VenaSeal Closure System

Medtronic plc
(888) 283-7868
www.medtronic.com

KEY FEATURES

- Specially formulated n-butyl-2-cyanoacrylate
- Delivery system included (catheter, guidewire, dispenser, tips, and syringes)
- No thermal energy, tumescent anesthesia, sclerosants, or capital equipment required

Medtronic plc has received US Food and Drug Administration (FDA) approval for the VenaSeal closure system for the treatment of symptomatic lower extremity varicose veins through endovascular embolization with coaptation. This closure method uses the injection of a clear liquid, a specially-formulated n-butyl-2-cyanoacrylate, that polymerizes into a solid material, sealing the diseased vein. Proper placement of the catheter is monitored via ultrasound.

William Maisel, MD, Acting Director of the Office of Device Evaluation in the FDA's Center for Devices and Radiological Health, described VenaSeal as the first system approved to permanently treat varicosities via an adhesive sealant. "Because the VenaSeal system does not incorporate heat application or cutting, the in-office procedure can allow patients to quickly return to their normal activities, with less bruising," commented Dr. Maisel in the FDA's announcement.

E-tegra Stent Graft System

Jotec GmbH
+49 (0) 7471 / 922 0
www.jotec.com

KEY FEATURES

- Asymmetric spring configuration
- Seamless and soft polyester cover
- Active proximal fixation
- Low crossing profile
- Various configurations

Jotec has received CE Mark approval of the E-tegra AAA (abdominal aortic aneurysm) stent graft system, which is indicated for endovascular treatment of infrarenal AAAs with aortic neck angulation up to 75°. The device is now available and is being introduced into the European market.

E-tegra has an asymmetric spring configuration for high 3D flexibility while maintaining longitudinal stiffness. This asymmetric shape, along with a new, seamless polyester cover, support flexibility, conformability, and vessel adaption, even in complex anatomies. The device features active fixation at the laser-cut proximal stent, which can be released separately for precise positioning. The proximal sealing stent is specially designed for effective sealing.

E-tegra's delivery system has a crossing profile of 18 F (16 F for extensions) and offers good pushability and flexibility without kinking. The catheter has a hydrophilic coating for introduction and advancement even in narrow and tortuous vessels. The delivery system also features the proven Squeeze-to-Release deployment mechanism.

Spinr High-Performance Guidewire Controller

Distal Access
(954) 534-9345
www.distalaccess.com

KEY FEATURES

- Polycarbonate handles
- Novel core screw drive
- Connects to 0.014–0.038-inch guidewires
- Designed for improved torque, control, and performance
- No motors or complex electromechanical mechanisms required

Distal Access has announced FDA clearance of the Spinr high-performance guidewire controller for use in the coronary and peripheral vasculature to maneuver guidewires during interventional and diagnostic procedures. During use, clinicians insert a Spinr onto the proximal end of a guidewire, advance the Spinr close to the guidewire access site in the body, and tighten the Spinr cap onto the wire. Then, the clinician can squeeze and release the front handle to rotate-oscillate the guidewire with improved torque, control, and performance.

"Controlling guidewires is important to successful patient outcomes," said Vasili Lendel, MD, interventional cardiologist at Arkansas Heart Hospital in Little Rock, Arkansas. "Basically, if a guidewire cannot cross a lesion, we may not be able to treat the problem. Devices that help guidewires access and cross lesions can help improve procedure safety and effectiveness." ■