

Vela Proximal Endograft System

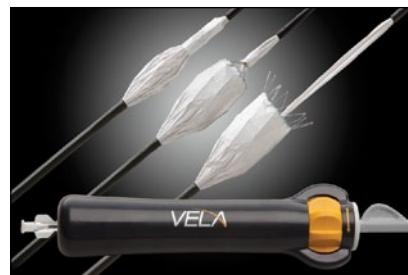
Endologix
(949) 595-7200
www.endologix.com/Vela

KEY FEATURES

- Circumferential graft line marker for enhanced visibility
- New delivery system
- ActiveSeal technology

Endologix (Irvine, CA) has announced the United States launch of the FDA-approved Vela proximal endograft system, which is designed for the treatment of proximal aortic neck anatomies during endovascular aneurysm repair. The Vela system, which was developed with feedback from leading physicians, features a new delivery system and a circumferential graft line marker for enhanced visibility during the implantation procedure.

One of the first Vela procedures in the United States was performed by Julio Rodriguez, MD, FACS, a vascular surgeon at the Arizona Heart Institute in Phoenix, Arizona. In the company's press release, Dr. Rodriguez commented, "The Vela delivery system is very intuitive, and the endograft has excellent visibility."



Phoenix Atherectomy System

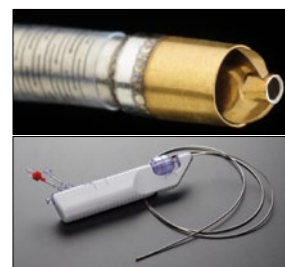
AtheroMed, Inc.
(650) 473-6846
www.atheromedinc.com

KEY FEATURES

- Cut, capture, and clear mechanism of action
- Able to treat soft plaque or calcium
- Profile down to 5 F
- No capital equipment required
- Front-cutting, single insertion device

AtheroMed, Inc. (Menlo Park, CA) has received CE Mark approval and FDA 510(k) clearance to market the Phoenix Atherectomy System, a pushable, over-the-wire system that uses a rotating, front-cutting element located at the distal tip of the catheter to shave diseased material directly into the catheter. The debulked material is then continuously captured and removed by an internal Archimedes screw that runs the length of the catheter. This cut, capture, and clear mechanism of action creates a single insertion device that also potentially reduces the risk of distal embolization.

The Phoenix Atherectomy System is available in multiple sizes to allow treatment from the thigh to the foot. 1.8 mm (5 F) and 2.2 mm (6 F) catheters are available for treating lesions located below the knee, and a 2.4 mm (7 F) deflecting tip catheter can be used to debulk larger vessels above the knee. The system has been proven effective in a broad range of disease types, from soft plaque to calcified arteries.



OffRoad Re-Entry Catheter System

Boston Scientific Corporation
(508) 650-8000
www.bostonscientific.com

KEY FEATURES

- Designed to bypass CTOs via subintimal space
- Unique conical positioning balloon directs the lancet
- Microcatheter lancet for lumen re-entry

Boston Scientific Corporation (Natick, MA) has announced the United States launch of the FDA-approved OffRoad re-entry catheter system for the treatment of chronic total occlusions (CTOs) in the major arteries of the legs. The device is designed to navigate past CTOs by traveling within the subintimal space of the vessel wall. When inflated, a conical positioning balloon deflects off of the stiffer media/adventitia toward the softer intima, directing the microcatheter lancet into the true lumen and allowing the interventionist to position a guide-wire across the CTO to perform angioplasty or stent treatment.



"In my opinion, the biggest challenge with the subintimal approach is the ability of the device to re-enter the true vessel lumen after crossing," said J.A. Mustapha, MD, who performed the first use of the OffRoad system. "The unique design of the OffRoad system facilitates re-entry, giving me confidence that I will be able to successfully deploy the tools I need to treat the blockage."

Kavs Endovenous Double-Lumen Balloon Catheter

F Care Systems
(786) 288-0740
www.fcaresystems.us

KEY FEATURES

- Designed for controlled sclerosis of varicose veins
- Can be used in a private office or clinic
- Equipped with depth markings every 10 cm

F Care Systems (North Miami, FL) has announced that it has received US Food and Drug Administration 510(k) approval for the Kavs endovenous double-lumen balloon catheter, designed for the treatment of varicose veins by means of catheter-assisted venous sclerotherapy.

The Kavs device is a double-lumen catheter made of radiopaque polyurethane equipped with a latex balloon at the distal end. After the device is advanced into a vein, the balloon is filled with NaCl, blocking the vein. The position of a colored stopcock indicates the filling of the balloon. A sclerosing agent is injected, and the effect is controlled via ultrasound. Afterwards, the sclerosing agent is aspirated, the vein is unblocked, and the catheter is removed. ■

