# Product News

*Continued from page 50*

tem. In addition to simplicity and ease of use, the 6F/0.035" over the wire delivery system provides the physician with a means for very accurate stent deployment.

## Natec Medical receives the CE mark for additional sizes of Ebony peripheral dilatation catheter

Natec Medical has received the CE mark for the Ebony percutaneous transluminal angioplasty (PTA) 0.014" RX for lengths up to 200mm. According to the company, this catheter was designed to reach remote infrapopliteal lesions, offering excellent pushability, crossability, trackability and flexibility.

Ebony PTA 0.014" RX has been developed to reach specific diameters at specific pressures. Sizes range currently from 2 to 8mm in diameter, and up to 200mm in length.

## Cordis launches Powerflex Pro .035" PTA dilatation catheter in Europe

Cordis has announced the launch of the Powerflex Pro .035" percutaneous transluminal angioplasty (PTA) dilatation catheter in Europe for the treatment of peripheral vascular disease in the lower extremities.

This balloon catheter offers many features and benefits to aid in patient treatment; including long lengths up to 220mm to treat long lesions in one uniform dilatation, short balloon shoulders for accuracy and post-dilatation ballooning, along with a rated burst pressure of up to 18 atmospheres to treat calcified lesions.

## Gore receives the CE mark for new Excluder AAA Endoprosthesis Sizing Options

Gore has received the CE mark for the 23mm and 27mm diameter sizes of the contralateral leg component of the Gore Excluder AAA Endoprosthesis for treatment of abdominal aortic aneurysm (AAA). The new diameter devices provide physicians with the ability to repair aneurysms in a wider range of anatomies eligible for minimally invasive endovascular aneurysm repair.

"By adding new diameter options to the Gore Excluder device, patients with large iliac arteries can now be treated with fewer components. This will simplify the EVAR procedure for these patients, widen its applicability, and reduce its costs," said Michel Makaroun, professor and chair, Division of Vascular Surgery, University of Pittsburgh School of Medicine, Pittsburgh, USA.

Once the physician has positioned the Excluder in the diseased aorta, the Gore C3 Delivery System uniquely and intuitively enables repositioning of the stent graft.

## Vector PTA balloon gets FDA clearance

The FDA has given clearance to r4 Vascular to market its Vector Percutaneous Transluminal Angioplasty (PTA) balloon catheters in 28 sizes. All Vector balloon catheter sizes are rated for up to 30 atmospheres of pressure and are radiopaque when deflated or inflated.

Vascular narrowings, lesions, and blockages range from short and focal, to long and diffuse. Some lesions can be treated with basic low- pressure balloon catheters rated between 10 and 20 atmospheres, while other blockages may require advanced high-pressure balloons rated up to 30 atmospheres. High pressure balloons are used to treat the full range of blockages, saving the physician and patient from the difficulties of initiating the procedure with a low-pressure balloon only to find out during the procedure that a high-pressure balloon is necessary.

R4's patent pending Vector balloon catheter also includes radiopaque stripes on the balloon so physicians do not have to use viscous contrast media to visualise the balloon under X-ray. Instead, clinicians may use low-viscosity saline which reduces inflation/deflation time up to 50% and may reduce x-ray exposure to the patient and clinicians. Vector includes advanced catheter shaft technology to improve catheter tracking and handling.


Excluder

## TriReme Medical receives FDA clearance for expanded matrix of sizes of Chocolate PTA balloon catheter

TriReme Medical announced that it has received FDA clearance for an expanded matrix of sizes for its Chocolate PTA balloon catheter. Chocolate is now approved for the percutaneous transluminal treatment of lesions in the peripheral vasculature in balloon diameters from 2–4mm and in balloon lengths up to 120mm.

Chocolate's novel design incorporates a constraining structure over a semi-compliant balloon to facilitate the formation of small modules ("pillows"). Through this advanced mechanism of action, Chocolate minimises shear stress and allows for uniform inflation and rapid deflation. The Chocolate "pillows" can expand locally to facilitate plaque modification and are designed to lower the strain and trauma induced on the vessel wall.

"Chocolate has become an essential part of my routine practice for treating below-the-knee lesions," said Rajesh Dave, chief medical executive and director at Cardiac Catheterization Laboratories, Holy Spirit Cardiovascular Institute, Camp Hill, Pennsylvania, USA. "With the approval of these new sizes, I will be able to expand my use of Chocolate and begin to treat patients with disease in the popliteal artery where we usually prefer not to stent."

## FDA clears Amplatzer Vascular Plug 4

The FDA has given clearance to St Jude Medical to market the Amplatzer Vascular Plug 4 (AVP 4) for use in transcatheter embolisation procedures within the peripheral vasculature.

As the industry's first vascular plug that can be delivered using a standard diagnostic catheter, the AVP 4 offers physicians the ability to treat smaller and more difficult-to-access blood vessels using vascular plug technology. The AVP 4 also provides full cross-sectional vessel coverage and may be recaptured and repositioned prior to deployment, allowing physicians to block a vessel with greater precision and speed than is achievable with conventional embolic coils.

"The Amplatzer Vascular Plugs have been beneficial in precisely targeting specific vessels for embolization," said Jafar Golzarian, University of Minnesota Medical Center, Minneapolis, USA. "With the Amplatzer Vascular Plug 4 we now have the ability to use a diagnostic catheter to deliver the device, which means that patients in need of embolization of smaller, more tortuous vessels can benefit from this technology."

"Approval of the AVP 4 represents a significant milestone for our U.S. vascular business," said Frank J Callaghan, president of the St Jude Medical Cardiovascular Division. "This technology simplifies the peripheral embolisation procedure for physicians by eliminating the need for catheter exchanges and blocking or redirecting blood flow through the peripheral vessels in a more efficient manner than with surgical clips or embolic coils. We are excited to offer the US market a more complete family of vascular plugs for peripheral embolisation."

The Amplatzer Vascular Plug 4 received the CE mark in July 2009.


HQS introducer

## AlSeal announces successful case with its devices in Sweden

AlSeal has announced that Thomas Larzon, Örebro, Sweden, has successfully used both the company's HQS active valve (22F/300) and XCath, a three-way device to convert the HQS active valve into multiple accesses, in a clinical case in June. The devices were used in a fenestrated graft procedure with a Cook Medical device.

"Dr Larzon was satisfied with the products and said he would use them on a regular basis. This is an important milestone for AlSeal and will contribute to increase the company's reputation and development," the company stated in a press release.

AlSeal's device was the winner of two consecutive Innovation Showcase Dragons' Den competition: HQS in 2010 and XCath in 2011. AlSeal received the CE mark for the HQS active valve in 2009 and for XCath in 2011.

## Vascular Solutions launches microcatheter

Vascular Solutions has launched the SuperCross FT, a new flexible-tip version of its line of SuperCross microcatheters. SuperCross FT has been designed to address the majority of complex interventional procedures in which a flexible tipped microcatheter is needed.

Vascular Solutions' family of SuperCross microcatheters consists of single lumen, over-the-wire microcatheters designed for guidewire support and exchange, as well as the infusion of contrast media or therapeutic agents in the coronary and peripheral vasculature. The full-length braided stainless steel construction and low profile of the SuperCross microcatheters allow access to small and tortuous vessels and enhance the ability to cross plaque lesions.

The international newspaper for vascular specialists

BIBA Publishing

vascularNEWS INTERNATIONAL

Issue 55

September 2012

James H Black III: Genetic testing
Page 6

Profile: Frank Lederle
Page 28

venousNEWS
Page 38

# Intensive endovascular simulation training improves performance

**The use of an intensive simulation-based endovascular curriculum during a resident's vascular surgery rotation improves the technical skills of surgical residents, a new study has demonstrated. The prospective, randomised trial conducted in a US institution has also shown that endovascular simulation training translates into improved performance in the operating room**

Jason T Lee

It is acknowledged that good training programmes should include 3D imaging, the importance of sizing, specific pre-procedure simulation, and more recently, rehearsal. These are all key to decision making and contribute to procedural success.

A randomised trial conducted in the US evaluated the importance of surgical simulation as a training tool for residents training in endovascular surgery. The results were presented by principal investigator and lead author Jason T Lee, associate professor of surgery and program director of the residency/fellowship, Stanford University School of Medicine, at the Vascular Annual Meeting of the Society for Vascular Surgery in National Harbor, USA, in June.

This prospective, randomised trial was conducted over the past four years in the Goodman Simulation Center and funded by the Robert Wood Johnson Physician Faculty Scholars Program.

**In the study, 25 consecutive surgical residents rotating on the Stanford vascular service from 2008 to 2012 were randomised to either an intensive simulator-based endovascular teaching curriculum or the standard rotation.**

Thirteen residents were in the simulation group, and 12 in the control group, with pre-rotation assessments and demographics obtained at the beginning of the two-month block.

Endovascular skills were assessed pre- and post-rotation on a high-fidelity simulator using a previously validated endovascular global assessment scale (score 1–5), and included a live angiosuite patient evaluation at the end of the rotation.

At baseline, the two cohorts were similar in terms of their demographics, prior experience, and performed equally on the pre-test, which consisted of an iliac stent case (1.5 vs. 1.6 out of 5, p=non-significant) and a renal stent case (1.4 vs. 1.6, p=non-significant). In the experimental group, the residents received weekly mentored skills sessions with a faculty vascular surgeon practicing various procedures on a Simbionix AngioMentor system. These 13 experimental residents worked an additional 9.3 hours on the simulator throughout their rotation, while the remainder of metrics between them and the control group were similar in terms of average number of cases performed (56 vs. 51), duty hours reported (77 vs. 78), weekly hours of reading (7 vs. 8), and distribution of endovascular versus open cases (59% vs. 52%). Post-rotation assessment confirmed improved performance for the entire cohort on the simulator, documenting the educational efforts and learning that occurred while rotating (1.6 to 3.3 out of 5 on the iliac module, 1.5 to 3.2 on the renal module), with significantly better performance in the experimental cohort (3.7 vs. 2.8).

Most importantly, improved

*Continued on page 2*

## Stem cell mobilisation shows trend in improving amputation rate in critical limb ischaemia

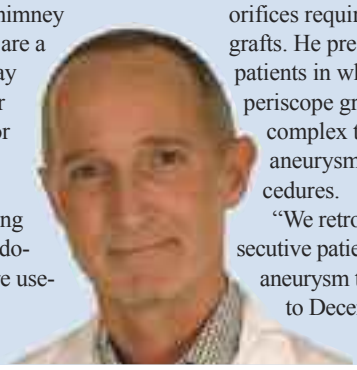
**Results of STEMPAD, a small randomised study presented at the Vascular Annual Meeting (National Harbor, USA, June 2012), showed a trend toward improved major leg amputation-free survival with stem cell mobilisation therapy in patients with critical limb ischaemia. At 12 months, the amputation rates were 50% for patients treated with mobilisation therapy and 83.3% in the control group (p=0.188)**

Eric T Choi, associate professor of Surgery, chief, Section of Vascular Surgery, Temple University, Philadelphia, USA, told delegates that, in 1997, Jeffrey Isner's lab in Boston discovered that a subset of bone-marrow-derived circulating cells was able to differentiate into endothelium and promote new blood vessel growth (Asahara *et al*. *Science* 1997; 275:964–7). He continued, "In 2006, Dan Link's lab in St Louis showed that two types of such bone marrow-derived angiogenic cells are CD31, CD34, CD105 and CD144-positive endothelial progenitor cells (EPCs) and CD14, CD54-positive

*Continued on page 2*

## Chimney and periscope grafts safe and effective to facilitate EVAR or hybrid procedures for complex aortic aneurysms

Mario Lachat, Clinic for Cardiovascular Surgery, University Hospital Zurich, Zurich, Switzerland, told delegates at the Vascular Annual Meeting in National Harbor, USA, that chimney and periscope grafts are a safe and effective way to facilitate EVAR or hybrid procedures for complex aortic aneurysms, and that these techniques, using only off-the-shelf endograft components, are useful to treat ruptured aneurysms involving vital aortic branches.



Mario Lachat

Lachat said that chimney and periscope grafts allow maintaining the patency of aortic branches when their orifices require coverage by aortic stent grafts. He presented a series of 85 patients in which chimney and/or periscope grafts have been used to treat complex thoracic and/or abdominal aneurysms or to simplify hybrid procedures.

"We retrospectively analysed 85 consecutive patients with complex aortic aneurysm treated from February 2002 to December 2011. Aneurysms in-

*Continued on page 2*