StarFlex Septal Repair Implant

COMPANY	NMT Medical, Inc.
PHONE	(617) 737-0930
WEB	www.nmtmedical.com

KEY FEATURES

- Constructed from a low-profile, MP35N framework
- Implant framework and fabric made from biocompatible materials
- Comprised of two umbrella-shaped discs, one for each side of the septum

NMT Medical, Inc. (Boston, MA) recently announced that the United States Food and Drug Administration granted premarket approval to the company's StarFlex septal repair implant for the treatment of ventricular septal defects. The StarFlex is constructed from a low-profile, MP35N framework and is comprised of two umbrella-shaped discs, one for each side of the septum. According to the company, both the framework and fabric are made from the most biocompatible materials known for this application. Using spring coils in the framework, the StarFlex implant can be collapsed into a catheter for insertion into the heart. Once inserted through the catheter, the StarFlex implant is opened, with one umbrella positioned on each side of the defect. The spring coil design allows the septal repair implant to stay securely in place at the site of the defect and to conform to variations in the anatomy of the septum. StarFlex adds a flexible, self-centering system to the CardioSeal implant, the company stated. Once in position, the StarFlex is released from the catheter and tissue grows into and around the fabric and metal framework.

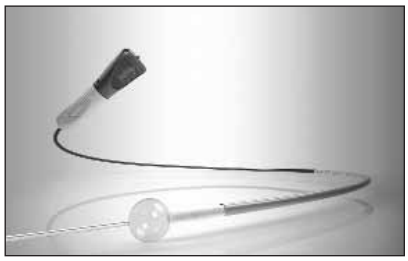
Mynx M5 Vascular Closure Device

COMPANY	AccessClosure, Inc.
PHONE	(877) 700-6969
WEB	www.mynx.com

KEY FEATURES

- Delivered through existing 5-F procedural sheath
- Eliminates need for sheath exchange
- Saves procedure time and expense
- Preserves size of arteriotomy and tissue tract
- Avoids potential tissue trauma

AccessClosure, Inc. (Mountain View, CA) introduces its newest addition to the Mynx family, the Mynx M5 Vascular Closure Device. Designed specifically for 5-F closure, the Mynx M5 delivers an extravascular, conformable sealant through the existing 5-F procedural sheath, eliminating the need for a sheath exchange and preserving the size of the arteriotomy. In addition, the Mynx M5 provides all the same benefits as the 6/7-F Mynx. With patient comfort in mind, the device is deployed gently, avoiding cinching and tugging of the artery. Without the use of a suture or permanent metal implant, the Mynx sealant is placed on the surface of the artery. According to the company, it immediately seals both the arteriotomy and the tissue tract, rapidly absorbing blood and subcutaneous fluids and minimizing ooze. The Mynx sealant then dissolves completely through hydrolysis within 30 days, leaving nothing behind but a healed artery.

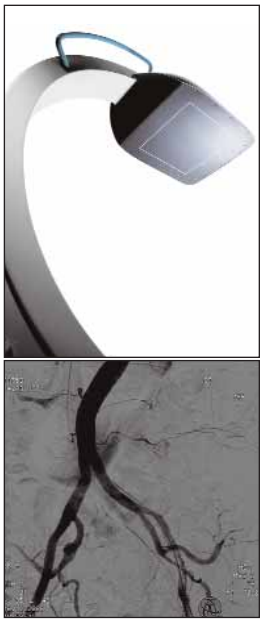


Ziehm Vision RFD

COMPANY	Ziehm Imaging, Inc.
PHONE	(951) 781-2020
WEB	www.ziehm.com

KEY FEATURES

- 30- X 30-cm flat panel detector provides improved dynamic range and increased field of view
- Pulse technology at up to 25 frames per second provides sharp, high-contrast images
- Larger C-arm opening and 165° orbital rotation allows better access to the patient



Ziehm Imaging, Inc. (Orlando, FL) recently announced it has received 510(k) clearance from the US Food and Drug Administration for its mobile fluoroscopic imaging system, the Ziehm Vision RFD. Designed for procedures common in endovascular surgery, interventional radiology, and interventional cardiology, the Ziehm Vision RFD mobile C-arm combines innovative flat-panel technology with object-detected, dose-control software and specially designed anatomical programs for fully digital, distortion-free imaging. The Ziehm Vision RFD has pulse technology at up to 25 frames per second, which provides sharp, high-contrast images of vascular, bone, and soft tissue structures. According to the company, the Ziehm Vision RFD's advanced design and the flat-panel detector's increased field of view provide physicians with a wide range of benefits; the 30- X 30-cm flat-panel detector with 1,500- X 1,500-pixel resolution provide extended dynamic range and 49% greater anatomical viewing when compared to 12-inch image intensifier systems. "Using fully digital technology, we are setting standards for C-arms in terms of image quality and patient care," comments Klaus Hörndler, chief executive officer of Ziehm Imaging. "Our aim is to evolve x-ray–based imaging methods consistently so that we can provide physicians with the best possible technology to enable enhanced treatments."

Amplatz SST Guidewire

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

KEY FEATURES

- Inner-core construction
- Radiopaque tip
- PTFE coating
- Available in straight and modified J configurations

Vascular Solutions, Inc. (Minneapolis, MN) recently launched the Amplatz SST line of 0.035- and 0.038-inch guidewires designed for extra support during catheter placement in diagnostic angiography and interventional procedures.

Amplatz SST guidewires have an inner-core construction that provides added strength for increased support, a radiopaque tip for enhanced visibility, and a PTFE coating for enhanced device tracking, the company stated. The Amplatz SST guidewire is available in straight and modified J configurations and in 0.035- and 0.038-inch diameters. Amplatz SST guidewires are currently available in the United States. ■

ThromCat XT

COMPANY	Spectranetics Corporation
PHONE	(800) 633-0960
WEB	www.spectranetics.com

KEY FEATURES

- High-speed rotary helix
- 7-F guide catheter compatibility
- Single-use, disposable device
- New catheter jacket technology

Spectranetics Corporation (Colorado Springs, CO) recently reported that it has received CE Mark approval for its next-generation ThromCat XT Thrombus Removal System, a single-use, disposable device indicated for mechanical removal of thrombus from coronary and peripheral arteries.

According to the company, the ThromCat XT System is an improvement to the current ThromCat System with enhanced thrombus removal and several advancements in ease-of-use. The ThromCat XT System generates a consistent vacuum pressure at the tip of the catheter to draw thrombus into the extraction ports where it is then macerated by an internal helix. Without further contact with the blood stream, the thrombus is then transported to an external collection bag. The ThromCat XT is completely disposable and offered in 150-cm lengths to treat vessels 2.5 to 7 mm in diameter.

Xience Prime Coronary Stent System

COMPANY	Abbott Vascular
PHONE	+31 43 358 6750
WEB	www.abbottvascular.com

KEY FEATURES

- Same proven drug and polymer as Xience V
- Enhanced Multi-Link design with improved flexibility and deliverability
- Cobalt chromium allows for thin struts while maintaining strength
- Excellent visibility under x-ray
- Broad size matrix, lengths up to 38 mm

The Xience Prime Everolimus Eluting Coronary Stent System (Abbott Vascular, Santa Clara, CA) received CE Mark for the treatment of coronary artery disease in Europe in June 2009. This next-generation drug-eluting stent is based on Abbott's Xience V stent and is built upon the proven Multi-Link family of bare-metal stents. Xience Prime uses the same low dose of everolimus, proven biocompatible polymer, elution profile, and thin cobalt chromium stent material as Xience V and offers an advanced stent design and delivery system to provide physicians greater flexibility and improved deliverability, enabling them to more easily treat challenging lesions.

"The Xience Prime stent platform and delivery balloon are designed to be highly deliverable, and as such, Xience Prime has the potential to simplify procedures in challenging cases," said Marco A. Costa, MD, PhD, FACC, FSCAI, Director of the Interventional Cardiology Center, and director of the Center for Research and Innovation, Harrington-McLaughlin Heart and Vascular Institute, Case Western Reserve University, and Principal Investigator of SPIRIT PRIME, a trial of Xience Prime for US approval. ■