

ConcierGE Guiding Excellence Catheter

Merit Medical Systems, Inc.
(800) 35-MERIT
www.merit.com

KEY FEATURES

- Improved kink resistance¹
- Better 1:1 torque response^{1,2}
- Soft, atraumatic tip

The ConcierGE Guiding Excellence guide catheter (Merit Medical Systems, Inc.) has received European CE Mark and US Food and Drug Administration (FDA) 510(k) clearance. The ConcierGE is intended for use for intravascular introduction of interventional or diagnostic devices into coronary or peripheral vascular systems and is available in sizes of 5, 6, 7, and 8 F. ConcierGE is composed of a nylon-blend shaft material with wire braid technology and offers better kink resistance and improved 1:1 torque.

1. Test results are based on 6-F guiding catheter comparison. Data on file.
2. At ½ hub rotation. Data on file.



Mozec Rx PTCA Balloon Dilatation Catheter

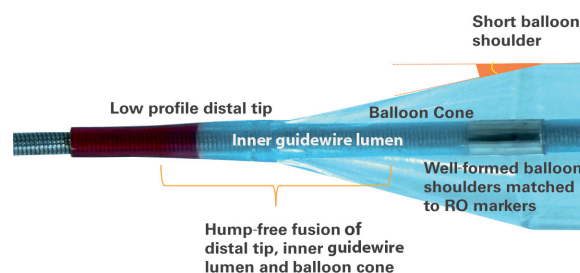
Meril Life Sciences Pvt. Ltd.
+91 2239350700
www.merillife.com

KEY FEATURES

- Low tip entry profile
- Low crossing profile
- Biocompatible, hydrophilic, and lubricious coating
- Flexible, kink-resistant shafts
- Available in 73 sizes

Meril Life Sciences, a large Indian medical device group, has received FDA clearance for its Mozec Rx PTCA balloon

dilatation catheter. Mozec is available in diameters from 1.5 mm to 4.5 mm and lengths from 9 mm to 41 mm in the United States. Mozec balloon models with 1.5 mm to 4.5 mm diameters are indicated for treating the stenotic portion of coronary arteries or bypass grafts to improve myocardial perfusion, and balloon models with diameters of 2.25 mm to 4.5 mm are indicated for postdelivery expansion of balloon-expandable stents. This approval comes back to back with approvals received from China's CFDA, Korea's KFDA, and Health Canada. Mozec has been DCG(I) approved in India, has received CE Mark, and is commercially available in geographies spanning Latin America, Europe, the Middle East, Africa, and Southeast Asia. Meril is now actively seeking partners for Mozec distribution in the United States and Canada.



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

ND Infusion Catheter

Translational Research Institute
(480) 309-2884
www.trimedical.com

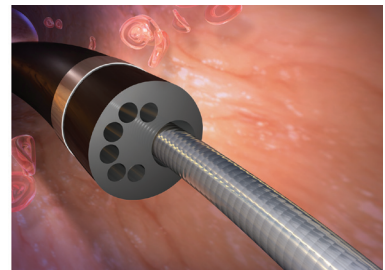
KEY FEATURES

- Provides localization of physician-specified agents
- Spray mechanism improves distribution
- Low radial balloon forces minimize vessel trauma
- Single-size expandable balloon up to 4.5 mm
- Reduced shear stress on injected agents
- Easy-to-use monorail system

The ND infusion catheter, developed by Translational Research Institute (TRI), has received FDA 510(k) clearance and CE Mark approval. It can be used to infuse physician-specified drugs when treating conditions including cardiovascular and peripheral vascular disease.

The ND infusion catheter is a balloon catheter designed to isolate a specific treatment region from blood flow while directing the infusion of fluids into the specified region through multiple channels at the distal end of the catheter. The multiple-lumen spray mechanism helps to disperse therapeutic agents in a flow pattern that potentially allows for more homogeneous mixing and tissue distribution of the physician-specified fluid into the bloodstream compared to a single-lumen infusion catheter.

The catheter has a length of 135 cm, a diameter of 3 F, and is intended to be used with a ≥ 6 -F guide catheter and 0.014-inch rapid-exchange guidewire for positioning. The variable-diameter balloon (1.7–4.5 mm) controls blood flow by adapting to different vessel diameters and is uniquely designed to reduce radial forces, potentially minimizing vascular trauma. An integrated expansion segment is designed to provide for volumetric expansion of the infusate and regulate the flow velocity before the agent enters the multiple lumens, potentially decreasing the likelihood of catheter occlusion.



Artis One Angiography System

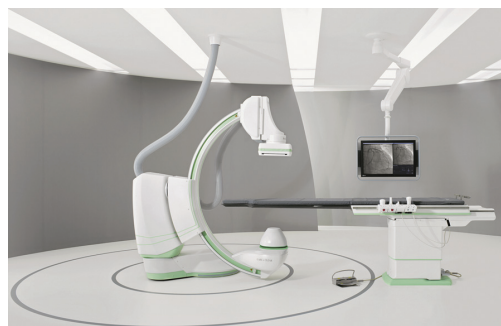
Siemens Healthcare
(888) 826-9702
www.siemens.com/healthcare

KEY FEATURES

- Highly flexible system
- Covers most angiographic procedures
- Provides improved patient access
- Enables cardiac imaging from multiple projections in one sweep

Siemens Healthcare has received FDA approval for the Artis One angiography system, designed for routine interventions including peripheral vessel occlusions, functional tests of dialysis shunts in patients with kidney failure, diagnostic or minimally invasive angiographic treatment of narrowed coronary arteries, and pacemaker implantations. The system offers new tools for cardiac imaging: HeartSweep uses dual-axis rotational angiography to image the entire heart in a single, smooth C-arm movement.

This space-saving, floor-mounted system features several axes that can move independently of one another, allowing positioning flexibility similar to ceiling-mounted systems and accommodating full head-to-toe coverage for patients up to 6 feet 10 inches in height. An on-screen, menu-guided user interface allows the interventionist to navigate directly using the 30-inch heads-up display.



Somatom Force CT System

Siemens Healthcare
(888) 826-9702
<http://usa.healthcare.siemens.com/computed-tomography>

KEY FEATURES

- Conducts kidney-friendly scanning
- Freezes motion with free-breathing CT
- Advances preventative care initiatives with low-dose lung and colon scanning

Siemens Healthcare has received FDA approval for the Somatom Force CT system, a new-generation, dual-source CT system designed to extend advanced imaging to patients including young children, patients with renal insufficiency, and patients

who are unable to hold their breath. The Vectron tube delivers routine adult imaging with fast, low-dose protocols. In cardiac imaging, the device can obtain an entire study at a native temporal resolution of 66 ms, including fast-moving anatomy, such as the right coronary artery.

"The massively enhanced tube power of the Somatom Force enables imaging that can be acquired at very low kV settings—and thus at a lower level of radiation dose," said Joseph Schoepf, MD, Director of CT Research and Development and Professor of Radiology and Cardiology at Medical University of South Carolina. ■

