Medical Device Daily™
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The MDD Interview

Apple: 'Community effort' led to what is now the nation's largest HIE

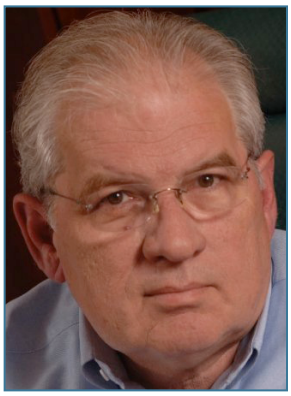
1st of 2 parts

By JIM STOMMEN, *MDD* Contributing Writer

Harold Apple is CEO and president of the **Indiana Health Information Exchange**, the nation's largest HIE organization. IHIE connects the state's hospitals, physicians, long-term care facilities and other healthcare providers, enabling medical information to follow patients regardless of treatment location to improve care coordination and patient outcomes. Physicians in the IHIE network provide care to more than 10 million patients.

Apple was formerly the majority owner, CEO and president of Vector Technologies, a business process outsourcer, consulting and software development company in the life insurance sector. He also was one of the founders of the Indiana Software Association and the Indiana Information Technology Association.

MDD: What is the genesis of health information exchanges, and are there similarities in each HIE's mission?



HAROLD APPLE
Heads up Indiana HIE

Apple: The Indiana Health Information Exchange had its genesis probably a couple of decades ago, and it's a very different form. There's an entity in Indianapolis by the name of the Regenstrief Institute, and the technology that we use was actually invented by Regenstrief. It's primarily a medical informatics organization. They have a couple of other missions, but by far their largest focus is on medical informatics, and they've had a long-term partnership with a public safety hospital in

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NewCo on the Go

Stealth Therapeutics develops 'invisible' chest port device

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

Stealth Therapeutics (Madison, Wisconsin) has an implantable device that could become an alternative to traditional chest ports. Earlier this week, the company reported the successful implantation of the FDA-cleared Invisiport.

The device is intended to be used in patients suffering from diseases that require long-term intravenous treatment, such as cancer, cystic fibrosis, Lyme disease or infection.

Stealth said that its Invisiport product provides the same function as conventional implanted ports, but features a patented self-deploying wing that minimizes insertion size and supports stability once implanted in a patient's

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Washington roundup

Maker of injectors apparently out of business after warning

By MARK McCARTY
***Medical Device Daily* Washington Editor**

The cost of doing business in the medical device space may have collapsed another device manufacturer if the July 20 warning letter to **Arriol International** (Santo Domingo, Dominican Republic) is any indication. The maker of osseous injection systems hosted an FDA field investigator for only four days – a substantially shorter length of time than is required for many inspections – and responded to the April 9-12 inspection with an April 27 response, but the telephone number listed for the firm registers as no longer in use, and an e-mail to the firm's customer service department bounced back as undeliverable.

This was the second warning letter in recent weeks

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Don't miss today's MDD Extra: Orthopedics

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AHC Media

Report from Europe

Europe builds strong evidence for contrast-enhanced ultrasound

By JOHN BROSKY
***Medical Device Daily* European Editor**

PARIS — While contrast enhanced ultrasound (CEUS) remains an off-label use beyond cardiac applications in the United States, European physicians are rapidly compiling a powerful clinical case for applying the technique for tumor detection and tissue characterization almost everywhere else in the body.

In August, CEUS was recommended by the UK's **National Institute for Health and Clinical Excellence** (NICE) for the detection of focal liver lesions, for characterizing cirrhosis, for investigating potential liver metastases.

NICE is Europe's only methodic health technology assessment authority and both is widely followed and highly influential with its sharp eye for opinions on cost-effectiveness.

At this time last year, the European Federation of Societies in Ultrasound Medicine and Biology (EFSUMB; London) issued guidelines on Liver CEUS as well as recommendations on non-hepatic applications.

This week, gastrointestinal CEUS is a thematic focus for scientific sessions at Ultraschall-Dreiländertreffen, the annual Three Countries Ultrasound Meeting, in Davos, Switzerland.

The three countries for the all-German congress are Austria, Germany and Switzerland.

The 2012 congress president André Dietschi from the **Santémed Health Center** (Winterthur, Switzerland), told European Hospital that where recent technical developments in ultrasound have been less than revolutionary, developments in contrast agents are far more exciting.

"Emerging expertise about their effects and potential areas of application have attracted significant attention," he said. "There are basically no restrictions to experimenting in new areas of application because the contrast agent will cause no harm, while the potential benefits are significant."

While several companies are advancing CEUS agents toward the market, notably Sonozoid from **GE Healthcare** (Waukesha, Wisconsin), the dominant agent in clinical practice in Europe is SonoVue from **Bracco Diagnostics** (Milan, Italy) that has been available since 2001 in Europe.

The approval of CEUS in the U.S. remains fixed at the FDA approval for cardiac imaging in patients with suspected or established cardiovascular disease to improve visualization of cardiac chambers and endocardial borders.

In Europe SonoVue is approved for liver, breast and vascular applications.

An aqueous suspension of microbubbles in the blood will enhance the ultrasound signal, illuminating a target area.

The distinguishing quality of SonoVue is the use of sulfur-hexafluoride microbubbles that Bracco claims further amplifies the signal quality yielding diagnostic information comparable to more expensive imaging techniques such as nuclear medicine, contrast-enhanced computed tomography (CT) or magnetic resonance imaging (MRI).

Bracco reported to the FDA in March 2011 that the database of pooled data on SonoVue for 70 completed clinical includes 5,275 patients with only three patients reporting adverse events where the contrast agent could not be ruled out as the cause.

In the 18 months since that report, the database of clinical studies has grown rapidly.

European clinicians have a long advance on American colleagues for exploring every aspect of a CEUS examination from transducers to dosage.

A special supplement to the *European Journal of*

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AHC Media

Financings roundup

Mainstay raises $20 million for lower back pain device

A *Medical Device Daily* Staff Report

Mainstay Medical (Dublin, Ireland) says it has completed an oversubscribed Series B financing round for $20 million (€15.3 million) led by Fountain Healthcare Partners. Other new investors in the round include Medtronic, Capricorn Venture Partners, and Seventure Partners. Existing investors Sofinnova Partners and Twin City Angels also participated.

Mainstay says this funding will advance the on-going development of its new device for the treatment of patients with chronic non-specific low back pain. As part of the financing, Mainstay relocated its head office and executive leadership to Dublin, Ireland from Minneapolis.

Mainstay has developed an implantable device, like a pacemaker for the back, to restore spine stability to ameliorate pain and allow patients to return to work. The company plans to use the proceeds of the Series B financing to expand the team for product development, quality, clinical, regulatory and administration, as it moves towards its goals of achieving regulatory approval in Europe and running a global clinical trial leading to an FDA pre-market approval submission.

"We are excited about Mainstay, and the potential to relieve the back pain suffered by millions of people worldwide," said Manus Rogan, co-founder and managing partner at Fountain Healthcare Partners. "We are particularly pleased that Mainstay and the syndicate of international investors has recognized the economic value and attractiveness of Ireland as a location to build an innovative medical device company."

Rogan will join Mainstay's board of directors. Stephen Oesterle of Medtronic, Frank Bulens of Capricorn, and Iain Wilcock of Seventure will become observers. Existing independent director Andrew Weiss will continue.

"Our early clinical results are very encouraging, and with this new investment we will be able to make great progress in advancing Mainstay's products from concept to reality, and start to build our business," said Mainstay CEO Peter Crosby.

In other financing activity:

• **DJO Global** (San Diego) reported the preliminary results of its operating subsidiary, DJO Finance's cash tender offer for any and all of its 10.875% senior notes due 2014.

As of the early tender deadline on Sept. 24, $363 million aggregate principal amount of the notes had been validly tendered and not validly withdrawn. The company has elected to exercise the early settlement election described in the offer. Holders of notes who validly tendered and did not validly withdraw their notes on or prior to the early

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Agreements/contracts

Johns Hopkins to install 3M's 360 documentation system

A *Medical Device Daily* Staff Report

The **Johns Hopkins Hospital and Health System** (Baltimore) has selected the **3M** (St. Paul, Minnesota) 360 Encompass System to integrate and automate coding, clinical documentation improvement, and performance monitoring in a single workflow. The technology from 3M Health Information Systems will help the organization capture complete documentation, improve coding accuracy, speed time to billing, and report outcomes data that truly reflects the care provided.

The 3M 360 Encompass System addresses the inefficiencies of multiple coding and documentation processes and the added costs of unconnected systems, offering a breakthrough answer to the challenges of healthcare reform and ICD-10. The 3M solution promotes complete capture of patient severity in physician documentation to improve case mix and significantly reduces the time and resources needed to prepare physicians for ICD-10.

With the 3M Coding and Reimbursement System as its foundation, the 3M 360 Encompass System uses complete ICD-10-CM and ICD-10-PCS coding content. The application natively codes in ICD-10 and enables coding in ICD-9 while viewing the ICD-10 equivalent. 3M is an international leader in coding and patient classification systems with more than 5,000 hospitals worldwide using 3M coding solutions to code and group patient data for decision support, quality measurement, and reimbursement.

3M Health Information Systems delivers software and consulting services.

In other agreements/contracts news:

• **Covenant Security Services** (Philadelphia) and **W.L. Gore & Associates** (Flagstaff, Arizona) extended its security partnership to Gore's Arizona facilities.

Covenant, which has been providing security services to W.L. Gore's Eastern Cluster for more than six years, will now be the fluoropolymer manufacturer's preferred national security provider. Best known for its Gore-Tex fabrics, W.L. Gore also makes technological, medical, pharmaceutical, and consumer products.

"Covenant is not just a vendor, or provider to Gore, they are truly a partner," said Ken Ford, W.L. Gore's Global Security Leader. "Our partnership with Covenant goes back to 2006, and since that time, Covenant has continued to raise the bar on quality, training and service. The success is a true reflection on the Covenant team's efforts to understand and deliver service that is aligned with our environment and culture."

Covenant Security Services is a security services firm that partners with Fortune 500 companies.

• **MD Buyline** (Dallas) has agreed to a national, three-year contract with **Novation** (also Dallas), a healthcare supply chain expertise and contracting company. Terms of the contract state that Novation will make MD Buyline's services available to the network of 65,000+ members it serves through December 2015.

The MD Buyline suite of offerings helps ensure that hospitals and health systems optimize the clinical and financial impact of their medical technology decisions. "Our members recognize us as an objective third party that they can trust for evidence-based information, research, and strategic support to help them optimize their investments," said Satin Mirchandani, CEO of MD Buyline. "We are proud to be in business with Novation, and we look forward to providing the members Novation serves with the clinical, financial, and operational information needed to align their medical technology strategies with the realities of the new healthcare economy."

• **Radisphere** (Cleveland) has partnered with the **National Rural Health Association** (NRHA; Washington) to bring high quality, lower cost radiology services to the rural hospital community.

Radisphere's Gold Partnership demonstrates what it calls its commitment to bringing a proven and tailored solution for hospitals under 100 beds. Radisphere offers a network of subspecialty radiologists who perform final reports and consults for small hospitals.

NRHA is a nonprofit organization working to improve the health and well-being of rural Americans and providing leadership on rural health issues through advocacy, communications, education and research.

Radisphere's delivery model combines local radiologists who provide hands-on patient care, the largest network of subspecialty radiologists, and a cloud-based technology platform.

• **CivaTech Oncology** (Research Triangle Park, North Carolina) was awarded a $1 million phase II contract from the **National Institutes of Health** (Bethesda, Maryland) and the **National Cancer Institute** (Atlanta) to further develop CivaSheet, a bioabsorbable uni-directional device for treatment of non-small-cell lung cancer. This contract's objective is to meet regulatory requirements that will enable the CivaSheet to be introduced into clinical practice.

CivaTech makes low dose rate brachytherapy devices. The company's first device, the CivaString, has been cleared by the FDA for use in localized tumors. The company is also developing implantable bioabsorbable brachytherapy products for the specialized treatment of breast and other localized cancers. ■

Deals roundup

Vivonics completes its buy of Biomedical unit of Infoscitex

A *Medical Device Daily* Staff Report

Vivonics (Waltham, Massachusetts) reported the completion of its acquisition of all assets related to the Biomedical division of **Infoscitex** (IST; Waltham).

Vivonics was founded specifically to acquire the IST Biomedical business by Gordon Hirschman, who was IST executive VP in charge of that division prior to the acquisition.

"Establishing our business as a separate company will allow us to focus our full attention on the development and commercialization of advanced biomedical technologies" said Hirschman, now president/CEO of Vivonics.

All previous employees of the IST Biomedical division have agreed to join Vivonics, assuring continuity for on-going developments.

The charter of Vivonics is to develop innovative technologies that improve or maintain health or help optimize human effectiveness within complex systems, from the initial concept through to viable products. Some of the technologies currently under development include: an implantable artificial lung based on microfluidics, an advanced socket for adapting a prosthetic leg to the amputee's residual limb, a robotic device to assist with ultrasound scans, and molecular technology using advanced DNA aptamers for therapeutic and diagnostic applications.

In other dealmaking activity:

• **Aviv REIT** (Chicago) reported that it has acquired a post-acute and long-term care skilled nursing facility (SNF) located in Kentucky for $9.9 million.

The property will be triple-net leased to publicly-traded Advocat, a new tenant relationship for Aviv. Advocat is an operator of SNFs in the U.S., with 48 facilities located in eight states.

The triple-net lease has a 15 year term, an initial cash yield of 10.2% and annual compounded escalators based on CPI. The transaction was funded with cash on hand.

"We are excited about this transaction as it represents a new strategic relationship for Aviv," said Craig Bernfield, chairman, president/CEO of Aviv. "This acquisition was an opportunity to acquire a quality care center that recently underwent a $3 million renovation and we are also pleased to further diversify our portfolio by entering into a new state. We look forward to growing our relationship with Advocat."

• **Accenture** (New York) has completed its acquisition of **Octagon Research Solutions** (Wayne, Pennsylvania), a provider of clinical and regulatory information management solutions and software for the pharmaceutical industry. The acquisition was reported on Aug. 2.

The acquisition enhances Accenture's existing clinical services capabilities – including clinical data management, clinical programming and safety case processing, among others – and adds regulatory submission services, thereby extending Accenture's business process outsourcing capabilities for the pharmaceutical industry. As a result, Accenture says it can now provide the first comprehensive clinical and regulatory services to pharmaceutical companies globally, helping them get medicines to market more quickly and cost effectively.

"Our pharmaceutical clients around the world are looking for proven clinical and regulatory services that can improve the efficiency and effectiveness of their drug development business," said David Boath, North American managing director for Accenture's Life Sciences industry group. ■

Grants roundup

GigaGen awarded more than $1M for Cell-Seq technology

A *Medical Device Daily* Staff Report

GigaGen (San Francisco) said it has received more than $1 million in grants to develop and validate technology that will help predict the occurrence and severity of immune flares in transplant recipients and people with autoimmune disease.

According to the company, physicians lack methods to affordably identify and track the specific immune cells that cause immune-related disorders, partly because the genetic identities of these cells vary among patients. Using microfluidics, next-generation sequencing, GigaGen says its Cell-Seq technology will enable physicians to monitor a patient's disease-specific immune activity and guide personalized care to prevent and treat immune flares.

Three of the grants, which were awarded by the National Institutes of Health and National Science Foundation, will support development, validation, and characterization of Cell-Seq, which is designed to measure genotype and expression of dozens of target genes across millions of single cells. A fourth grant will support development of web-based tools for processing, analysis, and visualization of Cell-Seq data.

In other grant activity, **Ensysce Biosciences** (Houston), a nanotechnology company, said it has received a SBIR award of roughly $300,000 to optimize the formulation of its single walled carbon nanotube (SWCNT)/siRNA complex for therapeutic delivery. These funds, along with the recent $1 million raised in June and the State of Texas Emerging Technology Funds that had been awarded to the company previously, will allow the finalization of the formulation prior to undertaking investigational new drug studies.

According to the company, carbon nanotubes provide a means to deliver unmodified, large active molecular agents through natural barriers within the body and specifically into cancer cells. ■

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Indianapolis, Wishard Health Services.

Initially the mission was to get health records into an electronic form and over the first decade or so of the Regenstrief Institute's existence, they developed systems primarily for Wishard. Subsequently they started getting some recognition on a little broader basis. About 10 years ago or so, the other hospitals in the city – there are primarily four other main healthcare institutions – got together with Regenstrief and Wishard and decided to start sharing their records, at least on a local basis as best they could at that point in time. In 2004, the organization was formalized under the name Indiana Health Information Exchange and it was established as a not-for-profit supporting entity, meaning that it was to support those five major hospitals.

At that point in time, when they started sharing records electronically between the institutions, Regenstrief developed some technology that captured the information as it passed through the software from one hospital to another and started building a significant clinical database. That database is now manifested itself into a collection of some 12 million patient records and something on the order of 15 terabytes of data on the history of patients, initially in Indianapolis and the surrounding county area. But under the coordination and management of IHIE, it has really expanded significantly.

It was an unusual situation because the hospitals, while they are significant competitors on a regular basis, decided to join together to improve patient care in the community by sharing these records among themselves. Subsequent research has shown that any given patient probably receives as much as 40% of his or her care outside of the domain of their primary care physician and, depending on his association with whichever hospital he is associated with, would always have the problem of the care being delivered to his patients across multiple entities.

This whole effort started creating a master patient record independent of wherever that patient received his or her care. Early on, our mission primarily was exchanging medical records or delivering lab results and prescriptions and X-rays from the point of origin to the primary care or referring physician, so there would be a more complete record of the medication, the diagnoses, various laboratory tests, and today we transmit a million to a million and a half such transactions a day amongst these entities.

The step up was about three years ago or so, when we started actually analyzing that data with help from Regenstrief analysts, most of whom are either PhDs or MDs, and we started generating quality results of care on these patients. If a doctor chooses to participate in that program, one of the major payers in Indiana offers an incentive for demonstrating over the course of time improvement in a patient's care.

MDD: The Indiana Health Information Exchange is the nation's largest, and seemingly most well-respected, HIE. How did you get there?

Apple: We got where we are with lots of hard work and lots of cooperation from the various stakeholders in the care delivery process, and ultimately the cooperation from payers, especially over the past three or four years. There's a built-in contention between providers and payers, but all have kind of joined together with the hopes of improving the delivery of healthcare in Indiana, and thereby hopefully in reducing the costs. It took us lots of decades to get us in the fix we're in nationally, and it's going to take awhile to get out of it. Many of these activities we're involved with today were the result of a community effort, starting many years ago.

MDD: Could you delve into the statistics behind what you're doing, starting with patients and healthcare organizations served?

Apple: Right now we're in a big push, as a result of the federal Beacon program, to sign more hospitals within the state. Based on our original charter as a nonprofit organization, we're pretty much limited to working within the state at this point in time. We have about 60 of the 120 or so hospitals in the state of Indiana online right now, and have over 90 under contract. We're in a push to get those other 30 hooked into us as soon as possible. It's a complex and labor-intensive process because of the multitude of systems we have to communicate with, so we're focused heavily on trying to clean up that whole process and make it more efficient, more cost-effective. With 90 of 120 hospitals in the state signed up so far, it's a fairly significant roster. We also communicate with 122 of the 123 or 124 hospitals in Indiana for the purposes of providing data to the U.S. Department of Health related to non-communicable disease reporting. That's the result of a program that started several years ago to report to the Center for Disease Control certain disease states that are of interest to them, so for that one specific purpose, we pretty much touch all the hospitals in the state.

MDD: Of the 30 or so hospitals that you've not yet signed up, do they tend to be larger or smaller institutions?

Apple: Smaller ones. And there are other HIES that operate in the state of Indiana. One in South Bend is a small, local entity and services 10 or 12 hospitals in the South Bend area. Then there are two major hospitals in Fort Wayne that are not yet a part of our network whose area is kind of separated from the rest of the state from a population point of view. But we have a program going on with the health information technology group that is under the guidance of state government to communicate with those other HIEs so that we can at least use them as transfer points rather than rebuilding connections with the hospitals that they serve. Eventually, and by that I mean probably within a year, we'll be able to intercommunicate with each of those locales.

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Apple

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MDD: Obviously, reaching such magnitude in terms of whom you're serving doesn't happen overnight. What were the key steps taken along the way?

Apple: The key step is that we focus intensively on governance. The technology is always an issue, but it's really important that people trust how we behave as an organization and that's probably one of the most important competitive advantages that we've installed over the course of our existence. Care is tightly woven into the trust element, so we keep that very, very high on our list.

MDD: Indiana traditionally has been among the lower-ranked states in terms of such health indicators as obesity, smoking, diabetes and heart disease. How has IHIE and its programs impacted those issues?

Apple: Most of that impact is just starting to be realized. If we think of the broad segments of time, most of the first seven or eight years were focused on building the exchange, and that was focused more on the exchange of records between physicians. There wasn't a lot of focus on population health; it was more in the sense of providing immediate care.

What has really happened over the past three or four years is building a program that's more oriented around wellness in terms of generating the quality measures that are coming out of a program called Quality Health First. We're just starting to realize some of the benefits of being able to analyze the data we hold and being more proactive in reporting back to physicians and institutions in terms of how we're doing. For example, to physicians participating in the Quality Health First program we provide alerts for diabetic patients who, for instance, have not picked up their latest insulin prescriptions or alerts on females who have not had their regular mammograms and colorectal cancer exams and those kinds of things.

So the proactivity that is required to help impact these chronic diseases is really a later-stage program for us. Even though it's been a goal for a long time, it's a very complex process to be able to impact that goal. As with the state of healthcare nationally, it took us decades to get us into this fix; now it will it's going to take us awhile to get out of it. It is definitely a high-priority objective for us, but the challenge is that it is one that will have to be realized over a longer period of time, so there's no immediate gratification there.

MDD: When you're trying to save people from themselves, that's not always an easy task.

Apple: Yes, that's certainly the case with behavior change. How do you create population behavior change? One by one is how you do it. ■

(Next week, in Part 2 of this MDD Interview, Harold Apple discusses how his organization's business model compares with those of other HIEs elsewhere, IHIE's involvement in the federal Beacon Community program, and the importance of paying strong attention to privacy and security measures.)

Product Briefs

• **Keller Medical** (Stuart, Florida) reported the launch of the Marsupial Pouch, designed for women who undergo breast surgery and discharged from the hospital with drains. Made from plush terry cloth, the Marsupial system is comprised of two parts, an adjustable, elastic belt and a pouch to hold the drains. Patients who have used the Marsupial reported experiencing the following benefits: kept reservoirs and tubing secure; concealed unsightly drainage; improved mobility; and provided increased comfort when sleeping.

• **Precision Spine** (Parsippany, New Jersey) received FDA clearance for the ReForm Pedicle Screw System. The ReForm Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The ReForm Pedicle Screw System is also intended for non-cervical pedicle screw fixation for the following indications: severe spondylolisthesis (grades 3 and 4 of the L5-S1 vertebra) in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after attainment of a solid fusion.

• **Tangent Medical** (Ann Arbor, Michigan) has received FDA clearance for the NovaCath Secure IV catheter system, a product designed to set new standards in peripheral IV catheter design, functionality and performance. The NovaCath Secure IV catheter system integrates a series of next-generation technologies designed to address IV therapy challenges including catheter stabilization, healthcare worker safety, tubing management and patient comfort. Tangent says this system is designed to establish a new standard in catheter design, functionality and performance.

• **Teleflex** (Limerick, Pennsylvania) received FDA approval for the Arrow FlexBlock continuous peripheral nerve block catheter. Teleflex says the Arrow FlexBlock continuous peripheral nerve block catheter is intended for clinicians who use ultrasound-guidance when placing continuous peripheral nerve block catheters. The echogenic, coil-reinforced FlexBlock catheter body is constructed of polyurethane, and the unique catheter design offers a combination of ultrasound visibility, flexibility, and excellent kink resistance. The FlexBlock catheter's tip design is intended to provide clinicians with a predictable spread of anesthetic.

Stealth

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arm, attributes that are mutually exclusive in existing devices. Patients can benefit from a smaller incision. With the smaller incision requirement, the Invisiport may allow a shorter implant procedure time. The Invisiport offers a microinvasive, patient-friendly alternative to traditional chest ports and peripherally inserted central catheters (PICCs).

"Our device, the Invisiport, is implanted in the arm," Peter Drumm, Stealth Therapeutics CEO told *Medical Device Daily*. "But if it is implanted in the arm then there's some benefits to a patient and to the clinician, because it is much easier to put in an arm port rather than chest port. Less anesthesia is required and there's less chance of a punctured lung."

He added, "In our first patient [prior to the implant], she had a bunch of PICC lines, and she couldn't lifeguard, she couldn't teach swimming lessons, she couldn't take a shower. So her quality of life has improved significantly by having this particular device."

The device received FDA approval last year, and the company is currently discussing whether or not to seek clearance for the Invisiport outside of the U.S.

"We've talked about going over to Europe, but we don't have any plans at this point but it's being discussed at a board level," Drumm said.

The Invisiport is a cylinder with a hollow space inside that is sealed by a soft top. The Invisiport includes a catheter that is inserted inside one of the large veins that delivers blood to the heart. When a special needle is put into the soft top of the Invisiport, it creates "access" to the bloodstream, allowing medications and fluids to be given and blood samples withdrawn.

"In addition, there are lots of cancer patients that are considered with the aesthetics of a chest port," he said. "Breast cancer patients – they don't want to be reminded they have cancer. They don't want the stigma associated with having a chest port implanted in their chest. So this is a good alternative."

Drumm added, "What we're trying to do is allow people to live their normal lives as best they can even though they have challenging medical conditions. When I met our first patient . . . and I asked her what was the change for her when she received the Invisiport, she said she was able to gain some of her freedom back. Just being able to go swimming, being able to wear normal clothes and blend in with other people . . . she got some of her freedom back."

Stealth Therapeutics was founded in January 2006 for the purpose of designing and developing a portfolio of improved venous access devices.

The firm's FDA submission and commercialization work has been supported by the Kegonsa Seed Fund, Wisconsin's premier seed venture capital fund operated by Ken Johnson. Drumm declined to say how much money the firm had raised.

In the future, the company plans to expand its product portfolio.

"We've got a couple of additional products but it's a little too early to talk about them," Drumm told *MDD*. "We've got two additional products coming out next year and we're currently working through the testing and regulatory part." ■

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Financings

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deadline will receive the total tender offer consideration for the notes tendered on Oct. 1, subject to the consummation of a debt financing expected to close on that date.

Credit Suisse Securities is the dealer manager for the tender offer.

DJO makes devices designed to provide solutions for musculoskeletal health, vascular health and pain management.

• **Precision Optics** (Gardner, Massachusetts) said it has entered into definitive agreements with institutional and accredited investors for the sale and purchase of units consisting of an aggregate of roughly 2,777,795 shares of common stock, and five-year warrants to purchase up to about 1,944,475 shares of common stock. The unit price is 90 cents. The warrants have an exercise price of $1.25 a share, subject to adjustment and a call provision if certain market price targets are reached, and are exercisable in whole or in part, at any time prior to expiration.

The company will receive about $2.5 million in gross proceeds from the offering. The offering is expected to close on or about Friday, subject to customary closing conditions. Net proceeds from the offering will be used for working capital needs and for general corporate purposes including funding of start-up costs associated with the company's order for micro endoscopes as well as other recently received orders for new products.

Loewen, Ondaatje, McCutcheon acted as the exclusive placement agent for the offering.

• **Transcat** (Rochester, New York), a distributor of professional grade handheld test, measurement and control instruments and accredited provider of calibration, repair, inspection and other compliance services, said it has entered into a new secured revolving credit facility with Manufacturers and Traders Trust.

The credit facility agreement provides a $20 million secured revolving credit facility that matures on Sept. 20, 2015. Borrowings under the facility may be used for working capital, with up to 50% available for acquisitions. The facility also provides the flexibility to repurchase shares of the company's common stock and the issuance of dividends.

The new credit facility agreement replaces the company's prior $15 million secured revolving credit facility. ■

Washington

Continued from Page 1

dealing with a firm that either closed its doors or at least appears to have done so, the first being **Generic Medical Devices** (Gig Harbor, Washington), which found its business model badly damaged by its selection of urinary tract slings as one of its first offerings (*Medical Device Daily*, Sept. 13, 2012). GMD informed FDA in July it would shutter operations.

Arriol was cited for failure to track data from non-conforming products for longer than a month, and FDA alleged that the company had not investigated a redacted number of non-conformances in 2012. One of the problems with the company's response was that it was not in English, but the warning letter also indicated that documentation of corrective action had not been included.

FDA alleged the company had run a validation protocol for sterilization dated April 21, 2010, but the batch was not tested by a contract testing facility until May 5 that year. The firm's response was apparently that the May 5 test had demonstrated bioburden was at allowable levels until after the quarantine period had passed, and promised to run tests to establish 20-day data for hold times. FDA noted that Arriol did not document completion of this effort nor did it provide evidence of systemic corrective actions that addressed "other validation processes." FDA informed the company that its products could be refused entry to the U.S.

FDA: Epimed selling without clearance

Contract manufacturing can ease operating costs, but the Sep. 19 warning letter to **Epimed International** (Irving, Texas) is yet another reminder of the hazards, but perhaps more problematic was the allegation that the company was marketing radio-frequency thermocouple electrodes without a working 510(k). The warning letter says that Epimed had filed a 510(k) for one of its RF thermocouple electrodes with nitinol probes August 26, 2010, but that the application was deemed not substantially equivalent Sept. 1, 2011, slightly more than a year later. The company apparently refilled this past June 6, but FDA states that application had not been processed as of the date of the warning letter.

A two-part citation dealing with procedures dealing with acceptance of incoming product states first that Epimed had been conducting acceptance activities on the RF thermocouple probes "without knowledge of the device's original manufacturing specifications" as would be provided by the initial manufacturer, or how changes made by that manufacturer, "including sterilization cycles, will affect the device."

Also under acceptance activities, FDA said that Epimed failed to follow its own procedures requiring that incoming product be tested for Ohms, and also "accepted lots of devices that failed testing." In both cases, the warning letter states that the adequacy of the company's response could not be determined, due at least in part to "lack of evidence of implementation" of corrections.

FDA alleged that the "original supplier/developer" of RF probes "is not routinely contacted" to address complaints, and that documents did not support Epimed's claim that complaints were subjected to an "extensive investigation" to determine a root cause. Here again, the firm's June 7 response to the inspectional findings was deemed inadequate due to lack of documentation of corrective actions.

Perhaps suggestive of the origin of some of these difficulties is a citation stating that Epimed had no agreement with its supplier defining "responsibility for device attributes and quality requirements." Further complicating matters here was that Epimed is also said to have failed to require a change notification contract with the supplier of an unidentified product.

The warning letter asserted that Epimed had no specific design validation requirements for RF cannula addressing conformance of finished devices to a defined set of user needs and intended uses, but FDA also said its investigator found no information to identify the lots that had been used for validation activities or "evidence supporting the conclusions based on the test methods used."

Epimed did not respond to contacts for comment.

Senate staffer: CR allows FY 2012 user fees

Trying to figure out how the continuing federal budget resolution will affect device user fees is no mean trick, and the same can be said for the effects of budget sequestration. However, Jessica Frederick, a Senate Appropriations Committee staffer, told *Medical Device Daily* that the CR question is pretty clear. FDA "can only collect the same amount they could last year for the first six months of the year."

Frederick said Congress could have included an anomaly in the CR to allow the new user fee schedule to go into effect, but "we did not include that anomaly." She explained that the Office of Management and Budget had asked for an anomaly for FDA user fee programs, but the House was under instructions to limit its use of anomalies. "They thought it wasn't going to hurt the program that much if they didn't include the anomaly," she explained, thus it "didn't meet the high bar that was set for the anomaly."

As for sequestration, Frederick pointed out that the FDA budget "is not exempted, so I think they'll take the same cut as everyone else. The user fee programs are not exempted either."

The concerns are not identical across centers, however, Frederick explained. "I think PDUFA [the drug user fee agreement] would be fine, but the others would be a lot closer," she said. "There is a real concern" about how the cuts under budget sequestration interact with the triggers found in the various user fee programs, she remarked. ■

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Europe

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Ultrasound (Ultraschall in der Medizin) ahead of this week's Three Country Meeting in Davos covers topics such as perfusion quantification, nodules characterization, and the range of developing diagnostic algorithms.

The mathematical models used to extract the visualization from the ultrasound signal becomes critical to bring perfusion quantification with CEUS to the standards established for contrast enhancement with CT and MRI.

Time intensity curve parameters emerging as essential criteria for CEUS diagnosis include especially the wash-in/wash-out analysis with bolus injection.

The recent European CEUS guidelines provide researchers with detailed discussion of these models, including pitfalls and artifacts that can be encountered.

Off-label usage by researchers in Europe is overtly encouraged by not only by Three Country Meeting president Dietschi but also the editors of the *European Journal of Ultrasound* who wrote in the August, 2012 supplement that CEUS presents a promising tool for studies in the musculoskeletal system, the gastrointestinal tract and in the chest.

As an example they cite explorations for endocavitary.

"Although the precise concentration of ultrasound contrast has not been defined yet, adding some drops of SonoVue® to a physiologic saline solution is all that is needed to outline fluid collections, to diagnose normal and abnormal connections between body cavities, to visualize bile duct obstructions and internal fistulae, and much more," they wrote.

Three years ago Bracco and **TomTec** (Munich, Germany) introduced SonoLiver, a PC-based software for radiologists to review off-line dynamic images of blood perfusion in the liver (*Medical Device Daily*, March 18, 2009).

The number of clinical studies for liver focal lesions jumped following the availability of the software on original equipment manufacturers platforms.

At Davos, discussion will build around the especially disruptive finding using dynamic contrast-enhanced ultrasound (DCE-US) that is proving to be a rapid, low-cost, safe and repeatable method for assessing the effectiveness of chemotherapies.

A consensus paper on DCE-US published in the journal *European Ultrasound* is led by Europe's most-published author on CEUS, Christoph Dietrich, MD, the current president of European Federation of Societies in Ultrasound Medicine and Biology (EFSUMB).

Co-author Nathalie Lassau, MD, from the prestigious **Institute Gustave Roussy** (Paris) is a pioneer of the technique who demonstrated in a multicenter study that DCE-US combined with a quantitative assessment of solid tumor perfusion using raw linear data could determine within two weeks of the start of treatment the effectiveness of 15 different antiangiogenic drugs across multiple types of cancers (*MDD*, Oct. 28, 2010). The cost of the exam using two bolus injections of SonoVue is €82 ($254).

Identifying non-responders in the first month of treatment could prevent patients from enduring a further five months of treatment and save healthcare systems an estimated $40,000 per patient. ■

Court report

Cepheid paying Abaxis more than $17 million to settle patent litigation

A *Medical Device Daily* Staff Report

Abaxis (Union City, California), a medical products company manufacturing point of care instruments and consumables for the medical, research, and veterinary markets, reported that a settlement had been reached in its lawsuit with **Cepheid** (Sunnyvale, California) over several Abaxis patents relating to reagent and chemical compositions and processes.

As part of the agreement, Cepheid will pay Abaxis $17.25 million, and all claims asserted against Cepheid in the pending litigation have been dismissed.

"This will allow both companies to move forward with ongoing activities in sales, development and manufacturing without the distraction of protracted litigation," said Clint Severson, CEO and Chairman of Abaxis. "We are pleased with the outcome of this agreement, and pleased that at Abaxis we can now all concentrate our activities in our core business areas: point of care testing and veterinary laboratory services." ■

People in the News

• **ApeniMED** (Minneapolis) has named Barbara Stinnett to its board. In addition to her role on the ApeniMED board, Stinnett is the CEO and managing partner of the Timmaron Group, an organization serving CEOs, boards, and investors. ApeniMED is a Health IT company, providing automated workflow solutions to healthcare providers.

• **First Warning Systems** (Reno, Nevada) has named Nola Masterson as senior business and strategy advisor. Masterson is managing director of Science Futures Management Company. Masterson is chairwoman of the board of Repros Therapeutics and serves on the board of Generex. The First Warning System is a breast health screening device and method based on disruptive technology and tissue health science. The system is a non-invasive breast physiology screening system, much more sensitive and much more cost effective than mammography.

• **M*Modal** (Franklin, Tennessee) said Mike Etue has joined the company as executive VP of sales, effective Oct, 1. Most recently, Etue was VP of sales and marketing, provider markets for OptumInsight. M*Modal is a provider of clinical documentation and speech understanding solutions.

MDD's Ortho Extra

Additional Developments in One of Med-Tech's Key Sectors

Thursday, September 27, 2012

Keeping you up to date in recent developments in orthopedics

Discovering that thigh size is a reason why hip implants fail may lead to better design . . .

University of Iowa (Iowa City) researchers have determined that thigh size in obese people is a reason their hip implants are more likely to fail. In a study, the team simulated hip dislocations as they occur in humans and determined that increased thigh girth creates hip instability in morbidly obese patients (those with a body mass index (BMI) greater than 40). The researchers propose that surgeons modify surgical procedures to minimize the chance of dislocation in obese patients and consider other designs for hip replacement implants. "We have shown that morbidly obese patients' thighs are so large that they are actually pushing each other outward and forcing the implant out of its socket," says Jacob Elkins, a UI graduate student and first author of the paper published in the journal *Clinical Orthopaedics and Related Research*. "Studies have shown up to a 6.9-fold higher dislocation rate for morbidly obese patients compared to normal weight patients. Total hip replacement gives mobility back to people who experience debilitating hip joint pain. According to the **National Institute of Arthritis and Musculoskeletal and Skin Disease** (NIAMS; Bethesda, Maryland), 231,000 total hip replacements are performed annually in the U.S. and more than 90 percent of these do not require follow-up repair or replacement. But when an implant fails, it is painful, and costly. Studies have shown that dislocation ranks as the most common reason for failed implants, according to Medicare hospital discharge data. Clinical studies point to an increased dislocation risk among obese patients with total hip replacements, but the reasons have remained unclear. Dislocation requires extreme range of motion, such as flexing at the waist. Given the reduced range of motion in the obese, why do they experience more dislocations? Using a computational model he created to understand how a hip implant works in patients, Elkins and research collaborators analyzed 146 healthy adults and six cadaver pelvises. They examined the effects of thigh-on-thigh pressure on the hip implant during a wide range of movements from sitting to standing. With the ability to simulate movements in human bodies of varying sizes, the team could test different implants. They also looked at the various implants' performances in different body types. They used a hip-center-to-hip-center distance of 200 millimeters as a basis for their analyses of thigh girth for eight different BMIs, ranging from 20 to 55. The research team ran computations to examine the joint stability of several different hip implants. They tested two femoral head sizes (28 and 36 millimeters), normal vs. high-offset femoral neck, and multiple cup abduction angles. The researchers report three main findings: thigh soft tissue impingement increased the risk of dislocation for BMIs of 40 or greater; implants with a larger femoral head diameter did not substantially improve joint stability; using an implant with a high-offset femoral stem decreased the dislocation risk. Surgeons treating obese hip implant patients can use the study findings to select better implant designs and modify their surgical procedures to minimize the chance of dislocation in obese patients, the researchers say.

Virtual foot set to help healing . . .

An advanced virtual model of the human foot has been created by researches to drive forward improvements in treating serious injuries and illness. The 3-D model depicts bones, joints, ligaments, muscles and tendons in an unprecedented level of detail. It will be used to develop advanced treatments for conditions ranging from foot and ankle problems to amputations. The EUR 3.7 million a-footprint project is being led by **Glasgow Caledonian University** (GCU; Glasgow, Scotland). Researchers worked in partnership with the **Maastricht University** (Maastricht, the Netherlands) and Danish biomechanical firm **AnyBody Technology** on what had been named the Glasgow/Maastricht Foot Model.It is estimated that 200 million Europeans suffer from disabling foot and ankle conditions and the model should lead to more efficient orthotic devices, cutting recovery times and reducing symptoms. It will also have aplications in treating flat feet or foot drop - which prevents recovering stroke patients from moving their ankles and toes. GCU's Professor Jim Woodburn, who is the project co-ordinator, said: "Previous to this development, most computer models of the human body ended in a black rectangle - the foot was simply too complicated to model. The Glasgow/Maastricht foot is a game-changer. "It opens the door to a huge range of applications, including the manufacture of better and more

efficient orthotics, resulting in quicker recovery times, reduced symptoms and improved functional ability for those suffering from conditions which afflict the foot and lower leg," Woodburn said. The simulation can be used to test potential cures as well as developing new orthotic devices, using 3-D printing techniques.

Gene discovery has potential for development of new medicines to prevent the most common fractures . . . A big international study has identified a special gene that regulates bone density and bone strength. The gene can be used as a risk marker for fractures and opens up opportunities for preventive medicine against fractures. The study, led by the Sahlgrenska Academy, **University of Gothenburg, Sweden**, was published in the journal *PLoS Genetics*. The international study, which involved more than 50 researchers from Europe, North America and Australia and was led by Associate Professor Mattias Lorentzon and Professor Claes Ohlsson at the Sahlgrenska Academy, University of Gothenburg, is based on extensive genetic analyses of the genetic material of 10,000 patients and experimental studies in mice. Through the combined studies, researchers have succeeded in identifying a special gene, Wnt16, with a strong link to bone density and so-called cortical bone thickness, which is decisive to bone strength. The genetic variation studied by the international research network could predict, for example, the risk of a forearm fracture in a large patient group of older women. "In the experimental study, we could then establish that the gene had a crucial effect on the thickness and density of the femur. In mice without the Wnt16 gene, the strength of the femur was up to 61 per cent lower," according to Mattias Lorentzon at the Institute of Medicine, the Sahlgrenska Academy, University of Gothenburg. The discovery opens up opportunities to develop new medicines to prevent the most common fractures. "Low cortical bone mass is a decisive factor in, for example, hip and forearm fractures. Unfortunately, the treatments currently used for brittleness of the bones have very little effect on the cortical bone mass," says Mattias Lorentzon. "If we can learn to stimulate the signaling routes of the Wnt16 gene, we could strengthen the skeleton in these parts too, thereby preventing the most common and serious fractures. The discovery of Wnt16 and its regulation of cortical bone mass is therefore very important," according to Mattias Lorentzon.

Study of spinal injury data may help surgeons treat injured soldiers and civilians . . . Spinal injuries are among the most disabling conditions affecting wounded members of the U.S. military. Yet until recently, the nature of those injuries had not been adequately explored. In a new study recently published in the J*ournal of Bone and Joint Surgery* (JBJS), a team of orthopedic surgeons reviewed more than eight years of data on back, spinal column, and spinal cord injuries sustained by American military personnel while serving in Iraq or Afghanistan. The injuries were then categorized according to anatomic location, neurological involvement, the cause of the injury, and accompanying wounds. The resulting analysis is an important first step in helping orthopedic surgeons develop treatment plans for these service members, as well as for severely injured civilians who sustain similar disabling injuries. Of 10,979 evacuated combat casualties, 598 (5.45%) sustained a total of 2,101 spinal injuries. Explosions accounted for 56% of spine injuries, motor vehicle collisions for 29%, and gunshots for 15%. Additionally, 92% of all injuries were fractures and 84% of patients sustained their wounds as a result of combat. In 17% of injuries to the spine, the spinal cord also was injured, and 53% of all gunshot wounds to the spine resulted in a spinal cord injury. Spinal injuries were frequently accompanied by injuries to the abdomen, chest, head, and face. "In these current military conflicts, the latest technologies in body armor, helmets, and other protective devices have helped save many soldiers' lives," said James Blair, MD, an orthopedic surgery chief resident in the Department of Orthopaedics and Rehabilitation, Brooke Army Medical Center (Fort Sam Houston, Texas). "We also have access to advanced life-saving techniques in the field and medical evacuation strategies that are keeping many more service members alive. "But when a person survives an explosion or vehicle collision, there has still been a great deal of force on the body," Blair adds. "Many of those survivors are coming to us with severe injuries to their spine and back. We needed to describe and characterize these injuries so recommendations can be made on how to provide the most effective treatment and rehabilitation for our wounded warriors." Although the survival rate is high for such injuries, the disability rate also is quite high. This affects not only the service members, but also their families and the U.S. healthcare system. Therefore, the study's authors note, further research is required to improve future outcomes for those with spinal injuries.

— Compiled by Holland Johnson, *MDD* Executive Editor
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