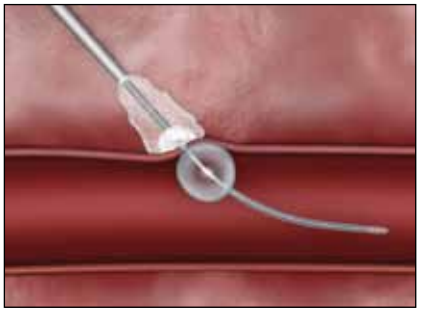
MynxGrip Vascular Closure Device

COMPANY	AccessClosure, Inc.
PHONE	(650) 903-1000
WEB	www.accessclosure.com

KEY FEATURES

- Sealant consists of polyethylene glycol, a water-soluble, bio-inert, nonthrombogenic polymer
- The only active extravascular closure device that leaves nothing behind
- Actively grips the artery while expanding and filling the tissue tract
- Provides durable hemostasis and a platform for natural healing



AccessClosure, Inc. (Mountain View, CA) recently announced US Food and Drug Administration approval of the MynxGrip Vascular Closure Device. Built on the Mynx platform, the MynxGrip Vascular Closure Device offers an active, extravascular, and patient-friendly vascular closure solution. MynxGrip adds the proprietary Grip Technology to the distal end of the original Mynx Sealant. The result is a sealant that actively grips and seals the arteriotomy while expanding and filling the tissue tract, providing effective hemostasis. The MynxGrip Sealant dissolves within 30 days, leaving nothing behind except a healed artery, the company stated.

EverFlex Self-Expanding Peripheral Stent System

COMPANY	Covidien
PHONE	(800) 716-6700
WEB	www.covidien.com/everflex

KEY FEATURES

- Broad size matrix deliverable through a 6-F catheter (20–200 mm lengths)
- Peak-to-peak connection nodes and spiral cell design disperse force uniformly
- Three-wave peak structure resists compression and provides excellent wall apposition
- Tantalum radiopaque markers enhance visibility
- Proprietary EX.P.R.T. Deployment System aids in precise placement

Covidien (Mansfield, MA) has announced that its EverFlex self-expanding peripheral stent system has received US Food and Drug Administration approval of an indication for placement in the superficial femoral artery (SFA) and proximal popliteal artery. Available in a 200-mm length, this fatigue-resistant, clinically proven SFA stent offers even longer stent options than the previous version, minimizing the need for multiple stents or stent overlap during SFA placement. The EverFlex stent system has a broad size matrix, and all sizes are deliverable through a 6-F catheter, providing the most appropriate single-stent fit (20– 200 mm in length, 6– 8 mm in diameter).

The DURABILITY II study generated the clinical evidence necessary to prove the safety and efficacy of the EverFlex stent in the SFA. The study enrolled 287 patients with long, complex, and highly calcified lesions (73% of patients received a stent 100 mm or longer, and 46.2% received a stent 150 mm or longer). The study showed no major adverse events at 30 days, a proven stent patency rate at 1 year by Kaplan-Meier analysis (86.2% had lesion lengths ≤ 80 mm, and 69.6% had lesion lengths > 80 mm), as well as a low 1-year stent fracture rate of 0.4%, the company stated.

Absolute Pro Vascular Self-Expanding Stent System

COMPANY	Abbott
PHONE	(800) 227-9902
WEB	www.abbottvascular.com/us/absolute-pro.html

KEY FEATURES

- Designed to ensure precise stent placement at the lesion site
- Incorporates advanced technologies for optimal stent visibility
- Provides flexibility to conform to challenging lesions
- Demonstrated to be safe and effective based on results of the MOBILITY trial

The Absolute Pro vascular self-expanding stent system (Abbott Vascular, Santa Clara, CA) is the newest addition to the company's growing portfolio of endovascular products. The Absolute Pro device recently received FDA approval for the treatment of iliac artery disease, a form of peripheral artery disease that affects the lower extremities.

Absolute Pro is a self-expanding nitinol stent system made of a flexible material that is designed to allow the stent to conform to challenging lesions. It incorporates advanced technologies for optimal stent visibility, with a delivery system that is designed to ensure precise stent placement at the lesion site. FDA approval was supported by the results of the MOBILITY clinical trial, which showed that the Absolute Pro device was safe and effective in patients with iliac artery disease, the company stated.

"With Absolute Pro, US physicians now have an additional option that is proven safe and effective to treat many patients with this debilitating disease," said Tony S. Das, MD, FACC, Director, Peripheral Vascular Interventions, Cardiology Section, Presbyterian Heart Institute in Dallas, Texas, and Coprincipal Investigator of the MOBILITY trial.

Aspire Max Thrombus Aspiration System

COMPANY	Control Medical Technology
PHONE	(954) 534-9345
WEB	www.aspirationmedical.com

KEY FEATURES

- Instantly create, increase, decrease, stop, maintain, or "pulse" aspiration force
- One-way valves to prevent accidental reinjection
- Large aspiration lumens for speed, force, and control
- Flexible shafts for kink resistance
- Bright integrated radiopaque tips

Control Medical Technology (Park City, UT) recently announced receipt of US Food and Drug Administration clearance to market the Aspire Max thrombus aspiration system. According to the company, the patented Aspire Max thrombus aspiration system bridges the gap between basic syringe-catheter kits and complex systems. The core Aspire Aspirator is a high-performance aspirator with integrated handles and valves that allow clinicians to instantly create, increase, decrease, slow, stop, or "pulse" aspiration force. Max thrombus aspiration catheters are proprietary large-lumen aspiration catheters available in multiple outer diameters and lengths to improve aspiration speed, force, and control.

The FDA clearance allows Control Medical to market the Aspire Max thrombus aspiration system, including an Aspire aspirator and a Max catheter in one package and/or Max aspiration catheters alone in multiple sizes with an indication to remove soft fresh thrombi, and emboli, from vessels in the peripheral vasculature.

Ebony PTA 0.014-inch RX

COMPANY	Natec Medical Ltd.
PHONE	+230 466 3054
WEB	www.natec-medical.com

KEY FEATURES

- Hydrophilic coating for improved performance
- Excellent kink resistance
- Exceptionally smooth and tapered soft tip
- Ultra-low balloon profile

The Ebony PTA 0.014-inch RX (Natec Medical Ltd., Réduit, Mauritius) recently received 510(k) clearance for dilatation in peripheral angioplasty of the above and below-the-knee arteries. This PTA catheter was designed for reaching remote infrapopliteal lesions, offering excellent pushability, crossability, trackability, and flexibility. The Ebony PTA 0.014 has a newly designed ergonomic hub to provide maximum comfort during the procedure. The balloon has been developed to reach specific diameters at specific pressures. It comes with two radio opaque markers for precise positioning in the stenosis. Device sizes range from 2 to 8 mm in diameter and lengths up to 60 mm. An extended sizes matrix up to 200 mm is forthcoming, the company noted. ■

EURO INNOVATIONS A preview of Europe's new products

Penumbra Separator 3D

COMPANY	Penumbra, Inc.
PHONE	(510) 748-3800
WEB	www.penumbrainc.com

KEY FEATURES

- Four intraluminal 3D chambers secure thrombus in the third, or radial, dimension to minimize embolization of new territory
- Reduced wall contact to minimize vessel injury
- Unique geometry facilitates smooth delivery and removal

The Penumbra Separator 3D (Penumbra, Inc., Alameda, CA) is a next-generation clot-engagement device for acute stroke that works in conjunction with aspiration at the site of the lesion to secure and remove clot for flow restoration. The Separator 3D's innovative intraluminal 3D chambers secure thrombus to better enable clot removal and minimize embolization of new territory. Its unique geometry reduces vessel wall contact for a favorable safety profile while also allowing smooth delivery and retrieval.

"The combination of the 3D Separator together with aspiration allows for removal of clots, due to their consistency, which could not otherwise be removed with stent retrievers alone. We have seen several cases in which lesional aspiration together with the 3D Separator has been key to the success of the procedure," said Dr. Werner Weber, Head of the Department of Radiology and Interventional Neuroradiology, Klinikum Vest, Knappschaftskrankenhaus in Recklinghausen, Germany.

The Penumbra Separator 3D system is CE Mark approved and is now widely available in countries that recognize the CE Mark. It is also currently under clinical trial in the United States. ■