GPSCath Balloon Dilatation Catheter

COMPANY	Hotspur Technologies, Inc.
PHONE	(650) 969-3150
WEB	www.hotspur-inc.com

KEY FEATURES

- Combines angioplasty and a targeted injection system in one device
- Balloon design is offered in multiple diameter sizes ranging from 5 to 8 mm
- Has a rated burst pressure of 16 or 20 atm

Hotspur Technologies, Inc. (Mountain View, CA) announced that the US Food and Drug Administration granted the company 510(k) clearance to market its GPSCath balloon dilatation catheter. The GPSCath is a specialty two-in-one device that combines angioplasty and a targeted injection system. According to the company, the device's proprietary and innovative VisioValve technology allows injection of physician-specified fluids, such as contrast, thrombolytics and nitro, without exchanging catheters or jeopardizing the guidewire position. The balloon design is offered in multiple diameter sizes ranging from 5 to 8 mm and has a rated burst pressure of 16 or 20 atm. The GPSCath is indicated for use in femoral, iliac, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous fistulas. The three Hotspur products that have received FDA clearance are the IQCath balloon dilatation catheter, GPSCath balloon dilatation catheter, and Keeper embolectomy catheter. The devices are commercially available in the United States and can all be used for dialysis applications, while the GPSCath and Keeper catheters also have indications for peripheral arterial disease procedures.

Azur Detachable 35 With HydroCoil Technology

COMPANY	Terumo Interventional Systems
PHONE	(800) 283-7866
WEB	www.terumois.com/azurD35

KEY FEATURES

- Intended to reduce or block the rate of blood flow in vessels of the peripheral vasculature
- Control allows the coil to be retracted and repositioned until it is securely placed for detachment
- Compatible with 0.038-inch lumen catheters
- Designed for use in the interventional radiologic management of arteriovenous malformations, arteriovenous fistulae, aneurysms, and other lesions of the peripheral vasculature

The Azur Detachable 35 system (Terumo Interventional Systems, Somerset, NJ) is a detachable hydrogel polymer embolic device featuring 0.035-inch coils designed to provide greater filling capacity, packing density, and mechanical occlusion particularly in the treatment of high-flow and challenging blood vessels, vascular malformations, and aneurysms. The hydrogel coating undergoes limited expansion within the first 3 minutes and fully expands within 20 minutes. The Azur Detachable 35 deploys in < 1 second while offering physicians the flexibility to position and observe the behavior of the coil in the vasculature before detachment. According to Terumo, the Azur Detachable 35 can be retracted and repositioned until it is securely placed, reducing the risk of nontarget embolization and coil migration. In addition, the Azur Detachable 35 is the only hydrogel embolic indicated for peripheral applications that is detachable and compatible with 0.038-inch lumen catheters. The microporous expandable hydrogel is biologically inert and provides scaffolding for natural tissue proliferation.

Formula 414RX Renal Stent

COMPANY	Cook Medical
PHONE	(800) 457-4500
WEB	www.cookmedical.com

KEY FEATURES

- Rapid-exchange stent system
- Ultra-low crossing profile
- Nonshortening stent cell design for on-target placement

In January 2011, Cook Medical (Bloomington, IN) announced premarket approval from the US Food and Drug Administration for the Formula 414RX balloon-expandable renal stent, an alternative treatment option for patients suffering from renal artery blockages. The Formula 414RX is a rapid-exchange stent system with a 0.014-inch guidewire. The device is indicated for use in patients with atherosclerotic disease of the renal arteries after suboptimal percutaneous transluminal renal angioplasty of restenotic lesions. The Formula 414RX stent is engineered to avoid shortening after deployment, which allows for more precise placement, the company stated.

At ISET 2011, Robert Bersin, MD, presented 9-month data from Cook Medical's REFORM clinical trial, which assessed the safety and effectiveness of the company's Formula stent. "The data for the REFORM clinical trial reflect the clinical performance and patency of this dedicated renal stent platform," commented Dr. Bersin, director of endovascular services at Seattle Cardiology and Swedish Medical Center. "These initial data indicate the balloon-expandable stent may offer a new treatment option for patients suffering from renal artery blockages."

SuperCross Microcatheter

COMPANY	Vascular Solutions, Inc.
PHONE	(763) 656-4300
WEB	www.vascularsolutions.com

KEY FEATURES

- 0.014-inch guidewire compatible and available in 130 or 150 cm lengths
- Distal 40 cm has a hydrophilic coating to reduce friction during deployment
- Catheter tapers to 1.8 F at the distal tip for navigating small, tortuous vessels and crossing tight lesions
- Full-length stainless steel braid and internal PTFE liner
- Fully embedded gold marker band on the distal tip

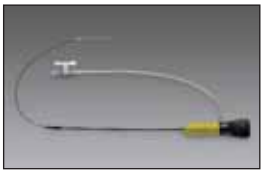
In January 2011, Vascular Solutions, Inc. (Minneapolis, MN) announced that the sterile, single-use SuperCross microcatheter is available in the United States and Europe. According to the company, the SuperCross offers superior crossability, flexibility, and exceptional guidewire support during coronary and peripheral catheterization procedures. It is compatible with 0.014-inch guidewires and available in 130 or 150 cm lengths. The distal 40 cm has a hydrophilic coating to help reduce friction during deployment. A full-length stainless steel braid provides improved flexibility, pushability, and kink resistance. The SuperCross' internal PTFE liner provides superb guidewire movement, and the tapered inner lumen provides a smooth transition during wire delivery for optimal guidewire control. The fully embedded gold marker band on the distal tip delivers radiopacity, enabling precise device placement during complex interventions. The SuperCross is intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary and/or peripheral vasculature, and it may be used to facilitate placement and exchange of guidewires and other interventional devices and to subselectively infuse/deliver diagnostic and therapeutic agents.

Mynx Cadence Vascular Closure Device

COMPANY	AccessClosure, Inc.
PHONE	(650) 864-5473 or (877) 700-6969
WEB	www.accessclosure.com

KEY FEATURES

- Definitive shuttle stop for consistent deployment
- Single marker on the advancer tube removes guesswork
- New sealant sleeve protects sealant during deployment
- Shortened procedure time by eliminating the need to presoak sealant during device preparation



AccessClosure, Inc. (Mountain View, CA) announced the launch of the Mynx Cadence vascular closure device in January 2011. With its simpler design and improved ease of use, Mynx Cadence offers physicians smoother device deployment while maintaining all the benefits of the original Mynx, the company stated. Three design changes on the new Mynx Cadence device make it easier and more consistent to deploy. A definitive shuttle stop when deploying the sealant reduces the possibility of over-shuttling. Additionally, a single marker on the advancer tube removes any guesswork around sealant compression. Finally, a new sealant sleeve protects the sealant during deployment and shortens the procedure time by eliminating the need to presoak during device preparation. These changes result in more consistent sealant delivery every time. As with the original Mynx, the Mynx Cadence device utilizes a conformable, water-soluble polyethylene glycol (PEG) sealant to seal the femoral artery, which dissolves within 30 days, leaving nothing behind but a healed artery. ■