

HeartLight EAS lights the way for catheter ablation of AF

By AMANDA PEDERSEN

Medical Device Daily Senior Staff Writer

A company known to use the slogan “see what you ablate, ablate what you see” at tradeshows has made large strides lately towards enabling electrophysiologists to do just that. The company has developed an atrial fibrillation catheter ablation system that incorporates, for the first time, an endoscope for direct visualization of a beating heart, in real-time and without radiation.

CardioFocus (Marlborough, Massachusetts) reported that a new study in the *Journal of Cardiovascular Electrophysiology* demonstrates the high acute and chronic success rates achievable with a single AF ablation procedure using the HeartLight Endoscopic Ablation System (EAS). The study was conducted by Boris Schmidt, MD, and colleagues at **Cardioangiologisches Centrum Bethanien**
See CardioFocus, Page 5

RSA beads could give insight into hip, knee implant failures

By OMAR FORD

Medical Device Daily Staff Writer

A new tracking method for patients with hip and knee implants can give greater insight on why some of these devices fail after they are implanted. The method which uses radiostereometric analysis beads (RSA), is being used by the **Midwest Orthopedics at Rush** (MOR; Winfield, Illinois) physicians, to monitor if a replacement implant is wearing down or moving.

The procedure, performed at **Central DuPage Hospital** (Winfield, Illinois) also provides the world’s first RSA registry for implants that allows scientists to collect data on materials and designs used for hip and knee replacement prostheses. A recently published study conducted in the Netherlands showed a 22 to 35% reduction in the number of revisions of RSA-tested total knee replacements as
See Implants, Page 6

International report

Mobile MIM issued device license by Health Canada

A Medical Device Daily Staff Report

MIM Software (Cleveland), a provider of medical imaging software, reported that Mobile MIM has been issued a medical device license by Health Canada for the addition of remote diagnostic X-ray and ultrasound viewing, as well as radiation treatment plan review and approval.

Mobile MIM 3.0 is now available on the Canadian Apple App Store for the iPad, iPhone, and iPod touch. The app includes sample images to demonstrate its expanded functionality.

Radiation oncologists can use Mobile MIM to review dose volume histograms, isodose curves, contours, and images for treatment plans – actions commonly restricted to a limited number of dedicated workstations. “Mobile
See International, Page 7

Washington roundup

DePuy: no more custom device sales after FDA warning letter

By MARK McCARTY

Medical Device Daily Washington Editor

The underlying issue may be a question of semantics, but the outcome of the Dec. 8 warning letter to **DePuy Orthopaedics** (Warsaw, Indiana) requires no finesse to comprehend. FDA said in the letter that the firm’s orthopedic device components that are based on orders placed by surgeons do not qualify as custom devices, and in a Jan. 19 e-mail to *Medical Device Daily*, the company said it has decided “at this time not to provide custom devices.” The dynamic has at least one orthopedic surgeon lamenting FDA’s strict enforcement of regulations because some patients are waiting months for implants that will fit their anatomies, if they get those implants at all.
See Washington, Page 8

Don’t miss today’s MDD Extra: Diagnostics

INSIDE:

TERUMO AMERICAS HOLDING TO ACQUIRE ONSET MEDICAL 2
MAYO, EXACT CANCER SCREENING TEST OBTAINS FAVORABLE RESULTS 3

AHC Media

*Deals roundup***Terumo Americas Holding to acquire Onset Medical****A Medical Device Daily Staff Report**

Terumo Americas Holding (Somerset, New Jersey), said that it has acquired **Onset Medical** (Irvine, California), a company that focuses on developing access sheath technology designed for multiple, minimally invasive clinical applications in cardiology and urology. Details of the transaction were not disclosed.

Terumo customers will have access to Onset's complete product lines. The SoloPath balloon expandable transfemoral and Transseptal catheters' expandable and collapsible sheath technology allows TIS to enter the global structural heart and aneurysmal repair markets, providing an access platform for complex, large-bore procedures including Transcatheter Aortic Valve Implantation (TAVI), Thoracic Endovascular Aortic/Aneurysm Repair (TVAR) and Endovascular Aneurysm/Aortic Repair (EVAR). The Pathway balloon expandable PCNL sheath and Pathway balloon expandable ureteral access sheath provide physicians with a one-step option for performing procedures such as Percutaneous Nephrolithotomy in the removal of large renal calculi (kidney stones).

"We welcome Onset to the Terumo family and look forward to providing our customers with current and future products based on the exciting CDT platform, which represents a tremendous complement to our overall value proposition as the leaders in entry site management and lesion access," said James Rushworth, senior VP and GM, Terumo Medical and president, Onset Medical. "CDT literally changes the way physicians enter the vascular system and manage the access site, while allowing them to achieve easier, safer access to the target

lesion in a variety of clinical applications. This strategic acquisition reinforces our commitment to pursuing unique technologies that meet the specialized needs of our customers and contribute to better outcomes for their patients." ■

*HIT roundup***Arnot Ogden to implement SIS Anesthesia solution****A Medical Device Daily Staff Report**

Surgical Information Systems (SIS; Atlanta) said that **Arnot Ogden Medical Center** (Elmira, New York) has expanded its relationship with SIS by selecting SIS Anesthesia to complement its current SIS perioperative record.

Arnot Ogden Medical Center is a not-for-profit, 256-bed medical facility serving Southern New York and Northern Pennsylvania. The SIS Anesthesia solution will reside on a shared database with Arnot's currently implemented SIS perioperative system for seamless integration of anesthesia and surgical documentation.

Arnot Ogden first implemented the SIS perioperative system in 2009, with that implementation including SIS Analytics, a surgery-specific business intelligence tool enabling decision makers to review and analyze information for trends, opportunities, and risks.

The facility will implement SIS's anesthesia information management system (AIMS), SIS Anesthesia, as well as SIS Analytics Anesthesia View, a turnkey anesthesia-focused business intelligence tool. According to SIS, anesthesia-specific business intelligence enables anesthesia providers to significantly enhance their data capture capabilities with intuitive, graphical data analysis of key business indicators such as anesthesia times, surgical times, and outcomes by caregiver. ■

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Agreements/contracts**Mayo, Exact cancer screening test obtains favorable results****A Medical Device Daily Staff Report**

Results of two studies suggest that a new, investigational colorectal cancer screening test developed in a collaboration between **Mayo Clinic** (Rochester, Minnesota) and **Exact Sciences** (Madison, Wisconsin) is highly accurate and significantly more sensitive than other noninvasive tests at detecting precancerous tumors (adenomas) and early-stage cancer. These findings have implications for clinicians and tens of thousands of Americans. Early detection is a key driver of better outcomes for colorectal cancer – a disease that affects 1 in every 17 persons and is the second-leading cause of U.S. cancer deaths.

The first study, to be published in the February issue of *Gastroenterology*, shows that a new multi-marker stool DNA test is highly accurate at detecting precancerous polyps and early-stage colorectal cancer. This is the first large-scale, blinded study to measure the new test's effectiveness. The second study, to be published in the March issue of *Clinical Gastroenterology and Hepatology*, shows that the stool DNA test is significantly more accurate than a new plasma test for identifying patients with large precancerous polyps or colorectal cancer, while delivering fewer false-positive results.

"Our findings in these studies underscore the great potential of the stool DNA test as a colorectal cancer screening tool," said lead author David Ahlquist, MD, of Mayo Clinic, principal investigator of both studies. "Along with its high accuracy, this test approach could improve participation rates due to its patient-friendly features. The test is noninvasive; requires no bowel preparation, medication restriction, or diet change; and can be performed on mailed-in samples without the need, expense, or inconvenience of a health care visit."

The stool DNA test works by finding signature genetic markers in stool samples mailed in by patients. A positive test would be followed by a colonoscopy to remove the polyps and prevent a subsequent cancer from forming, Ahlquist said.

Mayo Clinic has licensed intellectual property to and is a minor equity investor in Exact Sciences.

In other agreements/contracts news:

- **Terumo Cardiovascular Systems** (Ann Arbor, Michigan) has entered into an exclusive agreement with **LAAX** (Livermore, California) to distribute the TigerPaw System II, a left atrial appendage closure device.

The TigerPaw System II is indicated for occlusion of the left atrial appendage under direct visualization, in conjunction with other open cardiac procedures. It is new to the market following successful completion of a clinical trial. During its clinical trial the TigerPaw System II provided 100% occlusion at both post-op and at 90 days.

Clarification

In the January 18 story, "Private companies make their pitches to receptive audience," the figures in the table reflect Bausch + Lomb's 2011 plan and the company's CEO Brent Saunders indicated that results were on target to beat plan on the sales line, and based on trailing twelve month results through September, on the EBITDA line as well. The company indicated that the 2011 EBITDA figure should have been \$548 million.

Terumo Cardiovascular Systems makes medical devices for the cardiac surgery market and is the U.S. distributor for Vascutek Vascular Grafts. LAAX is a medical device company that makes technology for the effective occlusion and/or exclusion of the left atrial appendage.

- **Magellan Health Services** (Avon, Connecticut) and **VHS Phoenix Health Plan**, a subsidiary of **Vanguard Health Systems** (Nashville, Tennessee) have entered into a joint venture to bring together their behavioral health and medical management capabilities to manage integrated care in a holistic manner to better serve individuals with serious mental illness in the state of Arizona.

The joint venture, to be called Magellan of Arizona, will respond to a request for proposal (RFP) that is expected to be released by the state of Arizona in 2012 to manage behavioral health services for the general Medicaid population and integrated behavioral and physical health care for recipients with serious mental illness in Maricopa County. The RFP will likely address management services for the population currently served in Maricopa County by Magellan under its current contract which is set to expire on Sept. 30, 2013.

The joint venture will be structured with Magellan Health Services of Arizona owning 80% of the entity and Phoenix Health Plan owning the other 20%.

Magellan Health Services is a healthcare management organization. Vanguard Health Systems owns and operates 28 acute care and specialty hospitals and complementary facilities.

- **Nordion** (Ottawa) has signed a six-year contract to supply cobalt-60 to **Synergy Health** (Bedlington, UK), a contract sterilization service company. The contract extends until Oct. 31, 2017.

Cobalt-60 sources are used to sterilize more than 40% of the world's single-use medical devices and supplies, such as syringes, medical gowns, gloves, and masks. Gamma sterilization can also prevent the spread of food-borne illness and harmful agricultural pests by destroying microorganisms in foods.

Nordion makes gamma sterilization technologies, and offers a reliable supply of cobalt-60, complete cobalt lifecycle support, expert design, construction and maintenance of commercial irradiators, technical training and new application research and development. The company also makes medical isotopes, targeted therapies and sterilization technologies. ■

*Court report***Stryker reaches \$15M settlement in illegal OP-1 marketing case***A Medical Device Daily Staff Report*

Stryker (Kalamazoo, Michigan) reported that its **Stryker Biotech** (Hopkington, Massachusetts) unit has reached a settlement with the U.S. Attorney's Office for the District of Massachusetts. As part of the settlement, Stryker has agreed to plead to one misdemeanor charge and pay a non-tax deductible fine of \$15 million. The company said the payment will reduce its fourth-quarter and full-year profit by about 3 cents per share.

As a result of this resolution, the Department of Justice has agreed to dismiss all thirteen felony charges against Stryker Biotech contained in a 2009 federal grand jury indictment. Stryker had previously disclosed in March 2009 that its Biotech division was the target of a federal grand jury investigation being conducted by the U.S. Attorney's Office for the District of Massachusetts. With today's announcement, Stryker said it believes it has realized its goal of obtaining an appropriate resolution of this matter.

The company reported in 2009 that the U.S. Attorney's Office for the District of Massachusetts had filed a grand

jury indictment that included 13 felony charges against Stryker and several executives, including Mark Philip, the former president of the business. Federal prosecutors said the company engaged in an illegal marketing scheme to promote its OP-1 spinal implant and bone putty, which are used to stimulate bone growth. The FDA approved the products under a humanitarian device exemption, meaning they could not be sold for profit and could be used in the treatment of only one rare condition. The Justice Department said Stryker Biotech advised surgeons to combine the OP-1 products with Calstrux, a bone void filler Stryker makes. That combination of products had never been studied on people, and it had not been approved by the FDA. The mix of products caused "serious medical problems" for some patients, according to the Justice Department.

Stryker Biotech and Philip were also charged with making false statements to the FDA about the number of patients that the company was treating on an annual basis with OP-1 putty. Other charges were filed against sales managers William Heppner, David Ard, and Jeff Whitaker.

Piper Jaffray said it views Stryker's settlement with the Massachusetts Attorney General as favorable and thinks the deal will not have a material impact on the company's operations. Piper also noted in an analyst note that it finds Stryker shares attractive at current levels and keeps an Overweight rating on the name. ■

*Financings roundup***Bioconnect aims to raise up to \$10M in 'B' round***A Medical Device Daily Staff Report*

Bioconnect Systems (Ambler, Pennsylvania), developer of the Optiflow vascular anastomotic system, is reportedly looking to raise up to \$10 million in a Series B financing round.

The company's Optiflow system is designed to enhance a surgeon's ability to create precise vascular connections. The initial indication is the creation of an arteriovenous fistula needed for vascular access in hemodialysis patients. The system was approved in Europe in 2010 (*Medical Device Daily*, Sept. 22, 2010).

Bioconnect's venture capital investors include Fidelity Bioscience, Cardinal Partners, and MentorTech Ventures.

In other financing activity:

- **Sky Foundation** (Bloomfield Hills, Michigan), a non-profit organization that aims to raise awareness and funds research for the early detection of pancreatic cancer, said it raised about \$111,000 in 2011, bringing the total raised since its inception in 2008 to nearly \$340,000.

The Foundation's goal is to fund research to develop an advanced blood screening test identifying antibodies indicating a malignancy in the pancreas. The antibodies will be used as diagnostic markers that aid in the early detection

of pancreatic cancer.

Sky Foundation raised the money in a variety of ways: at its annual brunch in November, and through individual gifts, memorial donations, and smaller fundraisers.

- **Community Health Systems** (Franklin, Tennessee) said it intends to seek consent of lenders to amend its existing senior secured credit facilities to allow for the extension of a portion of its non-extended term loans on similar terms to its existing extended term loans, among other amendments. The extended loans will be subject to modified interest rates.

- **Sequenom** (San Diego) said it intends to offer and sell, subject to market and other conditions, shares of its common stock in an underwritten public offering. There can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering.

Jefferies & Co. is acting as sole book-running manager for the offering.

Sequenom is a life sciences company committed to improving healthcare through revolutionary genetic analysis solutions. ■

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CardioFocus

Continued from Page 1

(Frankfurt, Germany), and was recently published online.

In addition to the endoscope for direct visualization, the HeartLight EAS also includes a compliant, dynamically adjustable balloon catheter designed for improved contact with the pulmonary vein (PV) ostium (opening) irrespective of the individual patient anatomy, and utilizes laser energy for more efficient, durable and precise ablation treatment.

In the study, "Visually Guided Sequential Pulmonary Vein Isolation: Insights into Techniques and Predictors of Acute Success," physicians performed ablation with a single HeartLight EAS and single transseptal puncture on 35 patients with drug-refractory paroxysmal or persistent AF. PV isolation was achieved in 70% (96/137) of veins with an initial ablation. After assessment with a circular mapping catheter, continued ablation with the same HeartLight EAS device resulted in an overall 98% single procedure PV isolation rate.

Stephen Sagon, president/CEO of CardioFocus, told *Medical Device Daily* the study results were "better than expected."

Procedures were performed in a mean time of 154 ± 38 minutes with the ablation stage lasting an average of 89 ± 16 minutes and mean fluoroscopy time of 16 ± 6 minutes. Notably, between the first and last 12 cases a reduction in procedure time was observed (175 ± 48 minutes compared to 138 ± 26 minutes). The primary efficacy endpoint of the study was acute PVI, with a secondary endpoint of freedom from AF between 90 and 365 days post-ablation and off antiarrhythmic drugs. During a median follow-up of 266 days, 77% of patients (27 out of 35) remained free of any tachyarrhythmia recurrence and off drugs.

"In this study, physicians have demonstrated a high rate of clinical success achievable within a reasonably short procedure time, even among operators still in the midst of the learning curve," Sagon said. "This reinforces the advantages of HeartLight EAS' novel, adaptable and user-friendly design, and we look forward to continued positive experiences from this and other medical centers as they begin to standardize and master this ablation approach."

The company recently received a nod from the FDA to move forward with its investigational device exemption study in the U.S., Sagon said. The device was approved in Europe nearly three years ago (*Medical Device Daily*, July 9, 2009).

"Pulmonary vein isolation is a critical indicator of success in catheter ablation procedures for AF. However, this has traditionally been a very challenging and complex endeavor requiring an experienced operator, multiple ablation devices to account for varied patient anatomy, and even multiple transseptal punctures for access," Schmidt said. "In this study we set out to examine the feasibility of performing a streamlined, visually-guided ablation procedure and record best practices to achieve endpoints

of acute and chronic success. Our findings demonstrate that this unique approach to ablation may prove highly effective in treating AF patients."

With the increasing use of catheter ablation as a treatment option for AF patients, the short learning curve and simplified approach enabled by the HeartLight EAS makes it a "very promising system," Schmidt said, "especially as the technique continues to be adopted outside specialized ablation centers. In the paper, Schmidt and his colleagues documented their approach to performing ablation on the center's first series of patients to undergo treatment with the HeartLight EAS. He added that as the procedure continues to be standardized, additional centers will experience "these impressive, reproducible results."

CardioFocus secured \$5 million in debt financing last year from Silicon Valley Bank to initiate its pivotal trial in the U.S. and expand commercialization in Europe (*MDD*, March 22, 2011).

Previously the company had reported raising a \$215 million Series C round led by H.I.G. Ventures and KBL Healthcare Ventures with participation from Accuitive Medical Ventures, The Aurora Funds, Oxford Bioscience Partners and SV Life Sciences (*MDD*, April 25, 2006).

Sagon told *MDD* that the current take at academic meetings is that ablation results for treating AF are "not as durable as people had hoped." His company's approach to visual-guided ablation appears to be offering better durability with a shorter learning curve.

"I think if you're an electrophysiologist who is used to doing procedures that take many hours with lots of radiation exposure and getting mediocre results, this is a breath of fresh air," Sagon said. ■

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People in the News

- **Health Evolution Partners** (HEP; San Francisco) said Barry Smith has joined the firm as operating partner. Smith founded and served as chairman, president/CEO of VistaCare. Health Evolution Partners is a healthcare buyout firm.

- Ronald Geary, has joined **IntraHealth International** (Chapel Hill, North Carolina) as VP of finance and administration. Previously, Geary was CFO and treasurer of Jhpiego. IntraHealth International is a global health nonprofit.

- **Toshiba America Medical Systems** (Tustin, California) has named Nader Rad as VP and general counsel. Rad joined Toshiba in 1990 as associate general counsel and since then has served as deputy general counsel and general counsel before this latest promotion. Toshiba America Medical Systems makes diagnostic imaging systems, and coordinates clinical diagnostic imaging research.

Implants

Continued from Page 1

compared with non-RSA-tested total knee replacements in the national joint registries.

Scott Sporer and Wayne Paprosky, both MOR hip and knee orthopedic surgeons, are the first in the country to implant all compliant patients with RSA

“Essentially, RSA is a technology that allows us to monitor very closely the motion or migrations of joint replacement implants,” Sporer told *Medical Device Daily*.

The RSA analysis process is a team effort between the physicians and **Halifax Biomedical** (Mabou, Nova Scotia), the company that developed the stereo radiography technology. Once the beads, or biomarkers, have been inserted by the physicians into the bone surrounding the implant, two or more pairs of stereo X-ray images are taken and sent to Halifax Biomedical. Technicians use visual assessment software to monitor the position of the biomarkers in relation to the implants. A detailed report is then generated showing the stability of the implant.

RSA’s have been used before but not to this magnitude, he noted.

“So it’s something that in the past has been done for different studies specifically prior to the release of implants or immediately thereafter,” Sporer said. “In other words most studies were tailored to 50 patients or so, and the reason for that is because in order to do these studies the implants themselves required that beads be placed in them because it was a custom implant made at the company.”

But Sporer and colleagues are working beyond that issue and will place the tracking beads in virtually every implant they handle.

“Right now we’re using this on all of our elective total knee and total hip replacements,” Sporer said. “Between Dr. Paprosky and my practice its between 1200 and 1300 a year that we anticipate marking.”

RSA technology allows X-rays to be taken from different angles creating a “stereo,” three-dimensional image. Using beads as markers around the implant, RSA helps physicians determine a hip and knee patient’s progress and provides research for future implant design and technology. It also provides insight into the safest and most durable materials for implants.

“There’s new technology out that allows us to use standard implants and so any implant that comes from any orthopedic manufacturer,” Sporer told *MDD*. “It allows us to at the time of surgery, place these small 1 millimeter thick beads around the hip or knee replacement. This will then allow us to track very small amounts of motion.”

He added, “why this is important is because the one thing we’ve found within joint replacement is that implants that move after implantation have a much higher propensity for failure.”

In addition, if a patient complains of pain with an

implant, the tracking technology will give physicians the ability to compare a recent RSA scan to the original scan. If the physician notices instability, he or she can intervene, by possibly performing a surgery to stabilize the implant before more complications develop.

The move to develop this registry comes at a crucial time.

“Right now there’s a bill on the Senate floor that would require implant manufacturers to monitor implants after they are released,” Sporer said.

The proposal is an effort to address complaints by patient advocates and others about the 510(k) process that the FDA uses to clear the sale of certain implants like artificial joints.

“The problem is that what we see in the wear simulators and the laboratory don’t always correlate to what happens in the patient,” Sporer told *MDD*. “The hope would be to pick these failures up at a much earlier time frame.”

In the future, he said that he hopes to see the RSA registry spread nationwide.

“My hope is that at some point we can have a national registry where we could have multiple RSA centers and see data trends much quicker,” he said. ■

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Med-Tech Notes

ITA Partners changes name to eviti

ITA Partners (Philadelphia) has officially changed its company name to **eviti**. The company says the new name reflects its transformation to a health information technology business delivering web-based decision-support services to improve the quality of cancer care and reduce cost – beyond oncology pathways.

“Our customers have come to associate eviti with quality oncology treatment intelligence. In fact, payers using the eviti platform have seen the use of non-evidence-based, non plan-compliant care substantially decrease to less than 10% from historic levels between 32% and 41%,” said Eduardo Beruff, president/CEO, eviti. “This name change reflects eviti’s growing national prominence as evidenced by the 4,200 oncologists already registered to use the eviti platform.”

The eviti platform aligns physician, payer and patient priorities at the point of clinical prescribing to ensure the most appropriate, evidence-based oncology treatment is selected from the start. eviti’s independent, non-proprietary digital oncology treatment library comprises more than 1100 of the most appropriate, proven treatment options and thousands of clinical trials, covering all modalities for more than 120 cancer types.

International

Continued from Page 1

MIM provides a timesaving alternative to treatment plan review and approval by providing the necessary data and visualization for decision making while simultaneously reducing contention on costly treatment planning systems," said Jeremy Brockway, Software Director at MIM.

"Making Mobile MIM intuitive for radiation oncology was a primary goal, and we focused on creating the most natural and streamlined experience possible. The feedback so far has been overwhelmingly positive," commented Brockway.

"Not to be overlooked is the advent of viewing an X-ray on a handheld device in a diagnostic capacity. This is a milestone for mobile health," added Brockway. Mobile MIM is capable of displaying very large images, more than 25 megapixels, with lossless data compression.

Mobile MIM is a thick client that brings the data to the device for fast and consistent manipulation, independent of network performance. Device-level hardware encryption provides security for HIPAA compliance, and users have the additional security option of removing data from the device after viewing. For rapid access, images are displayed as they download. Data can be downloaded to Mobile MIM using MIMcloud or an on-site MIM workstation.

With the release of Mobile MIM 3.0, MIM Software also plans to launch a co-branded version of the app with its partner Accuray Incorporated. The co-branded Accuray version of the app, PlanTouch, will have an interface that allows physicians to review and approve a CyberKnife treatment plan via a direct link.

MIM Software provides practical imaging solutions in the fields of radiation oncology, radiology, nuclear medicine, neuroimaging, and cardiac imaging. MIM offers solutions for PC and Mac workstations, as well as mobile iOS and cloud-based platforms. MIM is a privately held company that sells its products globally to imaging centers, hospitals, specialty clinics, research organizations, and pharmaceutical companies.

SonoCiné granted Health Canada license

SonoCiné (Reno, Nevada), a maker of automated whole breast ultrasound (AWBU) screening systems for early detection of breast cancer, reported that it has been granted a Class 2 Medical Device License by the Medical Devices Bureau of Health Canada to sell and market its Automated Whole Breast Acquisition Screening System (AWBASS) as an adjunct to mammography for screening asymptomatic women for breast cancer.

The AWBASS is an accessory to already approved ultrasound scanners, providing computer controlled automatic acquisition and subsequent dynamic review of closely spaced consecutive 2-D images of the entire breast and lower axilla. The integration of SonoCiné AWBASS and a standard ultrasound scanner forms an Automated Whole Breast Ultrasound (AWBU) screening system.

The SonoCiné system received FDA 510(k) clearance in the U.S. in 2008 as an adjunct to mammography, but not a replacement for screening mammography.

"We are very pleased that we can now move forward and make the SonoCiné breast cancer screening examination available to the women of Canada," commented Karsten Damgaard-Iversen, CEO of SonoCiné, and added, "To date more than 18,000 breast screening examinations have been performed using the SonoCiné system, and our users continue to report on the high cancer detection and low recall rates that our proprietary image acquisition and dynamic review process enables them to consistently achieve."

The SonoCiné system was invented and engineered specifically for integration with standard ultrasound scanners to provide radiologists with an effective, systematic and automated screening examination for the early detection of mammographically occult breast cancers in asymptomatic women.

The high cancer detection performance reported by clinical users of AWBU is the result of a number of important system characteristics. These include separating the image data acquisition from the radiologist's review, automating and computer-controlling the screening of the entire breast and lower axillary lymph nodes, and maximizing lesion visualization and detectability using the company's proprietary dynamic review software. The risk-free procedure is fully documented, quality-controlled and pain-free.

Unlike mammography, the SonoCiné AWBU procedure requires no breast compression or X-ray radiation, and unlike MRI and MBI/BSGI, it requires neither a contrast agent, nor a radioactive tracer.

BGS use first clinical TrueBeam STx in Asia

Doctors at BGS Global Cancer Institute at **BGS Global Hospitals** (Bangalore, India) have begun delivering advanced radiotherapy treatments using the first clinical TrueBeam STx medical linear accelerator in Asia. A 57-year-old female patient with a brain metastasis received whole brain radiotherapy and this will be followed by stereotactic radiosurgical boosts to the lesion using the fast and precise system.

"The whole procedure, the imaging and treatment, was completed within five minutes," said Nirmala Srikantia, MD, senior consultant and chief of radiation oncology services at BGS Global Cancer Institute. "TrueBeam STx gives our oncologists the flexibility to deliver multiple high precision treatments such as this while minimizing the time required and, potentially, the inconvenience to the patient."

"The new system's advantages of speed and precision will help benefit our patients in receiving timely treatments. Our specialists will be able to offer high quality treatments to more patients and deliver them more quickly than has

See International, Page 9

Washington

Continued from Page 1

The warning letter to DePuy lists a series of devices implicated in the citation, including several components of the PFC Sigma knee system, the Agility ankle prosthesis, Global humeral stems and TriFlange acetabular cups, and the warning letter says that DePuy was “utilizing existing lines of products” that have been either approved or cleared “to manufacture these [custom] devices.”

The agency added that the definition of a custom device “does not include a quantitative limit or quantitative allowance,” adding that the devices listed in the warning letter “do not deviate from generally available devices or from applicable performance standards.” The agency sought to clarify with the passage, “although the devices’ size and shape may vary with each patient’s anatomy, the standardized design characteristics do not vary among the devices manufactured.”

FDA added the passage “the fact that the final specifications are tailored to match a patient’s anatomy does not preclude [the need for] a clinical study or submission of a marketing application.”

The warning letter cited the relevant passage from the regulations (21 CFR 812.3(b)), which says that in order for a device to be deemed a custom device, it “necessarily deviates from devices generally available or from an applicable performance standard or pre-market approval requirement in order to comply with the order of an individual physician or dentist.” Among the other requirements cited are that the device is “not generally available to, or generally used by, other physicians or dentists” and is “not generally available in finished form for purchase or for dispensing upon prescription.” The regulations also stipulate that such a device “is intended for use by an individual patient named in the order of a physician or dentist, or is intended to meet the special needs of a physician or dentist, in the course of professional practice.”

In its statement to *Medical Device Daily*, DePuy remarks that custom medical devices “have been an allowed exemption to FDA pre-market review . . . since 1976,” adding that while the company “believes it had complied with FDA requirements,” it would nonetheless put a halt to the practice of providing custom devices.

William Mihalko, MD, of the **Germantown Clinic** (Germantown, Tennessee) told *Medical Device Daily* that he can see both sides of this debate. Speaking on behalf of the **American Academy of Orthopedic Surgeons** (AAOS; Rosemont, Illinois), Mihalko also said the question of customization can be captured by more than one scenario.

“Sometimes [the product in question is] a product that they make, but that we’re asking for a smaller size or a variation of, and sometimes these are modular so that one piece is customized but what it is attached to is a standard product.”

“Sometimes we ask them to build something off a CT

scan that is absolutely unique for an individual patient, and that’s where FDA want’s their customizable definition to fall into,” Mihalko continued, adding that FDA would prefer that “it can be used uniquely for one patient, so that if you do a variation on an implant, you can use it only one time” for that specific patient.

Mihalko noted that manufacturers standardize their implant sizes knowing the percentage of the patient population those sizes will cover, but for some patients, “I go to the company and say I need this hip stem . . . in a smaller size.” At that juncture, FDA tells the manufacturer “they can make one of those at that size for someone and if they do it again,” it becomes a 510(k) or PMA, he said.

“I understand FDA’s concerns. They don’t want this to become a back-door approval process,” Mihalko remarked, “but no company is going to go through a 510(k) to sell 50 of these things, so now what do we do?”

Doctors are face-to-face with the small percentages of patients who can’t accommodate a standard size. Mihalko said, asserting, “there are patients whose needs are falling through the cracks,” a group that includes children with severe arthritis and bone cancer patients whose bodies are unusual in some dimension, such as bone length.

Industry “is kind of reeling back understandably” from customization, Mihalko said, “because they don’t want their hands slapped for meeting our needs,” and doctors “are caught between meeting our patients’ needs and [device makers] getting approvals.”

“I’ve heard from a hospital for special surgery” regarding a patient who needed a customized total elbow “and they couldn’t get it through” FDA, Mihalko stated. “It was specific to the anatomy and FDA’s response was that any 510(k) can be addressed in 90 days, but that’s not always the case.”

“Often we’re waiting months and months getting these patients into the operating room” because of this dynamic, Mihalko said. He said doctors are often “caught between FDA wanting to be certain everything is safe . . . and addressing each patient’s needs.”

“We understand where FDA is coming from, but there are these cracks, and regulations can’t cover all scenarios. It would be nice if we had a better option,” Mihalko lamented, noting that companies are saying “we don’t want to take the liability” associated with device customization.

CBO: Medicare demos offer ‘little or no savings’

The great hope for Medicare is that value-based payment (VPB) programs and disease management/care coordination programs will save money, but a recent posting at the director’s blog for the Congressional Budget Office lances that balloon with a posting stating that most such programs have had anything but a positive effect on Medicare spending.

The Jan. 18 blog posting says that CBO analyzed data from “10 major demonstration programs,” consisting of six

See Washington, Page 9

Covidien reports no injury from recalled BIS sensors

A Medical Device Daily Staff Report

In November 2011, **Covidien** (Mansfield, Massachusetts) initiated a voluntary recall of certain lots of its BIS Bilateral Sensors, due to a modification which inadvertently reversed the reference and left eye electrode. This modification could potentially cause a change in the performance of BIS monitoring systems when these sensors are used, resulting in the inaccurate calculation and presentation of processed EEG information for Bispectral Index (BIS), Density Spectral Array (DSA), and Asymmetry (ASYM) values.

The company reported that, to date, there have been no reports of patient injury related to the recalled products. The voluntary recall only affects lot numbers manufactured during a specific period of time. Only BIS Bilateral Sensors from the 58 lot numbers listed below are affected by this action.

Healthcare professionals and customers may report adverse events or quality problems experienced with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or by phone.

Product Briefs

- **Agfa HealthCare** (Mortsel, Belgium) received FDA clearance to market its DX-M computed radiography digitizer with needle-based detectors. The DX-M comes with Agfa HealthCare's Musica2 advanced image processing software and supports general radiography as well as digital mammography, according to the Mortsel, Belgium-based company. The DX-M can be used as a centralized or decentralized digitizer in the radiography department, supporting general radiography as well as digital mammography. As the reader unit can also be used with general radiography detectors, the DX-M is ideal for healthcare operations with a tight budget that wish to achieve high image quality in their X-ray imaging. The DX-M comes with Agfa HealthCare's MUSICA2 advanced image processing software for consistently high image quality and enhanced details.

- **Biotectix** (Ann Arbor, Michigan) reported the first-in-human (FIH) use of an electrostimulation device using its BT DOT conductive polymer coating technology. Patients were surgically implanted with novel gastric stimulation devices using electrodes coated with Biotectix's material. The company believes the FIH achievement represents a significant step toward commercialization of a core Biotectix product, BT DOT. The trial is the culmination of several months of activity with the device partner, from initial development and demonstration of the BT DOT coating on prototype designs *in vitro* to completion of stability, sterilization, and

International

Continued from Page 7

been possible in the past," added Srikantia.

Designed to advance the treatment of lung, breast, prostate, gynaecologic, liver, head and neck, and other types of cancer, the TrueBeam platform is made by **Varian Medical Systems** (Palo Alto, California). Initial TrueBeam STx treatments at BGS Global Hospitals will focus on brain, head & neck, gastro-intestinal and gynaecologic cancers using advanced techniques such as IMRT. The team intends to commence stereotactic radiosurgery treatments by the end of January.

Global Hospitals has acquired three TrueBeam STx systems – ordered in 2010 – for its sites in Bangalore, Chennai and Mumbai, because of the rapidly increasing cancer incidence in these major population centers, along with the strength of the neuroscience departments in those hospitals. ■

Washington

Continued from Page 8

disease management/care coordination programs along with four VBP demonstrations, and the conclusion drawn by CBO is that "most programs tested in those demonstrations have not reduced federal spending on Medicare."

Regarding the 34 programs that fall into the disease management/care coordination demonstrations, CBO said they had "little or no effect on hospital admissions" on average, although there was "considerable variation in the estimated effects among programs."

Still, CBO notes, "in nearly every program, spending was either unchanged or increased relative to the spending that would have occurred in the absence of the program" after tallying the fees paid to participating providers. The blog posting acknowledged that the programs that relied heavily on direct interaction between care managers and physicians had a more discernible effect on spending, but that "even those programs did not achieve enough savings to offset their fees."

On the subject of the VPB demo programs, CBO said that only one "has yielded significant savings," a program for bundled payments in connection with bypass procedures, which CBO credits with a 10% reduction in spending. The physician group practice demo, on the other hand, scored poorly, and as was the case with the remaining two VBP programs, "resulted in little or no savings for Medicare." ■

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durability testing. In the final phases, devices suitable for human uses were prepared and necessary IRB documentation was submitted and approved prior to initiation of the study. Treatment of additional patients is anticipated in the coming months.

MDD'S DIAGNOSTIC EXTRA

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

FRIDAY, JANUARY 20, 2012

PAGE 1 OF 2

Keeping you up to date in recent developments in diagnostics

PET imaging agent could improve evaluation efforts of Alzheimer's

. . . Data presented at the 6th Annual **Human Amyloid Imaging** meeting in Miami suggest that the investigational imaging agent [18F] Flutemetamol could add value to current diagnostic tools used by physicians to evaluate neurodegenerative conditions like Alzheimer's Disease (AD). [18F]Flutemetamol is a **GE Healthcare** (Fairfield, Connecticut) PET imaging agent in phase III development for the detection of beta amyloid. Data presented in two abstracts from a clinical trial of [18F]Flutemetamol in patients with suspected Normal Pressure Hydrocephalus (NPH), a progressive condition associated with dementia, gait abnormalities and urinary incontinence, undergoing shunt placement, correlated [18F]Flutemetamol uptake with histopathological tissue biopsies for beta amyloid *in vivo*. In a third abstract from another study, researchers correlated [18F]Flutemetamol uptake and structural Magnetic Resonance Imaging (MRI) in healthy volunteers and patients with a clinical diagnosis of AD or Mild Cognitive Impairment (MCI). "These results support the potential role of [18F]Flutemetamol in helping physicians detect amyloid deposits in the brain," said Jonathan Allis, MI PET Segment Leader, GE Healthcare Medical Diagnostics. "The ability to detect amyloid deposits in the brain could enable physicians to make a more accurate and earlier diagnosis of Alzheimer's Disease." The accumulation of beta amyloid in the brain may play a role leading up to the degeneration of neurons and is one of several biomarkers implicated in the development of AD. Currently, AD is confirmed by histopathological identification of tissue biomarkers, including beta amyloid plaques, in post-mortem brain samples. Targeted imaging agents are being studied to determine their ability to help physicians detect amyloid deposition in live humans. [18F]Flutemetamol is one part of a broad portfolio of diagnostic solutions that GE Healthcare is currently developing in the Alzheimer's field. The company is taking a comprehensive approach to understanding AD through its ongoing research to uncover the causes, risks and physical effects of the disease. GE Healthcare's global commitment to advance clinical knowledge and provide a variety of technologies to aid the fight in this epidemic may assist physicians in the acceleration of diagnosis and improvement of treatment decisions in all stages of the disease.

Proteus Biomedical launches microchip pill . . . Proteus Biomedical

(Redwood City, California) has launched a smart pill with an integrated microchip that tracks patients' adherence to their medication. The Helius system comprises an 'ingestible event marker' (IEM) pill, a sensor patch worn on the body and a smartphone application. The IEM is activated when subjected to water and is powered by a thin-film non-toxic battery. Once activated, the IEM sends a modulated high-frequency electrical signal, using the body as a conduit, to the patch applied to the skin. The system also allows for measurement of the heart-rate, internal body temperature, respiration rate, posture and sleeping patterns. All of this information is relayed via the app to a website that provides statistics in graph form. Thus patients and carers can check their chart to see if they have taken all of their pills or not. The information could also be sent to the doctor who prescribed the medication to see if it's having the desired effect. **The World Health Organization** (Geneva, Switzerland) estimates that 50% of patients fail to take their medicines correctly. This can result in patients not gaining the full benefit of their treatment or worse, being at risk of harmful reactions. Unused prescription medicine is also estimated to cost the NHS in the UK around £396 million a year.

DOES set to improve eye exams for youth . . .

Eighty-five percent of children's learning is related to vision. Yet in the U.S., 80% of children have never had an eye exam or any vision screening before kindergarten, statistics say. When they do, the vision screenings they typically receive can detect only one or two conditions. Three researchers at the **University of Tennessee Space Institute** (Tullahoma) are working to change that with an invention that makes children eye exams inexpensive, comprehensive, and simple to administer. "Eye exams can do so much more than just test vision," said Ying-Ling Ann Chen, device inventor and research assistant professor in physics. "They can detect learning disabilities, such

as dyslexia, or neural disorders such as autism. By not testing our youth, we are potentially missing the window for effective treatment for a lot of conditions." Called the Dynamic Ocular Evaluation System (DOES), the device was developed by Chen; Lei Shi, post-doctoral research associate in laser application; and Jim Lewis, professor emeritus in physics. The researchers hope the device will someday be used in pediatricians' offices across the country, and then expanded to other groups within population. DOES is low-cost, high-quality and operator- and child-friendly. It takes about a minute to train someone to use it. The test is done as the child watches a three-minute cartoon or plays a computer game. Infrared light is used to analyze the binocular condition and the assessment is reported on-site within a minute. Neither eye dilation nor verbal response is required. At the beginning of the cartoon, a three-second comprehensive test screens for binocular refractive risks, high-order aberration, scattering, ocular alignment and significant neural problems. The subsequent dynamic test searches for less significant signs of abnormal ocular alignment, neural responses, amblyopia, and — in the future — mental statuses that include dyslexia, attention deficit hyperactivity disorder, post-traumatic stress disorder and autism. The images and results are digitally recorded and can be electronically transmitted to specialists for referral if necessary. "Vision screening is important at an early age to detect several different causes of vision disorders," said Chen. "The few children that do get screened today aren't being screened adequately. For instance, many current screening methods do one eye at a time and studies show young eyes will accommodate significantly, and this causes inaccurate results." According to Chen, children usually do not visit eye doctors unless their eyes hurt. They do not know if their vision is impaired because they do not know what they should be seeing. By having easy-to-administer comprehensive tests as part of the pediatrician's visit, a lot of vision and vision-related diseases could be avoided or treated more effectively—such as lazy eye and cross eyes, which impacts up to 5% of the U.S. population. "During the critical period of childhood up until about age six, if one eye is not as good as the other, the brain will suppress the communication with that eye, and the vision could be lost permanently," said Chen. "This can cause a condition called amblyopia, or lazy eye, which can be prevented through detection."

New technology takes detailed images of brain . . . A new technology developed by neuroscientists at **Cold Spring Harbor Laboratory** (CSHL; Cold Spring Harbor, New York) transforms the way highly detailed anatomical images can be made of whole brains. Until now, means of obtaining such images - used in cutting-edge projects to map the mammalian brain - have been painstakingly slow and available only to a handful of highly specialized research teams. By automating and standardizing the process in which brain samples are divided into sections and then imaged sequentially at precise spatial orientations in two-photon microscopes, the team, led by Assoc. Prof. Pavel Osten and consisting of scientists from his CSHL lab and the **Massachusetts Institute of Technology** (Cambridge, Massachusetts), has opened the door to making whole-brain mapping routine. Specifically, says Osten, "the new technology should greatly facilitate the systematic study of neuroanatomy in mouse models of human brain disorders such as schizophrenia and autism." The new technology, developed in concert with **TissueVision** (Cambridge, Massachusetts) and reported on in a paper appearing online in *Nature Methods*, is called Serial Two-Photon Tomography, or STP tomography. Tomography refers to any process (including the familiar CAT and PET scans used in medical diagnostics) that images an object section by section, by shooting penetrating waves through it. Computers powered by mathematical formulae reassemble the results to produce a three-dimensional rendering. Two-photon imaging is a type used in biology laboratories, particularly in conjunction with fluorescent biomarkers, which can be mobilized to illuminate specific cell types or other anatomical features. The two-photon method allows deeper optical penetration into the tissue being sampled than conventional confocal microscopy. As Osten explains, STP tomography achieves high-throughput fluorescence imaging of whole mouse brains via robotic integration of the two fundamental steps – tissue sectioning and fluorescence imaging. In their paper, his team reports on the results of several mouse-brain imaging experiments, which indicate the uses and sensitivity of the new tool. They conclude that it is sufficiently mature to be used in whole-brain mapping efforts such as the ongoing Allen Mouse Brain Atlas project. One set of experiments tested the technology at different levels of resolution. At 10x magnification of brain tissue samples, they performed fast imaging "at a resolution sufficient to visualize the distribution and morphology of green-fluorescent protein-labeled neurons, including their dendrites and axons," Osten reports. A full set of data, including final images, could be obtained by the team in 6.5 to 8.5 hours per brain, depending on the resolution.

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