

FDA clears Power Wand IV catheter for reduced sticks

By AMANDA PEDERSEN

Medical Device Daily Senior Staff Writer

Access Scientific (San Diego) has received FDA 510(k) clearance for a device that it says will reduce the number of needle sticks hospital patients have to endure. The recently cleared device is the Power Wand, an extended-dwell, power-injectable 31-inch IV catheter delivered by means of The Wand Accelerated Seldinger technique.

According to the company, the device is designed to transform the in-patient experience, by allowing many if not most patients to have one and only one needle stick for vascular access throughout their hospitalization. The Power Wand can be used both for the administration of fluids/medications and for withdrawing blood for diagnostic tests, Access Scientific noted.

In addition to improving the inpatient experience,
See Power Wand, Page 5

SEMDA conference

Path to innovation strained, but opportunities still exist

By OMAR FORD

Medical Device Daily Staff Writer

ATLANTA – Since the global market crashed in 2008, the path to innovation for med-tech companies developing new and exciting technology has become a bit strained to say the least.

On Tuesday, the opening day of the 5th annual **Southeastern Medical Device Association** (SEMDA; Norcross, Georgia) conference, held at the Georgia Tech Global Learning Center, med-tech firms heard tips on how to successfully develop their devices, as well as emerging issues that have stalled and threatened the path to innovation.

Lee Herron VP of Commercialization for the Georgia Research Alliance, an organization dedicated to fostering
See SEMDA, Page 6

Report from Europe

Synthes and Materialise partner for new CMF surgical solutions

A *Medical Device Daily Staff Report*

Synthes (West Chester, Pennsylvania) and **Materialise** (Leuven, Belgium) reported an exclusive partnership for the development and distribution of Materialise's solutions for Cranio-Maxillofacial (CMF) surgery.

Materialise will provide pre-operative planning services directly to the surgeon via interactive, web-based collaboration tools, and will fabricate intra-operative guides and anatomical models. Synthes will distribute these intra-operative guides and models and continue to deliver patient specific surgical implants.

"This partnership will allow Synthes to continue our mission to improve patient care by optimizing operating room time and by improving the precision of surgery," said
See Europe, Page 7

Washington roundup

Expert: reg review times in China growing 'dramatically'

By MARK McCARTY

Medical Device Daily Washington Editor

FDA's annual conference with the **Association for the Advancement of Medical Instrumentation** (AAMI; Arlington, Virginia) included a session reviewing the market for devices in Asia, a topic never far from the minds of most in the U.S. device industry. While many concerns about China revolve around patent piracy, one expert on overseas markets said he sees regulatory review times at the State Food and Drug Administration (SFDA) as having "dramatically increased."

Ames Gross, President of **Pacific Bridge Medical** (Bethesda, Maryland), started his talk by contrasting the investment picture in India and China, noting that foreign
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Don't miss today's MDD Extra: Oncology

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AHC Media

*Deals roundup***CryoLife buying Cardiogenesis in \$22 million all-cash deal****A Medical Device Daily Staff Report**

CryoLife (Kennesaw, Georgia) and **Cardiogenesis** (Irvine, California) said the boards of both companies have approved a definitive agreement for CryoLife to acquire all of the outstanding shares of Cardiogenesis for \$0.457 a share. The all-cash deal values Cardiogenesis at roughly \$22 million, net of cash acquired and liabilities assumed.

The offer represents a 43% premium to Cardiogenesis' closing price Monday. The transaction is expected to be conducted as a tender offer followed by a merger and to close in mid to late May.

Cardiogenesis had sales of \$11.3 million for the year ended December 31, 2010. Cardiogenesis' market leading YAG laser system and single use, fiber-optic delivery systems are FDA approved for performing a surgical procedure known as Transmyocardial Revascularization (TMR), which treats patients with angina that is not responsive to standard medications. Patients undergoing TMR treatment with Cardiogenesis products have been shown to have angina improvement, longer event-free survival, reduction in cardiac related hospitalizations, and increased exercise tolerance. The current market potential for TMR surgical procedures in the U.S. is estimated to be greater than \$175 million. CryoLife says the delivery of biologic materials, such as stem cells, in conjunction with TMR could increase the estimated U.S. market potential to greater than \$700 million.

Cardiogenesis has also developed the Phoenix combination delivery system, which is designed to combine the intramyocardial delivery of biologic materials with TMR. The synergy of injecting biologics, such as stem cells

MDD's food for med-tech thought

"Medical devices have historically been the red-headed stepchild of the investment community. When times get tough medical devices become even more marginalized. Things will get better, but in the meantime we need to look for creative solutions..."

– Lee Herron VP of Commercialization for the Georgia Research Alliance, on the challenges facing innovation in the med-tech field, "Path to innovation strained, but opportunities still exist." pp. 1, 6.

or growth factors, with TMR may provide greater angina reduction, improve cardiac function and enhance quality of life in patients with diffuse disease who are not candidates for surgical bypass or intervention. The Phoenix System has received a CE mark and CryoLife intends to begin commercialization efforts in select European markets in the second half of 2011, with a more extensive launch expected in 2012.

"We believe this transaction will benefit the customers, employees and shareholders of both companies," said Steven Anderson, chairman and president/CEO of CryoLife. "Cardiogenesis brings developed technologies with proven clinical outcomes in the treatment of cardiovascular disease and a pipeline of potential new products that build on the TMR platform. Cardiogenesis' products greatly expand our customer offerings and we believe they will create opportunities for us to cross sell and rollout Cardiogenesis' products on a global platform."

In other dealmaking activity:

• **CareFusion** (San Diego) and **Frazier Healthcare** (Seattle) said they have completed the sale of CareFusion's OnSite services instrument management and repair business to affiliates of Frazier Healthcare. The companies first reported plans for the sale in January.

OnSite Services delivers education-based medical

See Deals, Page 4

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*Agreements/contracts***Health Care REIT forms partnership with Benchmark****A Medical Device Daily Staff Report**

Health Care REIT (Toledo, Ohio) has completed the formation of its \$890 million partnership with **Benchmark Senior Living** (Wellesley, Massachusetts). The partnership, which includes 34 high-quality, private-pay senior housing communities with an \$890 million investment balance, closed effective March 28th.

"The Benchmark Senior Living transaction underscores Health Care REIT's ability to execute its relationship investment strategy," said George Chapman, Health Care REIT's chairman, CEO and president. "This strategy has resulted in an unprecedented \$6.9 billion in gross investments announced in 2010 and 2011 with regionally dominant operators who have a track record of quality care, profitability and growth. This RIDEA partnership positions Health Care REIT for strong organic and external growth through Benchmark's future NOI growth and the right to fund certain future real estate investments pursued by Benchmark."

Benchmark says its communities exemplify outstanding

Clarification

A story on in the March 17 edition of *Medical Device Daily* on **EndoLumina** (Needham, Massachusetts), a new company focused on developing wireless sensing of upper GI bleeding, incorrectly said that capsule imaging products from other companies, including Given Imaging, require 24 hours to obtain results. Given's global marketing director, Jonathan Huber, who is based in the company's North American headquarters in Duluth, Georgia, said that "In fact, the entire PillCam ESO capsule endoscopy procedure can be performed in less than 30 minutes and physicians can view the esophagus in real time as the procedure is being performed." Huber added that a body of published clinical data supports the use of PillCam capsule endoscopy in a variety of settings, "with particular usefulness in the evaluation of esophageal varices and bleeding from the upper gastrointestinal tract in an emergency room setting."

asset quality and are located in highly desirable New England markets. The communities have an average age of twelve years and produce rental rates and occupancy in excess of industry averages, reflecting the best-in-class nature of the operations, locations and physical plants. ■

*HIT roundup***Nuance's PowerScribe now DOD-approved HIT solution****A Medical Device Daily Staff Report**

NuanceCommunications (Burlington, Massachusetts) reported that its radiology speech recognition reporting platform, PowerScribe, is certified for compliance with Department of Defense (DoD) security requirements, as tested and verified by the Department of Defense Information Assurance Certification and Accreditation Process (DIACAP). PowerScribe is now distinguished as a DoD-approved healthcare IT solution; it will be used across Air Force, Army and Navy Networks.

DIACAP certification is an intensive and stringent requirement for all IT systems that operate on a DoD network. As part of the process, Nuance worked with the DoD to test and confirm that PowerScribe's operating system is secure, reliable and unsusceptible to outside cyber-security threats and attacks.

"DIACAP certification is a critical component of the Department of Defense. It supports our mission to ensure the delivery of high-quality care within a secure environment," said Thomas Lewis, director of the U.S. Air Force PACS office. "With this certification, PowerScribe has provided the DoD Healthcare system

with another valuable option in the voice recognition business."

PowerScribe has been implemented across the Air Force, Army and Navy networks, helping to assist radiologists to dictate radiology reports directly into the Radiology Information System (RIS). PowerScribe has helped to significantly decrease report turn around time (TAT), allowing attending physicians to receive reports on their patients in the fastest time possible.

"Achieving DIACAP certification marks an important milestone for Nuance as we continue to expand our customer breadth in the government healthcare sector," said Janet Dillione, executive VP and general manager of Nuance. "Prospective government and non-government healthcare organizations can have complete confidence that our award-winning, radiology solution performs in accordance with some of the most rigorous security regulations there are."

In other HIT news, **PHT** (Boston) reported the availability of NetPRO, a browser-based ePRO and eCliniRO system designed to collect patient data via the Internet. NetPRO enables reserachers to access a larger global patient population while reducing costs of large Phase IV and extended post-market studies, according to PHT. Sponsors can use NetPRO to collect PRO data for regulatory submissions and label claims as well as for post-approval safety. ■

*Financings roundup***CardiaLen gets \$735,000 to complete cardioversion trial****A Medical Device Daily Staff Report**

CardiaLen (St. Louis), a device company focused on providing pain-free internal cardioversion therapy for atrial fibrillation (AF) with a low-energy implantable atrial cardioverter plus pacing device, received \$735,000 in funding from Broadview Ventures. The financing will be used as working capital and will help fund the completion of CardiaLen's preclinical animal studies in atrial fibrillation as well as finalize the development of the company's external low-energy pain-free atrial cardioversion device to be used in First-in-Man studies. The funds will not only help the company complete its current studies, but help develop the complete protocol for its first-in-man studies, it said.

"Clinical evaluation and the development of our cardioverters can be difficult and expensive. We are thankful for Broadview Ventures financing, and look forward to the successful completion of studies in atrial fibrillation utilizing this low-energy cardioversion technology," said Bob Calcaterra, CEO of CardiaLen. "We continue to reach milestones at CardiaLen, and are confident that our pain-free cardioverter-defibrillators will offer significant patient benefits."

CardiaLen also received a future commitment from Broadview Ventures for additional dollars upon achievement of certain research milestones. These additional funds will allow the company to begin and complete much of its first-in-man studies.

The most common cardiac arrhythmia (abnormal heart rhythm) is atrial fibrillation (AF or A-fib) and involves the two upper chambers (atria) of the heart. CardiaLen is developing implantable low-energy (low voltage) pain-free atrial cardioverters to help address the major unmet needs of this condition. AF has been estimated to affect more than three million people in the United States and over twenty million people worldwide. Pain-free operation is essential since AF patients typically remain conscious during episodes and since the condition is not immediately life threatening.

CardiaLen's low-energy cardioversion technology is based on work by Professor Igor Efimov, PhD, currently at **Washington University's** (St. Louis) Biomedical Engineering School. Professor Efimov and his research colleagues discovered that very low-voltage shock, applied in proprietary algorithms, induces virtual electrode polarization (VEP) at cardiac heterogeneities and opens a new approach to the long sought after goal of pain-free defibrillation.

CardiaLen holds rights to its low-energy cardioversion technology under an exclusive global license from Washington University in St. Louis and Case Western Reserve

University (Cleveland) to develop and commercialize certain intellectual property developed by Professor Igor Efimov, PhD. This technology has the potential to provide pain-free cardioversion-defibrillation therapy for both atrial and ventricular arrhythmias, conditions where major unmet needs exist, the company said.

In other financing news, **SoundCure** (San Jose, California) reported that it has formally closes a \$3 million round of funding to help launch the commercialization of its sound based tinnitus therapy first developed at the **University of California at Irvine** (UCI). Allied Minds, led the financing. SoundCure's tinnitus therapy pioneered by Dr. Fan-Gang Zeng at UCI with research funded by the **American Tinnitus Association** (ATA; Portland, Oregon) has shown great success in bringing relief to sufferers of tinnitus. The SoundCure technology utilizes unique tones and sounds customized to an individual's own tinnitus to help quiet the ringing.

The proprietary SoundCure audio stimuli are designed to be presented at a softer level than the patient's tinnitus to lower the patient's overall sound burden and reduce or eliminate the perception of tinnitus. The new funds will be used to realize an aggressive commercialization plan that brings with it a new medical device capable of delivering the suite of SoundCure's tinnitus therapies and directly address tinnitus in an approach to quiet and control the symptoms of tinnitus.

SoundCure was formed by Allied Minds, a capital investment firm, based on technology first pioneered by researchers at UCI who discovered a relation between certain tonal algorithms and specific therapeutic effects.

Allied Minds is a \$250 million private equity-funded innovation company with offices in Boston and Los Angeles. The company creates startup businesses based on early-stage technology developed at U.S. universities and national labs, and serves as a holding company that supports these businesses with capital, management and shared services. ■

Deals*Continued from Page 2*

instrument repair and instrument management programs to hospital systems domestically. The new company and its 240 employees will continue to deliver operating-room focused workflow improvement programs.

Financial terms of the agreement were not disclosed.

- A federal judge in Toledo, Ohio granted the Federal Trade Commission a preliminary injunction in its antitrust challenge of **ProMedica Health System's** (Toledo, Ohio) August 2010 acquisition of **St. Luke's Hospital** (Maumee, Ohio). ProMedica must hold St. Luke's separate from the system's operations until FTC's administrative complaint is resolved, including any appeals. ■

Power Wand

Continued from Page 1

the new device can help reduce healthcare workers' risk of an accidental, potentially dangerous needle stick, the company says.

"The Power Wand represents a sorely needed third option for vascular access: Where the risks of central venous access are not indicated and the repetitive insertion of peripheral IV catheters to complete therapy is inefficient, costly and ineffective – the Power Wand provides the answer. We believe it is a game-changing technology that will rapidly become the new standard of care," said Steve Bierman, MD, CEO of Access Scientific.

Bierman is an emergency physician and family doctor and he founded and invented the StatLock series of catheter stabilization devices. He told *Medical Device Daily* that he recently spoke with a patient who had endured 19 sticks to get an IV started – 11 on one arm and eight on the other – until finally the clinician decided to give him a central line.

Central lines are easier on the patient because they last longer than peripheral lines but they carry a tremendous number of risks, including the potential for catheter related blood stream infections, and the placement of the central line alone can result in a collapsed lung.

"When the focus is on patient safety and satisfaction in the absence of an indication for a central line, clinicians should insist on the Power Wand because a patient is not a pin cushion," Bierman said.

For the average adult patient, a four day hospital stay typically means they'll endure at minimum four or five needle sticks if a peripheral vascular access IV is used, Bierman said.

"As a doctor, I'm excited about this because I really think as many as four out of 10, maybe more, hospital patients are Power Wand candidates," he said.

He told *MDD* that while training a nurse in Kentucky on the Power Wand she told him the device "turns hard sticks into easy sticks."

The company plans to present preliminary results from its first clinical trial at the Infusion Nurses Society meeting in May. Earlier this month the company reported receiving a CE mark for the device, which is planned for initial distribution in Britain, Australia and South Africa.

Bierman said the Power Wand is ultrasound-guided into a vein in the upper arm where it can reside for up four weeks. He added that the device is 5 French so it is placed exactly where a 5 French PIC line would be placed.

"Our nonsignificant risk study in Florida strongly suggests . . . that the outcomes in terms of dwell time and reduced complications will be astounding," Bierman said.

Another advantage of the Power Wand, Bierman noted, is that nurses can use it to draw blood while the patient is sleeping.

The Power Wand is the second product Access Scientific has introduced. The company's Picc Wand, which

inserts a peelable sheath introducer into the vasculature by means of the Accelerated Seldinger technique, is being distributed by **Teleflex Medical** (Research Triangle Park, North Carolina). ■

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People in the News

- **Aerocrine** (Solna, Sweden) has named Kathleen Rickard, MD, as chief medical officer. Rickard is a specialist in pulmonary and critical care medicine. Aerocrine is a medical technology company focused on the improved management and care of patients with inflammatory airway diseases.

- **Catheter Connections** (Salt Lake City) has named Charity Williams as the company's new chief business officer and in-house counsel. Previously, Williams was director of marketing at Zevex. Catheter Connections makes vascular access products that protect patients during intravenous therapy.

- **Medrad** (Warrendale, Pennsylvania) has named Jack Darby as VP of Medrad Interventional. Previously, Darby was senior VP of global marketing at AGA Medical. Medrad makes medical devices ranging from fluid injection systems for radiology and cardiology, endovascular devices for the safe treatment of cardiovascular disease, and magnetic resonance-compatible accessories and equipment services.

- **Wi - Medical Device Development** (Englewood, Colorado) reported that Connie Gorden was named business manager and David Anderson director of therapeutics. announces the addition of two new key personnel. Gordon is a published inventor, with experience bridging sales, marketing and development. Anderson is a published inventor responsible for numerous innovations and trade secrets, Wi - Medical Device Development specialize in high-tech diagnostics, therapeutics and biologics products.

- **Zwick/Roell** (Kennesaw, Georgia) has named Bill Becker as managing director of Zwick USA. Becker was previously VP of Americas selling and worldwide application engineering for MTS Systems. Zwick USA makes material and component testing systems to the medical device and supply markets.

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SEMDA

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innovation in Georgia, along with Rusty Ross Sr., Technical Leader at **Kimberly Clark** (Roswell, Georgia), and Rafael Adino, R&D Director at **C.R. Bard** (Queensbury, New York), were on the panel and gave med-tech companies a clearer picture of the innovation landscape.

“When we look at trying to be successful with innovation today, as opposed to 10 years ago, it’s not about the technology per se,” Ross told the audience. “It’s about - do you have the value proposition for the technology thought through. Do you have the business plan thought through.”

“The value proposition and cost benefit of the device needs to really be factored in at the earliest stages,” Herron said.

Adino cautioned innovators to really do their homework when they were making a pitch to a larger med-tech company.

He said in some cases the inventor or small company trying to give a pitch to the larger company won’t investigate or take the time to find out more about what that company is doing.

“Often times the presentation is done in five minutes,” he said. “You realize after five minutes that these people have no idea what business you’re in. The idea sounds good on the phone . . . great, but they’re not asking key questions. What is our sales call point? What are our distribution points?”

Adino said that not knowing the answer to these questions could be a tremendous setback for inventors and small companies looking to further develop their devices.

Ross told the audience that now the landscape has changed dramatically, as opposed to a decade ago.

“There are lots of good ideas,” he said. “You’re no longer competing with devices and ideas that are right down the hall. You’re competing with hundreds of ideas and management has a lot of choices.”

Ross said that innovators also need to ask themselves this question before seeking to further develop their device.

“Are you a one hit wonder,” he asked “Or is this a platform technology?”

Networking and developing strong channels of communication is another key factor that companies need to focus on, the panel said.

“You can’t do it on your own,” Ross said. You have to play the cards you have, and find the cards you don’t have.”

He added that firms needed to take the time to attend meetings like SEMDA to help develop and foster relationships.

“You’ve got to come to meetings,” Adino said. “You’ve got to come to conferences.”

Herron cautioned and said that sometimes smaller firms or inventors might “establish a relationship with someone” at a larger med-tech company and find out a “year later” that person no longer works for the company.

He urged companies to establish more broad

relationships to avoid this issue.

Adino said that in his search for ideas, he often looks outside the industry and attends conferences that might not be in his realm of expertise.

“I try to go to conferences where [I don’t have a lot of knowledge in] just to see what they’re talking about . . . just to see what’s out there and what we might be talking about in the company.”

Members of the panel said that with the precarious situation regarding reimbursement models and regulatory issues, that innovation faces one of its toughest challenges yet.

“There’s a lack of technology at the right stage to address the right need,” Herron said. “Medical devices have historically been the red-headed stepchild of the investment community. When times get tough medical devices become even more marginalized. Things will get better, but in the meantime we need to look for creative solutions. . .” ■

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Court report

LecTec settles patent lawsuit with Chattem

A Medical Device Daily Staff Report

LecTec (Texarkana, Texas) said it has settled its pending patent infringement lawsuit against **Chattem** (Chattanooga, Tennessee). The trial with the other defendant in the lawsuit, **Prince of Peace Enterprises**, is still scheduled to proceed on April 11, with court-ordered mediation to occur on March 30. Chattem has agreed to make a one-time, \$3.6 million payment to LecTec for a non-exclusive license to LecTec’s U.S. Patent Nos. 5,536,263 and 5,741,510, and any other LecTec patents that claim priority from these two patents, for use in connection with any product or process sold or used by Chattem, other than products covered by exclusive licenses previously granted to other companies. Such settlement proceeds are before paying contingent legal fees and prior to any tax effect.

Greg Freitag, LecTec’s CEO, said, “This settlement provides LecTec with cash now without future risk, and will position the company for a positive future. We fully understand that some of our shareholders will be disappointed that the case against Chattem was not taken to trial, but the board and I are confident that this settlement is clearly in the best interests of LecTec and its shareholders.”

LecTec is an intellectual property licensing and holding company that holds multiple domestic and international patents based on its original hydrogel patch technology and has filed patent applications on a hand sanitizer patch. ■

Europe

Continued from Page 1

Michael Orsinger, president/CEO of Synthes. "Materialise and Synthes share the same core values: a desire to assist the patient and surgeon, as well as quality, innovation, education, and integrity. The partnership will reinforce our position as an innovator in CMF."

Ecron acquires majority stake in aCRONordic

Ecron Acunova (Frankfurt, Germany), a full-service contract research organization (CRO), said it has acquired a majority stake of **aCRONordic** (Hoersholm, Denmark), a CRO specialized in clinical research in Nordic countries covering Denmark, Sweden, Finland and Norway.

"A recent change in the strategy of sponsors in the healthcare industry asks for more global presence of preferred provider CROs," said D A Prasanna, founder and chairman of Ecron. He added that the merger yields "substantial synergy" to both companies because of their respective track records, local knowledge in their geographies, and reputation.

Artelon CMC Soft wins CE mark

In collaboration with **Small Bone Innovation** (SBI; Morrisville, Pennsylvania), **Artimplant** (Vastra Frolunda, Sweden) says it has developed a new product in its Artelon Spacer range with a similar user-friendly textile design to Artelon Tissue Reinforcement. The product, Artelon CMC Soft, has been granted CE-approval by the certification body Lloyd's and has thus been granted clearance for marketing in Europe.

According to the company, the major difference between the old Artelon CMC Spacer and the new Artelon CMC Soft is that the size can be adjusted and can thus be adapted to the requirements of each individual patient. Artimplant estimates that Artelon CMC Soft will gradually replace existing Spacer products for thumb base osteoarthritis in the CMC-joint.

BK introduces robotic ultrasound technology

BK Medical, a wholly owned subsidiary of **Analogic** (both Peabody, Massachusetts), introduced Advanced Robotic Ultrasound Technology (ART), what it bills as the industry's first complete ultrasound imaging solution for robotic surgery. This technology, which includes the Flex Focus 700 Ultrasound System, specialized transducers, and tools designed specifically for robotic-assisted surgery, was recently introduced at the 20th Annual **European Association of Urology** (EAU; Arnhem, the Netherlands) Congress in Vienna. ART is a performance ultrasound solution that may benefit surgeons performing robotic-assisted radical prostatectomy (RARP) procedures, and robotic-assisted partial nephrectomy (RAPN) procedures.

The new ART solution includes the Flex Focus 700, the 3DART high-resolution endocavity transducer, the

RST Robotic Stationary Transducer Arm for securing the endocavity transducer during procedures, and the first dedicated robotic transducer, ProART.

The new 3DART endocavity transducer is small in diameter for minimal patient discomfort with no moving parts touching the patient. The resulting 3-D data cube can be manipulated to assess anatomy and geometry of the prostate prior to surgery for planning purposes. During surgery, the 3DART transducer may also help identify useful landmarks and assessment of the posterior border of the prostate in real time during dissection.

The company's new ProART specialized robotic transducer is designed to address the challenges of ultrasound imaging during robotic-assisted surgery. The transducer is a curved linear array that images from 12-5 MHz with 2-D, color and spectral Doppler, and it can easily fit into a standard trocar. The ProART transducer has the potential to provide ultrasound guidance and verification during RAPN procedures. Early indications for ultrasound imaging also include identifying the pudendal arteries and nerves during RARP. ■

Med-Tech Notes

Edwards added to S&P 500 Index

Edwards Lifesciences (Irvine, California), a maker of heart valves and hemodynamic monitoring, said that Standard & Poor's (S&P) will add Edwards to the S&P 500 Index after the close of trading on March 31.

"We are honored to be added to the S&P 500 Index. We attribute this milestone to the company's solid performance, resulting from the hard work of our employees in the development of innovative medical technologies for patients," said Thomas Abate, Edwards' corporate VP/CFO.

Edwards Lifesciences's launch of Sapien XT in Europe led to an 87.2% rise in transcatheter heart valve (THV) sales to \$65.3 million during the 4Q10. Edwards is expecting greater contribution from THV in the forthcoming period. Although Edwards has witnessed strong growth in the THV banking on the successful launch of Sapien products in Europe, the product is yet to receive approval in the U.S.

In addition to the Heart Valve Therapy segment, new product launches in the critical care segment are also contributing to the growth. Although sales from the recently launched VolumeView and EVI000 were negligible during the quarter, these products have the potential to drive share gains going forward. The company expects to receive U.S. approval for these products in 3Q11.

Washington

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direct investment in China “is about five times what it is in India” at about \$100 billion annually. Gross pointed out that China spent only about 4.5% of GDP on healthcare in 2009, but that number is expected to trend upward, especially given the recent decision by Beijing to invest more than \$100 billion into healthcare in an effort to bring 90% of the population under health coverage.

Regarding SFDA, Gross said, “they’ve become much more rigorous” about device applications, which means that when combined with lack of staffing at SFDA positions, registration “can easily take between one and two years” even for products that require no clinical trials in China. However, Gross cautioned, “for people who are now bringing class III products, more and more will require local clinical testing.”

Part of the dilemma here is that devices have to go through local bench testing protocols regardless of other considerations, but “the testing centers are so backed up” that the traditional expectation regarding turn-around no longer holds, Gross said. Hence, “time frames for regulatory approval have dramatically increased,” he remarked, noting that even a class I product may take five months to push through the regulatory mechanism.

Product testing is mandated for class II and III devices, but “you have to get in line to get your product tested,” Gross said, and the backup has several contributors. While SFDA can waive a test, some testing centers aren’t equipped to handle all the tests they’re called on to conduct, so lack of expertise can impose drag. Also, “keep in mind there are only 10 national testing centers,” he said.

Gross recommended that device and diagnostics makers bear in mind that SFDA is demanding “more and more detail for the product standard,” a series of documents he described as “the most important part of the registration” for many items. He also urged sponsors to comb through their filings exhaustively for consistency. “You want to have the standard (document) match other legal documents,” because those documents cannot be revised once filed. Therefore, accuracy and consistency are both paramount.

Documents must be filed in both English and Mandarin, Gross said, but he advised that SFDA is “planning to make mandatory that registrants submit electronic copies” in addition to hardcopy, a requirement that would presumably bear the bi-lingual requirement as well. However, he hinted that activity that goes on behind the scenes in China is still often as important as the acknowledged formalities. “The main thing to think about when applying for registration in China is that what you think is happening is not necessarily what’s really happening,” he said.

House Judiciary to hear about patent bill

The House Judiciary Committee’s subcommittee for intellectual property is convening today to discuss the draft

patent reform bill that was leaked last week, and while a number of issues are likely to surface, the extension of prior user rights beyond business methods is certain to provide grist for the hearing. The notion of prior user rights surfaced briefly in a hearing in the subcommittee in mid-February (*Medical Device Daily*, Feb. 14, 2011), although a subsequent hearing also indicated some interest in the notion.

Rep. John Conyers (D-Michigan) brought up prior user rights during a March 10 hearing in the context of the movement toward the first-to-file found in both the House and Senate bills, and Andrew Pincus of the law firm of **Mayer Brown** (Washington) said that with first-to-file, “companies have to patent almost anything patentable,” thus flooding PTO with applications. He noted that other nations “provide prior user rights to protect companies that are [already] users” of the process in question. “We think it’s very important,” Pincus said.

Another witness at the March 10 hearing, Dan Burk, a professor of law at the **University of California Irvine** (Irvine, California), quipped, “a bill that implements first-to-file ... should be titled the Patent Lawyers Employment Act of 2011.” While Burke did not come across as an unflinching advocate of expanded prior user rights, he urged that Congress “think carefully about the benefits of [the] change” to first-to-file. “Maybe it’s worth it, but I’m not convinced,” he said.

Among the witnesses appearing at today’s hearing are David Kappos, director of the U.S. Patent and Trademark Office, and Jon Vaughn, executive VP of the **Association of American Universities** (AAU; Washington). A document obtained from the AAU website indicates that Vaughn expressed AAU’s support of efforts by a member of the House Judiciary Committee in 2007 to “eliminate the expansion of prior user rights in H.R. 1908 as marked up.” H.R. 1908 was the bill passed in 2007 by the House of Representatives, which the Senate failed to match, although a search of the bill suggests that prior user rights were encoded in the final bill only to the extent that PTO was instructed to study the idea.

Another witness at today’s hearing, Steve Bartlett, President/CEO of the **Financial Services Roundtable** (Washington), represents an entity that in the past has evinced support for prior user rights, although that support was secondary to other issues in 2007. According to the Roundtable’s legislative and regulatory roundup for 2007, prior user rights “accommodates university concerns,” although at the time, this was “at best, a tier 2 priority and not a defense often used by Roundtable members.”

FDA to hear Biomimetic’s bone graft PMA

FDA confirmed yesterday in the *Federal Register* that the orthopedics and rehabilitation devices advisory committee will take up the PMA application for the Augment bone graft sponsored by **Biomimetic Therapeutics** (Franklin, *See Washington, Page 9*

Product Briefs

• **Abbott** (Abbott Park, Illinois) has introduced a Micro-Implantation Cataract Suite designed to help improve cataract procedure outcomes and safety. Abbott says the Micro-Implantation Cataract Suite enables the surgeon to perform an entire micro-surgical procedure, which can reduce surgically induced astigmatism, provide a safer intra-operative environment, and promote faster healing and visual recovery. This advanced form of cataract surgery is performed using a micro-incision, which is smaller and therefore may provide added patient safety. During the procedure, the cataract is removed through the micro-incision, and a foldable intraocular lens is inserted into the eye.

• **Ascension Orthopedics** (Austin, Texas) a maker of PyroCarbon orthopedic devices, reported the release of the Titan Modular Shoulder Fracture Prosthesis. The company says the Titan system now provides a way to address difficult fracture procedures. The system's modularity allows the surgeon to fit patient anatomy by independently adjusting the height of the modular body and stem without need for jigs or use of cement. "The Titan system offers a modular fracture body – providing press fit application in managing comminuted proximal humerus fracture by hemiarthroplasty. By not using cement, I save considerable operative time and do not have to worry about the cement potentially causing a nonunion between the tuberosities and humeral shaft," said William Geissler, MD, of the University of Mississippi Medical Center in Jackson. "The reduced size fracture body makes it much easier to reduce the tuberosities to themselves. Also, the modularity of the different body heights enables me to obtain correct humeral head height to the glenoid after I have a tight fit of the stem in the proximal humerus. The prosthesis allows for a nice reduction, and the postoperative X-rays look very anatomic."

• **Biomagnetics Diagnostics** (San Francisco) reported further details in next steps to be taken toward full commercialization of the company's flagship Integrated Optical Biosensor (IOBS) diagnostic system. Biomagnetics is in collaboration with Los Alamos National Laboratory to develop the world's first integrated optical biosensor in a portable, handheld technology format designed to substantially lower unit costs and raise the detection levels of some of the world's most prevalent diseases.

• **Pathwork Diagnostics** (Redwood City, California) said that its laboratory has been awarded accreditation by the College of American Pathologists (CAP). The company's gene expression-based Pathwork Tissue of Origin Test, offered by the Pathwork Diagnostics Laboratory, helps identify the origin of metastatic and poorly differentiated tumors and increases pathologists' and oncologists'

confidence in the cancer diagnosis. "The CAP Laboratory Accreditation Program is the gold standard for laboratory accreditation with standards exceeding those set by the federal government," said pathologist Samuel Caughron, director of Molecular Pathology, MAWD Pathology Group, North Kansas City, Missouri. "CAP accreditation of the Pathwork Diagnostics Laboratory assures patients and physicians that specimens sent for the Tissue of Origin Test are processed with meticulous quality control and in accord with best established practices for laboratory medicine."

• **Toshiba America Medical Systems** (Tustin, California) said it is introducing upgrades to its Infinix-i product line. Upgrades include Volume Navigation 3-D roadmapping for all new Infinix-i systems, a 12" x 12" flat-panel detector on ceiling mounted C-arms and the Maquet Magnus OR table availability for the Infinix VC-i and CC-i systems. Now available on all Infinix-i systems, Toshiba's real-time Volume Navigation 3-D roadmap displays the deployment of coils during intervention on a cerebral aneurysm with exceptional clarity and precision. Volume Navigation links the movements of the system components with the fusion 3-D and fluoroscopic display, so despite changes in table and C-arm position for instance, the 3-D overlay is automatically aligned with the fluoroscopic image. Volume Navigation provides 2-D and 3-D roadmap display modes and allows physicians to fine-tune images with manual controls for device enhancement, further assisting physicians when making difficult decisions during advanced procedures. Volume Navigation is particularly helpful for procedures on intricate vascular regions, such as the brain, uterus and abdomen. The Infinix CC-i and VC-i ceiling mounted systems are now available with a 12" x 12" flat panel detector. This mid-sized panel allows for an improved field-of-view, provides two times as much anatomical coverage compared with traditional, smaller flat panel detectors and is optimal for performing a range of cardiovascular diagnostic and interventional procedures, including those on pediatric patients.

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Tennessee) on May 12.

The device is intended to facilitate fusion in the ankle and foot and help avoid other invasive procedures, such as autograft. According to a Sept. 8, 2010, statement at the firm's website, Biomimetic and FDA had completed a 100-day PMA filing meeting during which FDA is said to have raised "no unexpected issues" that would delay the PMA hearing. Biomimetic announced the tentative hearing date last month and announced it is also conducting a clinical trial of the device for lumbar interbody fusion that employs autograft as a comparator (*Medical Device Daily*, Feb. 22, 2011). ■

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MDD'S ONCOLOGY EXTRA

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Keeping you up to date on recent developments in oncology

Researchers at the University of Colorado identify colon cancer marker

... Establishing whether an enzyme is just a byproduct of an intracellular process or a factor in that process is not always an easy feat, but researchers at the **University of Colorado Cancer Center** (UC: Aurora, Colorado) believe they have identified an enzyme that occurs far too frequently and in concentrations too high to be just a byproduct. According to a March 24 statement at the UC website, a team led by Vasilis Vasiliou, PhD, professor of molecular toxicology at the UC School of Pharmacy, picked up on an enzyme produced by the ALDH1B1 gene that was present in 39 out of 40 colon cancer samples tested. According to the UC statement, the enzyme is "normally found only in stem cells, [but] was detected at extraordinarily high levels" in the 39 samples. The outcome, which was published in the Jan. 7 online edition of *Biochemical and Biophysical Research Communications*, is suggestive because "other potential colon cancer biomarkers have been identified in the past, but none thus far are present in such a high percent of the cancer cells and virtually none are over-expressed like this one," said David Orlicky, PhD, associate professor of pathology at the UC medical school and a member of Vasiliou's team. The logic behind assuming that the ALDH1B1 enzyme is more than just a byproduct is based on the idea that the enzyme would "not be present in every cell at such high levels if it were simply a byproduct of the cancer," according to the UC statement. Moving forward, Vasiliou's team is examining how the enzyme is "up-regulated into colon cancer cells and its exact role in the physiology of the tumor cells, but also of interest is a better understanding of the substrate, inhibitors and activators of ALDH1B1. "Our efforts are focused on developing a drug that could turn into a toxic compound and kill the cancer cell when acted upon by the enzyme," Vasiliou said. "It would act like a suicide pill, if you will." Vasiliou's team is said to be collaborating with scientists working at several other entities on this project, including the U.S. National Cancer Institute, the **University of Melbourne** (Melbourne, Australia), the **University of Heidelberg** (Heidelberg, Germany), and the **University of Oxford University** (Oxford, UK).

CPRIT awards almost \$37 million to SMC . . .

Funding for cancer research continues to flow despite the recession, and the University of Texas's **Southwestern Medical Center** (SMC; Dallas) reported last week that it has won a series of grants totaling more than \$36.7 million from the **Cancer Prevention and Research Institute of Texas** (CPRIT; Austin, Texas). According to the March 25 announcement by SMC, the funds will go to "support cancer-related projects and to recruit pre-eminent cancer investigators" to SMC's work, and the statement notes that CPRIT "was established in 2007 after Texas voters approved a constitutional amendment that authorized the state to fund cancer research and prevention programs." SMC states that its funds are part of a \$116 million bolus of monies set aside for 22 projects at 16 academic institutions and private firms located in the Lone Star State, and the balance of a total of \$216 million will be awarded by CPRIT by year's end. Roughly \$30 million of the award to SWC will be used to support "20 pre-eminent researchers," who are investigating technologies as well as "techniques for identifying and tracking cancers." Other efforts include research toward "repairing damaged DNA strands," development of new drug and drug-delivery systems, and establishment "of a Texas Cancer Cell Repository for storing cancer cells and tumors for future study." However, most of the balance of \$6 million will go toward recruiting three "pre-eminent researchers." Among the allocations of funds is a \$4.2 million for research into development of "a new type of cyclotron to develop novel radiotracers that probe specific biological or metabolic pathways of cancer allowing better positron emission tomography (PET) imaging," an effort spearheaded by Xiankai Sun, PhD. Daniel K. Podolsky, MD, President of UT Southwestern, said the funds "will accelerate dramatically the impact of UT Southwestern research on cancer care and illustrate the importance of teams of physicians and investigators working together to defeat cancer." Podolsky also said that funds from CPRIT "are providing a powerful engine to attract the best and brightest minds to UT Southwestern and to Texas."

Proton beam therapy gains foothold in metro Atlanta . . .

Despite the enormous cost associated with the construction of the cyclotrons needed to produce protons, therapy based on proton beams

continues to attract interest on the part of medical centers across the U.S. Among the latest entries into the proton beam cadre is **Emory Healthcare**, part of **Emory University** (both Atlanta), which announced on March 24 that it "has signed a letter of intent with **Advanced Particle Therapy**" (Minden, Nevada) toward a "final exploratory phase for development of The Georgia Proton Treatment Center," which would be the Peach State's first proton therapy facility. Noting that the closest proton therapy facility to Georgia is the facility operated by the **University of Florida Proton Therapy Institute** in Jacksonville, Florida, the Emory statement notes that roughly 1,500 patients have gone through the doors at the UF facility, which is one of only nine such plants in the U.S., a number that seems destined to rise in the next few years. The Emory facility has been designed with five treatment rooms to be powered by a proton system made by **Varian Medical** (Palo Alto, California), and the facility, the site of which has yet to be selected, is expected to devour 100,000 square feet and cost roughly \$200 million. Once the center is up and running, it is expected to demand a staff of roughly 110 and will treat approximately 1,900 patients each year.

Seattle also jumps on proton bandwagon . . . Atlanta's Emory is not the only institution to see a benefit in the mighty proton. According to a March 22 statement at the website for the **Seattle Cancer Care Alliance** (SCCA; Seattle), America's Pacific Northwest will soon have a proton beam resource to deal with cancers in that region. The March 22 SCCA announcement notes that **ProCure** (Oklahoma City, Oklahoma), will provide a cyclotron as part of a 60,000 square foot facility to help SCCA advance its research into cancer therapies. Norm Hubbard, executive VP at SCCA, said in the statement that proton therapy "has emerged as a compelling treatment for adults and children with cancer and other tumors. Prior to the development of this center, patients would have to travel hundreds of miles to receive this precise, life-saving treatment."

Colorectal cancer screening bolstered by UK organization . . . The cost of treatment of colorectal cancer and the disease's impact on western societies is the stuff of a lot of talk by health-care policy experts, and **Cancer Research UK** (CR-UK) London) has weighed in with a statement that screening catches 12% more cases in patients over the age of 60. In a March 23 statement, CR-UK notes that diagnosis of bowel cancer rates in those between the ages of 60 and 69 "went up by more than 12% in England from 2006 to 2008," an increase seen "shortly after the introduction of bowel screening in England" that commenced in 2006. Noting that such screening is offered to citizens aged 60 to 74, CR-UK indicates that colorectal cancer rates in the 60-69 cohort "were fairly stable, increasing by no more than 21% in any two-year period in the last decade," but that those rates began to trend upward, and rose by 6% in 2007 compared to the prior year using the fecal occult blood test. The CR-UK statement indicates that for citizens of the UK, early-stage detection offers a five-year survival rate of greater than 90%, but that outcomes for advanced cases fall to 5% at five years. Catherine Thomson, Cancer Research UK's head of statistics, said the numbers "are evidence that the bowel cancer screening program is helping to find cases of bowel cancer sooner." She also said that she and other health experts hope that the screening program "will soon reduce the number of deaths from bowel cancer."

Nordion says phase II TheraSphere data encouraging . . . Nudging a new cancer therapy forward is painstaking work, but **Nordion** (Ottawa) announced yesterday that the results of a phase II trial for the firm's yttrium-90 (Y-90) treatment for metastatic liver cancer showed consistent results across centers and demonstrated substantial efficacy. According to the firm's March 28 statement, Riad Salem, MD, of **Northwestern University** (Chicago), presented the findings in a March 27 session at the annual scientific meeting of the **Society of Interventional Radiology** (SIR; Reston, Virginia), which is taking place in Chicago. The trial ran from 2007 to earlier this year and enrolled 151 patients at five sites, including Northwestern, **Johns Hopkins University** (Baltimore), and the **Mayo Clinic** (Rochester, Minnesota). According to Nordion, the phase II trial showed that overall tumor response, "including stable disease, was 90% in metastatic neuroendocrine tumors and 69.2% in all treatment groups." TheraSphere uses glass beads between 20 and 30 micrometers in diameter to deliver radioactive Y-90, which are injected into the main artery of the patient's liver through a catheter, allowing delivery "directly to the tumor via blood vessels." Peter Covitz, MD, Nordion's senior VP for innovation, said the firm is "extremely pleased with the consistency of the results across all treating institutions," and that the results "will inform future development plans for TheraSphere."

– **Compiled by Mark McCarty, MDD Washington Editor**
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