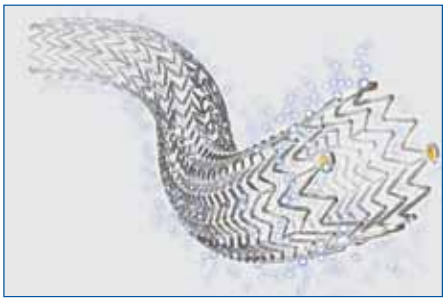
Zilver PTX Drug-Eluting Peripheral Stent

Cook Medical
(800) 339-2235
www.cookmedical.com

KEY FEATURES
- Self-expanding nitinol stent designed for the SFA
- Paclitaxel is released from the polymer-free stent within 72 hours
- Combines the benefits of mechanical and drug therapies
- Indicated for above-the-knee femoropopliteal arteries with reference diameters of 4 to 7 mm and total lesion lengths up to 140 mm per limb (280 mm per patient)



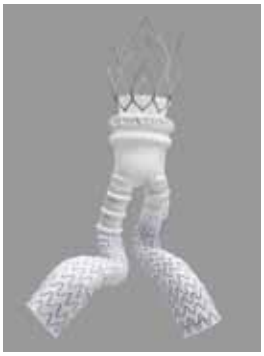
Cook Medical (Bloomington, IN) announced the US Food and Drug Administration approval of the Zilver PTX paclitaxel-eluting peripheral stent. Zilver PTX is the first drug-eluting stent approved for peripheral use in the United States. The device is intended to treat peripheral arterial disease in the superficial femoral artery, with approved indications for improving luminal diameter for the treatment of de novo or restenotic symptomatic lesions in native vascular disease of the above-the-knee femoropopliteal arteries having reference vessel diameters from 4 to 7 mm and total lesion lengths up to 140 mm per limb and 280 mm per patient. The stent is initially available in 80-mm lengths in 6- and 7-mm diameters. The indications for use allow two Zilver PTX 80-mm stents to be overlapped to treat longer lesions up to 140 mm in length. In a randomized trial, provisional Zilver PTX achieved an 83.4% patency rate at two years compared with 64.1% for a bare-metal stent, showing a drug effect.[1]

1. Dake M. Zilver PTX randomized controlled trial of paclitaxel-eluting stents for femoropopliteal disease: three-year results. Presented at: Vascular InterVentional Advances (VIVA); October 12, 2012; Las Vegas, NV.

Ovation Prime Abdominal Stent Graft System

TriVascular, Inc.
(855) 927-4669
www.trivascular.com

KEY FEATURES
- Lowest-profile, 14-F outer diameter
- Unique sealing technology
- Simple staged deployment
- Broadest indications for use
- Excellent clinical results



TriVascular, Inc. (Santa Rosa, CA) recently announced FDA approval of the Ovation Prime abdominal stent graft system for the treatment of abdominal aortic aneurysms. Delivered through a 14-F (4.7-mm) outer-diameter catheter, Ovation Prime is the lowest-profile commercially available system for endovascular aneurysm repair.

"I was impressed by the Ovation Prime system," commented Manish Mehta, MD, MPH, Director of Endovascular Services at the Vascular Institute for Health & Disease in Albany, New York. "We had a very favorable experience with Ovation in the clinical study and were excited to use Prime. The delivery system enhancements make Ovation even easier to use while building upon the confidence that comes from the strong clinical data."

The Ovation Prime system utilizes polymer-filled sealing ring technology and has the broadest indications for use of any endovascular graft, thereby expanding the pool of patients who are eligible for treatment.

Atlas Gold PTA Dilatation Catheter

Bard Peripheral Vascular, Inc.
(800) 321-4254
www.bardpv.com/_vascular/

KEY FEATURES

- Up to 18 atm of ultra noncompliance
- Short shoulders designed to minimize vessel straightening
- All sizes now available on longer 120-cm shafts
- Diameters from 12 to 20 mm

Bard Peripheral Vascular, Inc. (Tempe, AZ) has announced the launch of the Atlas Gold PTA dilatation catheter, an ultra noncompliant, ultra high pressure PTA balloon catheter designed to treat resistant lesions and dilate stents with confidence.

The Atlas Gold PTA dilatation catheter is an entirely new balloon design, featuring short shoulders to minimize vessel straightening, a tapered tip, enhanced trackability, and an indication for stent postdilatation and stent graft dilatation.

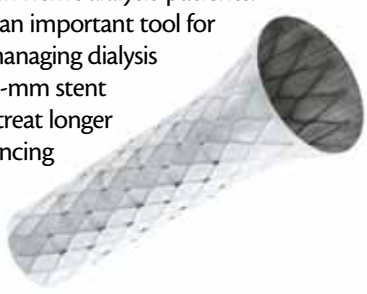
Flair Endovascular Stent Graft

Bard Peripheral Vascular, Inc.
(800) 321-4254
www.bardpv.com/_vascular/

KEY FEATURES

- New 70-mm stent graft length for treatment of longer stenoses
- Flared and straight configurations to optimize flow in different anatomies
- Proprietary inner-surface carbon-impregnation technology designed to decrease platelet accumulation

Bard Peripheral Vascular, Inc. (Tempe, AZ) recently announced the United States introduction of a new 70-mm length of the Flair endovascular stent graft, indicated for the treatment of stenosis at the venous anastomosis of arteriovenous grafts in hemodialysis patients.



The Flair endovascular stent graft is an important tool for interventionists in the United States managing dialysis access patients. The addition of the 70-mm stent graft length allows interventionists to treat longer stenoses with a single stent graft, enhancing overall practice efficiency.

According to Bard, the Flair endovascular stent graft is the only endovascular treatment proven in a controlled clinical trial to improve arteriovenous graft function over balloon angioplasty, the current standard of care. The Flair endovascular stent graft is available in both straight and flared configurations to accommodate differences in vein and graft diameter.

AngioSculpt XL PTA Scoring Balloon Catheter

AngioScore, Inc.
(877) 264-4692 or (510) 933-7900
www.angioscore.com

KEY FEATURES

- Helical scoring element provides 360° of scoring
- Nitinol-enhanced balloon deflation for excellent rewrap
- Semicompliant balloon with large working range (2 to 20 atm)
- No significant device slippage
- Low dissection rate

The new AngioSculpt XL PTA scoring balloon catheters (AngioScore, Inc., Fremont, CA), which recently received FDA 510(k) clearance, incorporate longer, 100-mm scoring balloons in diameters of 2, 2.5, 3, and 3.5 mm. These catheters are expected to be particularly useful in treating complex lesions typically encountered in the treatment of patients with critical limb ischemia and infrapopliteal peripheral artery disease, the company stated.

Thomas P. Davis, MD, Director of the Cardiac Catheterization Lab and Director of Peripheral Interventions and Disease at St. John Hospital and Medical Center in Detroit, Michigan, commented, "These longer AngioSculpt scoring balloon catheters provide physicians with important new devices for the treatment of challenging lesions below the knee because of their ability to achieve more predictable luminal expansion and a very low rate of dissection, potentially minimizing the need to perform adjunctive stenting."

EverFlex Self-Expanding Peripheral Stent With Entrust Delivery System

Covidien
(508) 261-8000
www.covidien.com

KEY FEATURES

- Entrust delivery system offers one-handed stent delivery
- 150-cm catheter length allows access to lesions via the brachial artery
- Ability to deploy all sizes of the EverFlex stent on a low 5-F profile without reducing radial force

Covidien (Mansfield, MA) announced CE Mark approval for the EverFlex self-expanding peripheral stent with Entrust delivery system. The system, specifically engineered for optimal control, is designed to allow physicians to consistently place stents in the desired location with accuracy and ease.

An alternative to the traditional two-handed approach, the Entrust delivery system is currently the only one-handed delivery system on the market with a triaxial design to offer a 5-F profile that is compatible with a 0.035-inch guidewire. This combination of features is designed for superior performance during stent delivery, even when treating patients with complex conditions. Other features include a diverse range of catheter lengths and a broad stent matrix for greater treatment options.

With the Entrust delivery system, physicians can deploy all sizes of the EverFlex stent on a low 5-F profile without reducing the stent's radial force. The EverFlex stent was shown to be safe and effective in the DURABILITY II clinical study. ■