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Vela™ Proximal Endograft System

The next generation of ActiveSeal™ EVAR technology.

BY JULIO RODRIGUEZ-LOPEZ, MD, FACS



The rapid acceptance of endovascular repair (EVAR) of abdominal aortic aneurysms (AAAs) over the past 15 years has been driven in large part by advancing endovascular skills, innovation in endograft technology, and physician expansion of the approach to patients with more complex anatomies.¹

The challenges to EVAR remain, as is well documented in the clinical literature. Proximal neck morphologies such as reverse taper, short length, angulation, and presence of calcification or thrombus, have been shown to predict both acute and long-term complications following EVAR.^{2,3} Precise procedural positioning of the endograft, and the ability to establish reliable acute and chronic proximal seal represent practical daily considerations for endograft selection and case strategy.

Since commercial introduction in 1999, the majority of traditional EVAR devices require the bifurcated component to establish both proximal fixation and seal through a combination of the stent radial force and active fixation elements (e.g., hooks, barbs). The flow divider of these bifurcated components is commonly positioned high in the aneurysm sac and experiences the peak axial⁴ and lateral⁵ forces that can affect proximal seal or device stability. Across these devices, delivery system mechanisms are highly manufacturer-specific. For example, the Medtronic Endurant® (Santa Rosa, CA) and Cook Medical Zenith® (Bloomington, IN) systems employ a “top-cap” style mechanism retaining the barb-bearing suprarenal sections of the stent graft until final deployment, whereas the Gore Excluder® C3® (Flagstaff, AZ) system relies on partial reconstrainability of the proximal infrarenal segment to enable multiple repositioning attempts.

ENDOLOGIX ENDOGRAFT ARCHITECTURE

An alternative approach to proximal fixation designs has been clinically validated involving anatomical fixa-

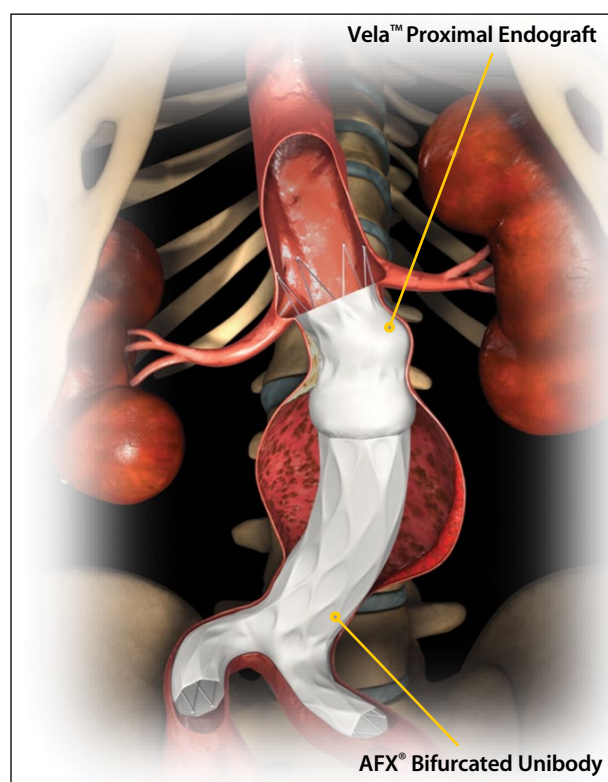


Figure 1. Endologix endograft architecture.

tion of a unibody endograft with proximal seal achieved using a proximal endograft component. This is embodied in the AFX® Endovascular AAA system (Endologix, Inc., Irvine, CA) as shown in Figure 1. Both stent graft components feature a high-columnar strength cobalt chromium (CoCr) alloy stent with highly conformable ePTFE material attached at the stent ends. The placement of the main unibody on the aortic bifurcation shifts the maximum forces acting on the endograft away from the proximal neck to the bifurcation,^{4,6} while inhibiting migration. This

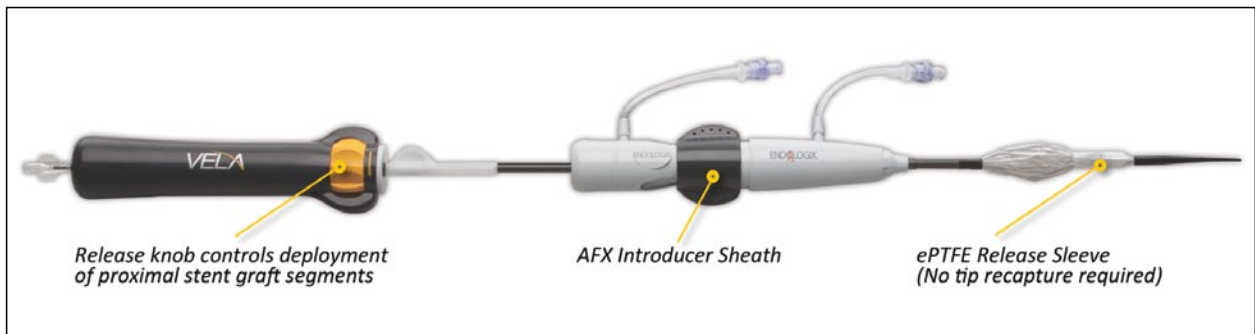


Figure 2. Vela delivery system.

“anatomical fixation” technique allows the design of the proximal endograft to be focused on achieving proximal seal. The graft material moves independently of the stent⁷ and has been shown to conform to the aortic wall beyond the anatomical neck⁸ (ActiveSeal™ technology). As such, the device may be of particular utility in a variety of straightforward and irregular neck anatomies. The pooled analysis of 157 patients treated with this anatomic fixation technique and endograft design demonstrated no migrations, ruptures, or aneurysm-related mortality at up to 5-year follow-up.⁹ Aneurysm sac diameter reduction or stability was observed in 93% of patients, and remarkably, a low 1.2% rate of limb occlusion occurred. Despite the inclusion of patients with multiple hostile neck anatomies, a low rate of endoleak and reintervention was observed. More recently, community-based real-world outcomes among 108 patients treated with the AFX System demonstrated similar outcomes at up to 1-year follow-up in both friendly and hostile anatomies.¹⁰

VELA Proximal Endograft

The Vela™ Proximal Endograft is the next-generation aortic neck component of the AFX® System, which has

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been recently FDA approved and launched in the United States. Unique to Endologix, the endograft is available in both suprarenal and infrarenal configurations and features a full circumferential graft line marker sewn into the proximal edge of the graft material. The marker facilitates the precise radiographic positioning of the component with respect to the renal arteries. The circumferential nature of the marker allows operators to adjust C-arm angulation during the procedure before committing to the final endograft deployment.

The all-new delivery system of the Vela™ Proximal Endograft provides the operator with control over stent

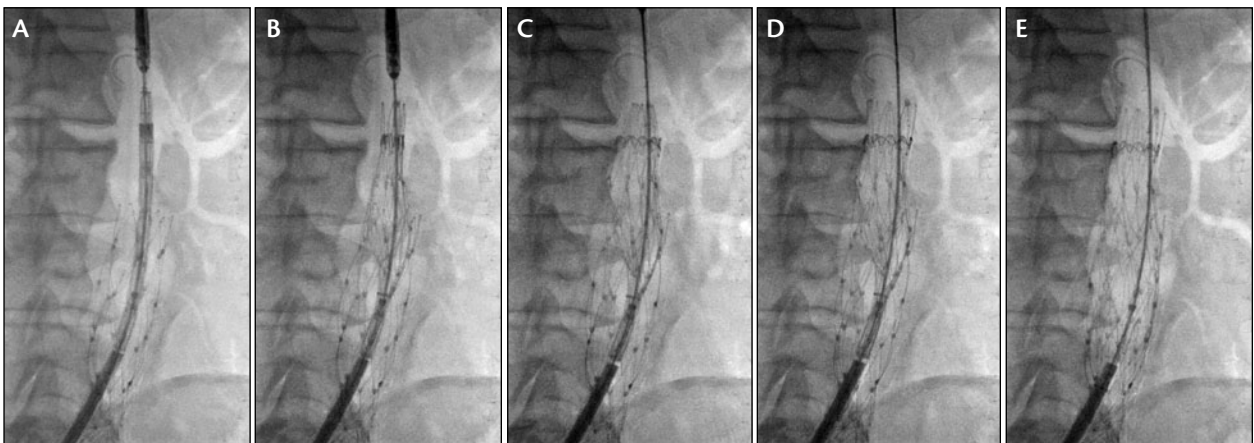


Figure 3. Vela deployment sequence: device insertion (A), unsheathing of the proximal segment (B), initiation of the proximal stent release (C), completion of sleeve release and deployment of proximal and mid stent graft (D), and distal segment deployment (E).

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Figure 4. Aortic neck before (A) and after (B) Vela deployment.

graft deployment and flexibility to craft the deployment strategy according to patient anatomy (Figure 2). The proximal two segments of the stent graft are constrained by the ePTFE release sleeve. When advanced using the release knob located in the delivery system handle, the release sleeve deploys these two segments. In contrast to a more rigid “top cap,” the release sleeve design obviates the need to recapture the device tip (top cap) prior to delivery system removal. Procedurally, the Vela deployment sequence begins with the operator using a simple pin-and-pull technique to unsheath the constrained proximal segments and the middle segment of the stent graft, while maintaining the ability to reposition the device both cranially and caudally (Figure 3). When the desired positioning of the device is achieved, the proximal segments of the stent graft are released by advancing the sleeve. At this stage, the stent graft-aortic wall apposition is established from the middle section up, self-centering the graft in the aorta and minimizing the effect of wire bias in the neck. With the distal segments of the stent graft still retained by the sheath, the physician maintains the ability to retract the device into final position if desired prior to completion of deployment.

ARIZONA HEART EXPERIENCE

The Arizona Heart Institute and Hospital have a long-standing tradition of pioneering innovation in aortic aneurysm repair and was responsible for the development of the first-generation anatomical fixation endografts. Most recently, we’ve been among the early adopters of the Vela™ Proximal Endograft. Since the commercial

availability of the device in late January 2014, we have performed a number of procedures using this technology in both emergent and elective cases. Figure 4 illustrates a final result of one of these cases. The combination of the ActiveSeal™ endograft technology with enhanced visualization and predictable precision of the deployment makes Vela a key component of our toolbox for endovascular repair of AAA. ■

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