

**AFX 2 Anatomically Fixed Endografts for AAA Repair: The LEOPARD RCT 5 year results Show it has Similar Outcomes to Other Proximally Fixed Endografts**

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MM2494 Rev 01

### Faculty Disclosures

- I disclose the following financial relationships:
- Amsel Medical, Endologix, Philips, Silk Road, Vasorum

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### Purpose

- The LEOPARD trial is the first randomized controlled trial (RCT) comparing the outcomes of endovascular aneurysm repair (EVAR) using commercially available devices in a real-world population.
  - ~One third of patients in each group treated outside IFU
- LEOPARD designed to be consistent with current treatment guidelines for evaluation and follow-up
  - Though with increased sensitivity for events due to higher compliance with post operative surveillance

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### Design

- Anatomical Fixation (AF) is compared to Proximal Fixation (PF)
- PF is a group of 3 EVAR comparators
- Primary Endpoint is a composite of several Aneurysm-Related Complications ("ARC")
- "At-or-better" design: Evaluates non-inferiority, then superiority, in two steps at 1 year
- 8% non-inferiority margin (determined by steering committee)

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### Design

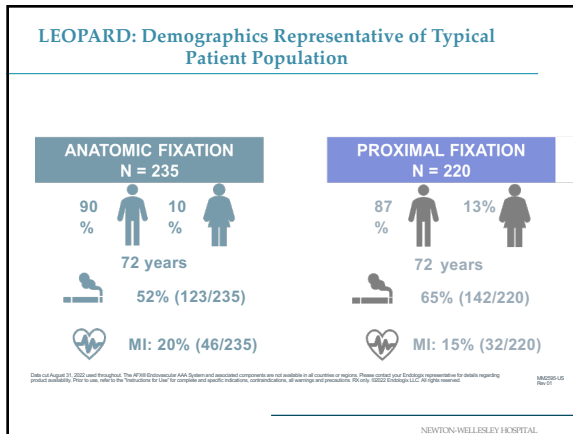
- All device-related events and MAEs identified in study reviewed and adjudicated by independent physician adjudicator
- Imaging-driven results also reviewed and assessed by independent core lab
- >4000 imaging studies obtained

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### Enrollment: 455 Total Patients

ANATOMIC FIXATION	PROXIMAL FIXATION			
	235	ENDURANT	EXCLUDER	ZENITH
AFX WITH DURAPLY/AFX2	91	72	57	
235				

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### LEOPARD: Vascular Characteristics Across Treatment Groups and Reflect Real-World Population

	Anatomical Fixation AFX DURAPLY / AFX2 N = 235	Proximal Fixation EVAR Comparator N = 220
Max aneurysm diameter	56.1 mm	55.8 mm
Max neck diameter (lowest renal)	24.6 mm	24.8 mm
Max iliac artery diameter	18.4 mm	18.3 mm
External iliac Minimum Diameter	7.3 mm	7.2 mm
Aortic Neck Angulation (°)	15°	15°
Off Anatomical IFU	34%	35%

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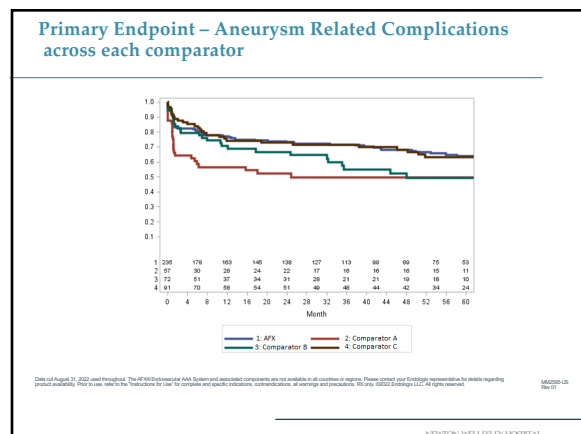
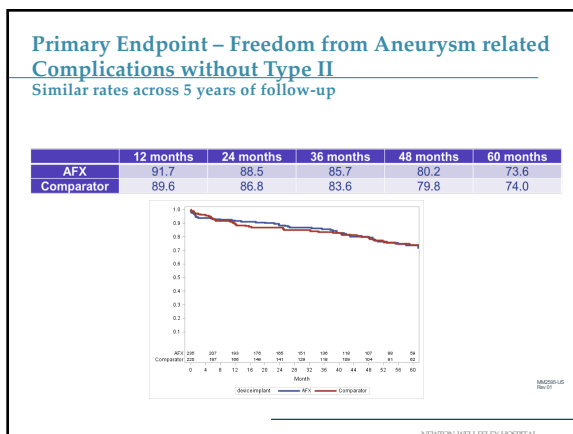
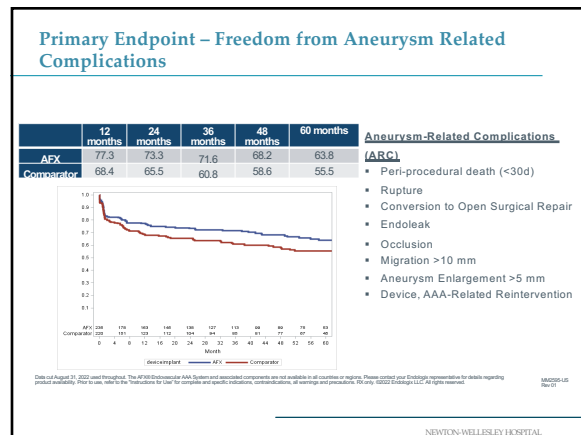
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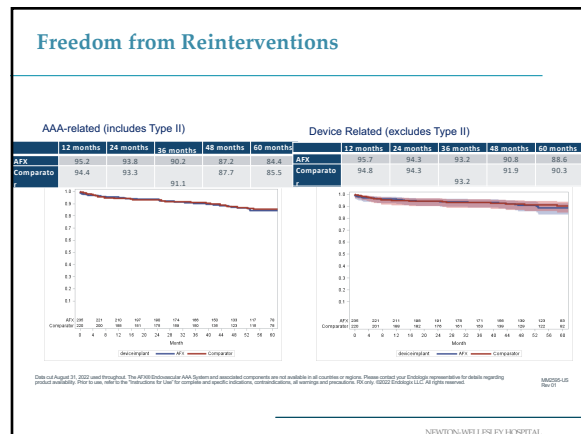
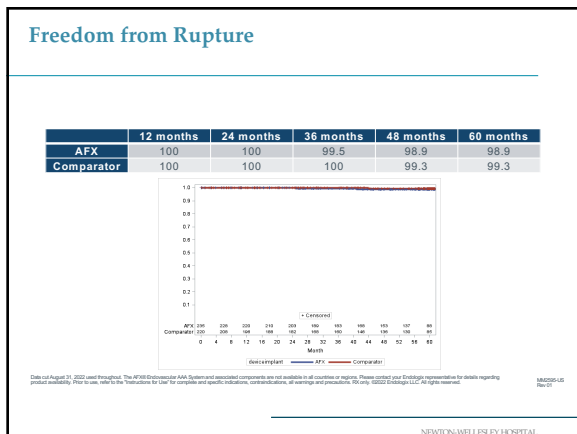
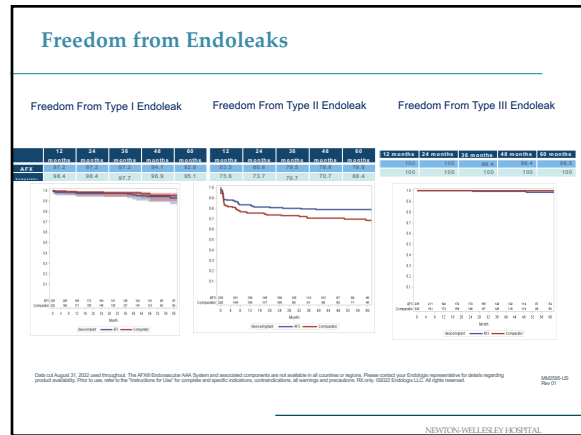
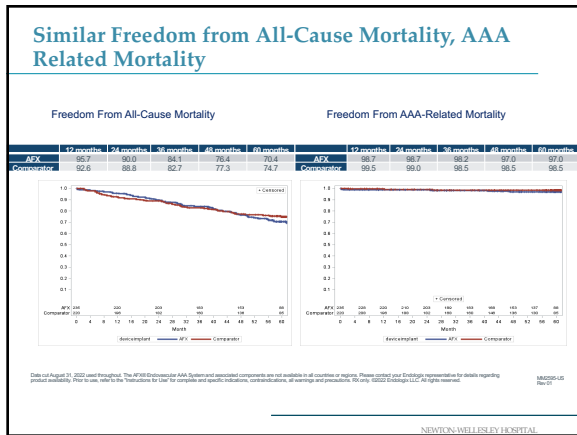
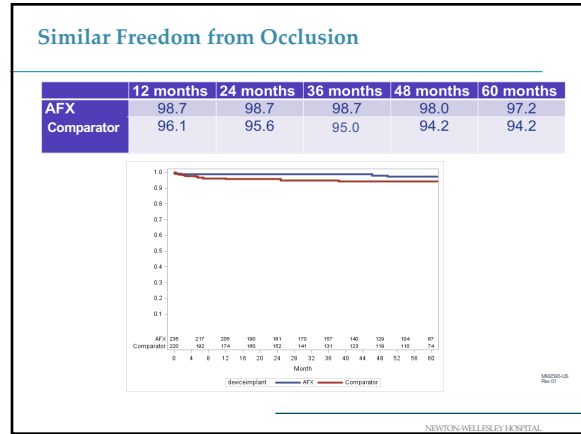
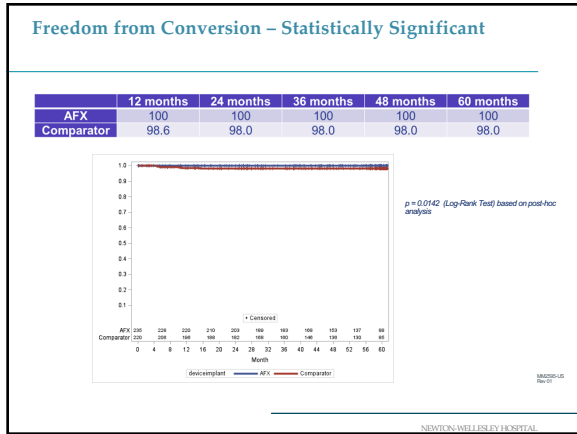
### Level 1: LEOPARD Procedural Characteristics

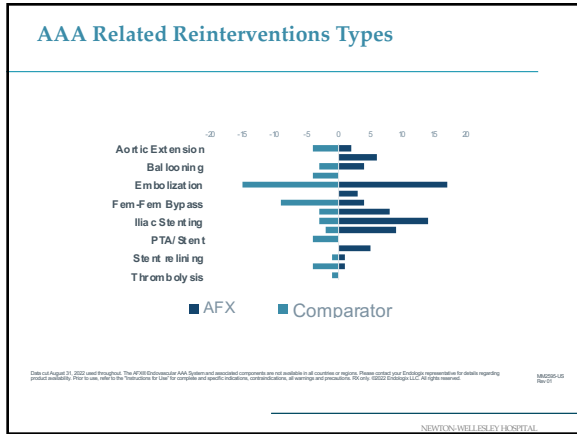
	Anatomical Fixation AFX / AFX2 N = 235	Proximal Fixation EVAR Comparator N = 220
Total Procedure Time (Min)	79.5 (30, 374)	90.5 (34, 303)
Fluoroscopy Time (Min)	16.0 (3, 116)	18.5 (5, 84)
Total Anesthesia Time (Min)	152.5 (57, 490)	166 (65, 390)
Contrast Volume (mL)	68 (15, 220)	84 (15, 345)
Bilateral Percutaneous Access	69.4%	66.4%
General Anesthesia	82.1%	85.0%
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)

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### Conclusions:

**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 5 years**

**Need to evaluate Anatomic Fixation and Proximal Fixation in different patient populations**

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