Medical Device Daily™
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HIMSS 2012

Getting patients involved in healthcare the goal of the PHR

By DIANA TUCKER
***Medical Device Daily* Contributing Writer**

LAS VEGAS — It may have started with electronic health records (EHR), also known as electronic medical records (EMR), but now it is about the personal health record (PHR), or how to get the patient involved in managing their own healthcare. From gaining patient involvement up front as they register for a doctor's appointment, to following their health afterwards—whether from their home, nursing care center, or any other distant place, the big move here at the 23rd annual **Health Information Management Systems Society** (HIMSS; Chicago) meeting is to get the patient

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Boston Scientific obtains nod for DES to treat AMI patients

By OMAR FORD
***Medical Device Daily* Staff Writer**

Some recent approvals from the FDA promise to take two of **Boston Scientific**'s (Natick, Massachusetts) stents into a market where no other drug eluting stents (DES) have gone before. The company revealed that it has received approval of an indication from the FDA, to have two of its stents - the Ion paclitaxel-eluting platinum chromium coronary stent system and Taxus Liberté paclitaxel-eluting coronary stent system, to treat acute myocardial infarction (AMI).

The firm said that these are the only two DES stents that have been awarded such a designation from the FDA.

The new indication, which accounts for about 10 % of all coronary interventions, is a result of FDA review of data from the Paclitaxel (TAXUS) clinical program and

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International report

BSX reports first implants of Teligen defibrillator in China

A *Medical Device Daily* Staff Report

Boston Scientific (Natick, Massachusetts) reported the first implants of a Teligen implantable cardioverter defibrillator (ICD) in China. The implants were performed by Farong Shen, MD, in **Zhejiang Hospital** (Hangzhou) and Wei Hua, MD, in **Fuwai Hospital** (Beijing). The Teligen family of ICDs, designed to treat sudden cardiac death, are the smallest and thinnest high-energy devices available in China. The devices offer extended battery longevity over previous Boston Scientific ICDs currently approved in China, as well as improved programming technology to offer patients enhanced clinical options. The Teligen family of devices was approved by the State Food and Drug Administration (SFDA) of the People's Republic of China in

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Agreements/contracts

GE and Masimo expand OEM partnership for rainbow SET

By AMANDA PEDERSEN
***Medical Device Daily* Senior Staff Writer**

GE Healthcare (Milwaukee) and **Masimo** (Irvine, California) reported today a long-term agreement allowing GE to incorporate Masimo's rainbow SET technology into many of GE's patient monitoring products. A Masimo spokesperson told *Medical Device Daily* this is not the first time the companies have worked together.

"GE currently is an OEM partner on our Masimo SET technology, our core offering, and they have been for quite a few years," Sheree Aronson said. "So this new agreement is an expansion because now they'll be incorporating not only our SET technology but also the additional rainbow platform that includes a variety of other non-invasive [solutions]."

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Don't miss today's MDD Extra: Diagnostics

INSIDE:

AHC Media

Financings roundup

Vascular Magnetics raises $7M to advance PAD system

A *Medical Device Daily* Staff Report

Vascular Magnetics (Philadelphia) said it has raised $7 million in a Series A financing to advance the development of its magnetically targeted drug delivery system for the treatment of peripheral artery disease (PAD). Devon Park Bioventures was the sole investor in the financing.

The company says its system, Vascular Magnetic Intervention (VMI), combines biodegradable, magnetic drug-loaded particles, a magnetic targeting catheter, and an external device for creating a uniform magnetic field. The field generates high force magnetic gradients in the catheter, so that when the drug-loaded particles are administered, the gradients direct them to the atrial wall. The particles remain in the atrial wall after the catheter is removed and release the drug over a sustained period, the company noted.

"This financing is an important endorsement of our highly innovative approach to treating peripheral artery disease, a major, growing clinical challenge that affects about 30 million in Europe and North America. At least 10 million patients live in the U.S.," said George Gemayel, PhD, chairman of Vascular Magnetics. "Current treatments for PAD such as angioplasty, grafts and stents, including drug eluting stents, are not durable, with arterial re-obstruction (restenosis) occurring frequently. Vascular Magnetics' innovative approach to enhance local drug delivery has great potential to transform PAD treatment by delivering anti-restenotic drugs specifically to diseased artery sites at higher concentrations than are possible with drug eluting stents."

The initial product Vascular Magnetics is developing employs paclitaxel, an established anti-restenosis drug that is a component of drug eluting stents used primarily to treat coronary artery disease. The underlying technology has longer term potential for the targeted delivery of therapeutics to other areas of the body, the company noted.

"The funds will allow us to complete the preclinical development of the system and conduct an initial clinical trial," said Richard Woodward, PhD, the company's co-founder/COO. "We expect to begin the clinical trial in 2014." The system is based on research by Vascular Magnetics' co-founder and founding scientist, Robert Levy, MD, who holds the William J. Rashkind Endowed Chair in Pediatric Cardiology at **The Children's Hospital of Philadelphia** and is director of the hospital's Cardiology Research Laboratory. "VMI shows great promise for improving outcomes for PAD and I am delighted that with Devon Park Bioventures' support this concept is moving forward," Levy said.

Vascular Magnetics was established in 2010 and has licensed its technology from Children's Hospital. It is the first company to spin out of that institution. The company was seeded by the QED Proof of Concept Program at the **University City Science Center** (Philadelphia).

In connection with the financing, Christopher Moller, PhD, and Marc Ostro, PhD, general partners at Devon Park Bioventures, will join the company's board.

In other financing activity:

· **Gynesonics** (Redwood City, California) says it has raised $5 million of a potential $7 million offering. The company offered debt, options, warrants and securities to raise the funds, according to a regulatory filing with the Securities and Exchange Commission.

Gynesonics makes minimally invasive devices designed to help women suffering from uterine fibroids, or noncancerous tumors that develop in the uterus.

The related parties listed on the filing include CEO Darrin

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HIMSS notebook

GE, AirStrip launch new patient monitoring tech

A *Medical Device Daily* Staff Report

At the **Healthcare Information and Management Systems Society** (HIMSS; Chicago) meeting in Las Vegas, **GE Healthcare** (Chalfont, UK) and **AirStrip Technologies** (San Antonio) have introduced AirStrip Patient Monitoring, which securely delivers patient monitoring information to critical-care physicians' iPhones and iPads. AirStrip helps physicians interact with, manipulate and zoom in on more than 100 clinical measurements and access physiologic data and monitoring waveforms, anytime and anywhere.

AirStrip Patient Monitoring is designed to help mobile physicians make efficient, informed clinical decisions across and beyond hospital boundaries. Critical-care physicians must make timely treatment decisions for the hospital's sickest patients. However, they face increasingly hectic patient care responsibilities, making it difficult to continuously be at the bedside. AirStrip Patient Monitoring can serve as an important clinical decision support tool and help expand physicians' access to patient information. If a nurse requires immediate consultation, physicians can be located anywhere and access critical patient information before determining appropriate care approaches.

In other news from the HIMSS floor in Las Vegas:

• **dbMotion** (Pittsburgh), a provider of connected healthcare solutions, released information about how its semantic interoperability platform delivers continuity of care documents (CCD) as a vital component of an iPad application developed by **Heritage Valley Health System**.

Heritage Valley, a progressive community-based healthcare organization located in southwestern Pennsylvania, developed the iPad application iCAP (internet Clinical Access Portal) to better equip providers across its extensive network with comprehensive information about patients they serve. The dbMotion Solution organizes and harmonizes data captured and stored in disparate health information technologies. It delivers the CCD to Heritage Valley providers so it can be used in a meaningful way.

The dbMotion interoperability solution semantically organizes volumes of data, enabling providers to easily access and manage information within familiar workflows.

• **Orion Health** (Santa Monica, California), a specialist in health information exchange (HIE) and healthcare integration solutions, introduced the new Orion Health Rhapsody Integration Engine version 5. Rhapsody provides comprehensive support for a vast range of communication protocols and message formats, ensuring connectivity between all systems. New features in Rhapsody 5 include an all-new monitoring system with an activity stream that presents messages and comments in real time so users can better monitor system status, and an IHE Toolkit for simplifying the use of IHE Integration Profiles.

Rhapsody IHE Toolkit addresses the challenge of creating IHE-compliant integration within and between enterprises, resulting in fast and cost-effective interoperability between products or an entire network, the company said.

Orion also reported new and enhanced functionality now available in the latest version of Orion Health HIE. Orion Health HIE, the technology backbone for enterprise and community-wide clinical data sharing, is used by hospitals, health systems and public HIEs across the U.S. Enhancements to Orion Health HIE improve the clinical workflow and enable healthcare organizations to better share critical patient information between provider facilities, HIEs, clinicians and patients; improve care coordination and quality of care; and meet Meaningful Use requirements.

• **ICA** (Nashville, Tennessee) has launched a new solution suite based on the CareAlign platform. The suite, or volume set, includes CareAlign CareExchange, CareConnect, CareCollaborate, CareMeasure and CareManage. Each volume provides a hospital, integrated delivery network (IDN), region or state the technology necessary to progressively exchange clinical information, increase care collaboration and manage healthcare risk across the continuum of care with the goal of improving patient outcomes while reducing costs.

The CareAlign CareExchange platform combines two interoperability frameworks in a single platform. The first framework is based on Integrating the Healthcare Enterprise (IHE) standards. The second framework includes NwHIN Direct and corresponding provider directory services.

CareConnect allows providers to securely collaborate with other providers and patients in a clinically relevant, non-intrusive manner across a wide variety of care settings. This volume can be implemented and adopted quickly providing a positive return on investment in a short timeframe.

CareCollaborate is a solution supporting interoperability via both standards-based and non-standards-based information exchange.

CareMeasure provides a reporting and analytics framework fully integrated into the health information exchange platform that can consume information being shared across the network in real-time to support broad scale reporting and bio-surveillance initiatives.

CareManage addresses the needs of risk-bearing entities. Whether the healthcare organization is managing the risk of it own employee base, developing an ACO or participating in other bundled payment methodologies, this solution is essential to the care management process.

ICA was established to take innovative technology developed by **Vanderbilt Medical Center** (Nashville, Tennessee) to the broader healthcare market, and now delivers a comprehensive health information exchange (HIE) and care management solution to hospitals, IDNs, communities and states. ■

HIT roundup

CogniFit releases new app for attentional processes

A *Medical Device Daily* Staff Report

CogniFit (New York), a developer of online brain training and cognitive programs, reported the release of its new application, called Concentration, designed to assess and train higher-order attentional processes such as focused attention and vigilance.

The company notes that with "more than 5 million children" diagnosed with ADD or ADHD in the U.S. alone, "assessing and training concentration and focus is a key element for a healthy and more productive lifestyle."

"Higher-order attentional processes such as the ability to willingly orient and focus our attention on a task, the ability to readily maintain a high degree of vigilance or the ability to willingly ignore potentially distracting elements in our surroundings are processes crucial to the initiation, preserverance and successful completion of a task," said Evelyn Shatil, PhD, chief scientist at CogniFit. "Yet, a very large number of adults, children and youth experience difficulties in the control and application of those concentration processes."

According to the company, the application is designed to specifically train the selective orientation of attention, focused attention, vigilance, updating of incoming information, visual attention and the operation speed of those processes. The application is priced at $4.99.

In other HIT activity:

• **The TriZetto Group** (Denver) reported new enhancements to the benefits administration, care management and network management capabilities of its enterprise solution platform. The upgraded platform is designed to help healthcare organizations improve administrative efficiency; achieve compliance; and enhance the cost, quality and delivery of care.

TriZetto said these are the first in the 5.X series of releases that it plans to introduce this year.

The 5.0 release of TriZetto's care-management solution, CareAdvance Enterprise, includes advanced functionality that streamlines utilization, disease and case management processes; expanded analytic capabilities; improved care work flow; and integrations with third-party systems to lower total cost of ownership. Additional capabilities in TriZetto's network management applications, NetworX Suite, support pricing for new ICD-10 codes and further efficiencies in hospital contract administration, the firm noted.

• **AirStrip Technologies** (San Antonio) has selected **Diversinet** (Toronto) and its government-certified solution for the crucial security validation needed to offer mobile healthcare applications to military and other U.S. government agencies.

AirStrip has chosen Diversinet's MobiSecure SDKs for an essential capability that assures military-grade authentication, encryption and other security features for mobile healthcare (mHealth) applications. Diversinet's technology will enable AirStrip to comply with Federal Information Processing Standards requirements, the company noted.

Integrating MobiSecure technology will enable AirStrip applications to provide levels of authentication and encryption necessary for use in such government organizations as military hospitals.

Additional factors in AirStrip's selection of MobiSecure included broad coverage of mobile devices, as well as capability for over-the-air device provisioning, which will allow physicians, nurses and other caregivers to begin using new devices immediately in the battlefield and other remote locations. ■

Court report

Sequenom asks court to stop Aria from selling Harmony

A *Medical Device Daily* Staff Report

Sequenom (San Diego), a life sciences company providing genetic analysis solutions, said it has filed a motion for preliminary injunction against **Aria Diagnostics** (San Jose, California) to stop Aria from selling tests for detecting fetal chromosomal aneuploidy, such as company's new Harmony Prenatal Test, pending the resolution of the lawsuit Sequenom filed in January.

The suit, filed in the U.S. District Court for the Southern District of California, alleges that Aria infringes U.S. Patent 6,258,540. Sequenom is asking the court to intervene to stop Aria's alleged infringement of the patent.

According to the company, Sequenom Center for Molecular Medicine (Sequenom CMM) was the first to sell a non-invasive prenatal diagnostics laboratory developed test for chromosomal aneuploidy. Sequenom says its MaterniT21 Plus LDT detects a genetic chromosomal anomaly known as Trisomy 21, the most common cause of Down syndrome, and also detects trisomies 18 and 13.

Aria just reported the name of its Harmony test earlier this month (*Medical Device Daily*, Feb. 7, 2012). According to the company, the test is a directed non-invasive approach to cell-free DNA (cfDNA) analysis in maternal blood to detect common trisomies linked to genetic disorders. The Harmony Prenatal Test uses new technology, Aria noted, that couples biochemistry, DANSR, and a proprietary algorithm, FORTE, to efficiently analyze patients' blood samples. ■

Grants roundup

NFCR issues grant for ovarian cancer detection

A *Medical Device Daily* Staff Report

The **National Foundation for Cancer Research** (Bethesda, Maryland) has awarded a grant to Robert Bast, Jr. of **The University of Texas MD Anderson Cancer Center** (Houston) to work with **Senior Scientific** (Albuquerque), a company owned by **Manhattan Scientifics** (New York), to apply Senior Scientifics' technology to the early detection of ovarian cancer.

Senior Scientific has pioneered a technology using special magnetic sensors and magnetic nanoparticles for a highly sensitive and very specific approach to cancer detection.

The new grant, titled "SQUID Imaging for Detection of Early Stage Ovarian Cancer," will augment Bast's ongoing program at The University of Texas MD Anderson Cancer Center with this emerging technology.

Bast is responsible for the discovery of the most accurate marker for this disease, CA-125.

The principal challenge in this grant is to overcome the problem of early detection of ovarian cancer where only 25% of ovarian cancer patients are currently detected in stage I. When the disease can be detected in Stage I, 90% of those patients can be cured. ■

Financings

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Uecker, and directors Doug Fisher, Ken Haas, Jonathan Mac Quitty, Tom Rodgers, and Karen Talmadge.

The company did not specify in the SEC filing how it plans to use the proceeds of the offering.

· **Health Evolution Partners** (San Francisco), a healthcare private equity firm, said it has acquired a majority interest in **Freedom Innovations** (Irvine, California), a provider of premium high-technology prosthetic devices focused on solutions for lower limb amputatees.

Freedom's senior management team will continue to lead the organization and will remain significant shareholders in the company. Financial terms of the transaction were not disclosed.

As part of the transaction, and to finance further growth opportunities for Freedom, Health Evolution Partners facilitated the completion of new senior credit facilities. The senior credit facilities were led by Madison Capital Funding and included BMO Capital Markets as co-lead arranger. ■

Med-Tech Notes

Mindchild forms advisory board for Meridian

Mindchild Medical (North Andover, Massachusetts) reported the formation of a clinical advisory board (CAB) for its Meridian non-invasive fetal heart monitor. The CAB will meet periodically to assess the development strategies for the Meridian Monitor and advise the company on the state of the fetal monitoring market. Adam Wolfberg, MD, currently chief medical officer for Mindchild, will assume the position of chairman of the CAB.

Joining the clinical advisory board are:

– Aaron Caughey, MD, PhD, is the chair of the department of OB/GYN and director of the Oregon Health Sciences University Center for Women's Health.

– Emily Hamilton is the senior VP of clinical research at PeriGen, and is adjunct professor of OB/GYN at McGill University.

– Gary Hankins, MD, is the Jennie Sealy Smith distinguished professor and chairman, University of Texas Medical Branch, department of OB/GYN.

– Michelle Murray, PhD, RNC-OB, is the founder/president of Learning Resources International.

– Michael Ross, MD, is professor of OB/GYN at the Geffen School of Medicine at UCLA.

Carestream to be used at NFL combine

On February 22, the first day of the 2012 National Football League Combine, more than 300 top college football players will undergo X-ray imaging exams using an innovative wireless, digital radiography detector from **Carestream Health** (Rochester, New York). These exams are part of a comprehensive physical being conducted at **Indiana University Health Methodist Hospital** (Indianapolis).

The annual scouting combine is a week-long event where selected college football players perform physical and mental tests for evaluation by NFL coaches, general managers and scouts in preparation for drafting new players.

Carestream says the speed of the DRX-1 detector will streamline the process of imaging hundreds of athletes while ensuring the quality of X-ray images, which will be closely examined by medical representatives of NFL teams. The detector delivers exceptional image quality for X-ray exams and offers image access in less than five seconds.

HIMSS

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involved in investing in their own healthcare.

This meeting set record attendance topping over 35,000 attendees: a population larger than many American cities. Vendors and education sessions demonstrated how health information can flow in a secure HIPAA accredited manner from patient to doctors' offices, hospitals, pharmacies, labs, and insurance carriers; all the while accumulating lab results, diagnostic imaging files, ICD coding, billing, and archiving.

Much of the focus was on interoperability, or the way to get these diverse individual systems to talk to each other, cleverly described by **Nextgen Healthcare** (Horsham, Pennsylvania) in their ad campaign as "Connectitis: A community-acquired condition caused by a loose patchwork of interfaced databases resulting in isolation and uncoordinated care." Nextgen has integrated their flagship EHR with their ambulatory EHR and their practice management system to automate contact with patients. Physicians can enhance care by ensuring patients are in compliance with treatment plans. Nextgen's system has demonstrated that there is revenue associated with proactive patient communication and care when it is tracked, captured, and processed through an integrated administrative workflow.

To this end, capturing patient engagement drew much attention, with the intent to get Americans involved in managing their own health. Two companies stuck out as frontrunners in patient engagement, although many vendors offered something geared toward patient involvement. **Tonic Health** (Menlo Park, California) has developed, and is just this week rolling out their first products that revolutionize medical data collection from the patient by making it more like a game than like a chore. Tonic employs contextually relevant graphics that are engineered toward patient engagement. This appealing cartoon-like patient interface achieves greater patient data collection, more accurate data, improved patient management and tracking that results in lower costs for everyone. The Tonic software allows clinicians to fully customize the content of their patient intake forms, questionnaires, surveys, etc. which result in those questions being asked in a fun, colorful, game-like format. These cuter versions of the questionnaires are then deployed to all of their iPads. Patients enjoy, engage with and complete the questionnaire (even if longer than most other questionnaires). Interestingly, Tonic has found that only 5 iPads are needed to manage 30,000 patients annually being seen in one office. They do recommend holding the patient's drivers license until the iPad is returned in order to avoid any temptation on the patient's behalf to take the iPad home with them. The data is then sent securely to an existing electronic health record or back end database. No other installation or integration is required. No data can be stored on the iPad — it is all sent to the cloud — rendering it 100% HIPAA-secured. All data collected using Tonic's platform can be mined, rendering it a huge clinical research tool as well. As Sterling Lanier, CEO of Tonic sarcastically said, "We are a patient engagement company that just happens to collect data."

On the other end of the patient-management-through-ease-of-engagement spectrum is **iMPak Health**'s (Neptune, New Jersey) system that is also just being rolled out beyond their pilot program at this meeting. **NoMoreClipBoard** (Fort Wayne, Indiana) joined iMpak to develop and market a patient-friendly system that manages patients' compliance following their visit to the doctor or hospital. Upon discharge, the patient is given a small cardboard record-keeper about the size of a greeting card. In it are a series of questions with multiple-choice answers specific to that patient's treatment plan that they respond to daily by pressing a small built-in button to answer each question. These cards are ideal for the millions of patients who are uncomfortable with computers or who cannot afford expensive technology. After about a month of this type of journaling, the patient uploads the information stored on the card by holding the card over virtually any smart phone. (Well, except iPhones for now. It is anticipated that the iPhone 5 will also have the Near Field Communication (NFC) capability required to do this that all other phones currently have.)

Once the data is uploaded, the card's data is cleared and ready to begin a new month. The initial application for these cards was to reduce readmission rates, one of the more costly events for a hospital and one that will cost the hospital even more once the new regulations are in place. By monitoring the patient's daily health journal, the treating physician can be alerted to the potential for an upcoming event and intervene prior to re-admitting the patient. The other great market for these devices will be for wellness, with cards designed for monitoring diet and exercise, medication compliance, cholesterol management, and a host of others. The first smart cards being designed for the more acute patient being discharged will be for chronic obstructive pulmonary disease (COPD), asthma monitoring, and heart failure.

These patient-centric data collection devices will reduce ER visits, hospital re-admission rates, and promote improved wellness, all of which will reduce our burgeoning healthcare costs. ■

Stents

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HORIZONS-AMI trial. In the global HORIZONS-AMI trial, 3,006 patients were randomized to receive either DES or bare-metal stents for the treatment of AMI, making it one of the largest randomized trials to study coronary stents in heart attack patients.

"To the best of my knowledge there are no other companies that have conducted trials like HORIZONS-AMI, that would be able to obtain an FDA indication for this patient group," Matt Franklin vice president, interventional cardiology marketing at Boston Scientific told *Medical Device Daily*. "We believe for the forseeable future that we'll be the only company with this indication."

With these recent approvals Boston Scientific finds itself in an unchallenged position to address a large patient pool. **The American Heart Association** (AHA; Dallas) estimates that heart attacks account for one out of every six deaths annually in the U.S. There are more than 1.2 million new and recurrent cases of heart attack each year, with about 34% resulting in death.

Franklin said that it was Boston Scientific's position in the DES market that helped facilitate it vying for this particular approval.

"It's difficult to comment on other company's motivations and why they choose to pursue a particular clinical strategy vs. another," Franklin told *MDD*. "I think in our case we've been the market leader in the [DES] space and we've invested heavily in our clinical program. "We believe that as leaders we should continue to advance clinical science and pursue these types of clinical initiatives and try to really bring these former understudied groups into the light."

The company's Ion stent system incorporates a platinum chromium (PtCr) alloy designed specifically for coronary stenting and intended to improve the acute performance of coronary stent implantation in the treatment of coronary artery disease.

Franklin said that the Taxus stent differs slightly because it is "based on an older stainless steel stent."

"The AMI indication is a testament to our long-term commitment to innovation and leading clinical science in support of advanced DES technologies," said Keith Dawkins, MD, Global CMO for Boston Scientific. "Clinical data from the HORIZONS-AMI trial showed that, in patients with AMI, paclitaxel-eluting stents were superior in efficacy to bare-metal stents, significantly reducing clinical and angiographic restenosis compared to bare-metal stents, while demonstrating a comparable safety profile at three years. We are proud that our investments in randomized trials such as HORIZONS-AMI have led to the approval of products to treat a broader range of patients with coronary artery disease."

Both stents previously have indications and are approved for use in Europe.

"All DES in the U.S. have a general indication for use in *de novo* native coronary arteries and they're bound by some sort of lesion length and vessel diameter. The paclitaxel was the first family or series of DES stents to receive a specific indication for small vessels (2.25 millimeters)," Franklin said. "It was also the first stent series to receive an indication for long lesions greater than 32 millimeters. And then with our Taxus Express product, we were the first company to receive an indication for treatment of bare metal instant restenosis. So this particular family of paclitaxel stents has a long history of firsts when it comes to indications."

The indications could help provide a boost for the company. Most recently Boston Scientific reported that its corporate credit rating was upgraded by Moody's Investors Service to an investment grade rating, Baa3, with a stable outlook (*Medical Device Daily*, Feb. 14, 2012).

"The new indication for heart attack patients should give U.S. physicians the confidence to treat this high-risk group with Boston Scientific's advanced paclitaxel-eluting stent technology backed by a robust clinical program that spans 10 years of research," said Hank Kucheman, CEO of Boston Scientific. The AMI indication reinforces the safety and effectiveness of the Ion and Taxus Liberté paclitaxel-eluting stents in treating challenging patients and lesions in both clinical and real-world practice. The inclusion of the Ion stent for this indication should be welcome news for physicians and patients. This innovative platinum chromium stent has been very well received since its U.S. launch last year based on its exceptional visibility, radial strength and deliverability." ■

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International

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November 2011.

Shu Zhang, MD, chairman of the Chinese Society of Pacing and Electrophysiology, said, "These new ICDs feature significant advances and will be a welcome technology for Chinese patients requiring implantable defibrillators." Wei Hua, MD, added, "The Teligen devices provide patients the thinnest ICDs with the longest projected longevity available, without compromising therapy options."

"Boston Scientific is committed to providing innovative products and therapies to Chinese physicians and their patients," said Joe Fitzgerald, senior VP and president of the Cardiac Rhythm Management group at Boston Scientific. "We believe today's first implant of our advanced ICDs combined with our recent launch of the Promus Element Plus coronary stent system in China positions Boston Scientific for future growth in this important market."

With the world's largest population, China represents one of the world's fastest-growing ICD markets. The company estimates annual market growth exceeding 15% over the next five years.

In July 2011, Boston Scientific reported a five-year, $150 million investment in China to expand its commercial presence. This new investment will support the establishment of a local, wholly owned manufacturing facility focused on serving Chinese market needs and developing a training center for Chinese healthcare providers.

Dynex gains SFDA approval to supply DS2 to China

Dynex Technologies (Chantilly, Virginia) reported that it has received approval from China's State Food and Drug Administration (SFDA) to market the DS2 automated enzyme-linked immunosorbent assay (ELISA) analyzer in China. The DS2 is Dynex's automated ELISA processing system for clinical diagnostic assays, capable of handling two microplates per assay run, greatly reducing required technician time while improving the speed and reliability of test results. The initial SFDA approval for the DS2 analyzer is effective for four years and allows assay developers, researchers and diagnostic laboratories throughout China to purchase Dynex DS2 systems immediately.

Dynex also reported that it will establish a branch in Hong Kong in the first quarter of 2012 to facilitate its activities and anticipated growth in the rapidly expanding Asia-Pacific market. Heading operations in this region will be Wally Fan, Dynex's new director of sales, Asia-Pacific Region.

Velos partnering with Cancer Trials Australia

Velos (Fremont, California), a developer of clinical research management software, reported the international multi-site deployment of Velos eResearch through a partnership with **Cancer Trials Australia** (CTA; Melbourne, Australia). Currently, eight sites are operating on the Velos platform, and the results thus far have been extremely positive. These sites include the **Peter MacCallum Cancer Centre**, **Austin Health**, and the **Royal Melbourne Hospital**.

"It has met our expectations in what we see as a complex logistics environment," said Marcus Clark, CEO of CTA. By the end of first quarter 2012, fourteen oncology clinical trial centers in the states of Victoria and New South Wales are scheduled to use Velos eResearch to provide integrated administrative management of their trial portfolios.

CTA is a non-profit, member-driven organization that works on behalf of both public and private hospitals to perform research governance, administration, and financial services, allowing the staff at these oncology trial centers to focus on patient care. In 2009, CTA and six of its members investigated a more efficient way to track and manage research information. CTA sites had been operating on a variety of decentralized processes that stifled the flow of timely information, which resulted in insufficient data analysis and impinged on resource priorities. CTA examined a number of different software products and encouraged users, such as research nurse managers, to engage in the selection of the product that would work best for them. "CTA members wanted a thoroughly proven product," said Clark.

CTA engaged Velos and both organizations worked with the research nurses to evaluate the product. "We believed that Velos eResearch's adaptability, as well as its advanced research administration and financial capabilities, would provide CTA and its sites with the perfect solution," explained Kamar Aulakh, COO of Velos.

After examining a number of different systems, CTA selected Velos eResearch. "As the application has been implemented across CTA sites, the results have been meeting our milestones, especially with the collection of patient visit data and streamlining of financial data flow. We are able to leverage the Velos eResearch platform to provide consolidated information across our sites, including visit monitoring, financial tracking, sponsor billing, budgeting, and customized reporting. CTA initiates over forty commercial studies at multiple sites every year, so it's important to invoice accurately and promptly," said Clark. ■

Agreements

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Masimo debuted its Measure-Through Motion and Low Perfusion pulse oximetry, known as Masimo SET, in 1995. That core offering virtually eliminated false alarms and increased pulse oximetry's ability to detect life-threatening events, according to the company. Ten years later, in 2005, Masimo introduced rainbow SET Pulse CO-Oximetry technology, allowing non-invasive and continuous monitoring of blood constituents that previously required invasive procedures, including total hemoglobin, oxygen content, carboxyhemoglobin, methemoglobin, and Pleth Variability Index, in addition to oxyhemoglobin, pulse rate, and perfusion index.

In late 2007 Masimo introduced Patient SafetyNet, a remote monitoring and wireless clinician notification system designed to help hospitals avoid preventable deaths and injuries associated with failure to rescue events (*Medical Device Daily*, Oct. 18, 2007). A little over two years ago the company added rainbow Acoustic Monitoring to the platform, a technology designed to provide non-invasive and continuous monitoring of acoustic respiration rate (*MDD*, Dec. 2, 2009).

The new agreement with GE not only expands Masimo's partnership with GE, but "also marks an important step forward making our rainbow SET technology available to more patients around the world," Aronson said.

Masimo says its SET and rainbow SET technologies can also be found in more than 100 multi-parameter patient monitors from more than 50 device manufacturers around the world.

"Combining Masimo's measurements advances with our innovative patient monitors enhances bedside clinical decision-making and ultimately, supports patient care," said Matthias Weber, general manager of Monitoring Solutions at GE Healthcare. "Through our focused Monitoring Solutions division, GE Healthcare is committed to optimally collecting information from the patient's body, and transforming it into meaningful intelligence for caregivers. Masimo's suite of noninvasive and continuous Rainbow SET measurements will further enhance the point-of-care clinical intelligence benefits already offered in GE Healthcare's patient monitors."

"GE Healthcare's patient monitoring lines have along history of innovative clinical management measurements and system solutions that enhance patient care decisions," said Rick Fishel, president of worldwide OEM business and corporate development at Masimo. "We are excited to announce this expansion of our partnership with GE Healthcare and are proud to work with them to incorporate rainbow SET measurements in their monitoring solutions to continue this tradition for the benefit of customers and the patients they serve."

In other agreement and contract news:

• **Teleflex** (Limerick, Pennsylvania) reported two new agreements with **HealthTrust Purchasing Group** (Brentwood, Tennessee).

The agreement for anesthesia airway products began Jan. 1 and extends through Dec. 31, 2014. The laryngoscope agreement begins March 1 and expires Feb. 28, 2015.

• **Rubicon Genomics** (Ann Arbor, Michigan), a company developing sample-specific pre-analytical processes to improve the capabilities and performance of DNA and RNA analytical platforms, reported a clinical supply agreement with molecular diagnostics firm **Agendia** (Irvine, California) for its TransPLEX whole genome RNA amplification technology. Agendia will incorporate Rubicon's TransPLEX kits into the analysis of formalin-fixed, paraffin-embedded patient samples for use with its Symphony suite of breast cancer diagnostics.

Financial terms of the agreement were not disclosed.

• **Amedisys** (Baton Rouge, Louisiana) said it is now a home health and hospice care provider for **Blue Cross and Blue Shield of Georgia** (BCBSGa) members. Becoming an in-network provider for BCBSGa enables Amedisys to care for more than 3.2 million people who are members of its commercial and Medicare Advantage plans.

• **Streamline Health Solutions** reported that **UC Health** (both Cincinnati) has signed an agreement to expand its use of Streamline Health's solutions into three facilities.

The facilities will also integrate Streamline Health's solutions with the system's electronic medical records (EMR) system through Streamline Health's Integration Suite for Epic EMR.

UC Health has used Streamline's AccessAnyWare content management system and HIM Suite workflows in its flagship facility, University Hospital, and in its newest hospital, West Chester Hospital. The system has contracted to expand the use of AccessAnyWare into three additional facilities: University of Cincinnati Physicians, the Drake Center, and the University Pointe Surgical Hospital.

By utilizing AccessAnyWare across the healthcare enterprise, UC Health facilities will now be able to move away from a paper-based medical record to an electronic record that can integrate seamlessly with the EMR system. This will allow physicians and other staff to securely and quickly access complete patient information from virtually anywhere within the health system. ■

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Product Briefs

• **Ascendx Spine** (Winter Park, Florida) said that it has received FDA clearance to market its Acu-Cut Vertebral Augmentation System for treatment of vertebral compression fractures (VCF). Current standard procedures for treating VCFs are 'Vertebroplasty' and 'Kyphoplasty.' The Acu-Cut Vertebral Augmentation System is designed to be an alternate solution for physicians who are currently treating VCF patients. Acu-Cut is a uni-pedicular vertebral augmentation system that creates a cavity for precise cement placement. While traditional technologies require passing next to both sides of the spinal cord to reach the entire vertebral body, the Acu-Cut Vertebral Augmentation System is designed to achieve this through single-sided access.

• MelaFind, developed by **Mela Sciences** (Irvington, New York), was shown to improve melanoma detection in a study of 179 dermatologists. The average sensitivity of dermatologists before obtaining the MelaFind output was 69%, and the average sensitivity after obtaining the MelaFind output was 94%, according to a recent study published online in the *Archives of Dermatology*. MelaFind, a non-invasive, multi-spectral computer vision system recently approved by the FDA, uses light from visible to near-infrared wavelengths to evaluate skin lesions up to 2.5 mm beneath the skin. The device analyzes the three-dimensional morphologic (i.e., structural) disorganization under the surface of the lesion and provides an unambiguous and easy to interpret output – high disorganization (positive) or low disorganization (negative) – that a dermatologist can incorporate into the biopsy decision-making process.

• **nContact** (Morrisville, North Carolina), a maker of epicardial ablation devices, said that a new preclinical study examines a minimally invasive percutaneous approach to accessing the heart that may enable electrophysiologists (EPs) to perform epicardial ablation for ventricular tachycardia (VT). The study was published in the February 2012 issue of *The Journal of Innovations in Cardiac Rhythm Management*. In the study, researchers sought to modify an existing epicardial ablation device's (nContact's EPi-Sense Guided Coagulation Device with VisiTrax) transdiaphragmatic approach to a percutaneous subxyphoid (below the sternum) approach that could enable epicardial ablation without requiring a more invasive surgical access.

• **Simbionix** (Cleveland) received FDA clearance for the EVAR (Endovascular Aneurysm Repair) application for the PROcedure Rehearsal Studio (PRS). The PROcedure Rehearsal Studio transforms the patient's CT scan into a 3-D visualization model. Simbionix has developed a revolutionary technology to use this 3-D visualization model within its endovascular simulator, the ANGIO Mentor, to allow surgeons to evaluate endovascular surgical treatment options before surgery. PRS provides a 3-D model of the patient's vasculature and true-to-life vessel measurement tools. After exporting the 3-D model into the Angio Mentor simulator practice environment, the physician is able to train and practice aneurysm repair on the patient's specific anatomy. For the first time, surgeons can practice endovascular abdominal aortic aneurysm repair, including precise deployment of the bifurcated and contralateral leg stent graft, deployment of iliac and aortic extensions and touch-up ballooning, the company said.

• **Teleflex** (Limerick, Pennsylvania), a provider of medical devices for critical care and surgery, has introduced an extension to its family of Hydrophilic catheters. The FloCath Quick Female Catheter kits are specifically designed for female use in intermittent catheterization. The Teleflex FloCath Quick Female Catheter is a compact catheter with an integrated saline wetting solution and a handling sheath to aid in insertion. Teleflex offers sterile saline rather than sterile water as it is closest to the body's natural fluid balance and can help reduce drying of the mucosal tissue. The Teleflex FloCath Quick Female Insertion Kit comes complete with the FloCath Quick Female Catheter and the insertion supplies many individuals require. It also includes a measured urine collection bag and a refuse bag for disposal; all in a compact package.

People in the News

• **Ascendx Spine** (Winter Park, Florida) has elected Magnus Persson, MD, to its board of directors. Persson has been a partner in two life sciences-focused venture capital firms, one with its base in Sweden with global reach and one in the San Francisco Bay Area in California. Ascendx Spine is a medical device company focused on the development and commercialization of innovative orthopedic devices for the spine and trauma markets.

• **Kindred Healthcare** (Louisville, Kentucky) said Ann Berzin has opted not to stand for re-election to the board of directors at the 2012 annual meeting of shareholders. Berzin serves as the chair of the company's nominating and governance committee and as a member of the audit committee. Berzin has served on the Kindred Board since November 2006. Kindred Healthcare is a healthcare services company with annual revenues of $6 billion and almost 76,900 employees in 46 states.

• **Vomaris Innovations** (Chandler, Arizona) has named Michael Nagel as its new president/CEO. Previously, Nagel was chief commercial officer of Neomend. The company makes Procellera, which it claims is the first totally self-contained, comfortable, cut-to-fit, electrically active wound dressing in the world.

MDD's Diagnostic Extra

ADDITIONAL DEVELOPMENTS IN ONE OF MED-TECH'S KEY SECTORS

FRIDAY, FEBRUARY 24, 2012

Keeping you up to date with recent developments in diagnostics

Ghost Imaging technique can lead to better detection . . . Ghost imaging (GI), and its even more oddly named cousin virtual ghost imaging (VGI), seem to contradict conventional wisdom by being able to image an object by simply counting photons in a "light bucket." This non-intuitive technique, however, can lead to better images when conditions are less than ideal. In a first-of-its-kind demonstration, a team of researchers from the **U.S. Army Research Laboratory** (Adelphi, Maryland), and the **University of Maryland** (Baltimore), captured reflected photons from a highly specialized laser beam to create a VGI image of a remote target. In the case of VGI, reflection does not refer to a mirror image of an object. Rather it is merely the individual reflected photons of light that are counted with a single-pixel camera known as a light bucket. "Virtual ghost imaging is an amazing tool," says Ronald Meyers, a quantum physicist with the U.S. Army Research Laboratory, in a paper published in the **American Institute of Physics**' (College Park, Maryland) journal *Applied Physics Letters*. "Because we are no longer bound by the need to collect spatial information - as is necessary in a typical camera - we can produce an image in some rather adverse and highly obscured conditions." In normal ghost imaging, harnessing information to make an image is a two-step process. First, you analyze the light source, which could be the sun or a lamp, with a charge-coupled device (CCD) camera. You then use a second detector, a light bucket, to count the reflected photons. By combining the data from the light source with the properties of the collected photons, an image can be created. The trick to making an image from photons that contain no spatial information lies in physics related to "entanglement," a property of light that Einstein referred to as "spooky action at a distance." Through entanglement, photons (individual packets of light) can share a certain degree of information. This property is already being developed for specialized communications and computers. Virtual ghost imaging is a more self-contained and robust application of this phenomenon. For example, in VGI, one light source was a laser that produced an incredibly coherent beam of light known as a Bessel beam. Bessel beams, unlike normal laser beams, produce concentric-circle patterns. If a portion of the beam is blocked or obscured along its trajectory, the original pattern eventually reforms. In their proof-of-concept demonstration, the researchers compared a Bessel beam's VGI imaging capabilities with that of a normal "Gaussian" laser beam. Their target was the letters "ARL." The light was then reflected back to the single pixel bucket detector. The researchers conducted this same test several times, placing different objects or an obscuring medium in the paths of the two light beams. In each case - whether passing through an offset aperture, cloudy water, or heat distortion -- the Bessel beam reformed to produce a recognizable VGI image. The Gaussian beam produced a much less faithful image, and, in the case of the offset aperture, produced virtually no image at all. "What this demonstrates is that by combining virtual ghost imaging with a highly diffraction-free coherent light source like a Bessel beam, it's possible to probe through conditions that would normally thwart other imaging technologies," Meyers says. According to the researchers, potential spin-offs of ghost imaging and virtual ghost imaging include applications in Intelligence-Surveillance-Reconnaissance (ISR), medical imaging, and quantum computing.

Researchers take one step forward in understanding Parkinson's and Alzheimers through 3-D microscopy . . . The understanding of diseases such as Parkinson's and Alzheimer's is set to take a step forward following groundbreaking technology which will enable cell analysis using automated 3-D microscopy. An initiative between the **Griffith's School of Information Communication Technology** (San Francisco) and the **Eskitis Institute for Cellular and Molecular Biology** (Brisbane, Australia) the technology will allow the automated identification, separation and analysis of cells as complex as nerve cells in the brain. "Scientists and clinicians will be able to superimpose multiple data sets in three dimensions using automated techniques and then conduct detailed analysis of the data in a far improved way from the two dimensional microscopy that is currently available," said Adrian Meedeniya, manager of Griffith's Imaging and Image Analysis Facility. Microscopy and image acquisition technology has undergone a recent revolution, with modern microscopes generating huge multi-dimensional data sets that can easily fill an entire hard drive. Manually analyzing these data-sets is incredibly time consuming and prone to human error

and bias. "One of the main motivations for establishing this collaboration with the School of ICT was to create the technology to efficiently deal with these huge data sets," Meedeniya said.

Noninvasive test can detect chromosomal abnormalities . . . Using a noninvasive test on maternal blood that deploys a novel biochemical assay and a new algorithm for analysis, scientists can detect, with a high degree of accuracy, the risk that a fetus has the chromosomal abnormalities that cause Down syndrome and a genetic disorder known as Edwards syndrome. The new approach is more scalable than other recently developed genetic screening tests and has the potential to reduce unnecessary amniocentesis or CVS. Two studies evaluating this approach are available online in advance of publication in the April issue of the *American Journal of Obstetrics & Gynecology* (AJOG). Diagnosis of fetal chromosomal abnormalities, or aneuploidies, relies on invasive testing by chorionic villous sampling or amniocentesis in pregnancies identified as high-risk. Although accurate, the tests are expensive and carry a risk of miscarriage. A technique known as massively parallel shotgun sequencing (MPSS) that analyzes cell-free DNA (cfDNA) from the mother's plasma for fetal conditions has been used to detect trisomy 21 (T21) pregnancies, those with an extra copy of chromosome 21 that leads to Down syndrome, and trisomy 18 (T18), the chromosomal defect underlying Edwards syndrome. MPSS accurately identifies the conditions by analyzing the entire genome, but it requires a large amount of DNA sequencing, limiting its clinical usefulness. Scientists at **Aria Diagnostics** (San Jose, California) developed a novel assay, Digital Analysis of Selected Regions (DANSR), which sequences loci from only the chromosomes under investigation. The assay requires 10 times less DNA sequencing than MPSS approaches. In the current study, the researchers report on a novel statistical algorithm, the Fetal-fraction Optimized Risk of Trisomy Evaluation (FORTE), which considers age-related risks and the percentage of fetal DNA in the sample to provide an individualized risk score for trisomy. Explains author Ken Song, MD, "The higher the fraction of fetal cfDNA, the greater the difference in the number of cfDNA fragments originating from trisomic versus disomic [normal] chromosomes and hence the easier it is to detect trisomy. The FORTE algorithm explicitly accounts for fetal fraction in calculating trisomy risk." To test the performance of the DANSR/FORTE assay, Song and his colleagues evaluated a set of subjects consisting of 123 normal, 36 T21, and 8 T18 pregnancies. All samples were assigned FORTE odd scores for chromosome 18 and chromosome 21. The combination of DANSR and FORTE correctly identified all 36 cases of T21 and 8 cases of T18 as having a greater than 99% risk for each trisomy in a blinded analysis. There was at least a 1,000 fold magnitude separation in the risk score between trisomic and disomic samples.

USB Memory stick could lead to significant strides sequencing DNA . . . It may look like an ordinary USB memory stick, but a little gadget that can sequence DNA while plugged into your laptop could have far-reaching effects on medicine and genetic research. **Oxford Nanopore Technologies** (Oxford, UK) built the device, called MinION, and claims it can sequence simple genomes – like those of some viruses and bacteria – in a matter of seconds. More complex genomes would take longer, but MinION could also be useful for obtaining quick results in sequencing DNA from cells in a biopsy to look for cancer, for example, or to determine the genetic identity of bone fragments at an archaeological dig. The company demonstrated that MinION has sequenced a simple virus called Phi X, which contains 5000 genetic base pairs. This is merely a proof of principle – "Phi X was the first DNA genome to be sequenced ever," said Nick Loman, a bioinformatician at the Pallen research group at the **University of Birmingham, UK**, and author of the blog Pathogens: Genes and Genomes. But it shows for the first time that this technology works, he says. "If you can sequence this genome you should be able to sequence larger genomes." Oxford Nanopore is also building a larger device, GridION, for lab use. Both GridION and MinION operate using the same technology: DNA is added to a solution containing enzymes that bind to the end of each strand. When a current is applied across the solution these enzymes and DNA are drawn to hundreds of wells in a membrane at the bottom of the solution, each just 10 micrometers in diameter. Within each well is a modified version of the protein alpha hemolysin (AHL), which has a hollow tube just 10 nanometers wide at its core. As the DNA is drawn to the pore the enzyme attaches itself to the AHL and begins to unzip the DNA, threading one strand of the double helix through the pore. The unique electrical characteristics of each base disrupt the current flowing through each pore, enough to determine which of the four bases is passing through it. Each disruption is read by the device, like a tickertape reader.

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