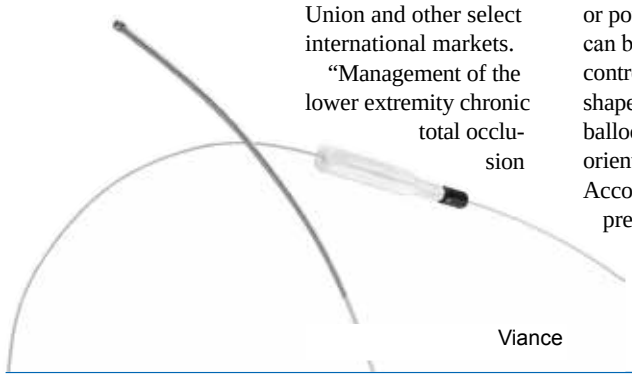
Product News

clinical trial for the Jetstream technology. “In the pivotal study of 172 patients, many of whom had more than one lesion, we successfully restored flow through 99% of the lesions and demonstrated significant clinical improvement post-procedure at 30 days, six and 12 months on both Rutherford and ABI scores.”

“The device allows us to quickly restore blood flow to the limbs by removing calcifications in diffusely diseased segments – including traditional zones where stents cannot be used – without the higher risks inherent in surgery,” said Anderson Mehrle, Jane Phillips Medical Center, Bartlesville, USA.



Viance

Covidien launches Viance Crossing Catheter and Enteer Re-entry System

Covidien announced at CIRSE 2012 the launch of the Viance Crossing Catheter and Enteer Re-entry System for treating chronic total occlusions. The devices are now available in the United States, the European Union and other select international markets.

“Management of the lower extremity chronic total occlusion remains challenging for endovascular physicians,” said David B Jessup, PeaceHealth St Joseph Medical Center in Bellingham, Washington, USA. “Effective devices for chronic total occlusion crossing and re-entry can expand the number of patients who have access to endovascular treatment of peripheral arterial disease, which may help patients avoid more invasive treatments and allow physicians to offer amputation-saving procedures.”

Competitive crossing devices rely on more aggressive cutting, grinding or pounding motions and can be more difficult to control. The distinctive shape of the re-entry balloon enables it to self-orient within the vessel. According to a company press release, no other product on the market utilises this balloon technology for a re-entry system.

Alseal receives FDA clearance for the HQS introducer

Alseal has announced that it received FDA 510(K) clearance for its HQS introducer in July 2012.

The HQS introducer is indicated for large endovascular access with a 300mm long sheath ranging from 18F to 26F. The valve diameter is actively adapted via a pusher to the outer diameter of the device introduced in the femoral artery either surgically or percutaneously. In a press release, Alseal stated that “whatever is the size or the profile of the endovascular tool which is passed through, the HQS valve provides full sealing. The device is versatile enough to accept and seal around any kind of endoprosthesis and associated delivery system. The HQS performance, which has been clinically evaluated, minimises significantly blood loss and consequently improve the safety of aortic endoprothesis procedures.

Alseal also informed that the company has a wide range of products associated with the HQS introducer, which were developed to secure percutaneous approach for endovascular aortic procedures “even in cases of difficult access and complex endoprosthesis deployment”.

HQS introducer

Natec Medical receives CE mark for Ebony PTA .035 OTW up to 200mm

Natec Medical has announced it has received the CE mark approval for Ebony PTA 0.035” OTW catheter for lengths up to 200mm. Ebony PTA.035” dilatation catheter is intended to dilate stenosis in the iliac, femoral, popliteal and renal arteries. Designed as a universal solution for peripheral dilatation, it combines an extremely low balloon profile with an excellent re-wrapping and controlled uniform expansion, Natec Medical stated. “The tapered tip is ensuring excellent crossability into the tight stenosis. Its large crescent shape allows for extremely rapid inflation/deflation. Its Polyn P balloon material gives an advantage for effective resistance to calcified lesions and multiple inflations,” the company added.

Ebony PTA .035” OTW covers balloon sizes from diameter 5 to 12mm, lengths 20 to 200mm, and catheter shaft lengths 80, 130 and 150cm. “Its hydrophilic coating provides unique trackability performances, combined with its exceptional pushability and crossability,” Natec Medical said.

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Early follow-up shows promising results with bioabsorbable stent in the superficial femoral artery

Optical coherence tomography imaging indicates good acute vessel wall apposition and no device fracture for the first self-expanding bioresorbable scaffold for the superficial femoral artery six months after implantation

"To date, we have seen excellent acute scaffold performance with post-procedural images showing the scaffold well apposed to the vessel wall," said STANCE trial principal investigator Andrew Holden, director of Interventional Radiology at Auckland City Hospital and associate professor of Radiology at Auckland University School of Medicine, Auckland, New Zealand. "The potential to effectively treat superficial femoral artery disease without a permanent metallic implant is welcome news for our patients."

Andrew Holden

Holden presented the new data at a late breaking trials session at the Vascular Interventional Advances (VIVA) congress (9–12 October, Las Vegas, USA). He highlighted the STANCE trial's pioneering use of optical coherence tomography to prospectively evaluate the performance of the Stanza bioresorbable device (480 Biomedical).

"The superficial femoral artery is a challenging anatomical location that subjects stents to complex biomechanical stresses," Holden said.

He added that the STANCE **trial is a prospective, single-arm, multicentre first-in-man and aims to assess the safety of Stanza in the treatment of de novo lesions.**

Holden told *Vascular News*: "In an image from a sheep with the scaffold in an artery (Image 1), you will note that, at one month, the scaffold struts have a thin cellular layer covering them. At six months, the struts are well encapsulated with a thicker covering. The struts are smaller, less well defined and are taking up the haematoxylin and eosin (HE) stain, indicating resorption." He added, "Optical coherence tomography data from a patient in our trial (Image 2) show appearances at the time the scaffold was implanted and then at six months. At six months, appearances correlate well with the histology slide from the sheep – the struts are well encapsulated and are resorbing."

Image 1: Sheep

Image 2: Patient

Stanza, Holden explained, is a flexible, self-expanding stent, with a composite structure of strong polylactic-co-glycolic acid

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Is the Cotavance withdrawal in the USA a setback for drug-eluting balloons?

Vascular News learned from industry sources at the CIRSE annual meeting (15–19 September, Lisbon, Portugal) that Bayer HealthCare is looking into discontinuing the production of the Cotavance drug-eluting balloon using the Paccocath technology as there have been problems of drug adhesion to the balloon. Industry sources told *Vascular News* that there have been cases of drug coming off the surface of the balloon before implantation. On being questioned on the topic, Bayer said that it has suspended its development programme for Cotavance only in the United States, due to recent regulatory changes – the regulatory pathway in the USA is seven years.

"Bayer Medical Care has suspended its US development programme for Cotavance in light of recent regulatory and market changes. This corresponds to our continuous prioritisation process. Cotavance is presently marketed in selected European countries where we continue to serve Cotavance customers. Current clinical studies outside the US, including EuroCANAL, COPACABANA and Definitive AR, continue at currently active sites," Bayer wrote to *Vascular News*.

This paper has also learned that companies have had difficulties with getting drug-eluting balloons reimbursed in Germany. Intellectual property issues have also been reported.

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ACST-2 first results indicate carotid revascularisation is becoming safer

Early results from ACST-2 suggest that modern carotid artery stenting and carotid endarterectomy have a low serious morbidity and mortality, according to early results of the Asymptomatic Carotid Surgery Trial 2 (ACST-2)

Blinded early results in the first 691 patients enrolled in the study were presented by Alison Halliday, University of Oxford, Oxford, UK, at the European Society for Vascular Surgery (ESVS) Annual Meeting in Bologna, Italy, on behalf of the ACST-2 investigators.

ACST-1, conducted between 1993 and 2008, randomised 3,120 patients with tight asymptomatic carotid stenosis to medical treatment alone or medical treatment plus carotid endarterectomy. The results, Halliday noted, showed that carotid endarterectomy reduced subsequent stroke risk by 50%, and that this benefit was maintained to 10 years.

"As a result of that, surgery for men and women under 75 years reduces the 10-year stroke risk, with an absolute reduction by 6%. And the same absolute benefit from surgery (6%) was seen in patients who were on statin at that time," she said.

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