Angio-Seal Evolution Vascular Closure Device

COMPANY	St. Jude Medical, Inc.
PHONE	(800) 253-9073
WEB	www.sjm.com

KEY FEATURES

- Automated collagen compaction system
- Single-handed deployment of an anchor, suture, and collagen seal
- Absorbed by the body within 60 to 90 days

St. Jude Medical, Inc. (St. Paul, MN) recently announced US FDA approval of the Angio-Seal Evolution Vascular Closure Device. The device is designed to enable physicians to quickly and effectively seal femoral artery punctures made during minimally invasive catheter-based procedures. The Angio-Seal Evolution platform features a new delivery system that reduces the variability that can occur as physicians deploy and secure the Angio-Seal closure system. Consistent with its predecessors, the Angio-Seal Evolution achieves hemostasis through the deployment of a bioabsorbable anchor, suture, and collagen seal. According to the company, single-handed deployment is possible, which allows physicians to more easily support the puncture site. The automated collagen compaction system ensures consistent compaction of the collagen against the exterior wall of the vessel, reducing procedural variables. The Angio-Seal Evolution closure system is fully absorbed by the body within 60 to 90 days. This reduces risks associated with foreign material left permanently in the body and allows for repeat procedures without concerns about previous placement of closure devices, the company says.

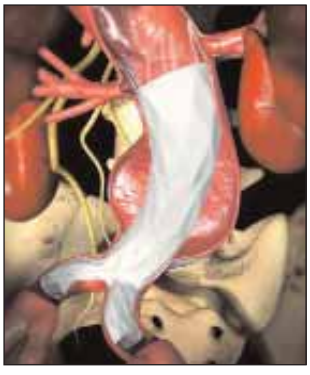
Powerlink XL System

COMPANY	Endologix, Inc.
PHONE	(800) 983-2284
WEB	www.endologix.com/powerlinkxl

KEY FEATURES

- Lowest-profile device to treat proximal necks >26 mm
- Suprarenal or infrarenal configurations available

Endologix, Inc. (Irvine, CA) recently announced FDA approval of the Powerlink XL system, indicated for the treatment of abdominal aortic aneurysm (AAA) patients with proximal aortic necks between 23 and 32 mm. "This is a brand new innovation that, because of its larger size, enables us to effectively treat AAA patients with challenging anatomy while lowering the patient's risks of open surgery," said Dr. Zvonimir Krajcer, co-director, Peripheral Vascular Disease Service at Texas Heart Institute.



The Powerlink XL system offers the benefits of treating large neck AAAs in the lowest-profile catheter of all commercially available devices in the US indicated for aortic necks >26 mm. According to the company, the low-profile Powerlink XL system expands the market for AAA procedures by enabling treatment in patients with limited or difficult vascular access. In addition to its low profile, the Powerlink system is the only commercially available AAA device with proximal extensions offered in both infrarenal and suprarenal configurations. By providing both design options, Endologix enables physicians to choose the most optimal device to treat a wide range of patient anatomies, the company stated.

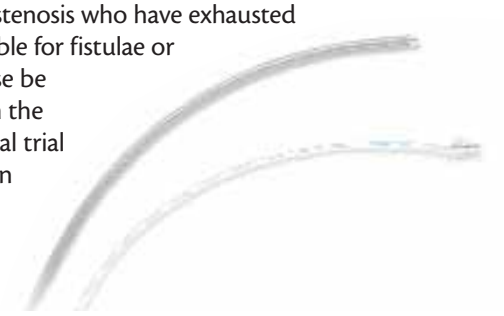
HeRO Vascular Access Device

COMPANY	Hemosphere, Inc.
PHONE	(888) 313-8233
WEB	www.heroaccess.com

KEY FEATURES

- Fully subcutaneous arteriovenous implant
- FDA classified as a graft
- Venous outflow component traverses central venous stenosis
- Conventional ePTFE graft with proprietary titanium connector
- Continuous arteriovenous access for long-term hemodialysis

The HeRO (Hemodialysis Reliable Outflow) Vascular Access Device (Hemosphere, Inc., Minneapolis, MN), a fully subcutaneous implant, traverses central venous stenosis allowing for long-term hemodialysis for patients with compromised vasculature. According to the company, the HeRO is clinically proven for use in patients with venous outflow obstruction or central venous stenosis who have exhausted arteriovenous access sites suitable for fistulae or grafts and who would otherwise be catheter-dependent. Data from the HeRO device multicenter clinical trial demonstrate a 70% reduction in bacteremia and improved adequacy of dialysis when compared to a tunneled dialysis catheter. The HeRO device provides flow and patency comparable to a conventional graft, the company says.



RapidBlue Endovascular System

COMPANY	InnerCool Therapies, Inc.
PHONE	(866) 682-2665
WEB	www.innercool.com

KEY FEATURES

- Cooling rates of 4°–5°C/h and warming rates of 2°–3°C/h
- Optically induced heparin-bonded catheter
- Small-profile flexible metallic temperature control element
- Integrated temperature sensor
- No intubation is required

InnerCool's (San Diego, CA) FDA-approved next-generation RapidBlue system for endovascular temperature modulation automatically cools or warms the patient as necessary to maintain the desired body temperature. The system provides rapid or gradual temperature modulation. A small-profile flexible metallic temperature control element yields fast and precise patented temperature control unlike inflatable plastic balloons. According to the company, the RapidBlue system has an excellent safety profile in part due to an optically induced heparin-bonded catheter, which reduces the chances for a deep vein thrombosis. A highly responsive integrated temperature sensor eliminates the need for slow-to-react bladder or rectal probes. The RapidBlue system includes a programmable console with an enhanced user interface and can be used both with InnerCool's standard and Accutrol catheter to quickly modulate patient temperature in association with surgery or other medical procedures for all patient sizes. Its closed-loop catheter-based system modulates whole-body temperature without fluid introduction or exchange by circulating cool or warm saline. No intubation is required, and only InnerCool's RapidBlue is capable of cooling awake patients, the company stated.

Carotid Wallstent Monorail Endoprosthesis

COMPANY	Boston Scientific Corporation
PHONE	(888) 272-1001
WEB	www.bostonscientific.com

KEY FEATURES

- Closed-cell design is intended to provide increased scaffolding for optimal lesion coverage
- Demonstrated the smallest free cell area when compared with the leading carotid stents in bench tests
- 5-F stent delivery system designed for deliverability through tortuous anatomy
- Indicated for use in eligible patients with ipsilateral or bilateral carotid artery disease

The FDA-approved Carotid Wallstent Monorail Endoprosthesis (Boston Scientific Corporation, Natick, MA) is a self-expanding carotid stent designed for the treatment of patients with carotid artery disease who are at high risk for surgery. According to the company, the stent features a closed-cell design that is intended to provide increased scaffolding for optimal lesion coverage. The Carotid Wallstent Endoprosthesis is a highly flexible, low-profile stent delivery system designed to provide excellent tracking through difficult anatomy.

The Carotid Wallstent Endoprosthesis is used in conjunction with the FilterWire EZ Embolic Protection System, which is designed to capture plaque debris released during the stenting procedure and to prevent it from traveling to the brain where it could create an increased risk for stroke. Together, the Carotid Wallstent Endoprosthesis and FilterWire EZ is the only carotid artery stent system indicated in the US for use in eligible patients with ipsilateral or bilateral carotid artery disease, the company stated.

EURO INNOVATIONS A preview of Europe's new products

Embozene Color-Advanced Microspheres

COMPANY	CeloNova BioSciences, Inc.
PHONE	(770) 502-0304
WEB	www.celonova.com

KEY FEATURES

- Microsphere size 40±10 µm
- 9 precisely calibrated sizes
- Anti-inflammatory and biocompatible properties
- Microspheres color-coded by size
- Includes tight tolerances compared to other embolics (±50 vs ±100 for most sizes)

Embozene Color-Advanced Microspheres (CeloNova BioSciences, Inc., Newnan, GA) are CE Marked, class III devices approved for use in the neurovascular and circulatory systems. They are specifically indicated for neurovascular arteriovenous malformations, uterine fibroids, hepatocellular carcinoma, arteriovenous malformations, and hypervascularized tumors. The Embozene Microspheres core technology platform is built on four design principles: biocompatibility, precise calibration, suspension, and particle integrity. Embozene Microspheres consist of a hydrogel core with a coating of Polyzene-F, CeloNova's proprietary polymer. Polyzene-F offers biocompatibility that approximates bioneutrality because it does not trigger inflammatory reactions, does not activate platelets or allow platelet agglomeration, and is bacteria resistant (among other properties). CeloNova offers the smallest spherical embolic on the market, 40±10 µm, designed for super-selective embolization, and the largest, 1,300±75 µm, as well as seven other tightly calibrated sizes. Every parameter relevant to the embolization procedure is optimized in Embozene Microspheres, the company says. ■