GuardDog Occlusion System

Possis Medical, Inc. (Minneapolis, MN) announces the launch of its GuardDog Occlusion System, the industry’s first .035-inch guidewire with a CO2-filled occlusion balloon. According to the company, the GuardDog Occlusion System is based on a .035-inch guidewire, which is easily sealed to maintain inflation of the balloon and provides occlusion until the guidewire is trimmed and the balloon is deflated, allowing for rapid reperfusion. The GuardDog can be delivered to the treatment site through a .038-inch diagnostic catheter. The tip features a shapeable section for easier placement into tortuous vessels. Radiopaque markers at either end of the soft, compliant balloon aid in proper positioning. The inflation device is preloaded with enough CO2 to perform three inflation-deflation cycles, the company says.

ClosureFast Radiofrequency Catheter

VNUS Medical Technologies, Inc. (San Jose, CA) announces the January 2007 launch of the ClosureFast catheter, an endovenous radiofrequency catheter that uses a segmental ablation approach to treat a 7-cm length of vein during a single 20-second treatment. According to the company, the ClosureFast catheter shortens procedure time, delivers optimal therapeutic power, and eliminates the variability of pullback speed to control power delivery. A 45-cm-long vein treatment is typically performed in 3 to 5 minutes, the company says. The ClosureFast catheter’s shaft markings facilitate quick and accurate repositioning to the adjacent vein segment for precise catheter positioning using ultrasound visualization. Thorough tumescent infiltration and external compression ensure good contact between the catheter and the vein wall. Fully compatible with existing VNUS RFGPPlus generators after a software upgrade, the ClosureFast catheter monitors treatment parameters in real time and delivers optimal therapeutic power through the system’s controlled feedback mechanism, the company says.
Cordis Endovascular (Division of Cordis Corporation, Warren, NJ) announced it has received FDA approval to market the Precise Stent and Angioguard Emboli Capture Guidewire, which are approved to treat carotid artery disease in patients at high risk for adverse events from carotid endarterectomy. According to the company, it is the only carotid system backed by a large, randomized clinical trial, the landmark SAPPHIRE study, to support the potential benefits of carotid artery stenting in patients who are ineligible, or considered high risk, for carotid endarterectomy. The Cordis Carotid System has been studied in more than 4,000 patients across both the SAPPHIRE trial and the Carotid Artery Stent Education System Post-Marketing Study (CASES-PMS), and demonstrated low stroke rates in both, the company says.

The Precise Stent comes in 20-, 30-, and 40-mm lengths and 5-mm to 10-mm diameters. The Angioguard Filter comes in 4-mm to 8-mm baskets, and the system covers a wider range of vessel sizes than any other carotid system on the market.

Stephen R. Ramee, MD, of Ochsner Health System, said, "More and more practitioners prefer carotid stenting over endarterectomy based on the clinical evidence and safety profile. The Cordis Carotid System is easy to prepare and use and has good retrievability, which is important in order to protect the patient’s brain from embolic material."

Cook Incorporated (Indianapolis, IN) has announced that it has received FDA clearance of its 36-mm Zenith Flex AAA Endovascular Graft and 22-F H&L-B One-Shot Introduction System with Flexor Sheath and Captor Hemostatic Valve. The Flex provides physicians with an endovascular solution for the interventional treatment of abdominal aortic aneurysms in large aortic necks ranging from 29 mm to 32 mm in diameter. According to the company, the state-of-the-art aortic endograft is designed to provide an effective, minimally invasive treatment option for patients with large abdominal aortic neck diameters who previously may not have been candidates for endovascular aortic repair.
Edwards Lifesciences Corporation (Irvine, CA) announces the US launch of its LifeStent FlexStar and FlexStar XL stent delivery systems. Edwards has received FDA 510(k) clearance for the FlexStar systems to treat biliary obstructions, as well as an expanded European CE Mark including the treatment of peripheral vascular disease. The FlexStar systems offer clinicians multiple methods for stent deployment and are now available in the US in stent diameters from 6 mm to 10 mm and lengths to 150 mm. The FlexStar systems are designed to optimize the delivery of Edwards’ LifeStent nitinol self-expanding stents, which are highly conformable and feature a triple-helix design, the company says.

Possis Medical, Inc. (Minneapolis, MN) announces the introduction of its new Fetch Aspiration Catheter. According to the company, the rapid exchange Fetch Aspiration Catheter offers physicians another option for the aspiration of small, fresh blood clots and other embolic debris from arteries. The catheter features an advanced braided shaft design used in other AngioJet thrombectomy catheters marketed by Possis. This braided shaft transitions to a flexible, hydrophilic-coated distal shaft that enhances pushability and trackability. Additionally, its proprietary convex tip design combined with a small outer diameter minimizes vessel trauma and enhances deliverability. A radiopaque marker band 2 mm from the distal tip provides visibility and easy positioning. The Fetch catheter is compatible with all .014-inch guidewires and any 6-F guide catheters, the company says.