Varithena (Polidocanol Injectable Foam) 1%

BTG plc
(855) 971-8346
www.varithena.com

KEY FEATURES

- Low-nitrogen polidocanol foam
- Treats a wide range of varicose veins
- Minimally invasive, nonsurgical procedure
- Requires no tumescent anesthesia or sedation

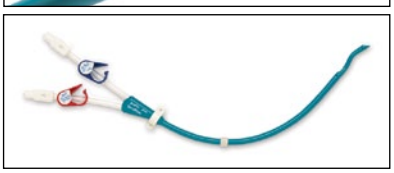
BTG plc (London, UK) announced FDA approval of Varithena (polidocanol injectable foam) for the treatment of patients with incompetent great saphenous veins, accessory saphenous veins, and visible varicosities of the great saphenous vein system above and below the knee. Varithena improves the symptoms of superficial venous incompetence and the appearance of visible varicosities. Varithena is a low-nitrogen polidocanol foam dispensed from a proprietary canister device. It is delivered under ultrasound guidance.

BioFlo DuraMax Dialysis Catheter

AngioDynamics
(518) 798-1215
www.angiodynamics.com

KEY FEATURES

- Provides long-term vascular access
- Designed to reduce surface thrombus accumulation



AngioDynamics (Latham, NY) announced FDA 510(k) clearance of its BioFlo DuraMax chronic hemodialysis catheter. BioFlo DuraMax is designed for use in attaining long-term vascular access for hemodialysis and apheresis. It is the first dialysis catheter with Endexo technology for resistance to the accumulation of blood components.

In vitro blood loop model test results showed 90% less surface thrombus accumulation on average compared to noncoated conventional catheters (based on platelet count)* and 83% less thrombus accumulation as compared to a heparin-coated dialysis catheter.** An in vivo sheep study with 31-day indwell time showed comparable thromboresistance to a heparin-coated dialysis catheter.

*The reduction in thrombus accumulation (based on platelet count) is supported by acute in vitro testing. Preclinical in vitro evaluations do not necessarily predict clinical performance with respect to thrombus formation.
**Based on benchtop testing performed up to 2 hours using bovine blood, which may not be indicative of clinical results. Data on file.

Supera Peripheral Stent System

Abbott
(800) 227-9902
www.abbottvascular.com/us/supera.html

KEY FEATURES

- Unique, proprietary interwoven wire technology mimics rather than resists the artery's natural movement
- More flexible, stronger, and resistant to kinks or fracture under vigorous movement compared to other nitinol stents used to treat blocked blood vessels in the upper leg
- Clinically proven results based on data from the SUPERB trial

The Supera peripheral stent system (Abbott, Santa Clara, CA) received United States FDA approval to treat blockages in the superficial femoral artery and proximal popliteal artery. It has also received CE Mark approval in Europe for the treatment of blocked blood vessels caused by peripheral artery disease.

Data from the SUPERB clinical trial, which were used to support FDA approval of Supera, have shown Supera to be highly effective in opening up blocked blood vessels in the upper leg, even in difficult cases, and results have been shown to last over time.[1] In addition, during the first year after treatment with Supera, there were no stent fractures, and at 2 years, there was a very low stent fracture rate of 0.5%.[1]

"Treatment with the Supera stent, as shown by the results of the SUPERB study, is very effective in easing leg pain, enabling the majority of patients to resume their activities," said Kenneth Rosenfield, MD, Section Head of Vascular Medicine and Intervention at Massachusetts General Hospital and the principal investigator of the SUPERB clinical trial.

1. Supera Peripheral Stent System Instructions for Use.

Mynx Ace Vascular Closure Device

AccessClosure, Inc.
(877) 700-6969
http://www.accessclosure.com/mynx-ace

KEY FEATURES

- Reliability of easy deployment
- Security of mechanical closure
- Safety of an extravascular sealant
- Designed for patient comfort

AccessClosure, Inc. (Santa Clara, CA) announced the United States launch of Mynx Ace, a vascular closure product that provides consistent results with a new, easy-to-use deployment system to seal femoral artery access sites.* The device joins the line of Mynx extravascular products designed for patient comfort by providing gentle vascular closure without the use of cinching, sutures, or metal implants to enhance patient satisfaction.[1] With Mynx Ace, physicians can consistently close access sites through a simple, three-step deployment system. Mynx Ace uses AccessClosure's proprietary Grip Technology, an extravascular sealant that actively adheres to the artery for safe and secure mechanical closure and dissolves within 30 days, leaving nothing behind in the healed vessel.

"After completing over 50 cases with Mynx Ace, I have found the system provides consistent results while offering the safety, security, and patient-friendly advancements I have come to trust in Mynx products," said Rajesh Dave, MD, a cardiologist with Holy Spirit Hospital in Camp Hill, Pennsylvania, in the company's press release. ■

*As compared to earlier generations of Mynx closure devices. Test data on file at AccessClosure.

1. Fargen KM, Hoh BI, Mocco J. Extravascular synthetic sealant closure provides less pain than a self-tightening suture vascular compression device. J NeuroIntervent Surg. 2011;3:219-223.