



Heart Rhythm Society

CardioFocus demonstrates notable progress for AF

By LARRY HAIMOVITCH

Medical Device Daily Contributing Writer

SAN FRANCISCO — As discussed in Tuesday’s issue of *Medical Device Daily*, there has been considerable progress in treating atrial fibrillation (AF) with catheter-based technologies in recent years. However, the rate of success, estimated at 57% for a single procedure, is far from satisfactory. Thus, the quest for better methods to perform AF catheter ablation continues at a strong pace. One company, which is demonstrating impressive progress, is privately-owned, venture capital-backed **CardioFocus** (Marlborough, Massachusetts). Two important abstracts that were presented here last week’s at the annual scientific sessions of the **Heart Rhythm Society** (HRS; Washington) demonstrated that the company’s technology could be a

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Deals roundup

PositivelD to pay up to \$8.2M for MicroFluidic

A *Medical Device Daily Staff Report*

PositivelD (PSID; Delray Beach, Florida) said it has agreed to acquire **MicroFluidic Systems** (Freemont, California), a company that produces automated instruments for a range of applications in the detection and processing of biological samples, for up to \$8.2 million.

MicroFluidic has secured more than \$45 million in government contracts, most of which have come from the Department of Homeland Security. PSID says it will initially pay \$12 million, \$950,000 of which will be paid in common stock and the rest in cash. Total potential consideration for the acquisition is \$8.2 million through 2014 based on revenue and earnings targets over a four-year period. This earn-out structure is based on little or no current federal government revenue but with submitted or in-process bids

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International report

Medtronic gets Health Canada okay for CryoAblation System

A *Medical Device Daily Staff Report*

Medtronic of Canada (Brampton, Ontario) has received Health Canada approval of its Arctic Front Cardiac CryoAblation Catheter System, the first cryoballoon in Canada indicated for the treatment of patients suffering from paroxysmal atrial fibrillation (PAF). Cryoballoon treatment involves a minimally-invasive procedure that efficiently creates circumferential lesions around the pulmonary vein, which is the source of erratic electrical signals that cause the irregular heartbeat.

“Cryoballoon technology is a major improvement over the traditional focal approach for the treatment of atrial fibrillation,” said Marc Dubuc, MD, cardiologist and electrophysiologist at the **Montreal Heart Institute**

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Washington roundup

FDA orders 522 studies for hip implants from 21 firms

By MARK McCARTY

Medical Device Daily Washington Editor

FDA has issued an order for 522 post-market studies from 21 companies making hip implants, a move that comes on the heels of a U.S. Senate hearing on medical devices last month. During the hearing, the Senate Special Committee on Aging heard from a patient who had received an implant made by **DePuy Orthopaedics** (Warsaw, Indiana) that had begun to slough off metal particles (*Medical Device Daily*, April 15) from the rotating juncture of the device, a metal-on-metal (MoM) arrangement found in DePuy’s ASR artificial hip.

The MoM configuration is not limited to the DePuy unit, however, as evidenced by the 20 other firms who received

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Don't miss today's MDD Extra: Orthopedics

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*Financings roundup***Sorin Group launches share buy-back program****A Medical Device Daily Staff Report**

Sorin Group (Milan) has launched a share buy-back program, previously authorized by its shareholders in September. The acquisition of Sorin treasury shares will be used in order to service the group's stock grant plan, which includes the management of the company, as well as the CEO/chairman, Sorin noted. The share buy-back program also provides for the purchase of treasury shares to service future stock option plans and for the purpose of stabilizing Sorin's share price, if necessary.

The program provides for the purchase, in one or more tranches, on a revolving basis, of up to 4,704,211 ordinary shares, or other number of shares up to 1% of the share capital, in the event that an increase or a reduction of the company's share capital is adopted.

The shares may be purchased at a price not higher or lower by 10% than the reference price recorded on the stock exchange in the trading session immediately prior to each purchase transaction.

The authorization to acquire treasury shares has been established for a maximum period of 18 months from the resolution of the shareholders' meeting, thus ending on March 14, 2012.

Sorin makes devices for cardiac surgery and for the treatment of cardiac rhythm disorders.

In other financing activity:

- **HealthSouth** (Birmingham, Alabama) said it has amended its credit agreement and added to it a \$100 million term loan maturing in 2016 that will initially bear interest at a rate of LIBOR plus 2.5%. In addition, the current \$500 million revolver maturity will be extended to 2016 and the interest rate spread will be reduced by 100 basis points to an initial rate of LIBOR plus 2.5%.

The company now intends to call \$335 million of the 10.75% senior notes next month, instead of \$285 million previously announced. The roughly \$353 million of cash required to fund this call will be funded using the proceeds of the \$100 million term loan, about \$77 million of cash on hand resulting from the \$120 million senior notes offering in March, and borrowings under the \$500 million revolver. As a result of this transaction and the initial call of the 10.75% senior notes, the company expects interest expense and amortization of debt discounts and fees to be about \$70 million in first half of 2011 and about \$57 million in the second half of 2011.

- **Lantheus Medical Imaging** (N. Billerica, Massachusetts) said it has completed its offer to exchange up to \$150 million in aggregate principal of its currently outstanding 9.750% senior notes due 2017 (initial notes) for an equal aggregate principal amount of its new 9.750% senior notes due 2017 (new notes). The exchange offer expired on Monday. All of the initial notes were submitted for exchange and the company has accepted all of the initial notes validly tendered.

Because the company issued the initial notes in a private placement transaction, they were subject to transfer restrictions. The purpose of the exchange offer was to allow holders of the initial notes to exchange their notes for new notes that did not have these restrictions. Following this exchange offer, the Company will continue to have \$400 million aggregate principal amount of notes outstanding. ■

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*Agreements roundup***Cardinal Health to distribute VerifyNow for Accumetrics****A Medical Device Daily Staff Report**

Accumetrics (San Diego), marketer of the VerifyNow System, the first rapid and easy-to-use point-of-care diagnostic system for measuring platelet reactivity to multiple antiplatelet agents, has signed a national distribution agreement with **Cardinal Health** (Dublin, Ohio) to distribute the system to hospitals, health systems and independent laboratories throughout the U.S.

The VerifyNow System is used by physicians to assess patients' platelet response to various antiplatelet therapies such as aspirin, Plavix and Effient. Accumetrics said up to one in three individuals may not be responding adequately to their antiplatelet therapy, and that patients with poor response may be at significantly greater risk of adverse events.

"We anticipate a more rapid adoption of the VerifyNow System as a result of this agreement with Cardinal Health," said Timothy Still, president/CEO of Accumetrics. "Cardinal's record of outpacing market growth is well-documented."

New recommendations about platelet reactivity testing were recently incorporated into the updated 2011 ACCF/AHA guidelines for the management of UA/NSTEMI patients, as well as the 2011 update to the surgical guidelines for pre-operative patient assessment.

Lisa Ashby, president of Cardinal Health's medical segment, said, "The ability to better determine the effect of therapies for patients is very important to our customers, and we are pleased to include the VerifyNow products as part of our laboratory cardiac offering."

In other agreements news:

- **Molecular Targeting Technologies** (MTTI; West Chester, Pennsylvania) said it has obtained an exclusive license from **Massachusetts General Hospital** (Boston) for novel fluorescence dyes developed by Scott Hilderbrand, PhD; Fangwei Shao, PhD; and Ralph Weissleder, PhD, MD.

"These new dyes can be manufactured very efficiently compared to existing dyes. We envision that these new dyes will be widely accepted by researchers due to their price, brightness and stability," said Brian Gray, VP of research at MTTI.

Hilderbrand, principal investigator at Mass General and **Harvard Medical School** (also Boston), said, "Due to the lack of availability of suitable near-infrared (NIR) imaging agents to address the requirements of our ongoing research, we were driven to develop a new imaging agent platform. The fluorophores of this new platform are highly scalable, are wavelength tuned to operate with commonly available NIR imaging systems, have excellent solution properties, show strong fluorescence, and have improved

photostability."

- **Advocate Trinity Hospital** (Chicago), part of the Advocate Health Care system, has signed an agreement to use **PerfectServe's** (Knoxville, Tennessee) clinical communications system. This is PerfectServe's third contract with the 11-hospital Advocate Health Care System, the largest integrated health system in the state of Illinois and one of the nation's top 10 health systems.

PerfectServe said its system enables hospitals and physician practices to eliminate communication breakdowns and improve the coordination of care. The first two Advocate hospitals to use this system are **Advocate Good Shepherd Hospital** (Barrington, Illinois), and **Advocate Lutheran General Hospital** (Park Ridge, Illinois).

"Our goal is to improve two-way communications among physicians," said Jon Bruss, president of Trinity. "With PerfectServe, we will have a more effective way to keep track of how physicians wish to be contacted, so in turn we can successfully contact them." Dr. Diana Grant, vice president of medical management at Trinity, added, "With our current process, it's very hard for physicians to return calls to patients and other colleagues. We need better doctor-to-doctor communications, and PerfectServe will improve that for us."

- **Auxilio** (Mission Viejo, California), a provider of managed print services (MPS) for the healthcare industry,

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*HIT roundup***Thoratec works with WiTricity for energy transfer technology****A Medical Device Daily Staff Report**

Thoratec (Pleasanton, California), a maker of device-based mechanical circulatory support therapies to save, support and restore failing hearts, reported a technology development agreement with **WiTricity** (Watertown, Massachusetts) relating to WiTricity's proprietary wireless resonant energy transfer technology for application in the field of mechanical circulatory support.

Through a collaborative effort over the past nine months, Thoratec and WiTricity engineers have demonstrated the ability to transfer power wirelessly to a HeartMate II LVAD in order to start and run the pump in a setting that replicates the Fully Implantable Ventricular Assist System (FILVAS) application. Thoratec will provide funding to WiTricity to further optimize its technology for use in a fully implantable HeartMate II system. The agreement provides Thoratec with an option, exercisable at the completion of the development phase, to license the WiTricity technology for incorporation into the company's broader FILVAS program, initially targeted for the HeartMate II platform but with potential future applications in Thoratec's next-generation pump platforms, including HeartMate III and HeartMate X.

"We've been extremely impressed with the WiTricity team and core technology," said Laxmi Peri, Thoratec's VP of research and development. "In particular, we believe the technology can enable user-friendly transcatheter energy transmission in a FILVAS setting, obviating the need for close coupling and perfect alignment between the system components," he added.

WiTricity's technology enables high-efficiency wireless energy transfer, through the use of proprietary resonant coils, with potential applications in numerous industries. By precisely matching and controlling the resonant frequencies of the two coils, the system enables energy to be transferred safely, with minimal loss to extraneous or off-resonant objects.

In other HIT news:

- **QuadraMed** (Reston, Virginia), a provider of healthcare technologies and services, said the New York City Health & Hospitals Corporation (HHC) has signed a five-year, \$20 million agreement to extend maintenance and support for QuadraMed's Electronic Health Record (EHR) solution. Included in the purchase is QuadraMed's Interoperability Package, which consists of software and services to help clients attain Meaningful Use.

A QuadraMed client since the early 90's and an early adopter of electronic health records, HHC recently completed an IT-facility upgrade to QuadraMed's current

5.2 software release of their EHR solution, QuadraMed Computerized-Patient Record (QCPR).

"Serving 13 Million New Yorkers annually, it's critical that NYCHHC employ extremely efficient clinical information systems to enhance patient outcomes while reducing operational costs. As a long-time QuadraMed client and partner for 20 years, we knew we could rely on their software and services to help us achieve our goals. The QCPR database upgrade is an important milestone in our continuing plans to achieve Meaningful Use," said Bert Robles, chief information officer of NYCHHC. "The new Interoperability solution should accelerate the process even further."

- **Forte Research Systems** (Madison, Wisconsin) has released the Spring 2011 version of Allegro CTMS@Site, the clinical trials management system designed exclusively for investigator sites. The company says there is an ever-increasing level of administrative overhead and regulatory exposure for today's investigator sites. In part, this is due to sites taking on more trials at a time when trials are becoming increasingly complex.

"To be competitive and efficient in the current environment, sites need to maintain tighter control over financials, be vigilant with regulatory compliance, achieve status as a preferred partner, streamline operations, and replace paper-based processes," said Srinu Kalluri, founder, president/CEO & chief customer experience services officer at Forte Research Systems.

For Clinical Trials Managers, Allegro CTMS@Site offers more control over the financial viability of their trials. The system comes with a suite of business development tools including a full-featured contact management database, integrated email, and task management tools, all of which help manage and track the contracting process with CROs and sponsors. The six-step, wizard-based budget creation tool is integrated with the protocol calendar as well as the institutional charge master. Managers can determine study feasibility and negotiate more effectively when they have accurate budgets prior to study startup.

- **CareTech Solutions** (Troy, Michigan), an information technology and web products and services provider for more than 180 U.S. hospitals, has unveiled its iDoc Savings Calculator. Located on the company's website, the online tool will estimate annual savings for an organization after it implements the company's document imaging and management solution.

CareTech Solutions' iDoc is a HIPAA compliant document imaging software solution, hosted in a SAS 70 Type II Accredited certified data center that holds the exclusive endorsement of the American Hospital Association. iDoc interfaces with all major business and clinical systems to transform paper and existing electronic medical and business files into one central data repository that can be searched, retrieved, shared and edited on the fly. ■

People in the News

• **GE Healthcare** (Chalfont, UK) reported the addition of two new members of its leadership team. Tom Gentile, currently VP of GE Aviation's Services division, has been named president/CEO of GE Healthcare's Healthcare Systems division. Mike Swinford, currently the services leader for GE Healthcare's North American division, has been named president/CEO of Global Services, a new business. GE Healthcare provides transformational medical technologies and services that are shaping a new age of patient care.

• **OncoSec Medical** (San Diego, California) has named three members to its leadership team. Michael Cross, PhD, a co-founder of OncoSec, was named chief business officer. Caryn Peterson was named VP, regulatory affairs. Peterson previously led worldwide regulatory affairs for Syndax. Veronica Vallejo was named controller and principal financial officer. Vallejo was a senior manager with the accounting firm of Mayer Hoffman McCann. OncoSec Medical's ElectroOncology therapies combine its electroporation delivery technology with chemotherapeutic or novel DNA-based immunotherapeutics.

Court report

Boston Sci gets verdict against Cordis in stent suit

A Medical Device Daily Report

Boston Scientific (Natick, Massachusetts) said a jury in the District Court for the District of Delaware found that **Cordis** (Bridgewater, New Jersey) owed Boston Scientific approximately \$19.5 million for infringing its Jang patent, which covers intellectual property associated with coronary stent technologies. The jury awarded \$18.5 million in lost profits and \$1 million in reasonable royalties to Boston Scientific.

Boston Scientific brought suit against Cordis for patent infringement in December 2009, shortly after the U.S. launch of Cordis' 2.25 mm Cypher Stent. On April 13, 2011 the Delaware Court ruled that, as a matter of law, Cordis infringed Boston Scientific's Jang patent and later found that Cordis' infringement was willful.

"We are pleased to see the jury recognize the value of our intellectual property," said Hank Kucheman, executive VP and group president, Cardiology, Rhythm and Vascular for Boston Scientific. "This is an important outcome in protecting our market position in small-vessel, drug-eluting stents against infringing products." ■

Medtronic names Ishrak as new chairman/CEO

A Medical Device Daily Staff Report

Medtronic (Minneapolis) has named Omar Ishrak as the company's new chairman/CEO, effective June 13.

Ishrak formerly was president/CEO of GE Healthcare Systems, a \$12 billion division of GE Healthcare supported by about 20,000 employees in 120 countries.

"We are delighted to welcome Omar Ishrak as Medtronic's chairman and CEO," said Ken Powell, lead independent director of the Medtronic boards. "Omar is an enormously talented executive with a truly global perspective and a proven track record of driving innovation and growth in the medical technology industry. We are confident he has the leadership credentials and experience to move the company forward, advancing its position as the world leader in the development and application of medical technology to address the global challenges of chronic disease."

Ishrak succeeds William Hawkins, who in December reported his intention to retire from the company (*Medical Device Daily*, Dec. 21, 2010).

"The board would like to thank Bill for a decade of service and leadership during which the company launched several important new technologies, made major investments in quality and innovation, and successfully navigated through an increasingly challenging environment," said Powell.

"I am honored and excited to have the opportunity to lead Medtronic – a great company with a renowned, mission-based heritage of saving and improving lives," Ishrak said. "I have admired Medtronic for many years and believe the company's 60-year history of innovation, unparalleled global footprint and unmatched capabilities present enormous opportunities to improve the health of millions of people worldwide. I look forward to working with the Medtronic team to continue to advance the company as a global healthcare leader."

Agreements

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reported a five-year MPS contract with **MemorialCare Health System** in Southern California that is worth an estimated \$16 million to \$18 million.

The contract includes Long Beach Memorial Medical Center, Miller Children's Hospital Long Beach, the system's corporate headquarters and the Memorial Medical Center Foundation, and will maintain and continue the MPS program under way at Saddleback Memorial campuses in Laguna Hills and San Clemente and Orange Coast Memorial Medical Center in Fountain Valley. MemorialCare Health System is located in both Los Angeles and Orange counties and has more than 1,500 beds, over 10,000 employees and a medical staff in excess of 2,300. ■

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force to be reckoned with in the coming years.

CardioFocus has developed an approach, a visually guided laser balloon (VGLB), primarily addresses paroxysmal (intermittent) AF. It features a 12 Fr deflectable sheath, a compliant and adjustable balloon that can be maneuvered easily into the pulmonary veins, ablative laser energy and direct endoscopic visualization. According to several industry experts that have been spoken to *MDD* in the past, the company's two key attributes are the direct visualization and its compliant balloon. The compliant balloon allows the physician to achieve optimal contact with the oft irregularly-sized pulmonary veins.

Direct visualization is very important because other ablation technologies (mainly radiofrequency) have used indirect X-ray guidance, which can be technically challenging and often results in incomplete isolation (ablation) of the PVs, leading to mediocre success in eliminating the AF.

Vivek Reddy, MD, from **Mount Sinai School of Medicine** (New York) presented the results of the first 200 patients treated in a multicenter clinical setting. A second important study, presented by one of Reddy's colleagues at Mount Sinai, Srinivas Dukkupati, MD, addressed the durability of pulmonary vein isolation.

Reddy presented the results of 200 patients treated at nine clinical sites with 33 operators, showing 78.4% of the PVs isolated on the first attempt, with 98.8% of the PVs isolated with a second ablation. Reddy also reported that the results improved substantially with more operator experience. For example, total procedure time dipped 16% after 15 cases, while fluoroscopy time decreased nearly by half.

Most importantly, after a six-month follow-up for over half the 200 patients enrolled in the study, the single procedure, drug-free rate of freedom from AF was 65%. This compares favorably to the single procedure success rate of 57% from a meta analysis of numerous randomized clinical trials and the less than 50% success rate reported in the PMA trials by both the **Biosense Webster's** (Diamond Bar, California) Thermocool catheter and the **Medtronic** (Minneapolis) Arctic Front cryoablation catheter.

Reddy concluded his presentation commenting that "this favorable experience sets the stage for truly comparative long-term efficacy and safety studies (versus radiofrequency ablation)." Indeed, CardioFocus hopes to initiate a randomized, multicenter trial comparing radiofrequency (RF) to VGLB in the United States in the second half of 2011.

Dukkupati also reported very positive results. This trial, conducted at both domestic and international sites with 56 patients, revealed that 86% of the patients' pulmonary veins were persistently isolated at three months, compared with previous rates of 38% to 57% with the "gold standard," traditional RF ablation.

Additionally, Dukkupati reported in a post-presentation interview that limited 12-month follow-up data on 35

AF imposes significant cost burden

Atrial fibrillation is the most common cardiac arrhythmia and it is widely appreciated that it imposes a significant burden to its patients. A new study now shows that the annual cost per year higher for a patient with atrial fibrillation is \$8,700 a year than one without AF, for a national annual cost of about \$26 billion.

Less than one-fourth of the extra cost in patients with AF was directly attributable to AF, about \$6 billion on a national basis, while almost 40% – more than \$10 billion nationally – was for non-cardiovascular reasons, report the authors, led by Michael Kim, MD, **Northwestern University** (Chicago).

The data, which was published online in the May 3 issue of *Circulation: Cardiovascular Quality and Outcome*, results from a study of payment data from both Medicare and commercial third-party payers.

Total annual direct medical costs were 73% higher for the study's patients with AF compared with an equal number of patients without the arrhythmia. Consistent with their higher cost, those with AF were hospitalized at several times the rate of patients without AF.

"I think it's going to be surprising to people how expensive atrial fibrillation really is," Kim said. "They get hospitalized twice as much in general. They have three times the rate of multiple hospitalizations and four times the number of cardiovascular hospitalizations relative to what is apparently the same group of patients but without atrial fibrillation."

Kim went on to say that atrial fibrillation is not generally seen as a condition that is nearly as costly as heart failure or end-stage renal disease, "but it's still a very expensive problem for our society, and the most expensive reason is cardiovascular hospitalization."

– Larry Haimovitch

patients showed that 71% were free of atrial fibrillation and are not taking anti-arrhythmic drugs.

Addressing the issue of a short learning curve, in the three centers in the study, seven operators performed fewer than 10 procedures, while two performed more than 10. "Even for the less experienced operators, more than three out of four pulmonary veins were isolated at the time of remapping," he said.

Regarding the safety profile, no patients experienced atrial esophageal fistula, stroke, transient ischemic attack or death, while one patient experienced cardiac tamponade and one had phrenic nerve palsy. There also were no cases of significant pulmonary vein stenosis.

Dukkupati concluded that the "visually-guided laser balloon can achieve high rates of acute and durable pulmonary vein isolation safely, even with limited operator experience."

Another company showing substantial progress in the field of AF ablation is **Endosense** (Geneva, Switzerland).

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Deals

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of \$29 million, several of which are expected to be awarded this year, PSID noted.

A 10-year-old company, MicroFluidic has 12 U.S. patents granted, 17 U.S. patents pending, six patent applications in Canada, six patent applications in Europe and four patent applications in Japan. According to PSID, MicroFluidic's IP portfolio related to sample preparation and rapid medical testing applications are complementary to PositiveID's portfolio of virus detection and diabetes management products.

"For years, we have been successful in winning contract awards from the federal government for bio-threat detection," said Allen Northrup, president/CEO of MicroFluidic. "As we look to the future, not only do we intend to continue to pursue those contracts, but we also

intend to commercialize our low-cost alternative PCR testing technology for clinical sample processing and detection that is able to provide results in less than seven minutes for proven applications including environmental bacteria, human papilloma virus and antibiotic resistant bacteria such as MRSA. We believe that becoming a part of PositiveID will significantly help us to accomplish those goals."

In other dealmaking activity, **Terumo Americas** (Somerset, New Jersey), a subsidiary of Japan's **Terumo** (Tokyo), said it has entered into a stock purchase agreement to acquire all the outstanding shares of **Harvest Technologies** (Plymouth, Massachusetts), a biotech company working to commercialize a point of care technology to help physicians derive adult stem cells from patients in just 15 minutes. Financial terms of the deal were not disclosed. ■

Product Briefs

- **3M Infection Prevention** (St. Paul, Minnesota) has introduced its 3M Clean-Trace hygiene management system. This solution is designed to help hospitals assess the cleanliness of a surface and validate the efficacy of cleaning protocols and worker performance in less than one minute. The Clean-Trace system detects adenosine triphosphate (ATP), a substance found in all living cells and present on any contaminated surface. Samples from high-touch surfaces in a hospital, such as bed rails, light switches or nurse call buttons, are collected using the 3M Clean-Trace ATP Surface Test. If the test picks up any organic material (ATP), it will emit light in direct proportion to the contamination level which can be read and quantified by the hand-held 3M Clean-Trace NGi Luminometer. Data collected can be uploaded to the 3M Clean-Trace online software which provides the users advanced data analysis with tracking and full trending capabilities including automatic report generation.

- **Advanced Photonix** (API; Ann Arbor, Michigan) has received a second order from a major manufacturer of extruded web plastic products for a T-Ray 4000 system to be deployed on a factory line for online process control. With the use of its patented fiber coupled transmitters and receiver's technology, API claims to be the first company to commercialize and deploy terahertz technology in a factor floor setting. API's T-Ray technology offers distinct advantages. Not only does it provide all the standard information produced by a nuclear gauge, but also supplies valuable information needed to control both quality and yield. Importantly, this is accomplished without contacting or impeding the manufacturing process. The T-Ray 4000 produces ultra-short pulses of terahertz light that lend themselves to variety of unique and novel applications including the ability to simultaneously determine thicknesses

of multiple layers, the density of individual layers and the detection voids delaminations between layers. The superior signal to noise ratio of the T-Ray platform allows even thick samples to be scanned with the utmost effectiveness.

- **Brainlab** (Munich) has received FDA clearance for its HybridArc radiosurgery planning solution. This software package is designed to enable healthcare professionals to increase the efficiency of existing Linac (linear accelerator) radiosurgery hardware and offer fast, high precision volumetric arc radiosurgery treatment without the need for costly hardware upgrades. HybridArc expands upon the clinically proven and well-established Dynamic Arc stereotactic treatment technique to offer high dose conformity to the target, while sparing nearby organs and offering less residual dose when compared to other techniques such as rotational Intensity Modulated Radiotherapy. HybridArc uses an adaptive dose calculation matrix that takes into account the different parameters affecting dose distribution to provide the necessary precision when opting for stereotactic radiosurgery. By using software automation, HybridArc calculates plans typically within a few minutes. Coupled with reduced treatment times, more patients can potentially benefit from advanced radiosurgery. From planning to patient treatment, HybridArc ensures clinicians can meet the demands of high dose single fraction radiosurgery.

- **Diagnostic Laboratory Medicine** (Bedford, Massachusetts) reported the availability of the AspirinWorks test. The Aspirinworks test is a urine test that measures aspirin effect, and is available in the eastern Massachusetts and southern New Hampshire area. The AspirinWorks test, made by **Corgenix Medical** (Broomfield, Colorado), determines the effect of aspirin on platelets by measuring the level of the biomarker called thromboxane B2. The higher the levels of thromboxane B2, the stickier the blood platelets and the less impact the aspirin is having. This crucial information allows physicians to individualize a patient's therapy, which may be as simple as adjusting the dose.

International

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and associate professor in the faculty of medicine at the **University of Montreal**. “The delivery of circumferential lesions around the pulmonary veins reduces the duration of the procedure while being effective and safe.”

Jean Champagne, MD, cardiologist and electrophysiologist at the **Institut Universitaire de Cardiologie et Pneumologie de Québec**, added, “It has been four years since I treated my first patient with the Arctic Front balloon as part of the STOP AF trial, and in my experience it allows for deeper lesions, has a higher healing rate than our current ablation technique and leads to very few long-term atrial fibrillation recurrences. We are pleased that this technology has finally been accepted in Canada and is now available to our patients.”

Cryoballoon-based technology is novel, Medtronic said, because it ablates or blocks the conduction of atrial fibrillation (AF) in cardiac tissue through the use of a coolant delivered through a catheter, rather than heat. This freezing technology allows the catheter to adhere to the tissue during ablation, allowing for greater catheter stability.

The Health Canada approval of the Arctic Front System was based on the pivotal STOP AF (Sustained Treatment of Paroxysmal Atrial Fibrillation) trial, which demonstrated the safety and efficacy of the device in treating and eradicating paroxysmal atrial fibrillation. The study showed that 69.9% of patients treated with the Arctic Front System were free from atrial fibrillation at one year, compared to 7.3% of patients treated with drug therapy only.

“This system was designed, developed and manufactured in Canada with a global mandate, including supplying the U.S. and Europe,” said Neil Fraser, president of Medtronic of Canada. “We are very excited this novel technology, which has already been used to treat more than 15,000 patients in more than 200 centers outside of Canada, is now also approved in this country.”

About 250,000 Canadians are estimated to have atrial fibrillation, which is the most common type of arrhythmia. AF accounts for 49% of arrhythmia-related hospital stays and more days in the hospital than all other arrhythmias combined. Half of all diagnosed atrial fibrillation patients fail drug therapy, and if left untreated patients have up to a five times higher risk of stroke and an increased chance of developing heart failure.

Medtronic acquired **CryoCath Technologies** (Montreal) and **Ablation Frontiers**, (Carlsbad, California) to form the AF Solutions division within the company’s Cardiac Rhythm Disease Management business. In combination with Medtronic’s existing EP Systems product portfolio, AF Solutions offers a broad line of diagnostic, cryoablation and radiofrequency ablation tools to diagnose and treat a broad spectrum of cardiac arrhythmias.

Case Western Reserve in China pact

Case Western Reserve University School of

Medicine (Cleveland) reported the signing of a 10-year research agreement with the **Shanghai Zhabei District Health Bureau** in China to study how an increasingly westernized diet and a less active lifestyle are affecting the health of residents of that country.

Researchers from the School of Medicine and Zhabei Health Bureau will track the health information of 48,000 children and adults in the Zhabei district over 10 years. They will study the prevalence of disease across multiple generations and the impact of environmental and genetic factors. The newly signed agreement expands the scope of a six-year collaboration that has existed between the health bureau and the School of Medicine around the education and training of family medicine physicians, a medical discipline that did not exist in China until recently.

Pamela Davis, MD, PhD, dean of the school of medicine and VP for medical affairs at the university, said, “What we learn will provide a critical understanding of how genetics, lifestyle, and environmental factors can adversely impact overall health, expanding our knowledge of many diseases, and how they evolve.”

Surveys of lifestyle and health information that have been collected from 48,000 Zhabei residents of all ages will serve as baseline data for the research, together with blood and DNA samples from 23,000 participants ages 35 and older. The data, which is linked electronically to healthcare centers throughout the district, will be updated every two years to identify patterns that emerge, including common risk factors for disease.

Case Western Reserve noted that rapid economic development in China has brought about “drastic lifestyle changes” that are altering the disease spectrum in the country. Increased fast food intake, overeating, and the adoption of more sedentary lifestyles have contributed to a rise in obesity, diabetes, heart disease, and cancer.

In 2009, the Chinese Ministry of Health designated the Zhabei District community health system as a model for identifying community health needs and developing healthcare delivery models. Between February and October 2009, the international research team completed the random survey of 48,000 permanent Zhabei residents, going door-to-door to gather information on their health histories.

Case Western Reserve also has signed a memorandum of understanding to establish a student exchange program with Fudan University School of Public Health and Zhejiang University School of Medicine, a research institution located in Hangzhou. The program will allow medical and public health students from the Chinese universities to come to the School of Medicine for observational training. Students from Case Western Reserve School of Medicine also will have the opportunity to travel to China to learn firsthand about the community health research initiatives underway.

The first group of Chinese students arrives in July. ■•

Washington

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522 orders for their hip implants. Among the other firms subject to the order are **Biomet** (Warsaw, Indiana), **Wright Medical** (Arlington, Tennessee), and **Stryker Howmedica** (Mahway, New Jersey).

To the casual observer's eye, the 522 studies seem likely to be expensive, given that the agency is mandating an eight-year follow-up. FDA wants measurements from serum and whole blood for both cobalt and chromium, as well as data on pain and functional scores for patients who do not elect to undergo revision surgery. To capture these data, FDA suggests "a cross-sectional study design which captures patients with or without revision," including imaging studies "to include findings of loosening, migration, subsidence, resorption, presence of osteolysis, and soft tissue masses." Other data the agency recommends the studies gather include evaluation of cardiac, neurological and immunosuppressive events and pain/functional scores using the Harris hip index.

The agency also seeks a failure analysis of explanted devices available for retrieval from patients who are in the study as well as an evaluation of all "reasonably available commercially marketed devices" explanted from patients who do not enroll. FDA does not explain the meaning of the term "reasonably available."

Regarding the tests of whole blood and serum for particulate matter, the agency pointed out that the currently available tests for detecting cobalt and chromium are limited, hence requiring that the companies validate whatever test they choose. FDA indicates it may not allow pooling of data collected from more than one lab, however. FDA states the firms have 30 days from the date of the May 6 letter to submit a post-market protocol.

Judge acquits Glaxo attorney in off-label case

A U.S. district court judge has dismissed the case against Lauren Stevens, an attorney formerly in the employ of **GlaxoSmithKline** (GSK; London), in a reversal that some in the legal community describe as a stunning setback for the U.S. Department of Justice.

According to a May 10 posting at the website [FDALawBlog.com](#), Judge Roger Titus of the U.S. District Court for the District of Maryland dismissed the DoJ case against Stevens after her attorneys filed a motion for judgment of acquittal, which Titus said was the first such motion he'd granted in nearly eight years at the Maryland district court. DoJ alleged that the attorney knowingly participated in a cover-up of the company's off-label promotion of Wellbutrin SR as a diet drug, but Titus said the evidence showed Stevens "was not engaged to assist a client to perpetrate a crime or fraud." Titus went a step further, asserting that DoJ should never have accessed company records in a crime-fraud exception to the attorney-client privilege rule.

Titus is also quoted as saying that Stevens "sought

and obtained the advice of counsel of numerous lawyers" prior to her briefing with FDA on the matter, and that she fully disclosed all she knew during those discussions. The ruling includes Titus' remark that "only with a jaundiced eye and with an inference of guilt that's inconsistent with the presumption of innocence could a reasonable jury ever convict this defendant," but the jurist is also reported to have said "there are serious implications for the practice of law generated by this prosecution."

Opinions in the blogosphere ranged from celebratory to indignant, and the case seems to echo some of the pushback against the government in its use of the provisions of the Thompson memo, which encouraged corporations to deny legal assistance to executives in exchange for leniency, but which has since been modified by the McNulty memo and the Phillip memo. However, even these modifications have not met with universal appeal on Capitol Hill as indicated by legislation offered by Sen. Arlen Specter (Pennsylvania), who at the time was a member of the GOP (*Medical Device Daily*, Feb. 24, 2009). Specter's bill never moved past committee, although a similar bill passed the House in 2007. Since 2007, no such legislation has made it as far as the floor of either chamber.

GOP frosh throw down the entitlement gauntlet

Politics may never change, but 42 members of the freshman class of the U.S. House of Representatives have done their best to raise the stakes in the current federal budget discussion with a May 10 letter to President Obama, asking the president if he is willing to "join us to stop the political rhetoric?"

The signers of the letter cite the results of last year's congressional elections as evidence of a popular demand for "solutions from Washington" in the form of "bold and decisive action ... to prevent another financial crisis." The letter notes that Obama described the budget plan put forth by Rep. Paul Ryan (R-Wisconsin) as a "serious proposal," and that the Ryan plan would not alter Medicare for those aged 55 and over. They state that the Ryan plan features several characteristics – including premium support – found in the recommendations of the National Bipartisan Commission on the Future of Medicare, which convened during the administration of President Bill Clinton. The commission was dissolved after recommending, among other things, an increase in the age of eligibility.

Stating that entitlement programs in the U.S. are "in their last years of solvency," the letter acknowledges "we have all been guilty at one time or another of playing politics with key issues." The signers indicate a wish to exercise an "opportunity to wipe the slate clean and fulfill the mandate set by the people to strengthen our country for future generations" by fixing the Medicare funding problem. Among the signers are Adam Kinzinger (R-Illinois) and Diane Black (R-Tennessee).

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Washington

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WLF weighs in on Florida healthcare lawsuit

The wheels of justice continue their slow grind on the constitutionality of the Patient Protection and Affordable Care Act of 2010, and the **Washington Legal Foundation** (WLF; Washington) has offered its views in a friend-of-the-court brief filed for the lawsuit filed in the State of Florida against the legislation.

In a May 11 statement, WLF states that its brief represents the views of 13 legal scholars whose positions are grounded in the assertion that the enrollment mandate runs counter to precedent where the Commerce Clause of the Constitution is concerned. WLF's senior litigation counsel, Cory Andrews, says in the statement that the enrollment mandate "threatens to upset the balance" of power between Washington and the states "by seeking to regulate Americans' economic inactivity," which is fundamentally different from the historical practice of regulating economic activity as such.

Supporters of the law take the view that the near-

inevitability of a citizen's partaking of healthcare services renders this argument moot, but case law has been sharply divided on this point, with each side winning at least two court decisions dealing with the law's constitutionality.

In a parallel development, the lawsuit filed in the State of Virginia will head to the U.S. Court of Appeals for the Fourth Circuit in a case that will be heard by three jurists appointed by presidents who were members of the Democratic Party. The judges are randomly selected, but the odds of this selection are not particularly good, given that five of the 12 judges were appointed by Republicans, while one was the subject of a nomination by President Bill Clinton that was continued by President George W. Bush. The losing side in this case can appeal to have the entire panel of judges hear the case, but an appeal to the U.S. Supreme Court would likely follow the final outcome at the Fourth Appeals Court. ■

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HRS

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The company's flagship product is the TactiCath, the first force-sensing ablation catheter designed to give physicians a real-time, objective measure of contact force during the catheter ablation procedure.

Numerous pre-clinical and human studies in the past couple of years have shown that insufficient force may lead to subpar results (low efficacy, longer procedure times) while excessive force can cause various adverse events (tamponade, esophageal injury).

Endosense recently reported (*Medical Device Daily*, May 5, 2011) that its TactiCath contact-force sensing ablation catheter has been used to perform more than 1,000 AF patient cases in Europe. Its distributor, **Biotronik** (Berlin, Germany) has built and is continuing to grow the market for the TactiCath as its exclusive distributor in Europe as well as Latin America, Canada, Africa and the Middle East.

In addition, Endosense recently said (*Medical Device Daily*, May 9, 2011) that it has engaged with **Rhythmia Medical** (Burlington, Massachusetts) and in a joint development project to integrate the contact-force data into Rhythmia's advanced three-dimensional cardiac mapping, visualization and navigation system.

Finally, Endosense and Siemens Healthcare reported the completion of prototype software integrating the contact-force data with Siemens' electrophysiology solutions. The new application, which was created under a joint development agreement originally announced in January, was designed to allow electrophysiologists to view catheter tip-to-tissue contact force within a fluoroscopically enabled, three-dimensional anatomic heart model during catheter ablation procedures.

A host of new clinical results were presented at HRS, with favorable early data from the company's EFFICAS I

post-market clinical trial that shed new insights into the relationship between catheter tip-to-tissue contact force and early pulmonary vein isolation line reconduction.

EFFICAS I is a 45-patient, single-arm, prospective, multi-center European clinical trial that was designed to demonstrate the correlation between contact forces applied during pulmonary vein isolation and atrial fibrillation treatment efficacy at three months. While investigators performed the procedure with the TactiCath, they were blinded to contact force measurements; however, the contact forces applied were recorded. Patients were re-assessed with a mapping catheter at three months to identify potential gaps in the PVI lines. Contact force parameters from initial procedures were then analyzed to determine the relationship with lesion formation.

Karl-Heinz Kuck, MD, **Asklepios Klinik St. Georg** (Hamburg, Germany), a veteran in the field of electrophysiology, said that "EFFICAS I shows for the first time a direct correlation between low contact force and post-operative PV isolation line reconduction at three month follow-up. " The EFFICAS I data showed this to be particularly true when low contact forces were applied at the first ablation site.

Full results from EFFICAS I will be applied to EFFICAS II, in which investigators will take full advantage of the real-time, objective TactiCath contact-force control features to improve their ablation technique during lesion creation. Now enrolling patients, the EFFICAS II study will measure reduction in PVI gaps as well as procedural improvements as compared to EFFICAS I.

Vivek Reddy, a widely respected EP practitioner is also very enthused about this technology, saying that "contact force is the last missing piece of information needed to improve the treatment of AF." ■

MDD'S ORTHO EXTRA

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

THURSDAY, MAY 12, 2011

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Keeping you up to date on recent developments in orthopedics

Surgeons rebuild pelvis of cancer patient . . . In a rare and medically remarkable operation, a multi-disciplinary team of surgeons at the **Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital** and **Richard J. Solove Research Institute** (OSUCCC; all Columbus) removed the left leg, hip and pelvis of a cancer patient, and used the healthy, living bones from his amputated leg to completely rebuild the connection between his spine and remaining right pelvis to support a high-tech prosthetic leg. “This procedure itself is actually the first time it’s ever been performed in the U.S.,” said Joel Mayerson, MD, an orthopedic oncologist who collaborated with a surgical team that included Ehud Mendel, MD, a spine neurosurgeon, and Michael Miller, MD, a plastic surgeon, on the complex case. The pelvic reconstruction surgery was so unusual that the surgical team submitted it as a case study to the *Journal of Neurosurgery: Spine*, which recently published it online. The surgery is called an “En Bloc” procedure, which translated from French means “as a whole, or in mass,” meaning that the surgeon must remove the entire tumor intact. Surgeries for bone tumors of the pelvis usually feature artificial parts or cadaver bones to reconstruct the pelvis. Often patients are confined to wheelchairs after surgery because their pelvises do not heal strongly enough to support their body weight using a prosthetic leg. The surgical team removed the tumor and worked together to design a method to rebuild the patient’s pelvis using titanium supports along with parts of the patient’s leg – including bones, muscles, skin and blood vessels. “Removing the tumor required removing the leg, yet many of the tissues in the leg were healthy,” said Miller, interim chair of Ohio State University Medical Center’s Department of Plastic Surgery, who specializes in reconstructive surgical oncology. “We wondered if it was possible to use the healthy parts of the patient’s leg to reconstruct his pelvis.” The custom device that Mendel fashioned features two large rods and a couple of smaller rods fixed to the pelvis and spine with 14 screws to help provide support while the leg bones fused together. The Ohio State surgery marked the first time that surgeons used living bone from the patient’s amputated limb to reconstruct the pelvis in this fashion.

Osteoporosis medicine can cause fractures . . . Bisphosphonates are a medication that has been administered since the 1990s, which reduces the overall risk of brittleness and incidence of osteoporosis. Bisphosphonates deactivate those cells used to break down bone and therefore prevent fractures caused by brittleness of the bone. Although, for some time, there have been doubts that bisphosphonates can be the cause of other forms of fractures such as fatigue fractures, by virtue of the fact that they also inhibit natural degradation of bone. Bone is unable to be replaced and certain types of bone fissures do not heal naturally. The first results were collated during 2007. These doubts have been confirmed by Per Aspenberg, a professor of orthopedics at **Linköping University** (Linköping, Sweden). Aspenberg and colleagues conducted a national study on 12,777 women 55 years or older. 59 of the subjects with femoral fractures were diagnosed as fatigue fractures (commonly called atypical femoral fractures). Of these 59 patients, 78 % had been administered with bisphosphonates whereas only 5% of all forms of fractures within the general population had received the same treatment. “There is an on-going international debate, deliberating the side effects of bisphosphonates. The results from this study will probably conclude the debate,” said Aspenberg. “The connection between the bisphosphonates and the fractures is so strong they we propose that a causal connection can be confirmed.” However, this study also indicates that the risk of fatigue fractures diminishes once a patient ceases to be administered bisphosphonates. Following a one-year cessation from the medication, the risk of a fracture occurring is reduced by 70 %. “This may indicate that one should seldom administer bisphosphonates and that the medication should be concluded after several years’ treatment,” said Aspenberg.

Evaluating rotator cuff tears via ultrasound and pre-op MRI is cost effective. . . While ultrasound is usually viewed as more cost effective, MRI is most often used to evaluate the rotator cuff. When performing a cost utility analysis, using an ultrasound as the initial imaging

test for rotator cuff tear, along with pre-operative MRI to identify alternative and concurrent diagnoses, can be a very effective hybrid imaging strategy, according to research presented at the 2011 **American Roentgen Ray Society's** (Leesburg, Virginia) annual meeting. The study, performed at **Duke University Medical Center** (Durham, North Carolina) and **Rush University Medical Center** (Chicago), used three evaluation techniques: the use of ultrasound alone, MRI alone, and a hybrid strategy of ultrasound for all patients followed by MRI for those patients who required surgery. "Several meta-analyses in the literature have found that ultrasound and MRI have similar accuracies for the evaluation of rotator cuff tears. Ultrasound is a cheaper imaging modality, yet MRI is much more frequently used for rotator cuff evaluation," said Robert Lee Suber, MD, lead author of the study. "The reasons for the preference of MRI may be related to the possibility of identifying alternative and/or concurrent diagnoses with MRI as well as surgeon preference for anatomic imaging prior to surgery," said Suber. "One of the imaging strategies we studied was an initial screening test with ultrasound. All those patients who required surgery or failed conservative treatment would then have an MRI. We found this to be more cost effective than everyone undergoing MRI as the initial evaluation," he said. "Our research shows that in populations with a lower pre-test probability of rotator cuff tear (e.g. patients seeing family practice physicians as opposed to a shoulder specialist surgeon) it may be more cost effective to initially obtain an ultrasound. Then if the patient needs to have surgery, they can get an MRI," he said.

PTSD common following significant orthopedic trauma . . . Although most commonly associated with military combat, post-traumatic stress disorder (PTSD) can occur in civilians, too – and with consequences that are just as serious, according to a new review article in the *Journal of the American Academy of Orthopaedic Surgeons* (JAAOS). PTSD is a type of anxiety disorder that occurs after a person experiences a traumatic event involving physical injury, and occurs in 20% to 51% of patients with an orthopaedic injury. "PTSD occurs with a significant frequency in civilian patients who have sustained an orthopaedic trauma, and it can hinder their emotional, physical and functional recovery following orthopaedic treatment," said Daniel Aaron, MD, a clinical instructor in the department of orthopaedics at **Brown University** (Providence, Rhode Island). Many types of accidents can cause PTSD, including car or motorcycle accidents, gunshot wounds, vehicle-pedestrian accidents and falls from height, among many others. "Generally, higher-energy mechanisms are most commonly associated with PTSD, but no specific type of fracture or injury has been identified," said Aaron. "Basically, any type of musculoskeletal injury that results from significant trauma may be associated with PTSD." PTSD can have a significant impact on a patient's ability to perform simple, daily chores, and can slow the rehabilitation process, even affecting how the patient experiences pain and perceives his or her recovery. "The development of PTSD adversely affects the ability of the patient to recover and may specifically compromise physical rehabilitation and patient satisfaction following orthopaedic treatment," Aaron said. "Without effective treatment, PTSD can hinder activities of daily living, such as bathing, eating, paying bills, shopping, laundry and other household chores. Patients with PTSD also may be delayed in returning to work." Recognizing the symptoms of PTSD early offers the best chance of effective prevention. Orthopaedic surgeons can improve patient outcomes by knowing which patients are at risk of developing PTSD and initiating prevention strategies, noted Aaron. Some studies indicate that when PTSD is identified early, progression of the condition may be prevented through use of medications, he added. "Identifying at-risk patients is an important first step in preventing the ill effects of PTSD," he said. Many orthopaedic surgeons may not recognize the signs and symptoms of PTSD, and remain unaware of prevention and treatment strategies. As a result, recovery can be delayed.

– **Compiled by Holland Johnson, MDD Managing Editor**
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