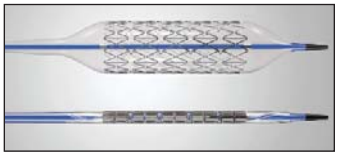
Formula 418 Renal Stent

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

KEY FEATURES

- Over-the-wire system balloon
- Ultra-low crossing profile
- Nonshortening stent cell design for on-target placement



After the announcement of positive 9-month primary patency results from its REFORM clinical trial, Cook Medical (Bloomington, IN) received premarket approval from the US Food and Drug Administration for the Formula 418 balloon-expandable renal stent, a device indicated for use in patients with atherosclerotic disease of the renal arteries after suboptimal percutaneous transluminal renal angioplasty of restenotic lesions. The Formula 418 stent is an over-the-wire system balloon with an 0.018-inch guidewire system. According to the company, the low-profile design of the stent is engineered to cross lesions with high pushability, trackability, and kink-resistance.

Robert M. Bersin, MD, presented the REFORM data at ISET 2011, revealing a primary patency rate of 91.7% and a 97% rate of successful delivery and deployment of Cook Medical's Formula stent. 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."

SmartNeedle Vascular Access System

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

KEY FEATURES

- Reusable hand-held monitor that connects to a one-time use needle
- Provides continuous auditory feedback to help locate and access the artery or vein
- Probe (essentially a microphone) located within the lumen of the needle to detect the sound of arterial and venous blood flow and transmit it to the battery powered monitor (essentially a speaker)

Vascular Solutions, Inc. (Minneapolis, MN) recently acquired the SmartNeedle vascular access system (formerly known as the pdAccess Doppler-guided needle access system), which comprises a hand-held monitor and one-time use needles designed to provide auditory ultrasound-guided access to arteries and veins during catheterization procedures. The SmartNeedle monitor is a reusable, hand-held device that transmits a continuous wave Doppler signal, providing continuous auditory feedback to help locate and access the artery or vein quickly and with confidence. If desired, the monitor can be covered with a disposable sterile bag for use in the sterile field. Sterile, single-use SmartNeedles range from 18- to 26-gauge, with bare-tip and sheathed IV options. Bare-tipped needles are available in 18-, 20- and 22-gauge sizes and consist of a detachable Doppler probe that is housed within the lumen of a standard sized introducer needle. IV sheathed needles, used when attempting to access a vessel with the intent of leaving a small catheter in place, are available in 22-, 24-, and 26-gauge sizes. SmartNeedle products are available in the United States and Europe.

Renegade Hi-Flo Fathom Preloaded System

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

KEY FEATURES

- Turn-for-turn torque response
- Single convenient platform
- Available in eight configurations with microcatheter lengths up to 150 cm

Boston Scientific Corporation (Natick, MA) announced availability of the Renegade Hi-Flo Fathom preloaded system for selective access and delivery of diagnostic, embolic, and therapeutic materials into the peripheral vasculature. The system will primarily be used treat uterine fibroids and liver cancer.

The Renegade Hi-Flo Fathom preloaded system combines the turn-for-turn torque response, support, flexibility, and high visibility of the Fathom-16 steerable guidewire with the performance of the Renegade Hi-Flo microcatheter, preloaded in a single convenient platform. The system will be available in eight configurations to suit a broad range of peripheral embolization procedures.

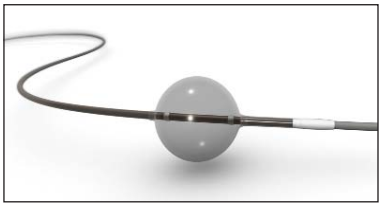
"The excellent deliverability, torque transmission, and flow capacity of the Renegade Hi-Flo Fathom preloaded system provides physicians with the performance they need to efficiently access tortuous vessels across many types of interventional oncology procedures," said Jeff Geschwind, MD, Professor of Radiology, Surgery and Oncology, and Director of Vascular and Interventional Radiology at the Johns Hopkins University School of Medicine.

Keeper Embolectomy Catheter

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

KEY FEATURES

- A specialty 2-in-1 device combines a latex-free embolectomy balloon and a targeted injection system
- Uses one catheter for the entire procedure
- Proprietary and innovative VisioValve technology injects physician-specified fluids
- Atraumatic, compliant balloon is expandable to treat and conform to vessels between 4 and 15 mm in diameter
- Indicated for use in the arterial, fistulae, and synthetic arteriovenous grafts



Hotspur Technologies, Inc. (Mountain View, CA) announced that the US Food and Drug Administration granted the company 510(k) clearance to market its Keeper embolectomy balloon catheter. The Keeper catheter is a specialty, two-in-one device that combines a compliant embolectomy balloon with Hotspur's proprietary VisioValve technology. According to the company, this unique valve allows the physician to inject fluids such as contrast or thrombolytics directly to an intended location without exchanging catheters or jeopardizing guidewire position.

The Keeper catheter is one of Hotspur's three FDA 510(k)-cleared products, all of which are based upon the novel VisioValve technology. In addition to the Keeper catheter, the GPSCath balloon dilatation catheter and the IQCath balloon dilatation catheter are now commercially available. The GPSCath pairs a high-pressure angioplasty balloon with the VisioValve feature, while the IQCath combines high-pressure angioplasty with an embolectomy coil and the VisioValve feature.

Lower Profile Gore Viabahn Endoprosthesis

COMPANY	Gore & Associates
PHONE	(800) 437-8181
WEB	www.goremedical.com/viabahn

KEY FEATURES

- Reduced delivery profile on 5- to 8-mm devices by 1 F size
- Stiffer catheter materials maintain pushability and trackability
- Same proven stent graft

Gore & Associates (Flagstaff, AZ) announced the first clinical use of the new Lower Profile Gore Viabahn endoprosthesis with heparin bioactive surface. The next-generation device includes a reduction in delivery profile to 6 F for 5- and 6-mm devices and 7 F for 7- and 8-mm devices and is delivered over a 0.014- or 0.018-inch guidewire. The reduced delivery profile will provide interventionists with more options for delivery with the same trackability and device performance as previous generations of Viabahn in treating stenoses and occlusions of the superficial femoral artery and iliac artery, the company stated.

The new Gore Viabahn device is available with a 120-cm-long delivery catheter and incorporates the Carmeda bioactive surface, comprised of derivatized heparin covalently bonded to the endoprosthesis luminal surface. This revision to the device is the latest in a series of continuous improvements to the Gore Viabahn endoprosthesis for the treatment of peripheral artery disease. ■