LEOPARD

Looking at EVAR Outcomes by Primary Analysis of Randomized Data

The LEOPARD Randomized Trial Comparing the Endologix AFX/AFX2® Endograft with Active Fixation to Proximal Fixation Endografts: 3-year Outcomes

Faculty Disclosure

LEOPARD

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I disclose the following relationships:

Clinical Research/Consultant/Speaker
Aptus, Bolton, Cordis, Cook, Endologix, Medtronic,
Nellix, Terumo, Trivascular, WL Gore

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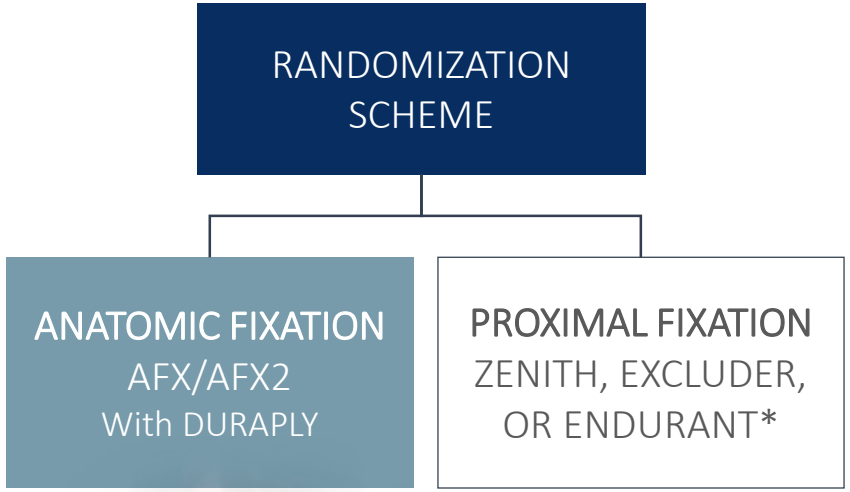
LEOPARD

Looking at EVAR Outcomes by Primary Analysis of Randomized Data



First contemporary RCT comparing EVAR devices

Prospective, randomized, multicenter trial

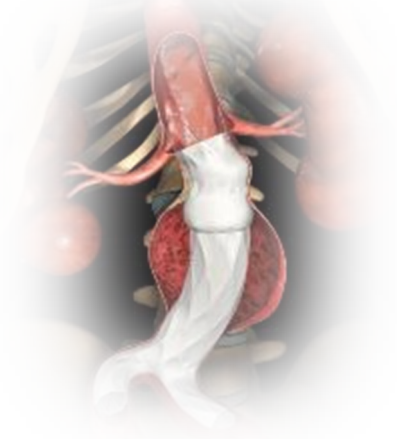
Real-world patient population**

Head-to-head comparison of EVAR endograft systems

At least 400 patients

Up to 80 US Centers

Follow-Up: 5 Years



One Device Selected Prospectively by Each Investigator

**LEOPARD includes results from a real-world patient population. 25% of Anatomical Fixation had vascular characteristics outside of approved anatomic IFU. Safety and effectiveness of AFX when used outside the IFU have not been established.

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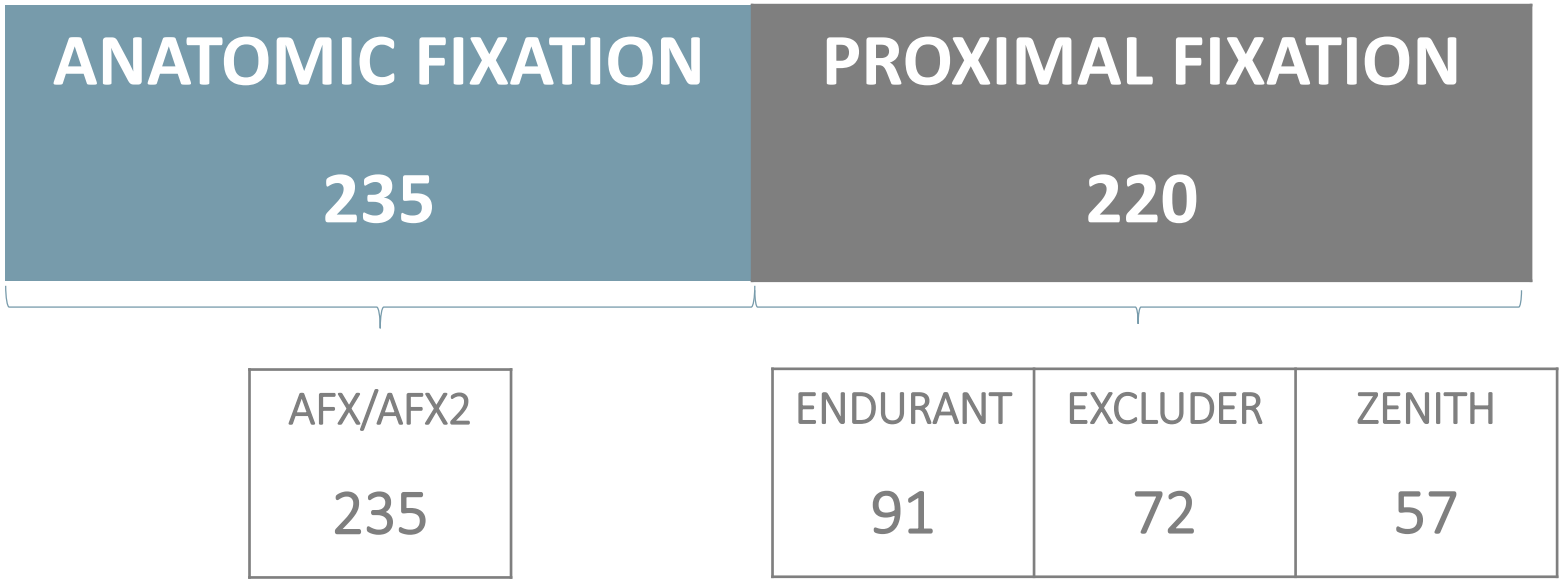
Enrollment

455 Total Patients



Data cut 10/30/2019; Total number accounts for as treated patients and includes subjects that exited

Similar Patient Demographics, Vascular and Procedural Characteristics

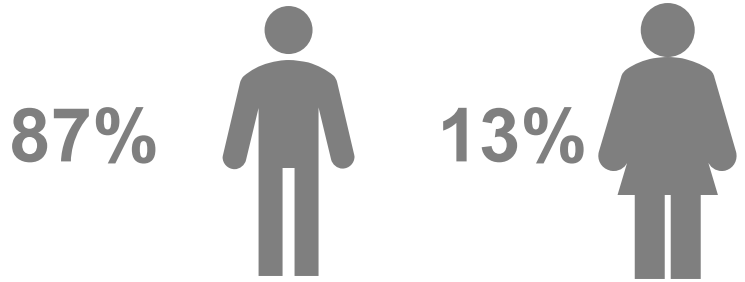
ANATOMIC FIXATION
N = 231

73† years

52% (118/229)

MI: 18% (41/229)

PROXIMAL FIXATION
N = 220



72 † years

64% (141/219)

MI: 14% (31/229)

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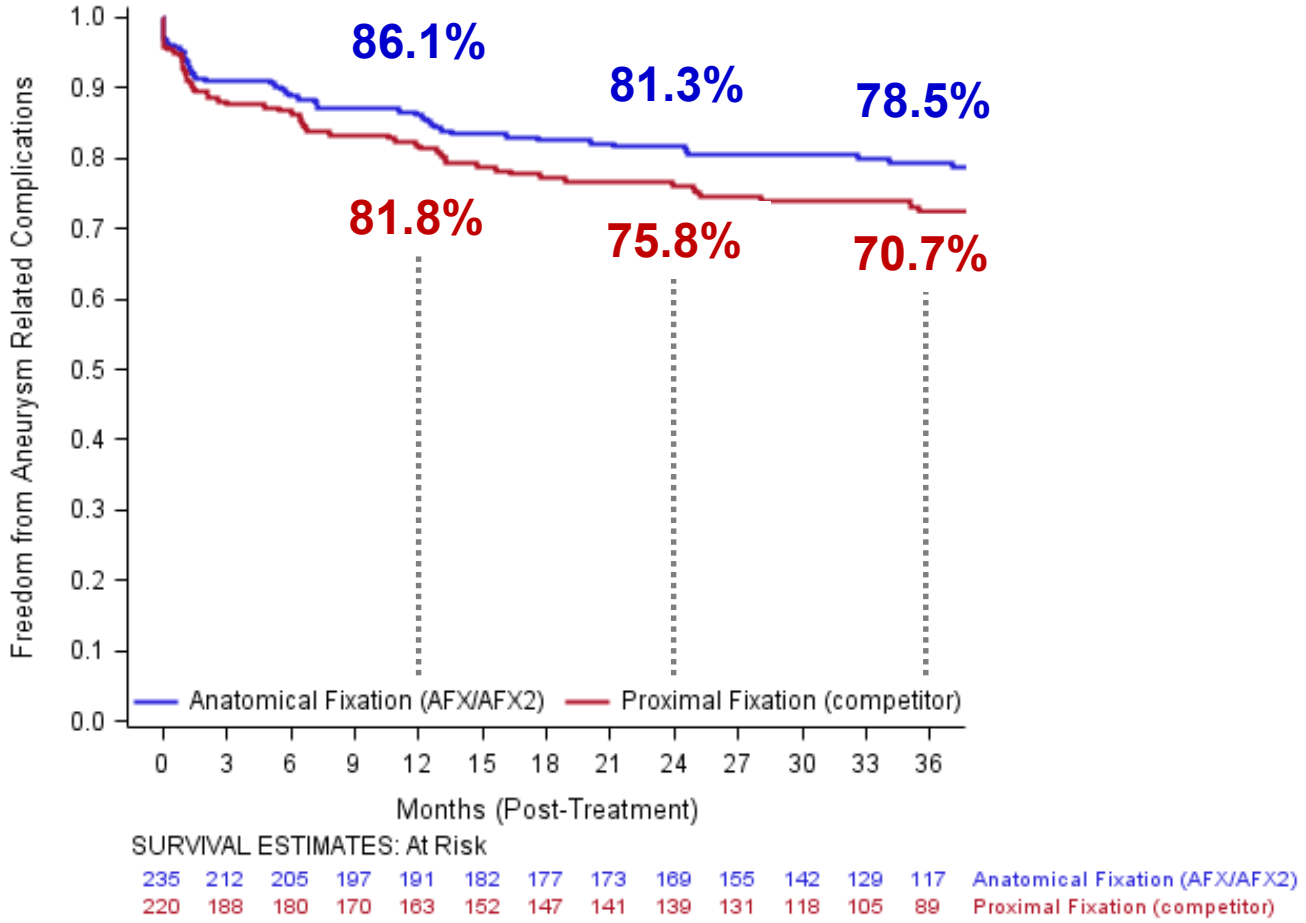
†mean age ±8 years; MI myocardial infarction history

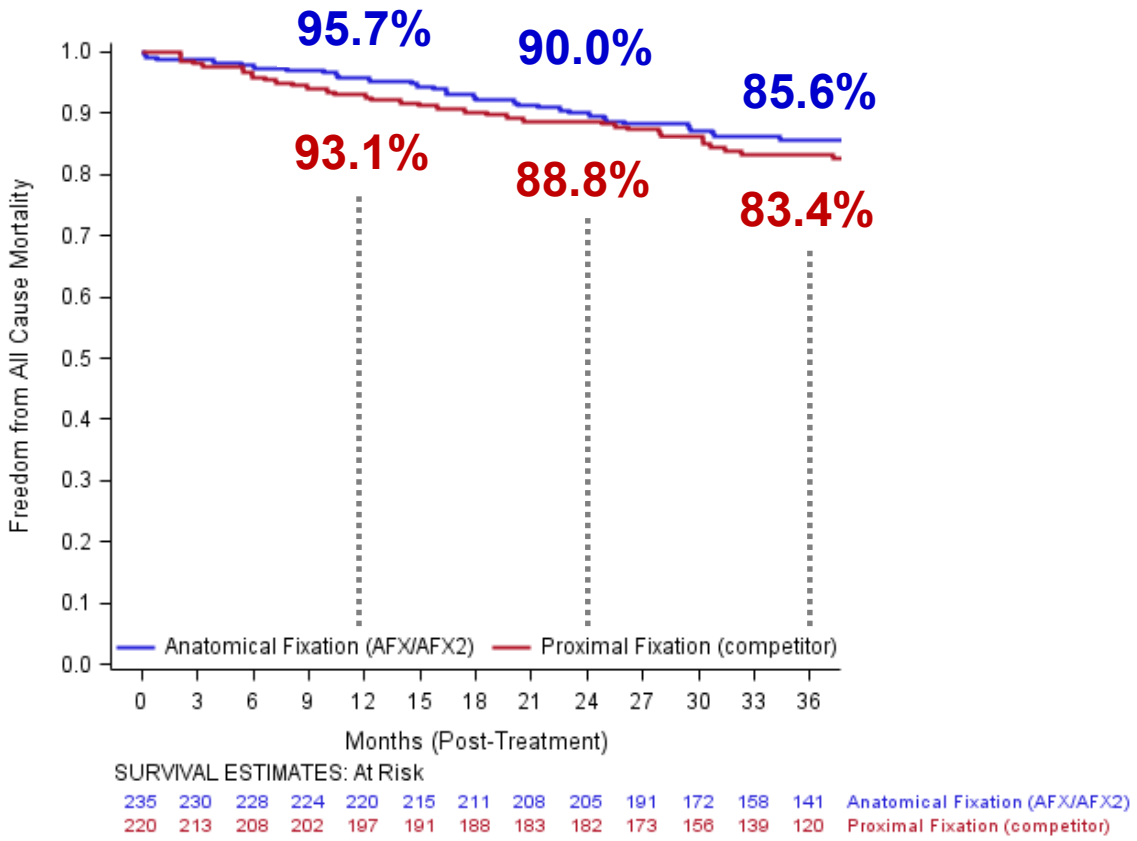
Similar Freedom From Aneurysm Related Complications (ARC)

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

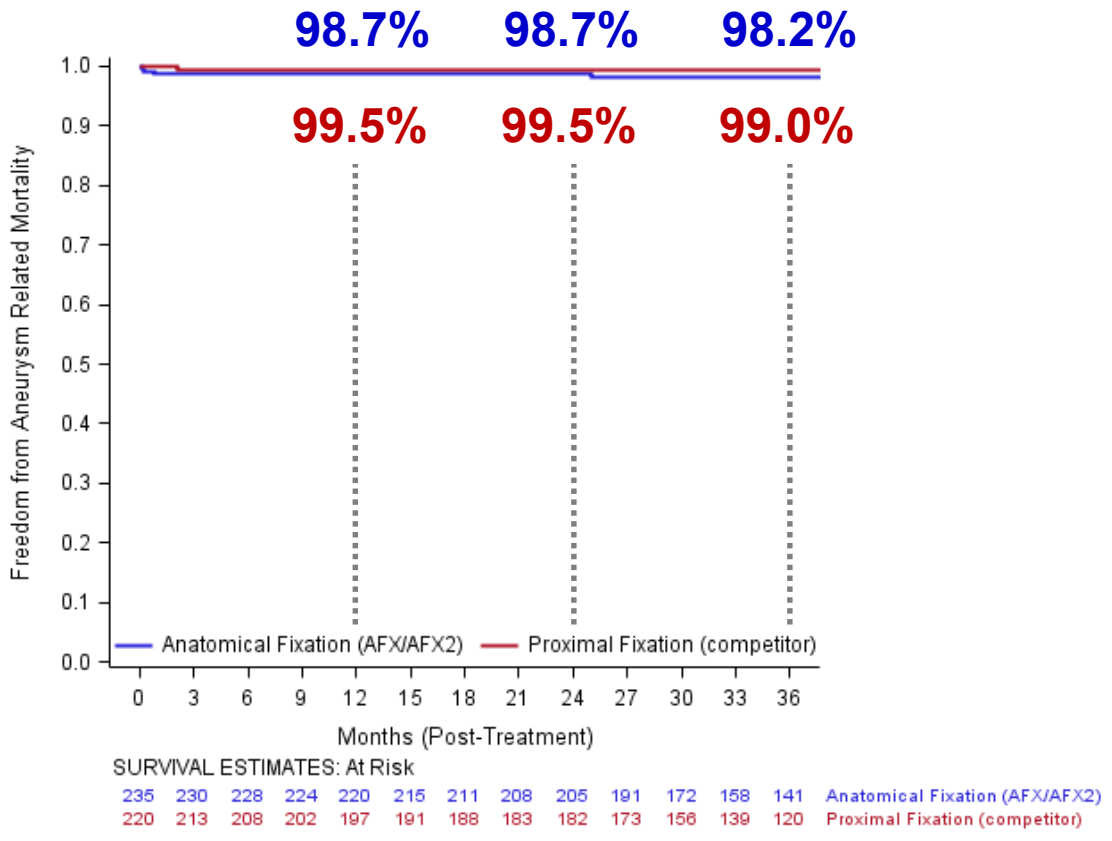


Similar Freedom From All-Cause Mortality, AAA-Related Mortality

Freedom From All-Cause Mortality



Freedom From AAA-Related Mortality



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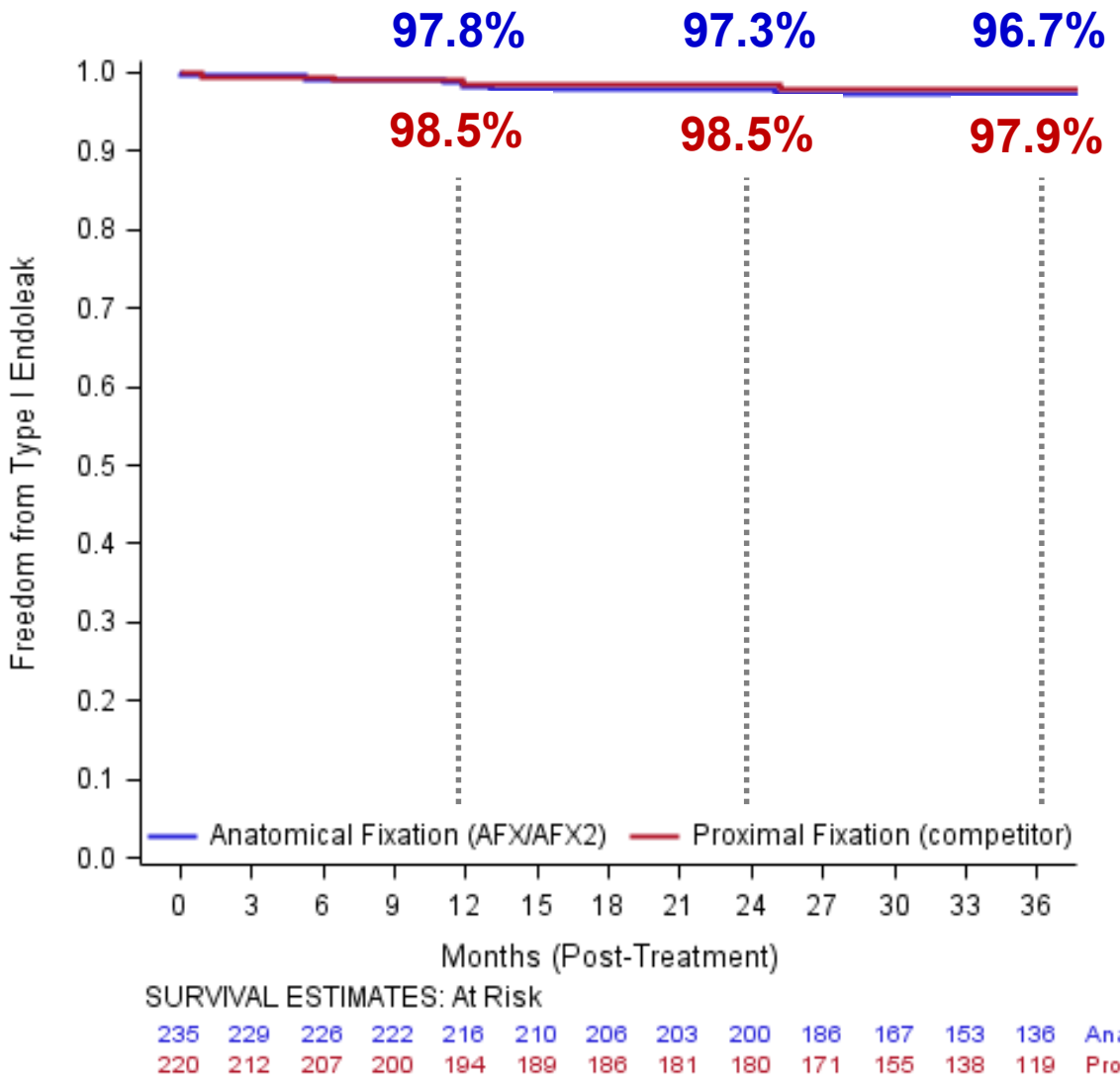
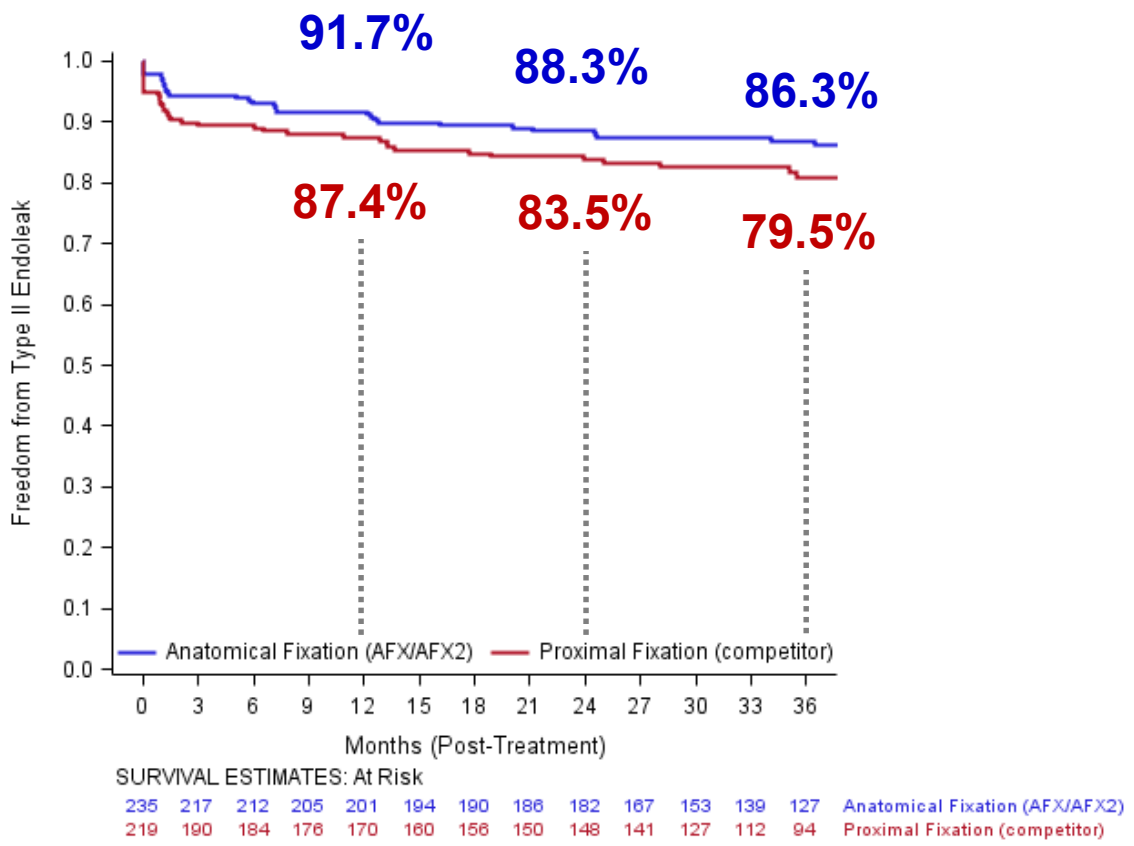
The AFX® System is approved to treat infrarenal abdominal aortic aneurysms. The AFX® Endovascular AAA System and associated components are not available in all countries or regions. Please contact your Endologix representative for details regarding product availability. Prior to use, refer to the "Instructions for Use" for complete and specific indications, contraindications, all warnings and precautions. Rx only
MM2178 Rev 01

Similar Freedom From Type I Endoleaks

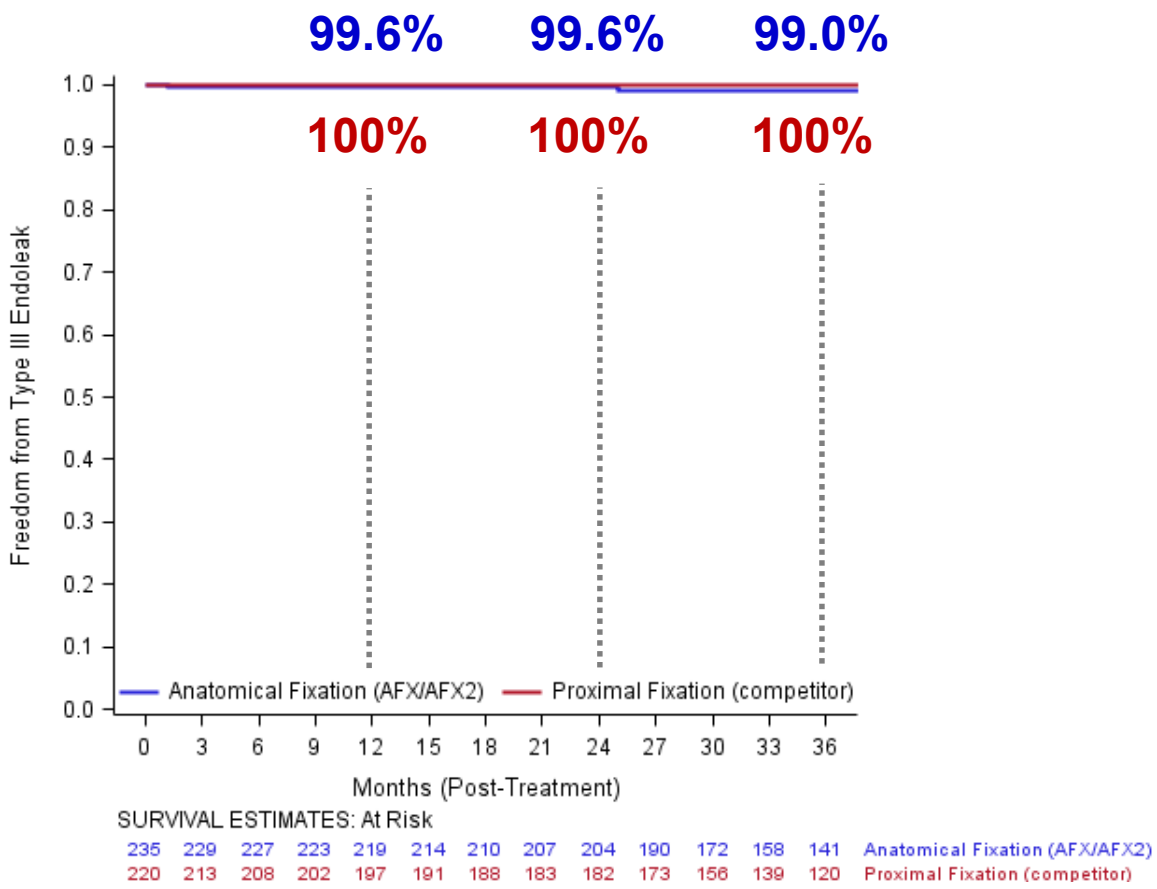


Similar Freedom From Type II or Type III Endoleaks

Freedom From Type II Endoleak



Freedom From Type III Endoleak



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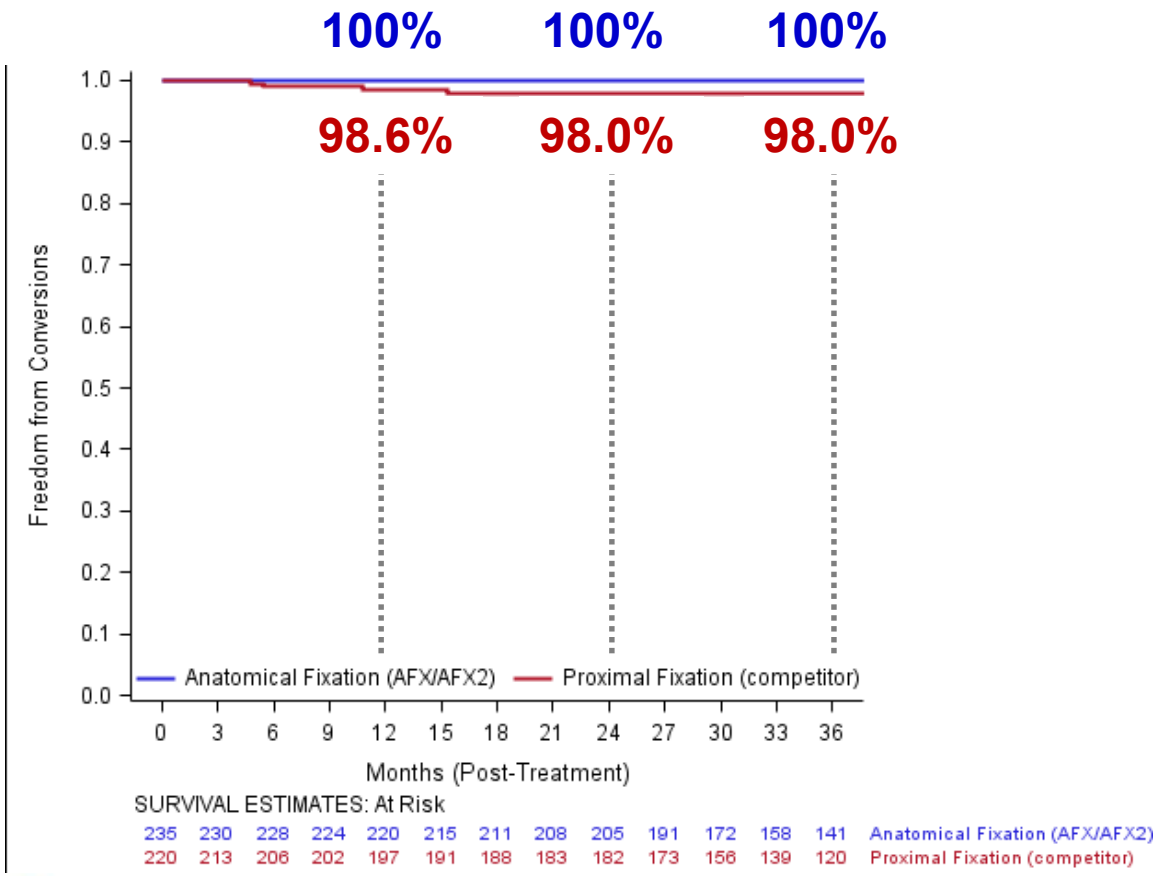
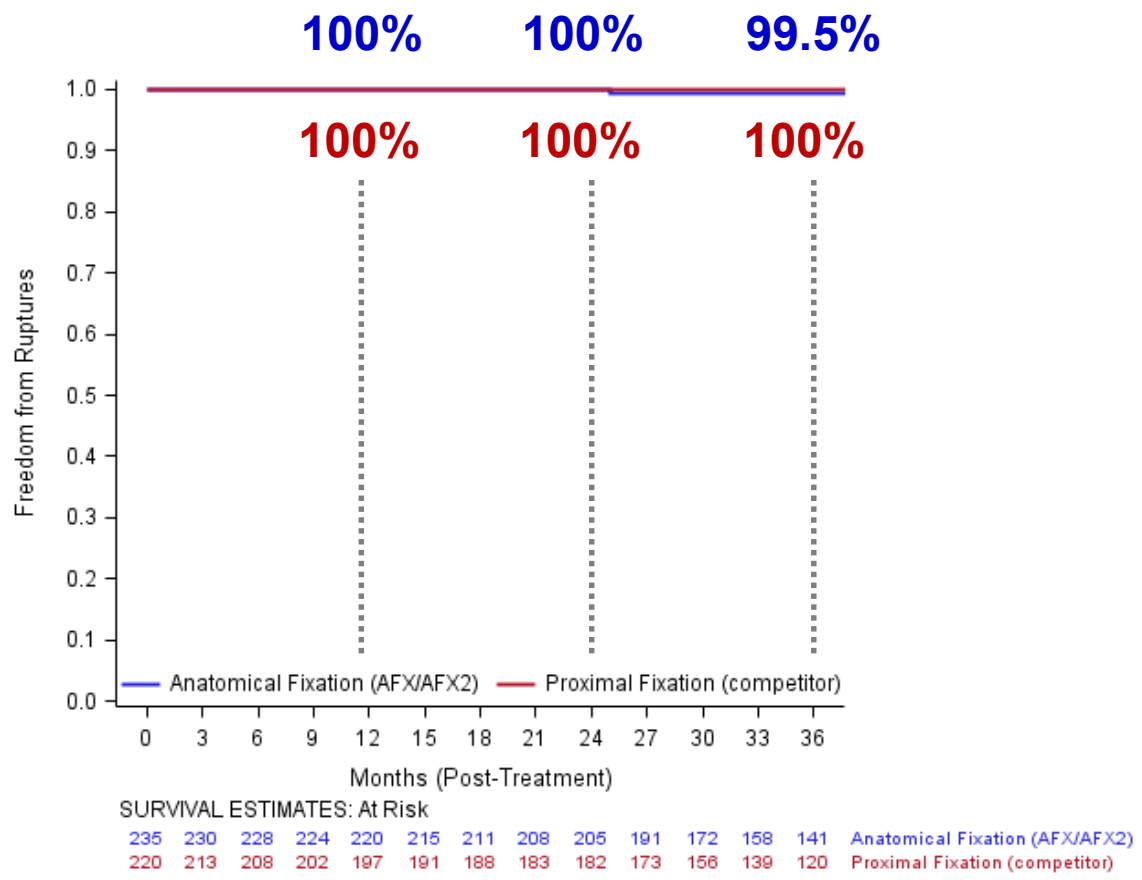
Similar Freedom From Conversion and Rupture

Freedom From Conversion



Freedom From Rupture



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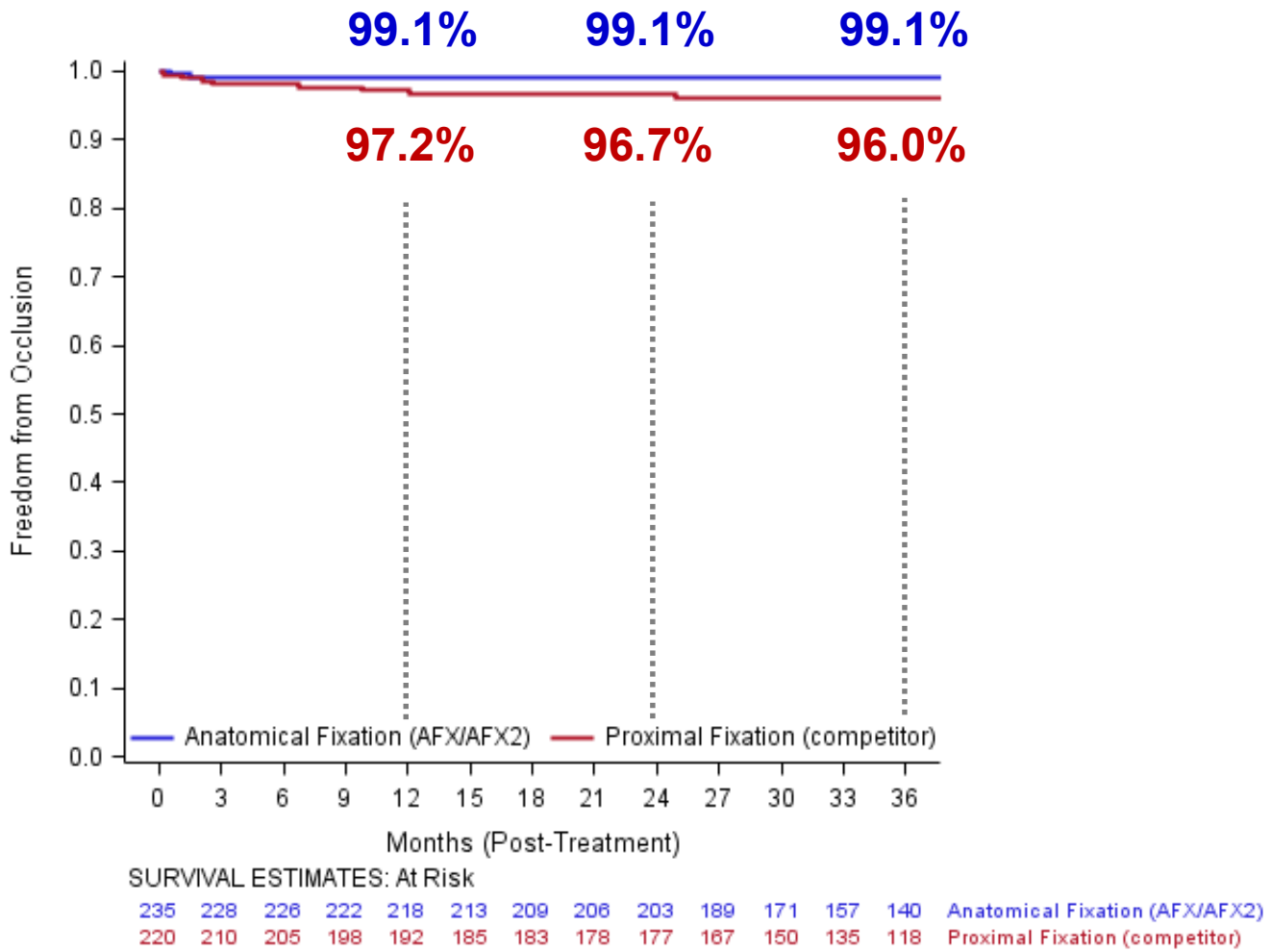
Similar Freedom From Occlusion



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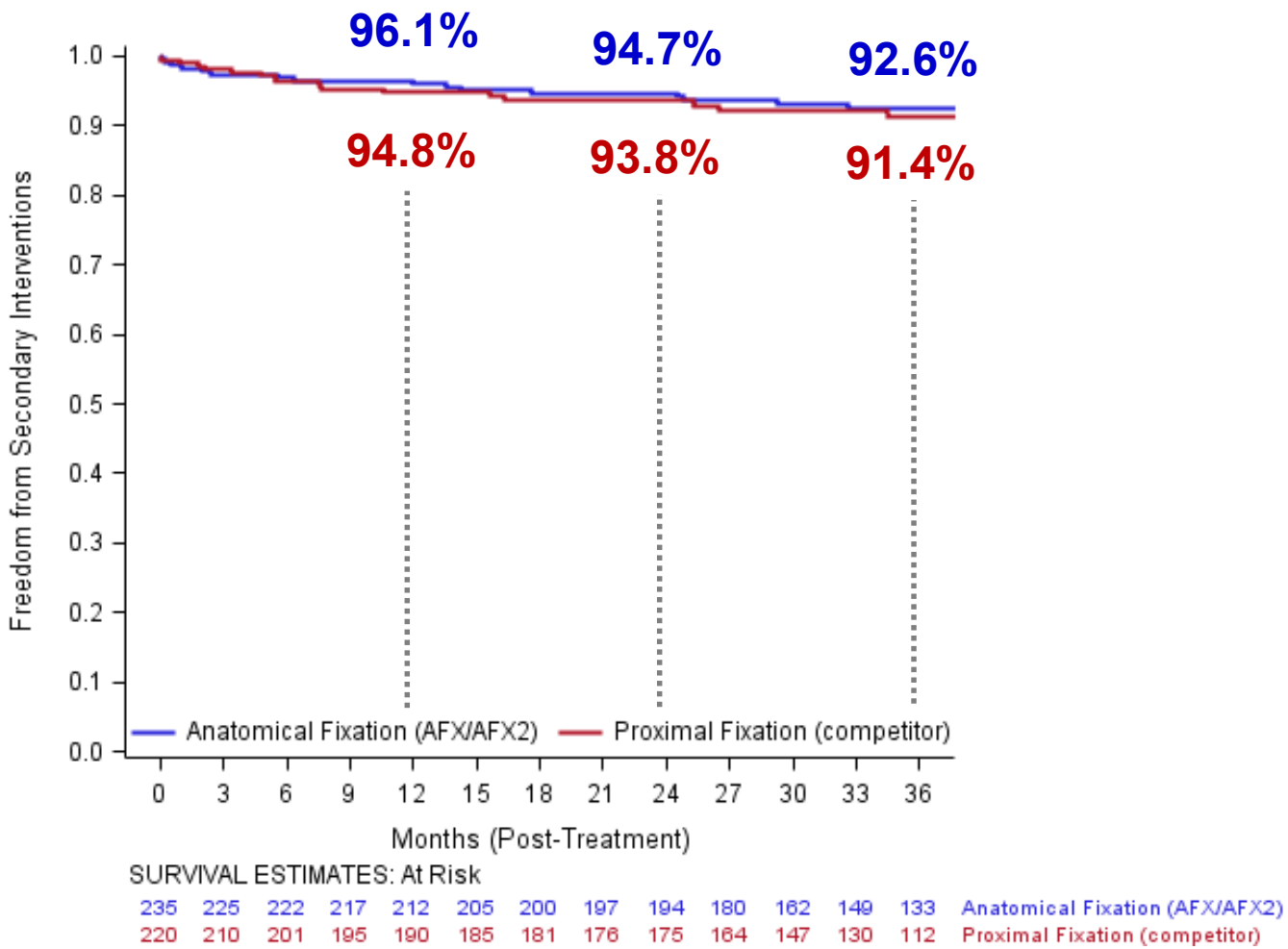
Similar Freedom From Reinterventions



REASON FOR REINTERVENTION	ANATOMIC FIXATION	PROXIMAL FIXATION
ENDOLEAK TYPE I	5	3
ENDOLEAK TYPE II	1	3
ENDOLEAK TYPE IIIB	1	0
OCCLUSION	1	8
STENOSIS	4	1
OTHER	3	4

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Conclusions from LEOPARD 3-year Analysis

- **Level 1 evidence** in contemporary, real-world patient population using commercially available EVAR devices
- LEOPARD is the **first RCT** comparing contemporary devices
- Provides the first modern randomized control group for future trials
- **Anatomic Fixation performed similarly to Proximal Fixation through 3 years**
- Need to evaluate Anatomic fixation and Proximal Fixation in different patient populations

INDICATIONS FOR USE: The Endologix AFX® 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: The Endologix AFX 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.

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.

The AFX® System is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.

CE marked. Please refer to current product instructions for use.

*LEOPARD includes results from a real-world patient population. 25% of Anatomical Fixation had vascular characteristics outside of approved anatomic IFU. Safety and effectiveness of AFX when used outside the IFU have not been established.

Patient Demographics

Patient demographics and comorbid risk factors indicate a typical contemporary AAA patient cohort

		ANATOMIC FIXATION	PROXIMAL FIXATION
AGE (YEARS)		73 ± 8	72 ± 8
GENDER	MALE	208 (90%)	192 (87%)
	FEMALE	22 (10%)	29 (13%)
RACE	CAUCASIAN	221 (96%)	199 (90%)
	NON-CAUCASIAN	10 (4%)	21 (10%)
ASA CLASS	1/2	71 (31%)	62 (28%)
	3/4/5	160 (69%)	158 (72%)

	ANATOMIC FIXATION	PROXIMAL FIXATION
HISTORY OF SMOKING	118 (52%)	141 (64%)
HYPERTENSION	189 (83%)	182 (83%)
CAD	92 (40%)	86 (39%)
MI	41 (18%)	31 (14%)
HYPERLIPIDEMIA	161 (70%)	159 (73%)
COPD	67 (29%)	67 (31%)
PVD	36 (16%)	41 (19%)
DIABETES	43 (19%)	43 (20%)
FAMILY HISTORY AAA	32 (14%)	28 (13%)

Vascular Characteristics Were Similar Between Groups

	ANATOMIC FIXATION	PROXIMAL FIXATION
MAXIMUM SAC DIAMETER (MM)	56.1 ± 8.0	55.8 ± 9.3
NON-ANEURYSMAL NECK LENGTH (MM)	24.3 ± 14.2	23.2 ± 13.2
MAX NECK DIAMETER AT LOWEST RENAL (MM)	24.6 ± 3.3	24.8 ± 3.6
COMMON ILIAC ARTERY DIAMETER, MAX (MM)	18.4 ± 4.9	18.3 ± 5.6
EXTERNAL ILIAC MINIMUM DIAMETER (MM)	7.3 ± 1.8	7.2 ± 1.8
AORTIC NECK ANGULATION (°)	15 ± 10	15 ± 9
MAXIMUM SAC DIAMETER (MM)	56.1 ± 8.0	55.8 ± 9.3
% REVERSE TAPER	16%	13%
NATIVE AORTIC BIFURCATION DIA ≤20 MM	9%	13%
% OFF ANATOMIC IFU*	25%	22%

*Based on each products Aortic Neck indication including neck length, angulation, and aortic neck diameter

Procedural Characteristics

	ANATOMIC FIXATION	PROXIMAL FIXATION
TOTAL PROCEDURE TIME (MIN)	80 (30, 374)	90.5 (34, 303)
FLUOROSCOPY TIME (MIN)	16 (3, 116)	18.5 (5, 84)
TOTAL ANESTHESIA TIME (MIN)	152.5 (39, 490)	166 (65, 390)
CONTRAST VOLUME (ML)	68 (15, 220)	84 (15, 345)
BILATERAL PERCUTANEOUS ACCESS	69.4%	66.4%
GENERAL ANESTHESIA	92.8%	93.6%
REQUIRING BLOOD TRANSFUSION	0.4%	0.9%
TIME IN ICU (DAYS)	0 (0, 7.3)	0 (0, 11.2)
TIME TO HOSPITAL DISCHARGE (DAYS)	1.3 (0.7, 16)	1.3 (0.7, 31)