Publication Summary: Use of linked registry claims data for long term surveillance of devices after endovascular abdominal aortic aneurysm repair: observational surveillance study¹

Goodney P, et al. Published in BMJ 2022

STUDY DESIGN
Observational surveillance study including 282 centers from the VQI-VISION dataset linked to United States Medicare claims from 2003 to 2018.

20,489 Patients Identified

Excluder | AFX | Endurant | Zenith

Early AFX | Late AFX

Due to AFX product modifications in late 2014, AFX patients were divided into 2 groups; early & late AFX, based on date before and after January 1, 2015.

MAIN OUTCOME MEASURES: REINTERVENTION AND RUPTURE OF ABDOMINAL AORTIC ANEURYSM POST-EVAR

Vascular Quality Initiative (VQI)

+ Vascular Implant Surveillance and Interventional Outcomes Network (VISION)

- VISION links VQI registry data to Medicare claims to generate novel registry-claims linked datasets
- VQI-VISION framework will be considered by the FDA for long-term surveillance of EVAR patient outcomes to help prevent avoidable harm
- VISION data is also used to generate Survival, Reintervention and Surveillance (SRS) reports as well as to analyze device performance and long-term outcomes of surgical techniques²
“The manufacturer of the AFX stent graft, Endologix, has improved its device, and a later iteration—also evaluated by Goodney and colleagues, appears to be performing well.”

—Robert J Hinchliffe, BMJ 2022

The conversion rates to open repair after EVAR also did not differ in patients treated with AFX devices and those treated with the other devices.

References

INDICATIONS FOR USE- EU: 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; 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- EU: The Endologix® AFX®2 Endovascular AAA Systems are contraindicated for use in patients 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.

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; 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 patients 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. CE marked. Please refer to current product instructions for use. Endologix®, AFX®, DuraPly®, VELA®, and ActiveSeal® are registered trademarks of Endologix LLC. The Endologix logo is a trademark of Endologix LLC in the United States and certain foreign countries. All other trademarks are the property of their respective owners. ©2023 Endologix LLC. All rights reserved. MM2608 Rev01