

catheter-based pH tests, the Bravo pH system is an ambulatory method of pH monitoring, which is considered the gold standard for pH measurement and monitoring of gastric reflux. The Bravo pH system collects data that are more reflective of the patient's normal daily routine to assess if the patient has GORD.

Traditional pH testing studies, sometimes combined with impedance measurement, involve the insertion of a very small catheter into the nostril and advancing it into the oesophagus, where it stays throughout the 24-hour testing period. Patients using the catheter method often do not follow their usual daily schedule so the pH measurements may not be predictive of GORD during the 24-hour testing period. Challenges to traditional catheter-based pH testing include throat irritation, difficulty sleeping and discomfort during eating and drinking.

### **SJM offers latest intracardiac ultrasound system**

St Jude Medical has released its ViewMate Z intracardiac ultrasound system and ViewFlexPlus intracardiac echocardiography (ICE) catheter.

The ViewMate Z system is designed for real-time image guidance and visualisation of the cardiac anatomy, and is able to deliver high-fidelity images that help direct diagnosis or therapy during complex electrophysiology procedures. The system is compatible with the ViewFlex Plus ICE catheter, which offers improved one-handed control, steering angles up to 120° and enhanced tip stability. The ViewMate Z system is designed to allow clinicians to better visualise a patient's cardiac anatomy and the effects of treatment in real-time. In addition, the cart-based system offers portability and optimises vital lab space while reducing obstructions in a clinician's workflow. The system was designed, developed and provided through SJM's development and distribution agreement with Zonare Medical Systems.

Zonare's Zone Sonography enables the ViewMate Z to provide advanced image quality, performance and features, as well as advanced image processing capabilities without the limitations of current systems. Conventional ultrasound systems acquire and process echo data line-by-line and are therefore limited by the time required for sound propagation in the patient's body. Zone Sonography technology is a new approach to echo data acquisition and image formation and acquires ultrasound data quickly in a relatively small number of large zones, each of which contain a volume of data equivalent to many lines in a conventional system. According to Zonare, Zone Sonography technology acquires data up to ten times faster than conventional systems.

### **Ekos obtains CE mark to treat forms of PEs**

Ekos has secured the CE mark for its EkoSonic endovascular system for the treatment of pulmonary embolism (PE). The system, which was originally designed and approved to dissolve blood clots in the arms and legs, now has the added indication for treating this major unmet medical need.

PE occurs in approximately one million patients in Europe annually (600,000 in the US), causing or contributing to 300,000 deaths each year. The condition is caused when a large blood clot obstructs the major blood vessels leading from the heart to the lungs. The victim's heart is suddenly overwhelmed with the task of pushing blood past this obstruction. Symptoms are similar to a heart attack. About 5 per cent of PEs result in rapid heart failure and shock.

A large dose of thrombolytic, a clot-dissolving drug, delivered to a vein was the only approved therapy for these patients, but has been linked with unintended bleeding as a potential damaging side-effect. Up to 40 per cent of PE victims have less critical obstructions, often called sub-massive PE, which are currently treated with anti-coagulant medication. These medications do not remove clot, and simply prevent the clot from growing larger. Studies suggest that failure to remove these sub-massive clots may have long-term adverse events including recurrent PE, chronic pulmonary hypertension and death. According to Professor Nils Kucher, from the University Hospital of Bern (Switzerland), and principal investigator of the Ultrasound Accelerated Thrombolysis of Pulmonary Embolism (ULTIMA) trial launched in 2010, because the Ekos system incorporates into the catheter body small ultrasound transmitters which condition the clot to more rapidly absorb the thrombolytic drug, it can dissolve the clot faster than thrombolytic drug alone.

### **Covidien offers improved peripheral stent system**

Covidien has unveiled its EverFlex+ self-expanding peripheral stent system in Europe. The system, which offers more durability and flexibility for physicians, represents the next generation of EverFlex stent technology for the treatment of peripheral arterial disease. The system also strengthens Covidien's portfolio of stents used for treating the superficial femoral artery (SFA) and proximal popliteal lesions.

The EverFlex+ system is designed to reduce the risk of fracture when elongated, improving clinical outcomes for patients.

With the availability of a transapical aortic prosthesis for sizes up to 27mm, the market for TAVI patients will be significantly expanded, providing life-saving therapy to patients previously left untreated, according to Dr Hans-Reiner Figulla, Co-Founder and SAB Head of JenaValve; and Professor and Director, Cardiology Clinic, Friedrich Schiller University in Jena, Germany.

JenaValve has TAVI systems for both transapical and transfemoral approaches (currently in development) to address the needs of the cardiac surgeon and cardiologist, respectively. Each of these systems is comprised of three components: a catheter delivery system; a self-expanding nitinol stent; and a heart valve - the transapical prosthesis uses a porcine root valve, whilst the transfemoral prosthesis is a pericardial tissue construct, allowing for a small catheter diameter. JenaValve expects to enter the European market with its transapical TAVI system in 2011.

### **Ekos' endovascular system plays major role in treating patients with lung clots**

According to data presented at the International Symposium on Endovascular Therapy (ISET) in Hollywood, CA, a tiny ultrasound device that helps dissolve blood clots has shown its potential to break up potentially deadly pulmonary embolisms (PEs), blockages of blood vessels in the lungs that can occur after long journeys, surgery and extended bed rest.

Between February 2009 and July 2010, 22 PE patients were treated at East Jefferson General Hospital in Metairie, LA, using Ekos' EkoSonic endovascular system and recombinant tissue-type plasminogen activator (rt-PA). Preliminary and posttreatment CT scans were performed on 21 patients, with the remaining patient treated based on echocardiography and ventilation/perfusion scanning. The primary endpoint in this retrospective evaluation was mortality, whilst secondary endpoints were improvement in the right ventricular end diastolic diameter to left ventricular end diastolic diameter ratio (RV/LV ratio) and reduction in clot burden. The presentation of the study coincided with CE mark approval for the EkoSonic system.

All 22 treated patients survived the trial. In the 21 patients with CT scans, the average RV/LV ratio pretreatment was  $1.33 \pm 0.23$  and  $1.00 \pm 0.13$  posttreatment ( $p < 0.001$ ). Clot burden, calculated from the CT scans using the modified Miller score (maximum 36), was reduced from  $17.8 \pm 7.4$  to  $10.0 \pm 4.0$ . Major bleeding complications occurred in four patients, all of whom required transfusion. Minor bleeding complications occurred in two patients, but no other complications were observed.

All of the bleeding complications were reported in the first 14 patients treated, who received an average of 47.6mg of rt-PA delivered over 22 hours. The dosing regimen for rt-PA was reconsidered and reduced in the remaining eight patients to an average dose of 20.8mg of rt-PA over 14.3 hours. No further bleeding complications were reported in the patients treated with the lower rt-PA dose.

Since July 2010, the number of patients treated at East Jefferson General Hospital had grown to 27, with all patients surviving the procedure and all benefiting from a significant reduction in right heart chamber size. According to Dr Engelhardt, Chairman of the Cardiovascular and Thoracic Surgery Division at East Jefferson General Hospital, the method could help "revolutionise" the way patients with PEs are treated and offers a viable option for the treatment of PEs.

In traditional therapy, clot-busting drugs are delivered to the blockage, but the method can take many hours or days. In the ultrasound method, the device is advanced through blood vessels to the site of the blockage, where it emits sound waves that loosen the clot, allowing the clot-busting drugs to dissolve it faster. The method is currently used to treat blood clots in the legs (deep vein thrombosis) and other parts of the body.

### **CDP develops prototype oxygen generator for battlefield environment**

Cambridge Design Partnership (CDB) has linked up with the Ministry of Defence, UK (MoD) to develop a lightweight portable oxygen generator that can be used in the military field.

Using a research grant from the MoD, CDP worked on addressing the logistical and safety issues relating to forward deployment of oxygen to the frontline. The subsequent prototype device has been unveiled at the CDE showcase and conference in London, UK. The grant, awarded by the MoD Small Business Research Initiative (SBRI), is aimed at developing innovative technologies for battlefield medicine. The research, carried out by Dstl Porton Down, confirmed that improved oxygenation can 'buy time' in blast injuries.

Although evidence exists that forward oxygen deployment can improve survival rates after blast injury, casualties are usually without oxygen before being evacuated by helicopter. This is because frontline personnel may not have access to vehicle support and the pressurised oxygen cylinders are heavy to transport and vulnerable to threats. Whilst portable oxygen generators are available these are very power hungry and require heavy batteries.