommendations/Requirements	3	8	-
Cautionary Product Use	*1*	*2*	-
Off-IFU	*2*	*6*	-
Indeterminate	5	-	-
2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018			
Intraoperative	1	1	-
Disease Progression	1	2	-
Usage Outside of IFU Recommendations/Requirements	8	5	-
Cautionary Product Use	*2*	*2*	-
Off-IFU	*6*	*3*	-
Indeterminate	5	-	-
2019 Reporting Period: Apr. 1, 2018 –Mar. 31, 2019			
Intraoperative	-	1	-
Disease Progression	2	2	-
Usage Outside of IFU Recommendations/Requirements	2	4	-
Cautionary Product Use	-	*1*	-
Off-IFU	*2*	*3*	-
Indeterminate	3	8	-
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**45**	**32**	**1**

‡43 complaints had multiple causative types attributed to a given event.

µ "Cautionary Product Use" is defined as non-recommended product usage that is warned or cautioned against in the IFU. "Off-IFU" is defined as product usage against the product indications or contraindications in the IFU. "Indeterminate" is defined as an event for which the failure and/or cause could not be confirmed due to insufficient imaging or medical records.

× "Unknown Graft Type" is listed for any event in which the graft type could not be identified due to insufficient medical records.

As outlined in **Table 41** and **Table 42** below, the time to event for the post-implant migrations reported between November 1, 2015 and March 31, 2019 typically occur 1-Year post-implantation or beyond for each of the different device types:

As noted above, the leading causative event for post-implant migrations with both the DURAPLY and STRATA ePTFE grafts involved patients whose devices were implanted outside of the IFU recommendations/ requirements and this non-recommended use was found to lead to a migration. Based on this cause, it follows that the majority of device migrations for the STRATA and DURAPLY ePTFE grafts occur post 1-Year implantation as component separation would occur over time if the implanted device did not meet the revised overlap requirements in the IFU. Additionally, migration of the proximal extension is likely to occur if adequate neck length and seal was not achieved. As detailed on page 34 above, there have been zero (0) migration events reported in the AFX System subjects in the LEOPARD Trial through May 6, 2019. Again, please ensure adherence to the approved instructions for use and refer to Section 6 (page 87) for patient and device selection recommendations.

Table 41. Time to Event for Post-Implant Migrations – AFX System Bifurcated Devices

Time to Event for Migration	AFX with STRATA	AFX with DURAPLY	AFX2
≤30 days	0	0	0
>30 days, ≤6 mo.	0	1	0
>6 mo., ≤1 year	0	0	1
>1 year, ≤2 year	1	3	0
>2 year, ≤3 year	1	2	0
>3 year, ≤4 year	16	2	0
>4 year, ≤5 year	13	0	-
>5 year, ≤6 year	9	-	-
>6 year, ≤7 year	5	-	-
>7 year, ≤8 year	1	-	-
Unknown	2	0	0
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**48**	**8**	**1**

NOTE: Within this table, dashes are used to denote timeframes for which follow-up does not exist, based on product introduction to the market.

Table 42. Time to Event for Post-Implant Migrations – AFX System Extension Devices

Time to Event for Migration	STRATA	DURAPLY	UNKNOWN GRAFT TYPE
≤30 days	0	5	0
>30 days, ≤6 mo.	1	3	0
>6 mo., ≤1 year	1	2	0
>1 year, ≤2 year	3	12	0
>2 year, ≤3 year	11	8	0
>3 year, ≤4 year	10	1	0
>4 year, ≤5 year	9	0	0
>5 year, ≤6 year	7	-	-
>6 year, ≤7 year	1	-	-
>7 year, ≤8 year	0	-	-
Unknown	2	1	1
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**45**	**32**	**1**

NOTE: Within this table, dashes are used to denote timeframes for which follow-up does not exist, based on product introduction to the market.

Type IIIa Endoleak

One-hundred and sixteen (116) Type IIIa endoleaks have been reported worldwide in patients treated with the DURAPLY ePTFE grafts (AFX Bifurcated with DURAPLY, AFX2 Bifurcated, and the AFX DURAPLY extensions) between November 1, 2015 and March 31, 2019. Over this same time period, three-hundred and forty-four (344) Type IIIa endoleaks have been reported worldwide in patients treated with the STRATA ePTFE grafts (AFX Bifurcated with STRATA and the AFX STRATA extensions). An additional seventeen (17) Type IIIa endoleaks related to AFX System extension devices have been reported worldwide during this same time period, for which the ePTFE graft type is unknown.

As outlined in **Table 43** and **Table 44** below, the majority of Type IIIa endoleaks for both the DURAPLY and STRATA ePTFE grafts involved patients whose devices were implanted outside of the IFU recommendations/requirements and this non-recommended use was found to lead to a Type IIIa endoleak. This would include, but is not limited to, patients that had anatomy outside of the IFU indications or patients that had been implanted with a device not meeting the revised overlap requirements in the IFU. Available data out to 54 months, inclusive of LEOPARD data that has more than 100 subjects out to 36 months, suggests that the corrective actions have been effective at reducing the occurrence of Type IIIa endoleaks. This trend is further supported by the available complaint data, which suggests The a lower total incident rate of Type IIIa endoleaks during the reporting period with both the DURAPLY ePTFE grafts with nearly twice as many cases as the STRATA ePTFE graft. Endologix is continuing to monitor the Type III endoleak rates for the AFX System and will continue to report out on this data in forthcoming Clinical Updates. As with all EVAR devices, it is important to adhere to the approved instructions for use. Please refer to Section 6 (page 87) for patient and device selection recommendations.

Table 43. Primary Causes of Type IIIa Endoleak – AFX System Bifurcated Devices

Cause of Type IIIa Endoleak‡µ	AFX with STRATA	AFX with DURAPLY	AFX2
2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016			
Intraoperative	1	-	-
Disease Progression	4	-	-
Migration	4	1	-
Usage Outside of IFU Recommendations/Requirements	47	8	-
Cautionary Product Use	*22*	*4*	-
Off-IFU	*25*	*4*	-
Indeterminate	29	4	-
2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017			
Intraoperative	1	-	-
Disease Progression	8	1	-
Migration	2	-	-
Usage Outside of IFU Recommendations/Requirements	52	12	1
Cautionary Product Use	*21*	*4*	*1*
Off-IFU	*31*	*8*	-
Indeterminate	33	6	3
2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018			
Intraoperative	-	-	-
Disease Progression	8	2	-
Migration	1	-	-
Usage Outside of IFU Recommendations/Requirements	14	9	1
Cautionary Product Use	*4*	*5*	-
Off-IFU	*10*	*4*	*1*
Indeterminate	9	3	-
2019 Reporting Period: Apr. 1, 2018 –Mar. 31, 2019			
Intraoperative	1	-	2
Disease Progression	16	4	-
Migration	2	1	-
Usage Outside of IFU Recommendations/Requirements	26	7	7

Table 43. Primary Causes of Type IIIa Endoleak – AFX System Bifurcated Devices

Cause of Type IIIa Endoleak‡µ	AFX with STRATA	AFX with DURAPLY	AFX2
Cautionary Product Use	*6*	*2*	*1*
Off-IFU	*20*	*5*	*6*
Indeterminate	51	26	12
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**253**	**71**	**25**

‡65 complaints had multiple causative types attributed to a given event.
µ "Cautionary Product Use" is defined as non-recommended product usage that is warned or cautioned against in the IFU. "Off-IFU" is defined as product usage against the product indications or contraindications in the IFU. "Indeterminate" is defined as an event for which the failure and/or cause could not be confirmed due to insufficient imaging or medical records.

Table 44. Primary Causes of Type IIIa Endoleak – AFX System Extension Devices

Cause of Type IIIa Endoleak‡µ	STRATA	DURAPLY	UNKNOWN GRAFT TYPE×
2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016			
Intraoperative	-	2	-
Disease Progression	3	-	-
Migration	1	-	-
Usage Outside of IFU Recommendations/Requirements	35	5	1
Cautionary Product Use	*14*	*1*	-
Off-IFU	*21*	*4*	*1*
Indeterminate	13	2	7
2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017			
Intraoperative	-	-	-
Disease Progression	4	-	-
Migration	3	-	-
Usage Outside of IFU Recommendations/Requirements	15	1	-
Cautionary Product Use	*7*	-	-
Off-IFU	*8*	*1*	-
Indeterminate	5	3	1
2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018			
Intraoperative	-	-	-
Disease Progression	2	-	-
Migration	4	-	-
Usage Outside of IFU Recommendations/Requirements	9	1	-
Cautionary Product Use	*4*	*1*	-
Off-IFU	*5*	-	-
Indeterminate	2	-	-
2019 Reporting Period: Apr. 1, 2018 –Mar. 31, 2019			
Intraoperative	5	-	-
Disease Progression	3	-	-
Migration	-	1	-
Usage Outside of IFU Recommendations/Requirements	3	8	2
Cautionary Product Use	*1*	*3*	-
Off-IFU	*4*	*5*	-
Indeterminate	13	1	9
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**91**	**19**	**17**

‡36 complaints had multiple causative types attributed to a given event.
µ "Cautionary Product Use" is defined as non-recommended product usage that is warned or cautioned against in the IFU. "Off-IFU" is defined as product usage against the product indications or contraindications in the IFU. "Indeterminate" is defined as an event for which the failure and/or cause could not be confirmed due to insufficient imaging or medical records.
× "Unknown Graft Type" is listed for any event in which the graft type could not be identified due to insufficient medical records.

As outlined in **Table 45** and **Table 46** below, the time to event for the Type IIIa endoleaks reported between November 1, 2015 and March 31, 2019 trends similarly for each of the different ePTFE graft types:

As noted above, the leading causative event for Type IIIa endoleaks with both the DURAPLY and STRATA ePTFE grafts involved patients whose devices were implanted outside of the IFU recommendations/ requirements and this non-recommended use was found to lead to a Type IIIa endoleak. Based on this cause, it follows that the majority of Type IIIa endoleaks for the STRATA and DURAPLY ePTFE grafts occur between 2- to 5-Years post-implantation as component separation would occur over time if the implanted device did not meet the revised overlap requirements in the IFU. As outlined in Section 4 (page 79), Type IIIa endoleaks were an early failure mode of the AFX System of devices due to inadequate overlap instructions in the IFU. The Instructions for Use were updated in June 2015 to provide oversizing and patient selection recommendations, which was approximately one year after DURAPLY was first commercialized. Available data out to 54 months, inclusive of LEOPARD data that has more than 100 subjects out to 36 months, suggests that the corrective actions have been effective at reducing the occurrence of Type IIIa endoleaks. Endologix is continuing to monitor the Type III endoleak rates for the AFX System and will continue to report out on this data in forthcoming Clinical Updates. Again, please refer to page 81 for recommendations regarding Type III endoleaks and Section 7 (page 90) for patient tailored surveillance recommendations for patients implanted with a STRATA ePTFE graft.

This time to event trend, however, does not carry over to the AFX2 Bifurcated with DURAPLY grafts, which were commercialized after the overlap instructions and sizing algorithm were added into the IFU. For AFX2, the Type IIIa endoleak occurrence remains low and there is no point in time that appears to be more prevalent. Endologix is continuing to monitor the Type III endoleak rates for the AFX System and will continue to report out on this data in forthcoming Clinical Updates.

Table 45. Time to Event for Type IIIa Endoleak – AFX System Bifurcated Devices

Time to Event for Type IIIa Endoleak	AFX with STRATA	AFX with DURAPLY	AFX2
≤30 days	2	5	2
>30 days, ≤6 mo.	0	6	8
>6 mo., ≤1 year	1	1	5
>1 year, ≤2 year	11	17	8
>2 year, ≤3 year	29	26	2
>3 year, ≤4 year	67	14	0
>4 year, ≤5 year	80	0	-
>5 year, ≤6 year	38	-	-
>6 year, ≤7 year	17	-	-
>7 year, ≤8 year	3	-	-
Unknown	5	2	0
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**253**	**71**	**25**

NOTE: Within this table, dashes are used to denote timeframes for which follow-up does not exist, based on product introduction to the market.

Table 46. Time to Event for Type IIIa Endoleak – AFX System Extension Devices

Time to Event for Type IIIa Endoleak	STRATA	DURAPLY	UNKNOWN GRAFT TYPE
≤30 days	3	4	3
>30 days, ≤6 mo.	0	3	0
>6 mo., ≤1 year	0	3	0
>1 year, ≤2 year	11	2	0
>2 year, ≤3 year	18	4	0
>3 year, ≤4 year	20	2	0
>4 year, ≤5 year	18	0	0
>5 year, ≤6 year	11	-	-
>6 year, ≤7 year	2	-	-
>7 year, ≤8 year	0	-	-

Table 46. Time to Event for Type IIIa Endoleak – AFX System Extension Devices

Time to Event for Type IIIa Endoleak	STRATA	DURAPLY	UNKNOWN GRAFT TYPE
Unknown	8	1	14
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**91**	**19**	**17**

NOTE: Within this table, dashes are used to denote timeframes for which follow-up does not exist, based on product introduction to the market.

Type IIIb Endoleak

One-hundred and forty-three (143) Type IIIb endoleaks have been reported worldwide in patients treated with the DURAPLY ePTFE grafts (AFX Bifurcated with DURAPLY, AFX2 Bifurcated, and the AFX DURAPLY extensions) between November 1, 2015 and March 31, 2019. Over this same time period, six-hundred and forty (640) Type IIIb endoleaks have been reported worldwide in patients treated with the STRATA ePTFE grafts (AFX Bifurcated with STRATA and the AFX STRATA extensions). An additional twenty-six (26) Type IIIa endoleaks related to AFX System extensions have been reported worldwide during this same time period, for which the ePTFE graft type is unknown.

As outlined in **Table 47** and **Table 48** below, the majority of Type IIIb endoleaks for both the DURAPLY and STRATA ePTFE grafts involved patients whose devices were implanted outside of the IFU recommendations/requirements and this non-recommended use was found to lead to a Type IIIb endoleak. This would include, but is not limited to, patients that had thrombus and/or calcium at the arterial implantation site, specifically the proximal aortic neck and distal iliac artery interface. Available data out to 54 months, inclusive of LEOPARD data that has more than 100 subjects out to 36 months, suggests that the corrective actions have been effective at reducing the occurrence of Type IIIb endoleaks. Endologix is continuing to monitor the Type III endoleak rates for the AFX System and will continue to report out on this data in forthcoming Clinical Updates. As with all EVAR devices, it is important to adhere to the approved instructions for use and take appropriate caution. Please refer to Section 6 (page 87) for patient and device selection recommendations.

Other than usage outside of the IFU recommendations/requirements, the leading causative event for Type IIIb endoleaks with the STRATA ePTFE grafts was deemed to be device related. As outlined in Section 4 (page 79), Type IIIb endoleaks are a known failure mode of the now-discontinued STRATA ePTFE material. This failure mode ultimately resulted in the removal of all STRATA devices from the field in December 2016. Refer to page 81 for recommendations regarding Type III endoleaks and Section 7 (page 90) for patient tailored surveillance recommendations for patients implanted with a STRATA ePTFE graft.

Table 47. Primary Causes of Type IIIb Endoleak – AFX System Bifurcated Devices

Cause of Type IIIb Endoleak‡µ*	AFX with STRATA	AFX with DURAPLY	AFX2
2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016			
Intraoperative	-	3	-
Post-Operative: Device Related	18	2	-
Usage Outside of IFU Recommendations/Requirements	95	11	-
Cautionary Product Use	*57*	*7*	-
Off-IFU	*38*	*4*	-
Indeterminate	52	3	-
2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017			
Intraoperative	5	1	1
Post-Operative: Device Related	63	6	-
Usage Outside of IFU Recommendations/Requirements	84	19	4
Cautionary Product Use	*50*	*12*	*2*
Off-IFU	*34*	*7*	*2*
Indeterminate	70	12	1
2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018			
Intraoperative	2	1	-
Post-Operative: Device Related	56	5	-
Usage Outside of IFU Recommendations/Requirements	33	5	3

Table 47. Primary Causes of Type IIIb Endoleak – AFX System Bifurcated Devices

Cause of Type IIIb Endoleak‡µ*	AFX with STRATA	AFX with DURAPLY	AFX2
Cautionary Product Use	*20*	*3*	*2*
Off-IFU	*13*	*2*	*1*
Indeterminate	17	7	1
2019 Reporting Period: Apr. 1, 2018 –Mar. 31, 2019			
Intraoperative	-	1	7
Post-Operative: Device Related	139	7	6
Usage Outside of IFU Recommendations/Requirements	27	13	7
Cautionary Product Use	*14*	*6*	*1*
Off-IFU	*13*	*7*	*6*
Indeterminate	74	29	21
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**523**	**94**	**37**

‡223 complaints had multiple causative types attributed to a given event.

µ "Cautionary Product Use" is defined as non-recommended product usage that is warned or cautioned against in the IFU. "Off-IFU" is defined as product usage against the product indications or contraindications in the IFU. "Indeterminate" is defined as an event for which the failure and/or cause could not be confirmed due to insufficient imaging or medical records.

**Complaints reported for aortoiliac occlusive disease and hyperdilation had been previously mis-recorded by Endologix as Type IIIb endoleaks. In light of this misclassification, these complaints have been excluded from this Type IIIb analysis.*

Table 48. Primary Causes of Type IIIb Endoleak – AFX System Extension Devices

Cause of Type IIIb Endoleak‡µ*	STRATA	DURAPLY	UNKNOWN GRAFT TYPE×
2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016			
Intraoperative	-	1	-
Post-Operative: Device Related	5	-	-
Usage Outside of IFU Recommendations/Requirements	14	1	1
Cautionary Product Use	*12*	-	*1*
Off-IFU	*2*	*1*	-
Indeterminate	13	-	5
2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017			
Intraoperative	1	-	-
Post-Operative: Device Related	22	-	2
Usage Outside of IFU Recommendations/Requirements	24	4	-
Cautionary Product Use	*12*	*2*	-
Off-IFU	*12*	*2*	-
Indeterminate	16	-	4
2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018			
Intraoperative	-	-	-
Post-Operative: Device Related	14	-	1
Usage Outside of IFU Recommendations/Requirements	6	1	-
Cautionary Product Use	*4*	-	-
Off-IFU	*2*	*1*	-
Indeterminate	2	3	3
2019 Reporting Period: Apr. 1, 2018 –Mar. 31, 2019			
Intraoperative	5	-	1
Post-Operative: Device Related	20	2	2
Usage Outside of IFU Recommendations/Requirements	11	3	-
Cautionary Product Use	*5*	*2*	-
Off-IFU	*6*	*1*	-
Indeterminate	12	1	12
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**117**	**12**	**26**

‡52 complaints had multiple causative types attributed to a given event.

µ "Cautionary Product Use" is defined as non-recommended product usage that is warned or cautioned against in the IFU. "Off-IFU" is defined as product usage against the product indications or contraindications in the IFU. "Indeterminate" is defined as an event for which the failure and/or cause could not be confirmed due to insufficient imaging or medical records.

**Complaints reported for aortoiliac occlusive disease and hyperdilation had been previously mis-recorded by Endologix as Type IIIb endoleaks. In light of this misclassification, these complaints have been excluded from this Type IIIb analysis.*

× "Unknown Graft Type" is listed for any event in which the graft type could not be identified due to insufficient medical records.

As outlined in **Table 49** and **Table 50** below, the time to event for the Type IIIb endoleaks reported between November 1, 2015 and March 31, 2019 trends similarly for each of the different device types:

As noted above, the majority of Type IIIb endoleaks for both the DURAPLY and STRATA ePTFE grafts involved patients whose devices were implanted outside of the IFU recommendations/requirements and this non-recommended use was found to lead to a Type IIIb endoleak. For the Type IIIb endoleaks reported between November 1, 2015 and March 31, 2019, the majority of Type IIIb endoleaks for the STRATA ePTFE graft occur between 2- to 5-Years post-implantation and occur between 1- and 4-years post-implantation for the DURAPLY ePTFE graft, as anatomical considerations (such as calcium at the implantation site) could lead to graft disruption over time. This difference in time to event for the STRATA and DURAPLY ePTFE grafts may, in part, be due to STRATA being phased out starting in mid-2014.[4,5]

DURAPLY Type IIIb endoleaks may have occurred acutely in patients that had significant calcium at the arterial implantation site (specifically the proximal aortic neck and distal iliac artery interface) that punctured the DURAPLY ePTFE graft during implantation or patients that were implanted with a competitor extension that was believed to have punctured the DURAPLY ePTFE graft during implantation.[5] As noted previously, the leading causative event for Type IIIb endoleaks with the STRATA ePTFE grafts was deemed to be device related. As noted on page 8 above, directionality had been inadvertently introduced into the STRATA ePTFE graft, which meant that it was less resistant to transverse propagation for a disruption in the graft material. This difference in material properties aligns with the higher rate of Type IIIb endoleaks with the STRATA ePTFE graft compared to its DURAPLY counterpart.

Available data out to 54 months, inclusive of LEOPARD data that has more than 100 subjects out to 36 months, suggests that the corrective actions have been effective at reducing the occurrence of Type IIIa endoleaks. Endologix is continuing to monitor the Type III endoleak rates for the AFX System and will continue to report out on this data in forthcoming Clinical Updates. Again, please refer to page 81 for recommendations regarding Type III endoleaks and Section 7 (page 90) for patient tailored surveillance recommendations for patients implanted with a STRATA ePTFE graft. Additionally, as with all EVAR devices, it is important to adhere to the approved instructions for use. Please refer to Section 6 (page 87) for patient and device selection recommendations.

[4] As a result of phasing out the STRATA ePTFE graft (beginning in mid-2014 and ultimately discontinuing in 2016), there is a difference in timeframes for STRATA and DURAPLY. Specifically, there is a lower number of STRATA subjects at the earlier time points (less than 2 years of follow-up) in this reporting period (November 2015 – March 2019). Similarly, because the DURAPLY ePTFE graft was not commercialized until mid-2014, there is a lower number of DURAPLY subjects at the later time points (more than 4 years of follow-up) in this reporting period.

[5] It is expected that STRATA would have a similar acute trend; however, there is a low number of STRATA subjects at the earlier time points (less than 2 years of follow-up) in this reporting period due to the phasing out and discontinuation of the STRATA ePTFE graft.

Table 49. Time to Event for Type IIIb Endoleak – AFX System Bifurcated Devices

Time to Event for Type IIIb Endoleak	AFX with STRATA	AFX with DURAPLY	AFX2
≤30 days	2	12	14
>30 days, ≤6 mo.	1	2	3
>6 mo., ≤1 year	2	6	7
>1 year, ≤2 year	26	20	11
>2 year, ≤3 year	78	33	1
>3 year, ≤4 year	158	19	0
>4 year, ≤5 year	140	0	-
>5 year, ≤6 year	65	-	-
>6 year, ≤7 year	37	-	-
>7 year, ≤8 year	5	-	-
Unknown	9	2	0
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**523**	**94**	**37**

NOTE: Within this table, dashes are used to denote timeframes for which follow-up does not exist, based on product introduction to the market.

Table 50. Time to Event for Type IIIb Endoleak – AFX System Extension Devices

Time to Event for Type IIIb Endoleak	STRATA	DURAPLY	UNKNOWN GRAFT TYPE
≤30 days	0	2	1
>30 days, ≤6 mo.	0	1	0
>6 mo., ≤1 year	0	2	0
>1 year, ≤2 year	6	4	0
>2 year, ≤3 year	16	3	0
>3 year, ≤4 year	24	0	0
>4 year, ≤5 year	32	0	0
>5 year, ≤6 year	21	-	-
>6 year, ≤7 year	5	-	-
>7 year, ≤8 year	0	-	-
Unknown	13	0	25
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**117**	**12**	**26**

NOTE: Within this table, dashes are used to denote timeframes for which follow-up does not exist, based on product introduction to the market.

Other Stent Graft Integrity Events

Eighty-six (86) non-Type IIIb endoleak device integrity events have been reported worldwide in patients treated with the DURAPLY ePTFE grafts (AFX Bifurcated with DURAPLY, AFX2 Bifurcated, and the AFX DURAPLY extensions) between November 1, 2015 and March 31, 2019. These included reports of device buckling/kinking (14), device fracture (5), device occlusion (45), and stent graft patency (40)[6,7]. Over this same time period, forty-eight (48) of these same device integrity events have been reported worldwide in patients treated with the STRATA ePTFE grafts (AFX Bifurcated with STRATA and the AFX STRATA extensions). These included reports of device buckling/kinking (9), device fracture (15), device occlusion (9), and stent graft patency (19)[8]. An additional three (3) non-Type IIIb endoleak device integrity events related to AFX System extensions (one (1) each of device buckling/kinking, device fracture, and device occlusion) have been reported worldwide during this same time period, for which the ePTFE graft type is unknown.

As outlined in **Table 51** and **Table 52** below, the majority of these device integrity events for both the DURAPLY and STRATA ePTFE grafts involved patients whose devices were implanted outside of the IFU recommendations/requirements. This would include, but is not limited to, patients that had highly angulated necks that were outside the IFU requirements. As with all EVAR devices, it is important to adhere to the approved instructions for use. Please refer to Section 6 (page 87) for patient and device selection recommendations.

Table 51. Primary Causes of Other Device Integrity Events – AFX System Bifurcated Devices

Cause of Device Integrity Events[‡µ]	AFX with STRATA	AFX with DURAPLY	AFX2
2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016			
Usage Outside of IFU Recommendations/Requirements	-	1	-
Cautionary Product Use	-	*1*	-
2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017			
Implantation Difficulties	-	1	-
Disease Progression	1	-	-
Usage Outside of IFU Recommendations/Requirements	2	2	-
Cautionary Product Use	-	-	-
Off-IFU	*2*	*2*	-
User Error	1	-	-
Indeterminate	1	-	1
2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018			
Disease Progression	-	-	1
Usage Outside of IFU Recommendations/Requirements	3	3	-
Cautionary Product Use	*2*	*1*	-
Off-IFU	*1*	*2*	-
User Error	-	1	-
Indeterminate	1	-	1
2019 Reporting Period: Apr. 1, 2018 –Mar. 31, 2019			
Implantation Difficulties	-	1	4
Disease Progression	1	-	-
Hyperdilation (>35%)	3	2	-
Pre-Existing Thrombus	-	-	1
Usage Outside of IFU Recommendations/Requirements	6	1	18
Cautionary Product Use	*1*	-	-
Off-IFU	*5*	*1*	*18*
User Error	-	1	6
Indeterminate	8	7	8
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**31**	**23**	**42**

‡Complaints had multiple causative types attributed to a given event.

[6] Complaints had multiple stent graft integrity types attributed to a given event.
[7] Stent Graft Patency is defined as the self-expanding implant not fully deploying/opening within the aneurysm.
[8] Complaints had multiple stent graft integrity types attributed to a given event.

Table 51. Primary Causes of Other Device Integrity Events – AFX System Bifurcated Devices

Cause of Device Integrity Events[‡μ]	AFX with STRATA	AFX with DURAPLY	AFX2

μ "Cautionary Product Use" is defined as non-recommended product usage that is warned or cautioned against in the IFU. "Off-IFU" is defined as product usage against the product indications or contraindications in the IFU. "Indeterminate" is defined as an event for which the failure and/or cause could not be confirmed due to insufficient imaging or medical records.

Table 52. Primary Causes of Other Device Integrity Events – AFX System Extension Devices

Cause of Device Integrity Events[‡μ]	STRATA	DURAPLY	UNKNOWN GRAFT TYPE[×]
2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016			
Disease Progression	-	1	-
2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017			
Usage Outside of IFU Recommendations/Requirements	2	-	-
Cautionary Product Use	-	-	-
Off-IFU	*2*	-	-
Endoleak	2	-	-
2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018			
Usage Outside of IFU Recommendations/Requirements	-	3	-
Cautionary Product Use	-	*1*	-
Off-IFU	-	*2*	-
User Error	-	1	-
Indeterminate	1	1	-
2019 Reporting Period: Apr. 1, 2018 –Mar. 31, 2019			
Implantation Difficulties	-	2	-
Disease Progression	1	1	-
Crown Separation	3	-	-
Hyperdilation (>35%)	2	-	-
Pre-Existing Thrombus	-	1	-
Usage Outside of IFU Recommendations/Requirements	6	5	-
Cautionary Product Use	*3*	*1*	-
Off-IFU	*3*	*4*	-
Endoleak	1	1	-
User Error	1	-	-
Indeterminate	4	10	3
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**17**	**21**	**3**

‡ Complaints had multiple causative types attributed to a given event.

μ "Cautionary Product Use" is defined as non-recommended product usage that is warned or cautioned against in the IFU. "Off-IFU" is defined as product usage against the product indications or contraindications in the IFU. "Indeterminate" is defined as an event for which the failure and/or cause could not be confirmed due to insufficient imaging or medical records.

× "Unknown Graft Type" is listed for any event in which the graft type could not be identified due to insufficient medical records.

As outlined in **Table 53** and **Table 54** below, the time to event for the device integrity events reported between November 1, 2015 and March 31, 2019 trends differently for each of the different device types:

As noted above, the leading causative event for device integrity events with the STRATA ePTFE grafts involved patients whose devices were implanted outside of the IFU recommendations/requirements. Based on this cause as well as the fact that the STRATA devices were discontinued globally in 2016, it follows that the majority of device integrity events for the STRATA ePTFE grafts occur at later time points.

While usage outside of the IFU recommendations/requirements was also the leading causative event for the DURAPLY ePTFE grafts, it is important to note that many of the device integrity events reported (including stent graft patency failures) are acute failures that typically occur during the index procedure. As Endologix has discontinued the AFX with STRATA device and ceased distribution of the AFX with DURAPLY device in the US, it follows that the majority of the stent graft integrity failures during the reporting period were attributed acutely to the AFX2 Bifurcated device since the AFX with DURAPLY device started being phased out of the market in early-2016.

Table 53. Time to Event for Other Device Integrity Events – AFX System Bifurcated Devices

Time to Event for Device Integrity Events	AFX with STRATA	AFX with DURAPLY	AFX2
≤30 days	2	6	15
>30 days, ≤6 mo.	0	4	14
>6 mo., ≤1 year	1	1	8
>1 year, ≤2 year	1	1	4
>2 year, ≤3 year	4	7	1
>3 year, ≤4 year	9	4	0
>4 year, ≤5 year	6	0	-
>5 year, ≤6 year	6	-	-
>6 year, ≤7 year	2	-	-
>7 year, ≤8 year	0	-	-
Unknown	0	1	0
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**31**	**23**	**42**

NOTE: Within this table, dashes are used to denote timeframes for which follow-up does not exist, based on product introduction to the market.

Table 54. Time to Event for Other Device Integrity Events – AFX System Extension Devices

Time to Event for Device Integrity Events	STRATA	DURAPLY	UNKNOWN GRAFT TYPE
≤30 days	1	5	1
>30 days, ≤6 mo.	0	4	0
>6 mo., ≤1 year	0	4	0
>1 year, ≤2 year	0	3	0
>2 year, ≤3 year	1	5	0
>3 year, ≤4 year	3	0	0
>4 year, ≤5 year	7	0	0
>5 year, ≤6 year	3	-	-
>6 year, ≤7 year	1	-	-
>7 year, ≤8 year	0	-	-
Unknown	1	4	2
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**17**	**21**	**3**

NOTE: Within this table, dashes are used to denote timeframes for which follow-up does not exist, based on product introduction to the market.

SECTION 4: Type III Endoleaks

Type III Endoleak Overview

As indicated above, 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. This monitoring found an increased rate of Type III endoleaks with the AFX System in comparison to the Powerlink System (data reported in **Appendix A**). An investigation subsequently commenced in January of 2013 for Type IIIa endoleaks (separation of bifurcated and accessory stent grafts at the point of overlap) followed by an investigation into Type IIIb endoleaks (disruption of the stent graft material) in September 2013. During this time, multiple labeling, product, and manufacturing changes were implemented by Endologix. These included updates to the product 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 AFX2 Bifurcated system. The chart below outlines the monitoring activities associated with Type III endoleaks as well as various product and IFU updates, with further discussion in the subsequent sections that have taken place since 2013 (**Figure 21**). Based on early discussions with the FDA and the recognition that non-expired STRATA product could still be remaining in the field, Endologix issued a customer communication in December 2016, which summarized the corrective actions implemented to address Type III endoleaks. This notification also requested the removal of any remaining STRATA devices in the field. See below for the timeline of Type III endoleak monitoring and actions.

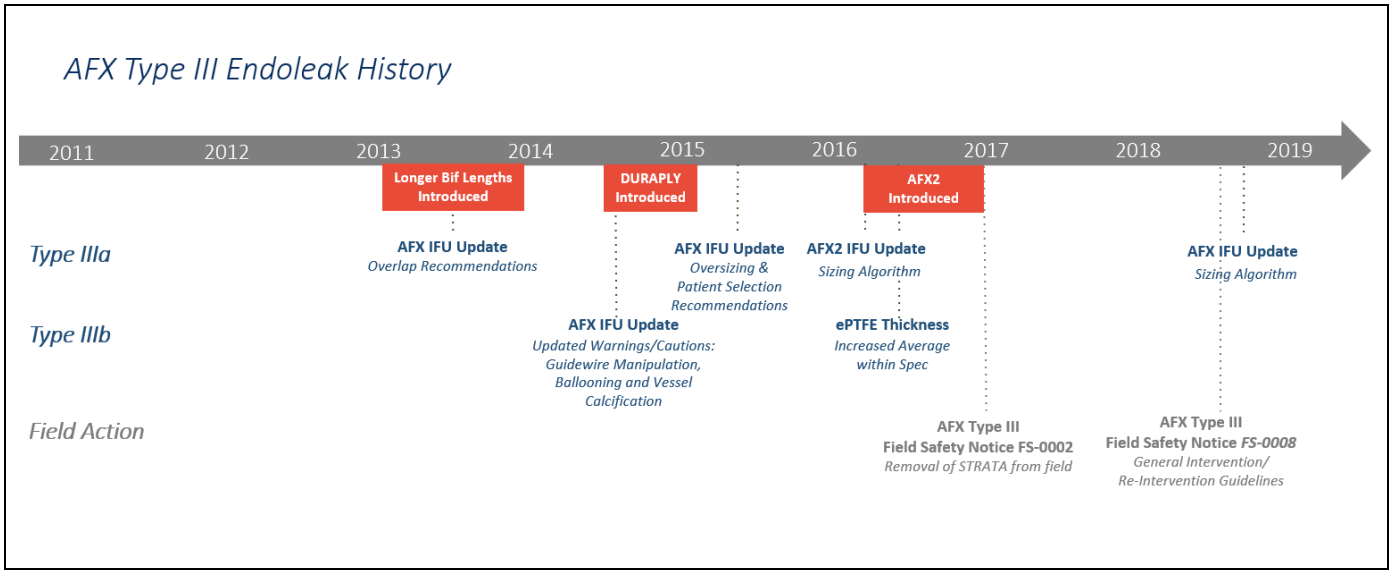

Figure 21. Timeline of Type III Endoleak Monitoring and Actions

The following outlines the investigations and actions since the initiation of the investigation in January 2013.

Type IIIa Endoleak Investigation and Corrective Actions

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, made between 2013 and 2018, 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.[9]
- 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.[10]
- 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.[11]

Furthermore, in January 2013 and November 2014, Endologix commercialized longer bifurcated lengths to provide more device options to maximize component overlap.[12]

Type IIIb Endoleak Investigation and Corrective Actions

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 (i.e., implantation in highly calcified anatomy/landing zone)
- Lateral movement and changes in implant stability
- Implant of other manufacturer's devices as proximal extensions

Endologix implemented additional 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. These IFU updates, which were made in 2014, may mitigate the identified contributing factors and help prevent the occurrence of Type IIIb endoleaks.[13]

Furthermore, the investigations noted that although initial testing found that the STRATA ePTFE graft met all the established mechanical and strength specifications of the original Powerlink ePTFE graft, the STRATA process did not incorporate material tear resistance in the transverse direction. This, combined with the serial wrapped layers, meant that the STRATA ePTFE graft remained less resistant to transverse propagation for a disruption in the graft material. In response to this, Endologix developed and commercialized a modified ePTFE graft material processing in July 2014, known as DURAPLY. This modification increased the transverse graft material tear propagation resistance compared to the STRATA graft while preserving biocompatibility, conformability, and other mechanical characteristics.[14]

Most recently in February 2016, Endologix introduced the AFX2 Bifurcated System. During the development of the AFX2 Bifurcated 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 manufacturing specifications.[15] The tightening of specifications was subsequently applied to the AFX with DURAPLY.

Monitoring of Type III Endoleaks Over Time

[9] IFU Update implemented in June 2013. Included in the December 2016 recall notice.
[10] IFU Update implemented in June 2015. Included in the December 2016 recall notice.
[11] IFU Update implemented for AFX2 in February 2016 and for AFX with DURAPLY in July 2018. Included in the December 2016 and July 2018 recall notices, respectively.
[12] Included in the December 2016 recall notice.
[13] IFU Update implemented in July 2014. Included in the December 2016 recall notice.
[14] DURAPLY implemented in July 2014. Included in the December 2016 recall notice.
[15] AFX2 Updates implemented prior to commercialization in February 2016. Included in the December 2016 recall notice.

As discussed above, the DURAPLY graft material (commercialized in 2014), longer bifurcated lengths (commercialized in January 2013 and November 2014), and the AFX2 Bifurcated System (commercialized in 2016) were implemented since the AFX System was introduced into the US and EU markets in 2011. Additionally, as noted above and referenced in the respective footnotes, several IFU updates were also made between 2013 and 2018. Endologix is actively monitoring the effectiveness of these changes through its post-market surveillance program. Available data out to 54 months, inclusive of LEOPARD data that has more than 100 subjects out to 36 months, suggests that the corrective actions have been effective at reducing the occurrence of Type IIIa and Type IIIb endoleaks. Endologix is continuing to monitor the Type III endoleak rates for the AFX System and will continue to report out on this data in forthcoming Clinical Updates.

Even though preliminary data suggests that these corrective actions have been effective in reducing the rate of Type III endoleaks, the Type III endoleak incidence rates have continued to increase as a result of the implanted AFX System devices that were manufactured with STRATA. Upon further discussion of these increased rates with various regulatory agencies, Endologix issued a customer communication in December 2016, which summarized the corrective actions implemented to address Type III endoleaks. This notification also requested the removal of any remaining STRATA devices in the field.

Recommendations for Type III Endoleaks

In conjunction with the December 2016 Field Safety Notice (FSN) with the AFX System, Endologix received requests from physicians on how to manage patients with AFX with STRATA grafts (see Appendix C for a complete list of AFX with STRATA identifiers). In response, Endologix convened a panel of six experienced AFX users on January 28, 2017 in order to review evidence and to provide a consensus on recommendations. The physicians had a broad range of experience with the AFX System from the users who primarily select competitive devices to the users who select AFX as their primary device of choice. The physicians came from a variety of hospital backgrounds, both community based and some part of a University system. Some of the physicians had published their experience with Type III endoleaks with the AFX device. Each member of the panel was asked to review the FSN Letter as well as to present at least one AFX case study for discussion. One of the key topics of the physician advisory panel meeting was to evaluate surveillance of patients who have been implanted with AFX with STRATA to determine if any additional recommendations should be communicated. The physician panel was specifically asked to consider whether the current surveillance regimen in the IFU was sufficient in terms of surveillance type and intervals given the increased rates of reported Type IIIb endoleaks in patients with AFX with STRATA. The physician panel reached the consensus that annual CT imaging (the current surveillance recommendation) is sufficient. This topic was re-visited in December 2017 when the physician panel was reconvened and the panel's recommendation remained unchanged as the increased radiation dosage and potential renal impairment from contrast associated with more frequent surveillance is not warranted at this time, especially for patients without clinical findings.

The specific recommendations are summarized below:

Raise Awareness

There is a need to continue raising awareness of the possibility of Type IIIb endoleaks in patients implanted with AFX with STRATA, as well as the importance of ongoing surveillance. The expert users believed that the issue was not with the occurrence of fabric holes (common in all sutured endografts), but rather with the potential propagation of those holes. The user group also suggested that physicians should reach out to any patients that do not currently comply with the IFU-recommended surveillance regimen and offer endograft assessments.

Understand the Risk

The group agreed that some patients may be at increased risk of Type IIIb endoleaks, especially if they have undergone any catheter-based procedures that involved wires and sheaths being passed through the existing AFX

endograft. The group came to the consensus that care should be taken during an intervention that may be traversing/crossing/transferring through the AFX System so as to ensure that the existing graft is not damaged. Based on the unique design of the AFX endograft, 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. These guidelines were added into the AFX System Instructions for Use in 2018 and 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. NOTE: these instructions were communicated to both AFX and non-AFX Users in July 2018 as part of a field safety notice.

Surveillance

The group came to the consensus that 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).[16,17] 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 the Instructions for Use. 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). Based on this feedback, Endologix has updated the AFX System Instructions for Use to outline these patient-tailored surveillance recommendations. Additionally, these instructions were communicated to both AFX and non-AFX Users in July 2018 as part of a field safety notice.

Secondary Intervention

The group strongly urged physicians to consider a secondary intervention involving placement of an additional device component for patients with Type IIIb endoleaks. There was also consensus that it is virtually impossible to identify patients whose risk of Type IIIb endoleaks are high enough to warrant prophylactic re-intervention. For additional guidance and recommendations, please contact your Endologix representative.

Channels of Communication

The group also recommended that Endologix provide physicians with a means of requesting details on any patients that have been implanted with the AFX with STRATA (see **Appendix C** for a complete list of AFX the STRATA identifiers). In line with that recommendation, physicians may send 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.

[16] 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.
[17] 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.

SECTION 5: Device Explant Evaluations

Endologix monitors product performance to ensure the ongoing quality, safety, and efficacy of its products. Upon explantation and return of a product, either after implantation during a clinical study or in commercial experience, an investigation is performed. The investigation includes a thorough review of the product manufacturing records, patient clinical information from the implant procedure and follow-up, available follow-up imaging studies, and clinician-provided explant observations and reports. An engineering evaluation of the returned device is performed using standard techniques, including x-ray and scanning electron microscopy. Independent gross and histopathological evaluations of explanted stent grafts are performed by a board-certified pathologist to assess the biologic response as well as device integrity.

This section details the device explant evaluations for the AFX System. Information on those explant evaluations for the Powerlink System are presented separately in **Appendix B**. Although information on the Powerlink System may be relevant with respect to reliance on anatomical stabilization rather than proximal fixation, other attributes of this earlier generation device limit the applicability of the information to the more contemporary device designs.

Device Explants (Lifetime)

Seventy-one (71) device explant evaluations have been conducted on the DURAPLY ePTFE grafts (AFX Bifurcated with DURAPLY, AFX2 Bifurcated, and the AFX DURAPLY extensions) during its lifetime (July 2014 – March 2019). Meanwhile, one hundred and three (103) device explant evaluations have been conducted on the STRATA ePTFE grafts (AFX Bifurcated with STRATA and the AFX STRATA extensions) during its lifetime (August 2011 – March 2019). An additional seven (7) device explant evaluations have been conducted on AFX System extensions, for which the ePTFE graft type could not be determined.

As outlined in **Table 55** and **Table 56** below, the leading reason for device explantation with the STRATA ePTFE grafts were patients that experienced a Type IIIb endoleak, followed by patients that experienced a Type IIIa endoleak. As outlined in Section 4 (page 79), Type III endoleaks are a known failure mode of the now-discontinued STRATA ePTFE material. These failure modes ultimately resulted in various updates to the IFU since 2013 as well as the removal of all STRATA devices from the field in December 2016. Refer to page 81 for recommendations regarding Type III endoleaks and Section 7 (page 90) for patient tailored surveillance recommendations for patients implanted with a STRATA ePTFE graft. Conversely, the majority of device explants with the DURAPLY ePTFE graft have been shown to occur acutely, predominantly due to either implantation difficulties or intra-operative complications (totaling 20 events). The second leading causative event for DURAPLY explants is post-implant aneurysm rupture (14 events), the majority of which resulted from a Type Ia, Type IIIa, or Type IIIb endoleak.

Table 55. Reason for Device Explantation – AFX System Bifurcated Devices

Reason for Device Explantation (August 2011 – March 2019)	AFX with STRATA	AFX with DURAPLY	AFX2
Implantation Difficulties	1	4	4
Intra-Operative Complications	2	4	4
Endoleak Type Ia	13	4	1
Endoleak Type Ib	4	4	-
Endoleak Type II	4	6	-
Endoleak Type IIIa	21	11	-
Endoleak Type IIIb	51	8	1
Endoleak Type V	1	-	-
Device Migration	7	1	-
Aneurysm Expansion	30	10	1
Aneurysm Rupture (post-implant)	24	9	2
Stent Graft Occlusion	5	5	3
Infection	1	3	4
Indeterminate	12	11	3
TOTAL Explant Evaluations‡	**83**	**38**	**18**

Table 55. Reason for Device Explantation – AFX System Bifurcated Devices

Reason for Device Explantation (August 2011 – March 2019)	AFX with STRATA	AFX with DURAPLY	AFX2

‡Complaints had multiple reasons attributed to a given event.

Table 56. Reason for Device Explantation – AFX System Extension Devices

Reason for Device Explantation (August 2011 – March 2019)	STRATA	DURAPLY	UNKNOWN GRAFT TYPE
Implantation Difficulties	-	1	-
Intra-Operative Complications	-	3	-
Endoleak Type Ia	8	5	-
Endoleak Type Ib	-	1	-
Endoleak Type II	2	1	-
Endoleak Type IIIa	6	1	1
Endoleak Type IIIb	14	2	1
Device Migration	5	1	-
Aneurysm Expansion	11	2	-
Aneurysm Rupture (post-implant)	3	3	-
Stent Graft Occlusion	-	2	1
Indeterminate	1	4	6
TOTAL Explant Evaluations‡	**20**	**15**	**7**

‡ Complaints had multiple reasons attributed to a given event.

The results of the explant evaluations are outlined in **Table 57** and **Table 58** below. As shown in these data sets, the majority of device explantations for both the DURAPLY and STRATA ePTFE grafts were related to patient anatomy and involved patients whose devices were implanted outside of the IFU recommendations/requirements. It is important to highlight that 100% of all AFX System subjects in the LEOPARD Trial data (page 34) are free from surgical conversion (and subsequently device explantation) at 3-Years. As with all EVAR devices, it is important to adhere to the approved instructions for use. Please refer to Section 6 (page 87) for patient and device selection recommendations.

Other than usage outside of the IFU recommendations/requirements, the leading observation for both the DURAPLY and STRATA ePTFE grafts were graft hole/tears, although that number remains low for the DURAPLY ePTFE grafts as compared to the Strata ePTFE grafts. Specifically, Endologix confirmed the presence of thirty-nine (39) graft holes/tears in the STRATA ePTFE grafts of the sixty-five (65) devices that were explanted due to a reported Type IIIb endoleak. Endologix also confirmed the presence of nine (9) graft holes/tears in the DURAPLY ePTFE grafts of the eleven (11) devices that were explanted due to a reported Type IIIb endoleak. As outlined in Section 4 (page 79), Type IIIa and Type IIIb endoleaks were an early failure mode of the AFX System of devices due to inadequate overlap instructions in the IFU as well as the Strata ePTFE material which introduced directionality into the ePTFE graft. The Instructions for Use were updated in June 2015 to provide oversizing and patient selection recommendations, which was approximately one year after DURAPLY was first commercialized. Available data out to 54 months, inclusive of LEOPARD data that has more than 100 subjects out to 36 months, suggests that the corrective actions have been effective at reducing the occurrence of Type IIIa and Type IIIb endoleaks. This is further supported by the data set below, which shows a relatively low number of device explantations resulting from Type IIIa or Type IIIb endoleaks with the DURAPLY graft during the past 3.5-year period, which encompasses the majority of the commercialization of the DURAPLY ePTFE graft. Endologix is continuing to monitor the Type III endoleak rates for the AFX System and will continue to report out on this data in forthcoming Clinical Updates.

Table 57. Device Explant Evaluation Results – AFX System Bifurcated Devices

Results of Device Explant Evaluation (August 2011 – March 2019)	AFX with STRATA	AFX with DURAPLY	AFX2
Patient Anatomy	64	28	11
Cautionary Product Use	*34*	*16*	*5*
Off-IFU	*30*	*12*	*6*
Graft Material Observations	35	4	2
Hole or Tear	*32*	*3*	*2*
Explant Damage	*3*	*1*	-
Stent Observations	25	2	3
Buckling/Kinking	*4*	*1*	*2*
Crown Separation	*5*	-	-
Device Fracture	*7*	-	-
Explant Damage	*9*	*1*	*1*
TOTAL Explant Evaluations‡	**83**	**38**	**18**

‡Evaluations had multiple result types attributed to a given event.

Table 58. Device Explant Evaluation Results – AFX System Extension Devices

Results of Device Explant Evaluation (August 2011 – March 2019)	STRATA	DURAPLY	UNKNOWN GRAFT TYPE
Patient Anatomy	17	15	-
Cautionary Product Use	*6*	*6*	-
Off-IFU	*11*	*9*	-
Graft Material Observations	7	3	1
Hole or Tear	*7*	*3*	*1*
Explant Damage	-	-	-
Stent Observations	4	2	-
Buckling/Kinking	-	*2*	-
Crown Separation	*2*	-	-
Device Fracture	-	-	-
Explant Damage	*2*	-	-
TOTAL Explant Evaluations‡	**20**	**15**	**7**

‡ Evaluations had multiple result types attributed to a given event.

As outlined in **Table 59** and **Table 60** below, the time to event for the completed device explant evaluations trends differently for each of the different device types:

As noted above, the leading reason for device explanation with the DURAPLY ePTFE grafts were attributed to acute factors such as implantation difficulties or intra-operative complications. Furthermore, the results of the explant evaluation found that the majority of the device explant cases with the DURAPLY ePTFE grafts were attributed to patient anatomy and involved patients whose devices were implanted outside of the IFU recommendations/requirements. Based on these reported reasons and identified observations, it follows that the majority of device explants for the DURAPLY ePTFE grafts occur peri-operatively as implanting the AFX System devices outside of the anatomical requirements/recommendations in the IFU would lead to difficulties in excluding the aneurysm and achieving adequate seal. It is important to highlight that 100% of all AFX System subjects in the LEOPARD Trial data (page 34) are free from surgical conversion (and subsequently device explantation) at 3-Years. As with all EVAR devices, it is important to adhere to the approved instructions for use. Please refer to Section 6 (page 87) for patient and device selection recommendations.

As noted above, the leading reason for device explantation with the STRATA ePTFE grafts were patients that experienced a Type IIIa or Type IIIb endoleak. The majority of these explants occurred between 2- to 5-Year post-implantation, which aligns with the maximum available follow-up of the AFX with DURAPLY ePTFE graft. Again, please refer to page 81 for recommendations regarding Type III endoleaks and Section 7 (page 90) for patient tailored surveillance recommendations for patients implanted with a STRATA ePTFE graft.

Table 59. Time to Event for Device Explantation – AFX System Bifurcated Devices

Time to Event for Device Explantation	AFX with STRATA	AFX with DURAPLY	AFX2
≤30 days	0	8	10
>30 days, ≤6 mo.	0	4	2
>6 mo., ≤1 year	1	5	2
>1 year, ≤2 year	4	7	2
>2 year, ≤3 year	14	7	1
>3 year, ≤4 year	28	5	0
>4 year, ≤5 year	19	1	-
>5 year, ≤6 year	11	-	-
>6 year, ≤7 year	5	-	-
>7 year, ≤8 year	0	-	-
Unknown	1	1	1
TOTAL Explant Evaluations	**83**	**38**	**18**

NOTE: Within this table, dashes are used to denote timeframes for which follow-up does not exist, based on product introduction to the market.

Table 60. Time to Event for Device Explantation – AFX System Extension Devices

Time to Event for Device Explantation	STRATA	DURAPLY	UNKNOWN GRAFT TYPE
≤30 days	0	5	0
>30 days, ≤6 mo.	0	1	0
>6 mo., ≤1 year	0	3	0
>1 year, ≤2 year	3	2	0
>2 year, ≤3 year	4	2	0
>3 year, ≤4 year	1	2	0
>4 year, ≤5 year	7	0	0
>5 year, ≤6 year	4	-	-
>6 year, ≤7 year	0	-	-
>7 year, ≤8 year	0	-	-
Unknown	1	0	7
TOTAL Explant Evaluations	**20**	**15**	**7**

NOTE: Within this table, dashes are used to denote timeframes for which follow-up does not exist, based on product introduction to the market.

SECTION 6: Notes to Clinicians

Patient Selection, Device Selection, and Follow-up Recommendations

The 17Fr AFX Introducer System may be introduced via either iliac artery. Common femoral artery access and aneurysm sac orientation are considerations. If one iliac artery is more tortuous, aneurysmal, or diseased, the other side may be considered preferable for delivery catheter access allowing for easier manipulation and control. Access vessel diameter and morphology (e.g., tortuosity, occlusive disease, presence of thrombus and/or calcification) should be compatible with vascular access techniques and the profile of the delivery systems. Vessels that are significantly calcified, occlusive, tortuous or thrombus-lined may preclude placement of the endovascular graft and/or may increase the risk of embolization. The patency of at least one internal iliac artery should be maintained to reduce the risk of pelvic/bowel ischemia.

Key anatomic elements that may affect successful exclusion of the aneurysm include severe proximal neck angulation, short proximal aortic neck seal zone, irregular calcification and/or plaque. It is also reported in the literature that aortic tortuosity and larger aneurysm size may result in progressive, long-term displacement of an endograft mid-section toward the aneurysm wall, thus elevating the risk of the junctional leaks and disconnections even in previously well-excluded aneurysms. Endologix recommends that physicians plan for maximum overlap of stent graft components, particularly in large or long aneurysms. In cases where adequate overlap cannot be achieved through a two-piece configuration, placement of a third (bridging) piece should be considered.

The following determinants should be considered in selecting devices during pre-implant planning:

- Angulation of the infrarenal aortic neck 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 the deployment procedure in tortuous/calcified iliac anatomy

All lengths and diameters of the stent grafts necessary to complete the procedure should be available to the physician, especially when pre-operative case planning measurements (treatment diameters/lengths) are not certain. This approach allows for greater intraoperative flexibility to achieve optimal procedural outcomes. Under sizing or over sizing may result in incomplete sealing or compromised flow. As shown in the clinical studies, the long main body of the anatomically-fixed bifurcated stent graft provides columnar strength and foundational support for the implant. Care should be taken to select the bifurcated device with the longest body length suitable for the patient's anatomy without compromising luminal blood flow. When accessory stent grafts are used to complete the repair, pre-procedure planning and device selection should aim to maximize overlap with the primary bifurcated stent graft. In patients with angulated aortic necks, very large diameter aneurysms, tortuous aortas, or long renal-to-bifurcation lengths, the use of an additional infrarenal proximal extension component may offer additional support to the initial bifurcated body-proximal extension stent graft junction.

Endologix recommends that the AFX stent graft component diameters be selected as described in the Instructions for Use (IFU) and that the stent graft diameter be at least 2mm larger than the normal aortic inner diameter (e.g., a 25mm diameter stent graft should not be deployed in a normal aortic inner diameter >23mm). The length of the graft-covered portion of the AFX stent graft implant should extend from the lowest renal artery to the common iliac artery seal zone location, ensuring preservation of at least one internal iliac artery. Note that the 34mm proximal extensions are indicated for use only with the 28mm bifurcated stent grafts. The safety and effectiveness of the 34mm proximal extensions implanted with the 22mm or 25mm bifurcated stent grafts have not been established. Endologix does not recommend the use of the 34mm stent graft with 22 or 25mm bifurcated stent grafts.

As summarized in Section 4 (page 79) above, Type III endoleaks may cause increased pressure within the aneurysm sac that could increase the risk of aneurysm rupture and patient death. Investigations into Type III endoleaks with the early AFX System devices 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

As explained in previous field safety communications, Endologix has taken a number of actions since 2013 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 such as changing from the original graft material processing referred to as STRATA to an improved process known as DURAPLY, and introduction of the AFX2 Bifurcated device manufactured with Duraply. Additionally, the STRATA graft was discontinued and was removed from the field in December 2016. Endologix has been monitoring the effectiveness of these changes through its LEOPARD Trial as well as its complaint monitoring system. Available data out to 54 months, inclusive of LEOPARD data that has more than 100 subjects out to 36 months, suggests that the corrective actions have been effective at reducing the occurrence of Type IIIa and Type IIIb endoleaks. Endologix is continuing to monitor the Type III endoleak rates for the AFX System and will continue to report out on this data in forthcoming Clinical Updates.

Continued monitoring and follow-up of patients treated with the device for endovascular stent grafts 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.

Duplex ultrasound may be used for those patients experiencing renal failure, who are otherwise unable to undergo contrast enhanced CT scan, or at physician discretion. 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) should receive more frequent follow-up.

If Type I or III endoleak is present, prompt intervention and additional follow-up post-intervention is recommended. The physician-defined schedule for patient follow-up should be maintained even in the absence of clinical symptoms (e.g., pain, numbness, weakness).

More frequent/additional surveillance and possible treatment is recommended for:

- Aneurysms with Type I or III endoleaks
- Aneurysm enlargement, ≥5mm in maximum diameter (regardless of endoleak status or type)
- Migration or lateral displacement of the implant
- Inadequate seal length (proximally or distally)
- Reduction in stent graft component overlap since the first post-operative exam
- Stent graft compression or kinking, or narrowing of a stent graft limb

When making a decision regarding reintervention or conversion to open repair, the individual patient's co-morbidities, life expectancy and the patient's personal choices should be considered. Additional endovascular intervention (e.g., additional component placement) or conversion to open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aneurysms, unacceptable decrease in seal zone length (proximal or distal), reduction in component overlap (e.g., separation or impending separation of the bifurcated stent graft body from the extension stent graft) and/or endoleak. An increase in aneurysm size and/or persistent endoleak may lead to aneurysm rupture. Patients experiencing endoleaks and/or reduced blood flow through the graft limb may be required to undergo secondary interventions or surgical procedures.

Federal Law (US) requires that all AAA stent grafts be tracked (per 21 CFR 821). That tracking includes a Patient Implant Card to be given to the patient upon release from the institution and a Device Tracking Form to be mailed or faxed back to the manufacturer.

Product Additions, Enhancements, and Improvements

Information on the performance of the Endologix stent graft design and implant technique has been received during controlled clinical study use, from early post-market physician training experience, during emergency use in patients who might not otherwise be treatable using another endovascular option, and from the more widespread commercial experience in the US and internationally. In addition, input for improvement opportunities has been obtained from focused physician groups. Outlined below are the primary product additions, enhancements, and/or improvements that have been made:

- In controlled clinical experience, it is evident that the prevention of distal migration or lateral movement and the associated sequelae is essential to ensuring long-term, sustained performance of any endovascular stent graft. In each associated clinical study described in this report, implantation of the bifurcated device on the aortic bifurcation with the long main body across the aneurysm, with achieved proximal seal has resulted in prevention of aneurysm rupture and inhibition of movement or migration. To allow for use of the device in patients with different length aortic and iliac anatomies, more bifurcated and extension stent graft options were introduced. In addition, to address the patient population with larger iliac artery anatomy, flared and stepped limb extensions were introduced.

- Published literature suggests that different patient anatomies and/or conditions may suggest preferential

device orientation (i.e., suprarenal vs. infrarenal placement).[18,19,20] Suprarenal orientation may be preferred in shorter, more angulated, thrombus-lined, or irregularly shaped infrarenal necks. Conversely, infrarenal placement may be preferred in patients with renal stent placement or renal artery stenosis, and in patients with long or tapered proximal infrarenal necks, where the radial force imparted by the proximal edge of the stent graft can be most effective. It may also be preferred in patients having competing angles in the infrarenal and suprarenal aorta, where suprarenal placement may result in incomplete device apposition. To provide a complete treatment offering to physicians and their patients, the company introduced stent grafts in both infrarenal and suprarenal configuration to accommodate physician requirements in treating their patients.

- Endologix treatment options facilitate endovascular repair in patients with proximal aortic necks between 18mm and 32mm in diameter, with device availability in both infrarenal and suprarenal configuration. Limb extensions in a variety of configurations and with flexibility as needed for the specific anatomy accommodate common iliac artery seal zones up to 23mm in diameter.

- In pursuing continuous improvement and in a concerted effort to be responsive to physician feedback, the company developed, obtained FDA approval, and introduced the 17Fr AFX Introducer System and a wide array of AFX bifurcated and accessory stent grafts. All AFX stent graft delivery systems are compatible with the AFX 17Fr Introducer System. This expanded offering is intended to enable physicians to achieve low profile access and to tailor the endovascular repair to each patient's unique anatomy.

- Bifurcated stent grafts with 20mm diameter limbs were made available to treat patients with common iliac arteries 14 to 18mm in diameter.

- Low outer profile 14Fr and 16Fr limb extension delivery systems have been made available for all limb diameters that do not require an introducer sheath but are compatible with the AFX Introducer System if so desired.

- The AFX Vela™ Delivery System was made available in early 2014. This system is compatible with the AFX Introducer System and includes a proximal extension stent graft having a radiopaque marker in the proximal edge for visual clarity of the graft line under fluoroscopy. The delivery system is designed with an integrated release sleeve intended for controlled delivery of the proximal extension at the target implant location.

- In 2014, Endologix developed and commercialized an improved ePTFE graft using proprietary processing methods which results in a high-density, multi-layered material referred to as DURAPLY™. This modification was intended to increase the graft material strength while preserving the material's biocompatibility profile, strength, and other conformability and mechanical characteristics.

- The latest offering in the AFX Portfolio, the AFX2 Bifurcated Delivery System, is FDA and CE Mark approved. It was introduced into the U.S. and international markets in 2016. AFX2 consists of a new delivery system that features an integrated 0.035" contralateral wire to replace the previous 0.014" wire, refinement of the hemostatic control within the handle, and reduction of the contralateral introducer from 9F to a 7F profile. The inclusion of a contralateral .035" wire eliminates the previous contralateral wire exchange reducing both the number and complexity of steps in deployment.

SECTION 7: Brief Summary of Indications, Warnings and Precautions from IFU

[18] Carpenter JP, Baum RA, Barker CF, et al. Impact of exclusion criteria on patient selection for endovascular abdominal aortic aneurysm repair. J Vasc Surg 2001;34:1050-1054.
[19] Gitlitz DB, Ramaswami G, Kaplan D, et al. Endovascular stent grafting in the presence of aortic neck filling defects: early clinical experience. J Vasc Surg 2001;33:340-4.
[20] Marin ML, Parsons RE, Hollier LH, et al. Impact of transrenal aortic endograft placement on endovascular graft repair of abdominal aortic aneurysms. J Vasc Surg 1998;26:638-46.

The Endologix bifurcated stent grafts and extension stent graft accessories are intended for endovascular treatment in patients with AAA. In 2013, an expanded indication including bilateral percutaneous access was approved by the US FDA. As outlined in the IFU, factors that are critical for a successful endovascular repair include the following:

- Appropriate patient selection for this endograft, including:
  - Adequate iliac/femoral artery access
  - Adequate proximal aortic neck seal zone (≥18 to ≤32mm diameter; ≥15mm length; and ≤60° angle to the aneurysm sac)
  - Adequate common iliac artery seal zones (≥10 to ≤23mm diameter; ≥15mm length; ≤90° angle to the aortic bifurcation)
- Device selection for the patient according to the IFU
- Device delivery and deployment according to the IFU
- Continued patient follow-up and imaging on a timely basis
- Imaging surveillance at an increased frequency for 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)

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.

The devices are contraindicated in patients who have a condition that threatens to infect the stent graft, or in patients with sensitivities or allergies to the device materials.

Adverse Event Reporting

Any adverse event (clinical incident) involving the AFX Endovascular AAA System should be reported to Endologix, Inc. immediately. To report an incident, call the Customer Service Department at 800-983-2284 (24 hours message service). Outside the US, contact your local Endologix representative.

Potential device or procedure-related adverse events that may occur and/or require intervention include, but are not limited to: amputation; anesthetic complications and subsequent attendant problems (e.g., aspiration); aneurysm enlargement; aneurysm rupture and death; aortic damage, including perforation, dissection, bleeding, rupture and death; arterial or venous thrombosis and/or pseudoaneurysm; arteriovenous fistula; bleeding; hematoma or coagulopathy; bowel complications (e.g., ileus, transient ischemia, infarction, necrosis); cardiac complications and subsequent attendant problems (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension, hypertension); claudication (e.g., buttock, lower limb); death; edema; embolization (micro and macro) with transient or permanent ischemia or infarction; endoleak; fever and localized inflammation; genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection); hepatic failure; impotence; infection of the aneurysm or device access site, including abscess formation, transient fever and pain; lymphatic complications and subsequent attendant problems (e.g., lymph fistula); neurologic local or systemic complications and subsequent attendant problems (e.g., stroke, transient ischemic attack, paraplegia, paraparesis, paralysis); occlusion of device or native vessel; pulmonary/respiratory complications and subsequent attendant problems (e.g., pneumonia, respiratory failure, prolonged intubation); renal complications and subsequent attendant problems (e.g., artery occlusion, contrast toxicity, insufficiency, failure); stent graft: improper component placement, incomplete component deployment, component migration, suture break, occlusion, infection, stent fracture, graft material wear, dilatation, erosion, puncture and perigraft flow; surgical conversion to open repair; vascular access site complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula, vessel damage, wound complications and subsequent attendant problems (e.g., dehiscence, infection); vascular spasm or vascular trauma (e.g., iliofemoral vessel

dissection, bleeding, rupture, death).

Patient Selection, Treatment, and Follow-up

The Endologix devices have not been evaluated in some patient populations, including those <18 years of age; pregnant or nursing females; mycotic aneurysms; traumatic aortic injury; uncorrectable coagulopathy; indispensable mesenteric artery; leaking, pending rupture, or ruptured aneurysms; revision of previously placed endovascular grafts; pseudoaneurysms resulting from previous graft placement; genetic connective tissue disease (e.g., Marfan's or Ehlers-Danlos' Syndromes); concomitant thoracic aortic or thoracoabdominal aneurysms, or patients with active systemic infections. Key anatomic elements that may affect successful exclusion of the aneurysm include severe proximal neck angulation (>60° between the infrarenal neck to axis to the aneurysm body); irregular and/or short proximal aortic neck (<15 mm); thrombus and/or calcium at the arterial implantation sites, specifically the proximal aortic neck and distal iliac artery interface. Irregular calcification and/or plaque may compromise graft integrity or the fixation and sealing of the implantation sites. Necks exhibiting these key anatomic elements may be more conducive to graft migration. The Endologix endografts are not recommended in patients who cannot tolerate contrast agents necessary for intraoperative and post-operative follow-up imaging.

Warnings and Precautions

All instructions should be read carefully. Failure to properly follow the IFU or to observe the warnings and precautions may lead to serious consequences or injury to the patient. The device should only be used by physicians and teams trained in vascular interventional techniques and in the use of this specific device. A vascular surgery team should always be available during implantation or re-intervention procedures in the event that conversion to open surgical repair is necessary. The device is for single use only; do not reuse the device. Refer to the IFU for all warnings and precautions. An overview is provided below:

- Catheter advancement should be performed under fluoroscopic guidance.
- Take care during manipulation of catheters, wires and sheaths within an aneurysm. Significant disturbances may dislodge fragments of thrombus which can cause distal embolization.
- Inaccurate placement, inadequate fixation and/or incomplete sealing of the stent graft within the vessel may result in increased risk of endoleak, migration or inadvertent occlusion of the renal or internal iliac arteries. Renal artery patency must be maintained to prevent/reduce the risk of renal failure and subsequent complications.
- Select the bifurcated body to achieve seal within the proximal neck, or to land no more than 2cm below the distal neck. When placing a proximal extension stent graft, select the longest extension device suitable for the patient to achieve significant overlap with the bifurcated stent graft body.
- When placing a limb extension stent graft, overlap with the bifurcated stent graft limb must be at least 20mm.
- Care should be taken not to damage the stent graft or disturb positioning after graft placement. Incorrect deployment or migration of the stent graft may require surgical intervention.
- When ballooning the stent graft, there is an increased risk of vessel injury and/or rupture, and possible patient death, if the balloon is not completely within the ePTFE graft covered portion of the stent graft. Over-inflation of a balloon 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.

Additional endovascular intervention or conversion to open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aneurysms, unacceptable decrease in fixation length (including reduction in component overlap) and/or endoleak. An increase in aneurysm size and/or

persistent endoleak may lead to aneurysm rupture. Patients experiencing reduced blood flow through the graft limb and/or endoleaks may be required to undergo secondary interventions or surgical procedures.

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 22**, 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.

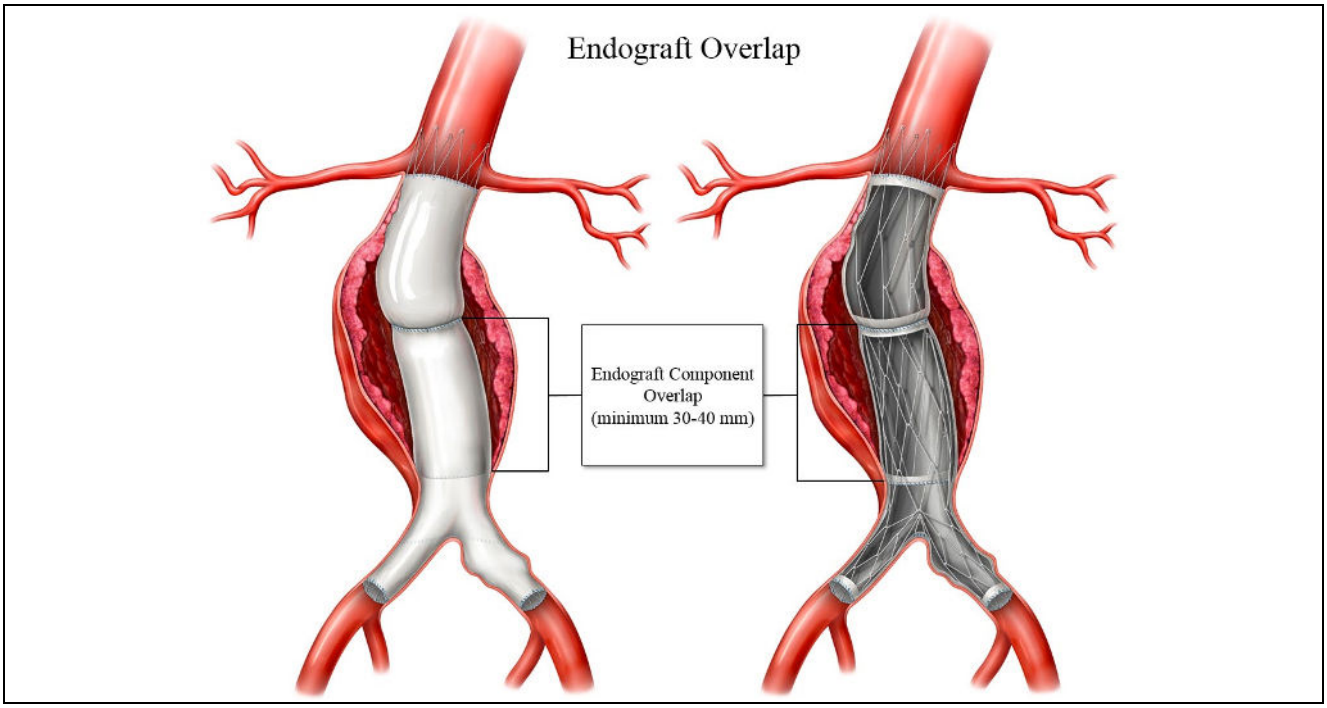

Figure 22. AFX Implant Design

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 the IFU for additional details.

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), Endologix recommends that physicians evaluate patients on an individual basis and prescribe their follow-up relative to the needs and circumstances of each individual patient. 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. 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).

Appendix A: Commercial Experience of the Powerlink System

As detailed above, Endologix maintains an active customer experience reporting system to collect, evaluate, and report complaints and adverse events in compliance with US and international requirements. This section details the commercial experience for the Powerlink System, the predecessor to the AFX System, which is no longer commercially available.

Market Status and Approvals

The Powerlink System was in commercial distribution in select countries outside of the US beginning in 2000 and in the US since FDA approval in October 2004. The Powerlink System was discontinued in 2015 as a business decision to migrate customers to the AFX System, its next generation product.

Devices Sold Worldwide

While the Powerlink System is no longer available on the market, there were over 64,000 Powerlink devices sold worldwide during its lifetime. **Table 61** provides a summary of the devices sold worldwide during its commercialization.

Table 61. Devices Sold ¥ Worldwide

Product Type	Powerlink System (May 1, 2000 – January 31, 2016*)			
	US	EU	ROW[α]	Total
Bifurcated	**16,703**	**4,802**	**5,551**	**27,056**
Extensions	**23,943**	**6,303**	**7,042**	**37,288**

¥The US data depicts the number of devices sold through direct sales. The OUS data depicts the number of devices sold through direct sales as well as distributor sales. Therefore, the data presented provides the largest number of devices that may have been implanted in each region.
** Distribution of the Powerlink System ceased globally in January 2016.*
[α] ROW is defined as "Rest of World".

Reported Adverse Events (Lifetime)

Table 62 summarizes adverse events reported for the Powerlink System device from its commercial release through March 31, 2019. **Table 63** summarizes adverse events reported for the Powerlink System device during the most recent four reporting periods.

Table 62. Summary of Performance (Worldwide Data, Cumulative) – Powerlink

Event Type (May 2000 – March 2019)	Powerlink System		
	US	EU	ROW[α]
Aneurysm-Related Mortality	56	6	5
Aneurysm Rupture (post-implant)	51	3	3
Surgical Conversion	203	46	14
Device Migration	20	1	1
Type IIIa Endoleak	91	-	4
Type IIIb Endoleak	62	4	7
Other Stent Graft Integrity Events*	104	8	3
Total Complaints‡	**1,542**	**157**	**1,823**

‡Multiple event types (harm and device) may be attributed to each complaint
[α] ROW is defined as "Rest of World".
*Other Stent Graft Integrity Events are defined as stent fractures, stent graft patency, kinking, buckling, occlusion within device (implant) and generalized "Stent Graft Integrity".

Table 63. Summary of Performance (Worldwide Data, by Reporting Period) – Powerlink

Adverse Event‡	2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016	2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017	2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018	2019 Reporting Period: Apr. 1, 2018 – Mar. 31, 2019
Aneurysm-Related Mortality	2	-	-	3
Aneurysm Rupture (post-implant)	4	2	2	4
Surgical Conversion	3	-	-	1
Device Migration	2	1	2	2
Type IIIa Endoleak	9	1	3	7
Type IIIb Endoleak	4	9	6	15
Other Stent Graft Integrity Events*	2	2	-	2

‡Multiple event types (harm and device) may be attributed to each complaint.
*Other Stent Graft Integrity Events are defined as stent graft patency, kinking, buckling, occlusion within device (implant) and generalized "Stent Graft Integrity". There were no stent fractures reported for Powerlink during the reporting period(s).

Commercial Experience Data Summary

Aneurysm-Related Mortality

Five (5) aneurysm-related deaths have been reported worldwide in patients treated with the Powerlink System between November 1, 2015 and March 31, 2019. As outlined in **Table 64** below, the majority of aneurysm-related deaths involved patients that had procedural and/or peri-operative complications. It is important to highlight that there were zero (0) aneurysm-related deaths resulting from aneurysm rupture reported during the 3.5-year reporting period.

Table 64. Primary Causes of Aneurysm-Related Mortality – Powerlink System

Cause of Aneurysm-Related Mortality‡	2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016	2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017	2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018	2019 Reporting Period: Apr. 1, 2018 – Mar. 31, 2019
Procedural and/or Peri-Operative Complications	1	-	-	5
Conversion to Open Repair (EVAR Not Attempted)	-	-	-	*2*
Procedure-Related (Post-Op, ≤30 days)	*1*	-	-	*3*
Pre-Existing Conditions	1	-	-	-
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**5**			

‡2 complaints had multiple causative types attributed to a given event.

Aneurysm Rupture (post-implant)

Twelve (12) aneurysm ruptures have been reported worldwide in patients treated with the Powerlink System between November 1, 2015 and March 31, 2019. As outlined in **Table 65** below, the majority of aneurysm ruptures involved patients that had experienced an endoleak. There was no predominant endoleak type that led to an aneurysm rupture during the 3.5-year period.

Table 65. Primary Causes of Post-Implant Aneurysm Rupture – Powerlink System

Cause of Aneurysm Rupture‡*	2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016	2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017	2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018	2019 Reporting Period: Apr. 1, 2018 – Mar. 31, 2019
Endoleak Type Ia	2	-	-	-
Endoleak Type IIIa	1	-	1	1
Endoleak Type IIIb	-	1	-	1
Endoleak (Indeterminate Origin)	1	-	-	-
Indeterminate	-	1	1	-
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**12**			

‡1 complaint had multiple causative types attributed to a given event.
*Aneurysm Sac Enlargement is not included as a causative event if the sac growth was attributed to an endoleak.

As outlined in **Table 66** below, there is no predominant time to event point for the ruptures reported between November 1, 2015 and March 31, 2019. As distribution of the Powerlink System ceased globally in January 2016, it follows that the majority of ruptures reported during the last four reporting periods occurred in the later follow-up timepoints.

Table 66. Time to Event for Post-Implant Aneurysm Rupture – Powerlink System

Time to Event for Aneurysm Rupture	Powerlink
≤30 days	-
>30 days, ≤6 mo.	-
>6 mo., ≤1 year	-
>1 year, ≤2 year	-
>2 year, ≤3 year	1
>3 year, ≤4 year	-
>4 year, ≤5 year	2
>5 year, ≤6 year	2
>6 year, ≤7 year	3
>7 year, ≤8 year	2
Unknown	2
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**12**

Surgical Conversion

Four (4) surgical conversions have been reported worldwide in patients treated with the Powerlink System between November 1, 2015 and March 31, 2019. As outlined in **Table 67** below, the majority of the surgical conversions for the Powerlink grafts were attributed to patient anatomy and involved patients whose devices were implanted outside of the IFU recommendations/requirements. The second leading cause for surgical conversions was due to aneurysm expansion from an unresolved endoleak.

Table 67. Primary Causes of Surgical Conversion – Powerlink System

Cause of Surgical Conversion‡µ	2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016	2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017	2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018	2019 Reporting Period: Apr. 1, 2018 – Mar. 31, 2019
Patient Anatomy	3	-	-	1
Cautionary Product Use	*1*	-	-	-
Off-IFU	*2*	-	-	*1*
Indeterminate	-	-	-	-
Occlusion	1	-	-	-
Aneurysm Expansion	2	-	-	2
Endoleak Type Ia	1	-	-	1
Endoleak Type IIIa	1	-	-	1
User Error	-	-	-	1
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**4**			

‡Complaints had multiple causative types attributed to a given event.

µ "Cautionary Product Use" is defined as non-recommended product usage that is warned or cautioned against in the IFU. "Off-IFU" is defined as product usage against the product indications or contraindications in the IFU. "Indeterminate" is defined as an event for which the failure and/or cause could not be confirmed due to insufficient imaging or medical records.

As outlined in **Table 68** below, there is no predominant time to event point for the surgical conversions reported between November 1, 2015 and March 31, 2019. As distribution of the Powerlink System ceased globally in January 2016, it follows that the majority of surgical conversions reported during the last four reporting periods occurred in the later follow-up timepoints.

Table 68. Time to Event for Surgical Conversion – Powerlink System

Time to Event for Surgical Conversion	Powerlink
≤30 days	-
>30 days, ≤6 mo.	-
>6 mo., ≤1 year	-
>1 year, ≤2 year	-
>2 year, ≤3 year	-
>3 year, ≤4 year	1
>4 year, ≤5 year	1
>5 year, ≤6 year	1
>6 year, ≤7 year	1
>7 year, ≤8 year	-
Unknown	-
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**4**

Device Migration

Seven (7) post-implant migrations have been reported worldwide in patients treated with the Powerlink System between November 1, 2015 and March 31, 2019. As outlined in **Table 69** below, the majority of the migrations for the Powerlink grafts for which a cause could be determined were attributed to disease progression.

Table 69. Primary Causes of Post-Implant Migration – Powerlink System

Cause of Migration‡µ	2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016	2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017	2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018	2019 Reporting Period: Apr. 1, 2018 – Mar. 31, 2019
Disease Progression	-	-	1	1
Usage Outside of IFU Recommendations/Requirements	2	-	-	-
Cautionary Product Use	*1*	-	-	-
Off-IFU	*1*	-	-	-
Indeterminate	1	1	1	1
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**7**			

‡1 complaint had multiple causative types attributed to a given event.

µ "Cautionary Product Use" is defined as non-recommended product usage that is warned or cautioned against in the IFU. "Off-IFU" is defined as product usage against the product indications or contraindications in the IFU. "Indeterminate" is defined as an event for which the failure and/or cause could not be confirmed due to insufficient imaging or medical records.

As outlined in **Table 70** below, there is no predominant time to event point for the post-implant migrations reported between November 1, 2015 and March 31, 2019. As distribution of the Powerlink System ceased globally in January 2016, it follows that the majority of migrations reported during the last four reporting periods occurred in the later follow-up timepoints.

Table 70. Time to Event for Post-Implant Migration – Powerlink System

Time to Event for Migration	Powerlink
≤30 days	-
>30 days, ≤6 mo.	-
>6 mo., ≤1 year	-
>1 year, ≤2 year	-
>2 year, ≤3 year	-
>3 year, ≤4 year	-
>4 year, ≤5 year	1
>5 year, ≤6 year	-
>6 year, ≤7 year	1
>7 year, ≤8 year	2
Unknown	3
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**7**

Type IIIa Endoleak

Twenty (20) Type IIIa endoleaks have been reported worldwide in patients treated with the Powerlink System between November 1, 2015 and March 31, 2019. As outlined in **Table 71** below, the majority of the Type IIIa endoleaks for the Powerlink grafts involved patients whose devices were implanted outside of the IFU recommendations/requirements and this non-recommended use was found to lead to a Type IIIa endoleak. This would include, but is not limited to, patients that had anatomy outside of the IFU indications or patients that had been implanted with a device not meeting the revised overlap requirements in the IFU.

Table 71. Primary Causes of Type IIIa Endoleaks – Powerlink System

Cause of Type IIIa Endoleaks‡µ	2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016	2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017	2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018	2019 Reporting Period: Apr. 1, 2018 – Mar. 31, 2019
Intraoperative	-	-	1	-
Disease Progression	1	-	1	1
Migration	1	-	1	-
Usage Outside of IFU Recommendations/Requirements	10	1	2	2
Cautionary Product Use	*5*	-	*2*	*1*
Off-IFU	*5*	*1*	-	*1*
Indeterminate	3	1	-	6
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**20**			

‡9 complaint had multiple causative types attributed to a given event.

µ "Cautionary Product Use" is defined as non-recommended product usage that is warned or cautioned against in the IFU. "Off-IFU" is defined as product usage against the product indications or contraindications in the IFU. "Indeterminate" is defined as an event for which the failure and/or cause could not be confirmed due to insufficient imaging or medical records.

As outlined in **Table 72** below, there is no predominant time to event point for the Type IIIa endoleaks reported between November 1, 2015 and March 31, 2019. As distribution of the Powerlink System ceased globally in January 2016, it follows that the majority of Type IIIa endoleaks reported during the last four reporting periods occurred in the later follow-up timepoints. Further, based on the leading causative event, this same time to event pattern also follows as component separation would occur over time if the implanted device did not meet the revised overlap requirements in the IFU.

Table 72. Time to Event for Type IIIa Endoleaks – Powerlink System

Time to Event for Type IIIa Endoleaks	Powerlink
≤30 days	1
>30 days, ≤6 mo.	-
>6 mo., ≤1 year	-
>1 year, ≤2 year	-
>2 year, ≤3 year	1
>3 year, ≤4 year	-
>4 year, ≤5 year	3
>5 year, ≤6 year	4
>6 year, ≤7 year	2
>7 year, ≤8 year	6
Unknown	3
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**20**

Type IIIb Endoleak

Thirty-four (34) Type IIIb endoleaks have been reported worldwide in patients treated with the Powerlink System between November 1, 2015 and March 31, 2019. As outlined in **Table 73** below, the majority of the Type IIIb endoleaks for the Powerlink grafts for which a cause could be determined involved patients whose devices were implanted outside of the IFU recommendations/requirements and this non-recommended use was found to lead to a Type IIIb endoleak. This would include, but is not limited to, patients that had thrombus and/or calcium at the arterial implantation site, specifically the proximal aortic neck and distal iliac artery interface.

Table 73. Primary Causes of Type IIIb Endoleaks – Powerlink System

Cause of Type IIIb Endoleaks‡µ	2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016	2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017	2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018	2019 Reporting Period: Apr. 1, 2018 – Mar. 31, 2019
Post-Operative: Device Related	1	2	2	1
Usage Outside of IFU Recommendations/Requirements	3	2	1	3
Cautionary Product Use	*1*	*1*	-	*1*
Off-IFU	*2*	*1*	*1*	*2*
Indeterminate	4	8	3	11
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**34**			

‡5 complaint had multiple causative types attributed to a given event.

µ "Cautionary Product Use" is defined as non-recommended product usage that is warned or cautioned against in the IFU. "Off-IFU" is defined as product usage against the product indications or contraindications in the IFU. "Indeterminate" is defined as an event for which the failure and/or cause could not be confirmed due to insufficient imaging or medical records.

As outlined in **Table 74** below, there is no predominant time to event point for the Type IIIb endoleaks reported between November 1, 2015 and March 31, 2019. As distribution of the Powerlink System ceased globally in January 2016, it follows that the majority of Type IIIb endoleaks reported during the last four reporting periods occurred in the later follow-up timepoints. Further, based on the leading causative event, it also follows that the majority of Type IIIb endoleaks would occur at later timepoints as anatomical considerations (such as calcium at the implantation site) could lead to graft disruption over time.

Table 74. Time to Event for Type IIIb Endoleaks – Powerlink System

Time to Event for Type IIIb Endoleaks	Powerlink
≤30 days	-
>30 days, ≤6 mo.	-
>6 mo., ≤1 year	-
>1 year, ≤2 year	-
>2 year, ≤3 year	1
>3 year, ≤4 year	1
>4 year, ≤5 year	1
>5 year, ≤6 year	5
>6 year, ≤7 year	5
>7 year, ≤8 year	6
Unknown	15
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**34**

Other Stent Graft Integrity Events

Six (6) non-Type IIIb endoleak device integrity events have been reported worldwide in patients treated with the Powerlink System between November 1, 2015 and March 31, 2019. As outlined in **Table 75** below, the majority of these device integrity events for which a cause could be determined involved patients whose devices were implanted outside of the IFU recommendations/requirements.

Table 75. Primary Causes of Device Integrity Events – Powerlink System

Cause of Device Integrity Events‡µ	2016 Reporting Period: Nov. 1, 2015 – Sept. 30, 2016	2017 Reporting Period: Oct. 1, 2016 – Aug. 31, 2017	2018 Reporting Period: Sept. 1, 2017 – Mar. 31, 2018	2019 Reporting Period: Apr. 1, 2018 – Mar. 31, 2019
Stent Graft Patency	2	1	-	-
Usage Outside of IFU Recommendations/Requirements	2	2	-	-
Cautionary Product Use	*1*	*1*	-	-
Off-IFU	*1*	*1*	-	-
Indeterminate	1	1	-	2
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**6**			

‡5 complaint had multiple causative types attributed to a given event.

µ "Cautionary Product Use" is defined as non-recommended product usage that is warned or cautioned against in the IFU. "Off-IFU" is defined as product usage against the product indications or contraindications in the IFU. "Indeterminate" is defined as an event for which the failure and/or cause could not be confirmed due to insufficient imaging or medical records.

As outlined in **Table 76** below, there is no predominant time to event point for non-Type IIIb endoleak device integrity events reported between November 1, 2015 and March 31, 2019. As distribution of the Powerlink System ceased globally in January 2016, it follows that the majority of these device integrity events reported during the last four reporting periods occurred in the later follow-up timepoints.

Table 76. Time to Event for Device Integrity Events – Powerlink System

Time to Event for Device Integrity Events	Powerlink
≤30 days	-
>30 days, ≤6 mo.	-
>6 mo., ≤1 year	-
>1 year, ≤2 year	-
>2 year, ≤3 year	-
>3 year, ≤4 year	-
>4 year, ≤5 year	1
>5 year, ≤6 year	1
>6 year, ≤7 year	2
>7 year, ≤8 year	2
Unknown	-
TOTAL Complaints (Nov. 1 2015 – Mar. 31, 2019)	**6**

Appendix B: Device Explant Evaluations of the Powerlink System

As detailed above, Endologix monitors product performance to ensure the ongoing quality, safety, and efficacy of its products. Upon explantation and return of a product, either after implantation during a clinical study or in commercial experience, an investigation is performed. The investigation includes a thorough review of the product manufacturing records, patient clinical information from the implant procedure and follow-up, available follow-up imaging studies, and clinician-provided explant observations and reports. An engineering evaluation of the returned device is performed using standard techniques, including x-ray and scanning electron microscopy. Independent gross and histopathological evaluations of explanted stent grafts are performed by a board-certified pathologist to assess the biologic response as well as device integrity. This section details the explant evaluations for the Powerlink System, the predecessor to the AFX System, which is no longer commercially available.

Device Explants (Lifetime)

Thirty-nine (39) device explant evaluations have been conducted on the Powerlink ePTFE grafts during its lifetime (May 2000 – March 2019). As outlined in **Table 77** below, the leading reason for device explantation with the Powerlink ePTFE grafts were patients that experienced intra-operative complications.

Table 77. Reason for Device Explantation – Powerlink System

Reason for Device Explantation[µ] (May 2000 – March 2019)	Powerlink System
Intra-Operative Complications	12
Endoleak Type Ia	5
Endoleak Type Ib	-
Endoleak Type II	6
Endoleak Type IIIa	5
Endoleak Type IIIb	3
Endoleak Type V	-
Device Migration	3
Aneurysm Expansion	7
Aneurysm Rupture (post-implant)	5
Stent Graft Occlusion	4
Infection	4
Indeterminate	5
TOTAL Explant Evaluations[‡]	**39**

[‡] Complaints had multiple reasons attributed to a given event.

[µ] "Indeterminate" is defined as an event for which the failure and/or cause could not be confirmed due to insufficient imaging or medical records.

The results of the explant evaluations are outlined in **Table 78** below. As shown in this data set, the majority of device explantations for the Powerlink ePTFE grafts were related to patient anatomy and involved patients whose devices were implanted outside of the IFU recommendations/requirements. Other than usage outside of the IFU recommendations/requirements, the leading observation were graft hole/tears although that number remains low for the Powerlink ePTFE grafts. Specifically, Endologix confirmed the presence of five (5) graft holes/tears in those Powerlink ePTFE grafts returned for evaluation.

Table 78. Device Explant Evaluation Results – Powerlink System

Results of Device Explant Evaluation[μ] (May 2000 – March 2019)	Powerlink System
Patient Anatomy	19
Cautionary Product Use	*9*
Off-IFU	*10*
Graft Material Observations	7
Hole of Tear	*5*
Explant Damage	*2*
Stent Observations	7
Buckling/Kinking	*3*
Device Fracture	*2*
Explant Damage	*2*
TOTAL Explant Evaluations[‡]	**39**

[‡] Evaluations had multiple result types attributed to a given event.

[μ] "Cautionary Product Use" is defined as non-recommended product usage that is warned or cautioned against in the IFU. "Off-IFU" is defined as product usage against the product indications or contraindications in the IFU. "Indeterminate" is defined as an event for which the failure and/or cause could not be confirmed due to insufficient imaging or medical records.

As outlined in **Table 79** below, the majority of device explants for the Powerlink System occurred acutely, within the first 30 days after implantation. As noted above, the leading reason for device explanation with the Powerlink ePTFE grafts were attributed to acute factors, such as intra-operative complications. Furthermore, the results of the explant evaluation found that the majority of the device explant cases with the Powerlink ePTFE grafts were attributed to patient anatomy and involved patients whose devices were implanted outside of the IFU recommendations/requirements. Based on these reported reasons and identified observations, it follows that the majority of device explants for the Powerlink ePTFE grafts occur peri-operatively as implanting the Powerlink System devices outside of the anatomical requirements/recommendations in the IFU would lead to difficulties in excluding the aneurysm and achieving adequate seal.

Table 79. Time to Event for Device Explantation – Powerlink System

Time to Event for Device Explantation	Powerlink System
≤30 days	11
>30 days, ≤6 mo.	8
>6 mo., ≤1 year	1
>1 year, ≤2 year	2
>2 year, ≤3 year	2
>3 year, ≤4 year	4
>4 year, ≤5 year	3
>5 year, ≤6 year	3
>6 year, ≤7 year	1
>7 year, ≤8 year	1
Unknown	3
TOTAL Explant Evaluations	**39**

Appendix C: AFX with STRATA Identifiers

As detailed above, Endologix had noted higher rates of Type III endoleaks with the original AFX System's ePTFE (AFX with STRATA) and subsequently took actions between 2013 and 2016 in an attempt to further reduce the rates of these Type III endoleaks. Ultimately, these actions culminated in the removal of any remaining STRATA devices from the field through a December 2016 Field Safety Notice. As noted in that December 2016 communication, AFX devices with the STRATA graft material can be identified by the finished good product code starting with the letter F (i.e., FXXXXX or FXXXXX-XX). A comprehensive list of affected finished good product codes (F#s) is provided below. Alternatively, physicians may request details on any patients that have been implanted with AFX with STRATA via 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.

Table 80. AFX with STRATA Identifiers

Model #	F #	Model #	F #	Model #	F #	Model #	F #
BA22-80/I20-40	F00627	BA28-100/I16-40	F00431	A28-28/C75-O20	F00394	A28-28/C95-O20N	F00727-09
BA22-100/I16-40	F00429	BA28-80/I16-40	F00426	A28-28/C95-O20	F00370	A34-34/C80-O20N	F00727-12
BA22-80/I16-40	F00424	BA28-60/I16-40	F00420	A31-31/C80-O20	F00398	I16-16/C55	F00561
BA22-60/I16-40	F00418	BA28-100/I13-40	F00414	A31-31/C100-O20	F00404	I16-16/C55	F00372
BA22-40/I13-40	F00611	BA28-80/I13-40	F00411	A34-34/C80-O20	F00400	I16-16/C55F	F00371
BA22-100/I13-40	F00412	BA28-60/I13-40	F00408	A34-34/C100-O20	F00369	I16-16/C88	F00373
BA22-80/I13-40	F00409	BA28-90/I20-30	F00659	A22-22/C55V	F00703-01	I20-13/C70F	F00376
BA22-60/I13-40	F00406	BA28-70/I20-30	F00658	A22-22/C75V	F00703-02	I20-13/C70F	F00566
BA22-90/I20-30	F00623	BA28-90/I16-30	F00423	A22-22/C95V	F00703-03	I20-13/C88F	F00567
BA22-70/I20-30	F00622	BA28-70/I16-30	F00417	A25-25/C55V	F00703-04	I20-13/C88F	F00377
BA22-90/I16-30	F00421	BA28-100/I16-55	F00368	A25-25/C75V	F00703-05	I20-20/C55	F00374
BA22-70/I16-30	F00415	BA28-80/I16-55	F00428	A25-25/C95V	F00703-06	I20-20/C55	F00564
BA25-120/I20-40	F00600	A22-22/C55	F00381	A28-28/C55V	F00703-07	I20-20/C55F	F00375
BA25-80/I20-40	F00645	A22-22/C75	F00384	A28-28/C75V	F00703-08	IS20-25/C55	F00378
BA25-120/I16-40	F00637	A22-22/C95	F00442	A28-28/C95V	F00703-09	IF20-25/C65	F00379
BA25-100/I16-40	F00430	A25-25/C55	F00382	A31-31/C80V	F00703-10	IS20-25/C65	F00380
BA25-80/I16-40	F00425	A25-25/C75	F00385	A31-31/C100V	F00703-11	I16-16/C55 SA	F00551
BA25-60/I16-40	F00419	A25-25/C95	F00390	A34-34/C80V	F00703-12	I16-16/C55F SA	F00553
BA25-100/I13-40	F00413	A28-28/C55	F00383	A34-34/C100V	F00703-13	I16-16/C88 SA	F00552
BA25-80/I13-40	F00410	A28-28/C75	F00386	A22-22/C55-O20V	F00726-01	I20-13/C70F SA	F00556
BA25-60/I13-40	F00407	A28-28/C95	F00391	A22-22/C75-O20V	F00726-02	I20-13/C88F SA	F00557
BA25-110/I20-30	F00642	A31-31/C80	F00396	A22-22/C95-O20V	F00726-03	I20-20/C55 SA	F00554
BA25-90/I20-30	F00641	A31-31/C100	F00443	A25-25/C55-O20V	F00726-04	I20-20/C55F SA	F00555
BA25-70/I20-30	F00640	A34-34/C80	F00397	A25-25/C75-O20V	F00726-05	IS20-25/C55 SA	F00558
BA25-110/I16-30	F00635	A34-34/C100	F00399	A25-25/C95-O20V	F00726-06	IF20-25/C65 SA	F00560
BA25-90/I16-30	F00422	A22-22/C55-O20	F00387	A28-28/C55-O20V	F00726-07	IS20-25/C65 SA	F00559
BA25-70/I16-30	F00416	A22-22/C75-O20	F00392	A28-28/C75-O20V	F00726-08		
BA25-100/I16-55	F00432	A22-22/C95-O20	F00405	A28-28/C95-O20V	F00726-09		
BA25-80/I16-55	F00427	A25-25/C55-O20	F00388	A31-31/C80-O20V	F00726-10		
BA28-120/I20-40	F00601	A25-25/C75-O20	F00393	A31-31/C100-O20V	F00726-11		
BA28-80/I20-40	F00663	A25-25/C95-O20	F00395	A34-34/C80-O20V	F00726-12		
BA28-120/I16-40	F00655	A28-28/C55-O20	F00389	A34-34/C100-O20V	F00726-13		

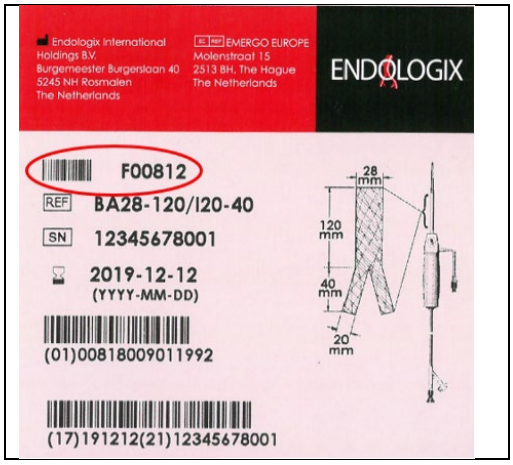

Figure 23. F# Label Location Example