Endologix

LEOPARD

LEADER IN EVAR TRIALS

MEANINGFUL EVIDENCE / STANDARD OF THE FUTURE

The first randomized controlled trial comparing the outcomes of endovascular aneurysm repair using commercially available devices in a real-world population

LEOPARD DEMONSTRATES POSITIVE AFX2 PERFORMANCE OUTCOMES

1:1 RANDOMIZATION | 455 PATIENTS | 56 US CENTERS

STUDY DESIGN

Patient and vascular characteristics were comparable between the two cohorts

EVAR Patients (N=455)

- **Anatomical Fixation (AF)** (n=235)
  - AFX with Duraply/AFX2
- **Proximal Fixation (PF)** (n=220)
  - ENDURANT
  - EXCLUDER
  - ZENITH

Primary Endpoint

Aneurysm-Related Complications (ARC)

- Peri-procedural death (<30d)
- Rupture
- Conversion to Open Surgical Repair
- Endoleak
- Occlusion
- Migration >10 mm
- Aneurysm Enlargement >5 mm
- Device, AAA-Related Reintervention

AFX2 REVEALED 5 YEAR RESULTS IN A RANDOMIZED CONTROLLED TRIAL COMPARABLE TO CONTEMPORARY PROXIMAL FIXATION ENDOGRAFTS

ADVANCING EVAR, MINIMIZING COMPLICATIONS

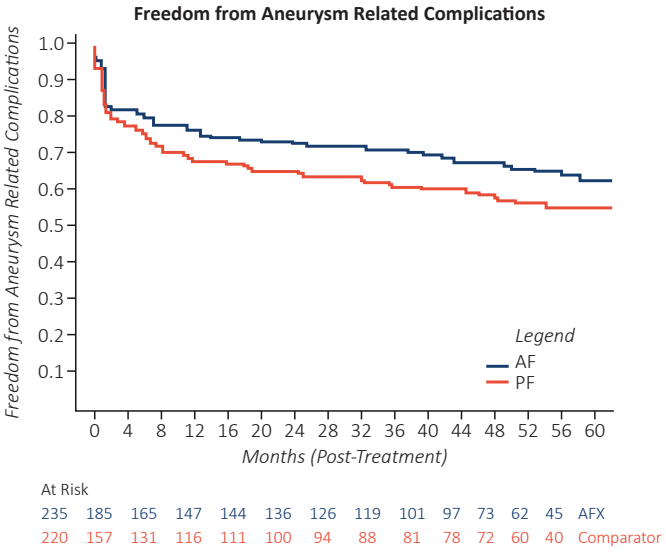
99%
Freedom From Rupture

97%
Freedom From ARC

1.5%
AFX/AFX2 Type III Endoleak rate at 5 years

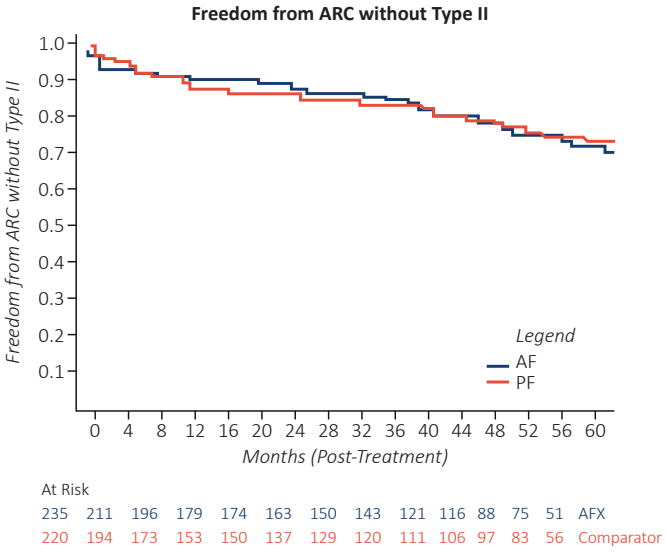
Data cut August 31, 2022 used throughout

FIVE YEAR RESULTS DISPLAY NOTABLE FREEDOM FROM ANEURYSM RELATED COMPLICATIONS WITH AFX2, WHEN CONSIDERING TYPE II ENDOLEAK RATES



At Risk

235	185	165	147	144	136	126	119	101	97	73	62	45	AFX
220	157	131	116	111	100	94	88	81	78	72	60	40	Comparator



At Risk

235	211	196	179	174	163	150	143	121	116	88	75	51	AFX
220	194	173	153	150	137	129	120	111	106	97	83	56	Comparator

ELEVATED PROCEDURAL PERFORMANCE WITH COMPARABLE PERIOPERATIVE OUTCOMES

PROCEDURAL CHARACTERISTICS

	Anatomic Fixation	Proximal Fixation
Total Procedure Time (min, max)	79.5 (30, 374)	90.5 (34, 303)
Fluoroscopy Time (min, max)	16.0 (3, 116)	18.5 (5, 84)
Total Anesthesia Time (min, max)	152.5 (57, 490)	166 (65, 390)
Contrast Volume (mL)	68 (15, 220)	84 (15, 345)

EVENT TYPE

Freedom-from-Event Estimates at 5 years

	AFX Duraply/AFX2	Comparators
Aneurysm-Related Mortality (ARM)	97.0%	98.5%
Aneurysm Rupture	98.9%	99.3%
Conversion to Open Repair	100%	98.0%
Type I Endoleak	93.3%	95.4%
Type II Endoleak	79.7%	69.4%
Type III Endoleak	98.6%	100%
Migration ≥ 10mm	96.8%	97.9%
Device Occulsion	96.6%	95.3%
Secondary Intervention	84.4%	85.5%

Data cut August 31, 2022 used throughout

INDICATIONS FOR USE- US : The Endologix® AFX®2 Endovascular AAA Systems are indicated for treatment of patients with abdominal aortic aneurysms having the vascular morphology suitable for endovascular repair using a surgical vascular access technique or a bilateral percutaneous technique; a non-aneurysmal aortic neck between the renal arteries and the aneurysm: with length of ≥15mm, diameter ≥18 to ≤32mm and neck angle of ≤60° to the body of the aneurysm; aortic length ≥1.0cm longer than the body portion of the chosen bifurcated model; common iliac artery distal fixation site with length ≥15mm, diameter of ≥10 to ≤23mm, and with ability to preserve at least one hypogastric artery; and with an iliac angle of ≤90° to the aortic bifurcation. Extension stent grafts must have the ability to overlap the bifurcated stent graft by at least 30 to 40mm proximally and at least 15 to 20mm distally.

CONTRAINDICATIONS- US: The Endologix® AFX®2 Endovascular AAA Systems are contraindicated for use in patents who have a condition that threatens to infect the graft and in patients with sensitivities or allergies to the device materials. Refer to the Instructions for Use for more information concerning Indications, Contraindications, Warnings and Precautions, and Adverse Events.

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CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. Rx only.

Note: Endologix products and associated components are not available in all countries or regions. Please consult with your Endologix representative for details regarding product availability. CE marked. Please refer to current product instructions for use.