

Lutonix 035 Drug-Coated Balloon PTA Catheter

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

KEY FEATURES

- Optimized drug coating formulation
- Designed to maximize efficacy without compromising safety
- Proven to be safe and effective in LEVANT 2
- Studied in over 1,000 patients
- Offered in 4- to 6-mm diameters and 40- to 100-mm lengths, with 75- and 130-cm shaft lengths

Bard Peripheral Vascular, Inc. recently announced FDA approval of the Lutonix 035 drug-coated balloon percutaneous transluminal angioplasty (PTA) catheter for PTA, after predilatation, of de novo or restenotic lesions up to 150 mm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4 to 6 mm. Lutonix 035 was proven safe and effective in LEVANT 2, a rigorous, randomized, blinded, controlled clinical trial that studied 476 patients with femoropopliteal disease at 54 trial sites. At 12 months, treatment with Lutonix 035 resulted in superior primary patency compared to PTA, quality of life improvements versus PTA, and noninferiority to PTA in terms of safety. Lutonix 035 also demonstrated similar risk for embolic events, amputation, and thrombosis as PTA at 12 months.

Lutonix 035 is the only FDA-approved drug-coated balloon in the United States. It is designed to enhance physicians' current femoropopliteal treatment algorithms and keep future treatment options open for patients. Please consult product labels and the electronic IFU at www.bardpv.com/Lutonix035-IFU.php for indications, contraindications, hazards, warnings, precautions, and instructions for use.

Acuson SC2000 Prime Ultrasound System

Siemens Healthcare
(888) 826-9702
www.siemens.com

KEY FEATURES

- New true volume 3D TEE probe
- True volume color Doppler visualization
- New automated valve analysis software

Siemens Healthcare has received FDA approval for the new Prime edition of its Acuson SC2000 premium cardiovascular imaging system. The system enables live, full-volume color Doppler imaging via a new 3D transesophageal echo (TEE) probe to allow an anatomically accurate view of the heart during interventional valve procedures, even in patients with electrocardiogram abnormalities. The system eliminates the need for multiple beats to form an image, allowing assessment of dynamic blood flow in real time.

"Volume color Doppler is extremely important," commented Lissa Sugeng, MD, associate professor of medicine at Yale University in New Haven, Connecticut, in the company's press release. "With Siemens' new volume acquisition, I can see the entire valve, locate the regurgitant jet, and assess the size of the orifice very quickly so that we can continue with the procedure." ■



Masters Parkway Series Microcatheters

Asahi Intecc Co. Ltd.
+31 (0) 20 7940642
www.asahi-intecc.com

KEY FEATURES

- Super-selective, high-flow microcatheters
- Tungsten braiding
- 1,000 psi
- Compatible with various embolic materials

Asahi Intecc Co. LTD (Nagoya) has received CE Mark approval for its Masters Parkway microcatheter series.

Masters Parkway microcatheters are dedicated to endovascular embolization. They are compatible with a wide variety of embolic materials and provide an optimal flow rate of 1,000 psi.

The lineup includes the Masters Parkway High-Flow 2.6-F, which is also available pre-loaded with a 0.021-inch guidewire (Masters Parkway kit), and the Masters Parkway Soft, which has a 1.9-F tip profile that targets super-selective embolization of hepatocellular carcinoma, allowing smooth navigation to distal vessels and delivery of embolic agents, drugs, and contrast. ■

