Medical Device Daily™
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Ventus gets 'bullet-proof' data that Provent works

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

Even the very best therapeutic device won't work if the patient refuses to use it.

Physicians who treat obstructive sleep apnea (OSA) have faced this dilemma for years; continuous positive airway pressure (CPAP) therapy – the current gold standard – works, but a lot of patients refuse to use it, or won't use it as long as they need to.

"We're talking about a chronic disease, and the person that treats the chronic disease is the patient, and if the patient doesn't use the device then it's worthless," Philip Westbrook, MD, told *Medical Device Daily* from a noisy gathering of sleep experts in San Antonio on Monday.

According to **Ventus Medical** (Belmont, California), two studies were presented this week at the Sleep 2010 meeting

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BD offers up nano-sized needle to deliver insulin

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

Becton Dickinson (BD; Franklin Lakes, New Jersey) is offering what it calls a tiny solution to a huge problem.

The company is tackling insulin delivery to diabetics and reported launching a nano-sized device designed to make the process a bit more palatable and less painless. Common practices have been a bit painful for the more than 5 million people in the U.S. that inject insulin or GLP-1 to manage their diabetes.

The company said its BD Ultra-Fine Nano, which is 4mm x 32G, is perhaps the world's smallest pen needle and that it has been proven every bit as effective as longer needles for people of varying body types.

"There's a common belief [in the medical community] that obese patients need a longer needle," Laurence Hirsch,

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Report from Europe

Study supports t-VNS device for hard-to-treat epilepsies

A *Medical Device Daily* Staff Report

An evaluation has revealed positive intermediate results for the first three months of clinical trial data for the treatment of therapy-resistant epilepsies with the world's first device using transcutaneous vagus nerve stimulation (t-VNS), from **cerbomed** (Erlangen, Germany).

According to the company, t-VNS proves its good safety profile and scores high on user-friendliness, and there are also preliminary indications of its effectiveness for the patients in the cMPsE01 pilot study.

The cMPsE01 pilot study is structured as an uncontrolled, single-center prospective pilot study with a verum group, carried out under the supervision of Hermann Stefan, MD, a professor at the epilepsy center of the **University**

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Washington roundup

FDA inks warning letter to Otologics for documentation

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

Songwriter Herman Hupfeld surely did not have FDA warning letters in mind when he penned the lyric, "a kiss is just a kiss," but sometimes a warning letter really is just a warning letter. The March 5 warning letter to **Otologics** (Boulder, Colorado) suggests that the fundamental things – such as keeping records up to date – still apply, regardless of whether the agency's prose compares well to Hupfeld's.

The warning letter cites the firm, which makes fully implantable hearing aids, only for several record-keeping lapses and closes with a response to Otologics' Dec. 8, 2009, response to the inspectional findings, which is said to have included a request for a meeting with the agency. FDA

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Don't miss today's MDD Extra: Oncology

INSIDE:

AHC Media LLC

Financings roundup

IncellDx closes $3M funding, initiates trial for HPV test

A *Medical Device Daily* Staff Report

IncellDx (Menlo Park, California) has closed a $3 million Series A financing. Proceeds will be used to advance the commercialization of IncellDx products and to initiate the U.S. clinical trial for HPV OncoTect, a E6, E7 mRNA test that is currently CE marked.

"We see enormous potential to initiate the U.S. clinical trial for HPV OncoTect, while at the same time expanding our existing commercial efforts for Europe and Southeast Asia," said Bruce Patterson, MD, founder and CEO of IncellDx.

The U.S. High Risk (HR) HPV testing market is estimated to be $300 million dollars and growing at an annual rate of 14%. The consensus guidelines published in ACOG recommend HR HPV testing for cervical cancer screening in women over 21 who have abnormal PAP smears and in women over 30 years of age when used in conjunction with a PAP test.

One of the limitations of existing screening tests is lack of specificity. "Since 92% of women spontaneously clear HR HPV infections in two years, many women with positive test results will not proceed to cervical cancer," Patterson said.

Since HPV OncoTect detects and quantifies the cellular oncogenes responsible for triggering progression to cervical cancer, it has the promise of improving specificity. The unique technology behind HPV OncoTect, has broad application for many infectious disease tests, which can be performed on the same platform.

In other financing news, **GE Capital** (Bethesda, Maryland), Healthcare Financial Services provided, as administrative agent, $120 million in senior secured credit facilities to **Schumacher Group** (Lafayette, Louisiana), the third largest company serving the outsourcing emergency services management industry. The credit facilities will be used to provide the company with additional growth capital and to refinance existing indebtedness. GE Capital Markets served as lead arranger. ■

MDD's food for med-tech thought

"We're talking about a chronic disease, and the person that treats the chronic disease is the patient, and if the patient doesn't use the device then it's worthless."

– Philip Westbrook, MD, chief medical officer at Ventus Medical, describing the current standard sleep apnea treatment, continuous positive airway pressure therapy, "Ventus gets 'bullet-proof' data that Provent works," pp. 1, 5.

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Society of Nuclear Medicine notebook

GE showcases molecular imaging advances at SNM

A *Medical Device Daily* Staff Report

GE Healthcare (Waukesha, Wisconsin) is highlighting its portfolio of molecular imaging technologies and agents at the 57th annual meeting of the **Society of Nuclear Medicine** (SNM; Reston, Virginia) this week in Salt Lake City.

"Our vision for the Molecular Imaging business is to apply innovation to improve the patient experience," said Terri Bresenham, VP of the GE Healthcare Molecular Imaging business. "We have shortened traditional exam times and reduced dose without compromising a clinician or researcher's ability to understand disease from the beginning."

One example of how GE Healthcare is improving experience for patients is through dose management. At SNM, GE Healthcare is showcasing the technique of Adaptive Statistical Iterative Reconstruction (ASiR) resulting in a reduction of CT dose by up to 40%. With this innovation across the Discovery PET/CT 600 series platform and Discovery NM/CT 570c, clinicians don't compromise image quality while reducing dose to their patients. Further, GE Healthcare is introducing new PET pediatric protocols available on the Discovery Dimension Console, that allow the lowest dose possible for the youngest patients.

PET/CT technology has also evolved with the patient in mind. With specialized detector configuration designed for sensitivity, event throughput and efficiency, researchers and clinicians have the necessary speed in workflow, protocol flexibility to help forge new frontiers in clinical techniques, drug discovery and motion management. The scan itself is also more efficient with a 2-meter scan option that allows clinicians to complete an entire head to toe examination in one scan.

The most commonly performed nuclear medicine procedure – whole body bone imaging – which includes a whole body planar and at least one position SPECT/CT, and traditionally required over 35 minutes to complete, has been shortened to 16 minutes imaging time with the state-of-the-art Discovery NM/ 670.

In other news from SNM, **Cell>Point** (Centennial, Colorado) presented clinical results for its cancer imaging agent, 99mTc-EC-G, used to assess the efficacy of chemotherapy.

The company noted that 99mTc-EC-G (99mTechnetium-EthylenediCysteine-n-acetyl-Glucosamine) is a SPECT (Single Photon Emission Computed Tomography) cancer imaging agent Cell>Point is developing as an alternative to FDG-PET (Fluorodeoxyglucose – Positron Emission Tomography) for diagnosing and staging patients with cancer.

In the reported study, Cell>Point enrolled seven patients with non-small cell lung cancer and receiving chemotherapy as part of a phase I trial performed to assess dosimetry, biodistribution and pharmacokinetics of the agent. All patients were imaged with FDG-PET to assess the efficacy of chemotherapy. Investigators performed 99mTc-EC-G SPECT imaging to compare with PET findings.

Image interpretation showed a 1:1 correspondence between FDG-PET and 99mTc-EC-G SPECT for all primary lesions. For PET, all primary lesions had a fluffy appearance and were larger than noted on the pretreatment PET, consistent with chemotherapy inflammatory response.

For SPECT, the primary lesions were smaller and more discrete, with clinical findings of chemotherapy efficacy. Two patients had confirmed false-positive FDG-PET findings due to infection.

"99mTc-EC-G shows promise for assessing the efficacy of chemotherapy during the course of therapy in this limited patient population," said David Rollo, MD, PhD, president of Cell>Point. ■

Grants roundup

VA seeks to stir innovation with funding initiative

A *Medical Device Daily* Staff report

Secretary of Veterans Affairs Eric Shinseki reported the opening of the Industry Innovation Competition by the **Department of Veterans Affairs** (Washington), the most recent effort under the VA Innovation Initiative. With this competition, VA seeks the best ideas from the private sector to address the department's most important challenges.

The VA Innovation Initiative (VAi2) is a department-wide program that brings the most promising innovations to VA's most important challenges by involving employees and the private sector in the creation of visionary solutions in service to Veterans.

Public and private companies, entrepreneurs, universities and non-profits are encouraged to participate in the competition, which targets advancements in:

- Telehealth: Potential applications for telehealth solutions are broad and varied and department officials are interested in pursuing integrated solutions that improve their ability to provide the right treatment at the right place and at the right time.
- New models of dialysis and renal disease prevention: VA says that alternative treatment strategies and dialysis technology can extend and improve our ability to provide quality care in a patient-preferred setting.
- Improvement of polytrauma care: VA says it provides comprehensive, inter-disciplinary rehabilitation care to veterans and returning service members with multiple injuries, or polytrauma. Solutions in areas such as the application of dynamic treatment algorithms, home monitoring of diverse and complex symptoms and assistive technologies can help the broad advancement of polytrauma care. ■

Agreements/contracts

IBM, ProtonMedia team to deliver 3-D environments

A *Medical Device Daily* Staff Report

IBM (Armonk, New York) and **ProtonMedia** (Lansdale, Pennsylvania) have entered into a teaming agreement that will result in the delivery of 3-D virtual collaboration and communication solutions engineered specifically for global life sciences organizations.

ProtonMedia's ProtoSphere technology will be the basis for customized, 3-D virtual collaboration environments to create high-performance workplaces. IBM's Global Business Services division will provide consultancy, integration, deployment, and installation services to life science customers around the world, leveraging the ProtoSphere platform. The companies are also in discussions for cross-marketing initiatives for their solutions.

"We're excited to collaborate with ProtonMedia," said Cindy Skirvin, partner of strategy and transformation workforce and talent solutions for IBM Global Business Services. "By combining our strengths and breadth of technology services with ProtonMedia's virtual collaboration platform, we're enabling organizations to address some of the most pressing issues facing them today, including speeding decision-making across the entire product life cycle, meeting human capital management needs, and improving workplace performance overall."

In other agreements and contracts news:

• **PolyOne** (Cleveland) and **Dow Corning** (Midland, Michigan) confirmed that PolyOne will distribute Dow Corning silicone products to healthcare device manufacturers and fabricators in the U.S., Canada and Mexico.

Dow Corning's silicone elastomers are used in a variety of medical device applications including, EKG tabs, catheters, angioplasty balloons, medical grade O-rings, tubing, stoppers and closures, among many other healthcare applications.

The agreement adds the first non-thermoplastic solution to PolyOne Distribution's healthcare portfolio.

• **Raydiance** (Petaluma, California) is partnering with **Rofin** (Hamburg, Germany) to introduce femtosecond laser technology to industrial production.

Rofin's first solution incorporating Raydiance laser technology is the new StarCut Tube Femto, a solution to offer cold laser cutting for makers of life-saving medical devices such as cardiovascular stents. The StarCut Tube Femto cuts sensitive materials such as gold, platinum, shape memory alloys and low-melting point polymers with high precision and cut quality, and no thermal effect. These unique capabilities are enabling totally new medical device designs while improving quality and manufacturing costs on existing products.

• **Oslo University Hospital** (Norway) and **Induct Software** (Boston) reported a long-term strategic partnership agreement under which the parties will work together to help Oslo University Hospital achieve its goal of becoming the world leader in healthcare innovation.

With 24,000 employees, the new Oslo University Hospital is one of the largest hospitals in Europe, with a yearly operating budget of 17B NOK ($2.6 billion).

Oslo University Hospital will work with Induct to ensure that Induct's web-based innovation management service meets the specialized needs of healthcare professionals at every level.

• **Zix** (Dallas), a provider of email encryption services, has reported a new, three-year contract with **Orlando Health** (Orlando, Florida), a $15 billion not-for-profit healthcare organization.

ZixCorp will provide Orlando Health with email encryption for 10,000 Orlando Health users through ZixGateway. Orlando Health will be able to secure protected health information and alleviate security and compliance burdens on employees. Within the ZixCorp solution, Orlando Health will also leverage ZixPort, a pull delivery technology that provides a secure portal for delivering sensitive information to external customers and partners that have not yet registered for a ZixCorp service.

• **Wolters Kluwer Health** (Minneapolis) said that the **Endoscopy Center of North Baltimore** (Towson, Maryland) has selected its ProVation MD software for gastroenterology procedure documentation and coding, and its ProVation EHR electronic health record and patient charting solution.

• **Medical Action Industries** (Brentwood, New York) has renewed a three-year, sole source national contract with **Novation** (Irving, Texas) to provide patient bedside plastics and stainless steel products to the members of VHA, the University HealthSystem Consortium and Provista.

This agreement, which is effective July 1, is a renewal of an existing agreement between the two organizations that does not establish minimum purchase requirements or require Novation's members and affiliates to purchase the company's products.

Medical Action has also been selected to participate in Novation's Patient Care Standardization Program, which allows Medical Action to provide even greater value to the members served by Novation.

In addition to patient utensils, such as wash basins, bedpans and urinals, the agreement also calls for Medical Action to be the exclusive supplier of specimen containers, laboratory plastics, reusable plastics and stainless steel products through the Novaplus private label program. Other terms of the agreement were not disclosed.

• **MedAssets** (Atlanta) has renewed a long-term spend management agreement with **University of Pittsburgh Medical Center** (UPMC), an $8 billion integrated global health enterprise. MedAssets will continue to provide its spend management solutions, including group purchasing services, supply chain data and analytical tools and custom interfaces to continuously improve UPMC's supply chain processes. ■

Ventas

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of the **Associated Professional Sleep Societies** (APSS; Westchester, Illinois) in San Antonio – including one that was a randomized, multi-center trial – that confirm the clinical efficacy of the company's Provent sleep apnea device.

"With the large randomzed multi-center clinical trial we finally have bullet-proof clinical data that this thing really works, and works very well," said Westbrook, the chief medical officer at Ventus.

He said the studies presented at the Sleep meeting show that the Provent device works – not for everyone, but for a large percentage of patients – and that the compliance to the therapy is "excellent."

"It's an easy disease to diagnose, but it's a very difficult disease to treat, and now we have another [device] in our toolbox," Westbrook said.

At the Sleep meeting, James Walsh, PhD, executive director of the Sleep Medicine and Research Center at **St. Luke's Hospital** (St. Louis, Missouri) reported that patients using Provent therapy had clinically meaningful and statistically significant decreases in the apnea-hypopnea index (AHI) – a measure of breathing disruptions during sleep. The therapy was accepted by 80% of patients who had previously refused CPAP therapy or used CPAP fewer than three hours a night on average. The study also found that Provent therapy use improved blood oxygen saturation, and resulted in less daytime sleepiness as measured by the Epworth sleepiness scale, the company noted.

"Current treatment options for obstructive sleep apnea are suboptimal," Walsh said. "When used properly, CPAP essentially eliminates sleep apnea, but a large percentage of patients are non-compliant and express significant dissatisfaction with CPAP. These data provide evidence that Provent is a treatment option for many patients who were unable to tolerate or unwilling to try CPAP therapy."

Ventus describes the Provent therapy as a "simple, noninvasive prescription treatment that works across mild, moderate, and severe OSA." The treatment uses nasal expiratory positive airway pressure (EPAP) and the device incorporates a valve design that is placed over the nostrils and secured with hypoallergenic adhesive, the company said. During inhalation the valve opens, allowing nearly unobstructed airflow, and during exhalation the valve closes, directing airflow through two small openings, which increases expiratory airway pressure.

After Walsh presented his study findings Monday, the Ventus booth at the meeting was buzzing with interest from the physician attendees, according to Meir Kryger, MD, a clinical professor of medicine at the **University of Connecticut** (Storrs) and director of Sleep Medicine Research and Education at **Gaylord Hospital** (North Haven, Connecticut).

"I'm standing in front of the program booth and it's crawling with people who are interested in this thing, and they're asking for samples and more information so there's a lot of interest in it," Kryger told *MDD* during a phone interview from the meeting.

Although many of the patients involved in the study responded very well to the treatment, Kryger said, "we don't know exactly yet how to identify the ideal patient." He said the treatment is so new that "all of us are [still] learning" how best to implement the therapy.

Kryger also emphasized the importance of patient compliance when treating patients with OSA.

"People who use [Provent] use it every night and they use it all night, and that's always been a problem with CPAP," he said. "Compliance is not fabulous and a certain percentage of people simply will not use CPAP."

Also during the Sleep meeting, Richard Berry, MD, from the **University of Florida** (Gainesville), reported results from a multi-center, randomized, controlled trial of Provent versus a placebo (or sham) device for OSA. This study also showed that Provent therapy significantly reduced AHI, improved oxygen saturation in the blood as well as reduced daytime sleepiness when compared to the sham device.

"Many OSA patients are inadequately treated due to adherence or efficacy issues with current therapy. Alternative effective treatments for OSA are needed," Berry said. "The results of the study suggest that Provent therapy is an effective treatment alternative for a substantial percentage of OSA patients."

The Provent device received FDA clearance in 2008, but the company has been used mostly at trial centers rather than being aggressively marketed while Ventus builds physician confidence, and a payor foundation, by developing clinical evidence of the device's effectiveness (*MDD*, June 15, 2009).

Kyger said he is "delighted" that there are now other options to treat OSA patients besides CPAP.

"The main thing is . . . with any disease you have to move forward with new treatments and there really have not been a lot of options with CPAP," Kryger said. "CPAP is an excellent treatment, but for some people it's not the best fit." ■

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Nano

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MD, VP of medical affairs at BD Diabetes Care, told *Medical Device Daily*. "There is actually no evidence to support that. There is, however, evidence that says shorter length nanos work every bit as well as longer needles. If you inject straight in 90 degrees with no pinch up so that the insulin will get into the fat . . . anatomically 4mm is long enough."

The closest needle to BD's Ultra-Fine Nano size is 5mm.

"Everywhere we go, when we hold up this needle and show physicians, they say 'wow, this is really small'," Hirsch said. "The size first and foremost assures that there is less pain during insulin delivery than in other longer devices. Nearly 75% of patients who took a survey and used the device preferred it over larger iterations and said that it was less painful. Now that's not 100% but [75%] is a significant amount."

According to a study published in the June edition of the *CRMO Journal*, in adults with Type 1 and Type 2 diabetes, the 4mm 32G pen needle provides equivalent glycemic control to 31G, 5 and 8mm PNs. The article also goes on to say that percent absolute changes in fructosamine were small, averaging 5 to 5.5% (median 11–13.5 mmol/L), and there was no suggestion of any trend in directional change in blood glucose levels with the new pen needle. The 4mm 32G PN was reported to be less painful, easier to use, caused no additional leakage and was preferred to the larger, longer needles by the study subjects.

"There's a common concern that shorter needles leak more," Hirsch said. "But this study said that there is no increase in leakage as compared to the 8mm and the 5mm."

Factors affecting patient perceptions of pain with injection therapy include needle diameter and length, tip sharpness including bevel angularity, polishing and smoothness of the cannula, as well as cannula lubrication. External cannula diameter has been shown to be especially important in several studies 21,22.

The article goes on to say that the evaluation in this study clearly showed significantly less pain with the 4mm 32G PN: subjects rated the new PN nearly 12mm less painful than the 5mm needle, and 23.3mm less painful than the 8mm needle – a nearly two-fold larger change. Using the VAS described with a center point anchor of 'No difference,' the maximum difference demonstrable would be 75mm between two devices/needles: the VAS score differences are nearly 16% and 31%, respectively, of the maximum, implying changes that can be appreciated by the subjects. Other studies and BD's prior investigations suggest that a 10mm difference is clinically meaningful, the company said.

The device has already been approved in Europe and was given FDA clearance in late April.

"To use the often cliched statement size matters and in this case smaller is better." ■

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Deals roundup

Sorin acquires Gish from Ventizz Capital

A *Medical Device Daily* Staff Report

Sorin Group (Milan, Italy), a company that specializes in the treatment of cardiovascular diseases, said it has acquired **Gish Biomedical** (Rancho Santa Margarita, California) from **Ventizz Capital Partners** (Dusseldorf, Germany), a private equity group focused on technology-oriented companies.

Gish makes disposable medical devices for cardiovascular surgery, with a focus on the Perfusionist. Gish products have been marketed both in the U.S. and worldwide for more than 25 years, the company said.

"We are excited by this opportunity to further strengthen our world leadership in providing patients and customers with the best solutions for extracorporeal circulation" said Michel Darnaud, president of the Cardiopulmonary business unit and Intercontinental at the Sorin Group.

The guidance previously provided to the market remains unchanged as a result of this transaction.

In other dealmaking activity:

• **America's Minority Health Network** (AMHN; Burbank, California) reported that it entered into a letter of intent (LOI) with **Gordon Communications** to acquire **Spectrum Health Network**. Spectrum is a digital signage waiting room network built for the multi-specialty group practice and independent physician associations.

Spectrum was developed to be an extension of the medical practice, enabling the group practice to relay custom produced health-specific educational based content to patients while waiting for their physicians.

Spectrum provides its clients with a powerful tool for practice enhancement, patient communications and as a viable method to deliver patient-directed educational initiatives.

The terms of the LOI includes the acquisition of all of Spectrum's assets and liabilities, and 100% of the outstanding common stock of Spectrum in exchange for shares of the company's common stock.

The number of AMHN shares to be issued in exchange for the Spectrum shares will be determined upon the completion of due diligence and prior to the preparation of a definitive agreement between the parties. The company intends to close the definitive agreement by July 15.

• **Halfpenny Technologies** (Bluebell, Pennsylvania), a health information exchange (HIE) solutions provider specializing in laboratory, pathology and physician electronic medical record system interoperability, said it has acquired **Laboratory Management Services** (LMS; Hauppauge, New York), a provider of clinical data acquisition and reporting solutions for health plans and clinical laboratories.

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Europe

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Hospital of Erlangen. The study includes 10 patients, for an expected therapy period of 9 months, cerbomed said.

The primary aim of the trial is to prove the safety and feasibility, as well as the compliance of t-VNS. The study's secondary aim is the early determination of whether t-VNS has anticonvulsive effectiveness, that is, whether it reduces the frequency and duration of episodes in hard-to-treat epilepsies, the company said. A further goal is to gather information for planning the number of cases, as well as specific inclusion and exclusion criteria for the planned follow-up study, which will focus on the effectiveness of t-VNS therapy, cerbomed noted.

"The enormous need for effective alternative forms of therapy for therapy resistant epilepsies was the stimulus to start clinically testing cerbomed's promising t-VNS technology," Stefan said. "We are pleased the intermediate results of the clinical trial have turned out to be so positive, and that they prove the safety and feasibility of t-VNS. Also, we have seen the first indicators of the possible effectiveness of the new therapy, which uses cerbomed's transcutaneous vagus nerve stimulator."

According to cerbomed, t-VNS uses the principle of invasive vagus nerve stimulation, which has been established as a method to treat therapy-resistant epilepsy, and is certified for use in North American and European markets. Until now, the only available product for VNS that is reimbursed by health insurance companies is a device which must be surgically implanted in the patient's neck, in the immediate vicinity of the vagus nerve, the company said. Taken together, the product and medical costs of invasive VNS are nearly $33,000 in the U.S.

According to cerbomed, it has developed technology that aims to make the transcutaneous application of VNS possible. This removes the need for an operation, thus eliminating the associated risks, costs and side effects, the company noted. This means a considerably more patient-friendly and economical treatment. The technology uses the fact that branches of the vagus nerve run immediately under the surface of the skin close to the ear, and are therefore suitable for stimulation through the skin, cerbomed said.

"The intermediate results of the pilot study confirm for us that developing our innovative transcutaneous vagus nerve stimulators will, in the future, provide people with hard-to-treat epilepsies with a safe and feasible treatment alternative," said Andreas Hartlep, PhD, managing director of cerbomed.

Elekta unveils next-generation MEG

At the **Organization of Human Brain Mapping**'s (Minneapolis) annual meeting in Barcelona, **Elekta** (Stockholm, Sweden) unveiled its next-generation magnetoencephalography (MEG) system, Elekta Neuromag TRIUX. A platform that addresses key requirements critical for monitoring normal and abnormal brain activity, Elekta Neuromag TRIUX was designed to operate in virtually any clinical environment, Elekta said.

According to the company, implementing a MEG program will be more practical for most clinical environments with the Elekta Neuromag TRIUX system's dynamic range, which has been increased three-fold, in addition to built-in active shielding, which protects its ultrasensitive sensor array from magnetic interference. These improvements make Elekta Neuromag TRIUX suitable for siting in even the busiest hospitals and research centers, the company said.

According to Elekta, the Neuromag TRIUX also provides several features designed to simplify day-to-day use of the system and enhance patient experience. These include a new connector panel with easy to access connectors and an all-new gantry that allows clinicians and researchers to conduct MEG measurements with the patient in a more comfortable upright position.

In addition, Elekta Neuromag TRIUX is undergoing a major revision to its system software to "perfect acquisition workflows" and routine quality assurance procedures, the company said.

"This system is now the definitive platform from which to launch MEG programs now and far into the future. In fact, many upcoming improvements and options presently in development may be ordered already today to ensure Elekta Neuromag TRIUX will be continually updated with releases as they become available," said Stephen Otto, chairman of Elekta's Neuromag business. "Current users also will be pleased to discover the time-proven triple sensor array remains unchanged to maintain full compatibility with the wealth of research conducted by the Neuromag user community."

Elekta says MEG is based on the detection of the very weak magnetic fields that originate from electrical activity within the brain. These signals are detected with a SQUID (superconducting quantum interference device) array placed close to the scalp, the company noted. Elekta Neuromag TRIUX will be available as a turn-key system or as a hardware / software upgrade for certain Elekta Neuromag models.

DSM in pact with Biomedical, Cortland, Secant

DSM (Urmond, Netherlands), manufacturer of Dyneema Purity, which is considered to be the world's strongest medical grade fiber, reported agreements with **Biomedical Structures** (Warwick, Rhode Island), **Cortland,** and **Secant Medical** (Perkasie, Pennsylvania).

According to DSM, these companies' experience in processing Dyneema Purity fiber in biomedical textile structures offers medical device companies the ability to use various constructions of Dyneema Purity, including the recently launched Dyneema Purity Blue, in commercial medical devices. Dyneema Purity Blue,

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Washington

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states that it would "reconsider" the request if the company believed "a meeting to discuss the necessary corrective actions will assist . . . in establishing and implementing effective corrective actions."

One of the citations deals with records of deviations from the study protocol, but FDA did not cite those deviations themselves, suggesting they were not inherently problematic. According to FDA, the protocol deviation section of a supplemental report dated July 29, 2009, indicated no deviations from the study protocol, but study site records are said to have indicated "at least 13 deviation forms found in subjects' files" at one study site and one deviation form for one patient each at another five sites.

The substantially redacted warning letter states further that the supplemental report "does not accurately reflect data recorded on case report forms" for two subjects at one site.

A pair of memos are said to explain the failure to perform the test, but details were redacted.

The warning letter indicates that the company undertook corrective actions, but deemed those corrections inadequate due to lack of documentation that the corrections were undertaken and completed. These include training of study site personnel training, but Otologics apparently also committed to a third-party audit, scheduled for the end of March.

Device shipment records also raised eyebrows at the agency, which states in the warning letter that "lot numbers for single-use kits ... do not correspond with the lot numbers on surgical report forms." The warning letter states further that there were discrepancies in serial numbers for devices implanted in two patients and that the invoices for two patients' shipping documents were missing at the time of the inspection.

FDA deemed inadequate the company's responses for these findings because the updated procedures failed to address "discrepancies ... such as incorrect serial numbers" and because Otologics' response did not document corrective training of study site personnel for device tracking.

FDA's web site indicates no close-out letter for this warning letter. At press time, Otologics had not responded to a call for comment.

Wayne State IRB caught in warning

Most who live within the geographic confines of the Information Age might acknowledge a love-hate relationship with computer software, which might be said of the institutional review board (IRB) at **Wayne State University** (Detroit, Michigan). FDA inked Wayne IRB an April 15 warning letter listing two well-detailed deviations from regulations, but the warning letter suggests – and an e-mail response to *Medical Device Daily* asserts – that the ever-present technoglitch is at the bottom of at least most of the problems cited in the letter.

FDA states in the warning letter that the IRB's documentation for board meetings lacked minutes for eight meetings held between May 2008, and October 2009. This citation was not directly blamed on computers, however. According to FDA, this oversight was attributed to a research compliance administrator and this problem "has been resolved in that [the administrator] no longer work[s] for" Wayne State. All the same, the agency asked for a corrective action plan as well as documentation that the corrective action has been put into play.

The warning letter charges that the IRB could not document votes taken during three meetings of the clinical and translational sciences board in November 2008, and notes that the IRB indicated it was "aware of this problem prior to the inspection." FDA states that the IT staff at Wayne State was working with the software vendor to correct this problem at or around the date of the warning letter.

Also cited in this section is that the software identified one board member as an unexpected problems consultant despite that the individual in question was a voting board member.

According to the warning letter, Wayne IRB was working on dynamic IRB membership reports and had hired a new associate director tasked with ensuring that procedures would be developed to take care of these issues. The IRB also informed FDA that the database in question was at the time experiencing "programming problems," and FDA asked for documentation regarding the measures undertaken to ensure the software performs appropriately.

The second citation states that one of the review boards lacked a voting majority for three votes taken between July 2007 and November 2008. Wayne's response was evidently that "an additional . . . staff member will attend the IRB meetings" to ensure a majority is present, but FDA was not mollified, asking for data on the qualifications of the person who would take charge of this function.

In an e-mail sent to *Medical Device Daily*, Wayne State indicated that "a key focus of the FDA audit was related to the Coeus software platform," which a web search indicates is published by the **Massachusetts Institute of Technology** (Cambridge, Massachusetts). The e-mail states further that Wayne State's IT staff and the software developer have jointly "developed a patch for their programming error, which resolved the problem" in the Wayne State system.

Julie O'Connor, director of research communications at Wayne State, informed *MDD* that the problem cited by FDA with regard to voting majorities was likewise due to the Coeus software, which she said had zeroed out several board members on each of the votes in question. A similar glitch is said to have led to the confusion regarding the membership of the consultant.

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Washington

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Wayne State also indicted that its corrective actions and its accreditation by the **Association for the Accreditation of Human Research Protection Programs** (Washington) "extend above and beyond the requirements of the FDA to assure Wayne State's commitment to the highest standards of human research protections."

FDA eyes DNA-array methodologies

Whatever one thinks of the scientific talent at FDA, it is beyond argument that the agency's scientists are simply outnumbered by those in industry and other government agencies. FDA has noticed an uptick in the use of DNA detection strategies other than karyotyping and has announced it will hold a half-day meeting at the end of this month on the subject to address its lack of familiarity with these alternate DNA typing technologies.

According to yesterday's edition of the *Federal Register*, the recent development of array-based cytogenic testing methods are making their way into clinical use, but FDA is concerned that "the results obtained . . . are not necessarily predefined and may not be associated with known clinical syndromes." The agency sees this knowledge gap as the reason that applications for single-nucleotide arrays and microarray-based comparative genomic hybridization technologies are presenting a challenge to the agency's "traditional method of . . . review."

The *FR* notice reminds the reader that interpreting the results of some of these tests is further complicated by the presence of copy number variations between healthy subjects, let alone between healthy and sick subjects. Because of this and a range of other issues, the agency wants input on a number of themes, including whether different requirements should be imposed on interpretations of genetic deletions versus duplications, and both of those versus translocations.

The meeting is scheduled for 1 p.m. on June 30 at the **Hyatt Regency Hotel** in Bethesda, Maryland. Interested parties should contact Susan Monahan at 301-796-5661 or at susan.monahan@fda.hhs.gov.

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Europe

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the first 100% colored implantable grade ultra high molecular weight polyethylene fiber, allows surgeons to take advantage of the fiber's uncompromised strength, ability to provide better contrast during arthroscopic surgeries and ease of differentiation between multiple sutures on multiple anchors, DSM said.

"Dyneema Purity Blue is a groundbreaking fiber for the medical community, providing surgeons with the innovative advantage of color differentiation and uncompromised strength in arthroscopic procedures," said Erik Becker, application manager medical at DSM Dyneema. "We are very proud to collaborate with the industry's leading medical textile contractors who have a proven track record of successfully designing and manufacturing biomedical textile structures with Dyneema Purity, which are used in commercial medical devices for various orthopedic and cardiovascular applications."

Dyneema Purity is used in medical implant applications, the company noted. ■

Deals

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LMS will be integrated with Halfpenny's core HIE business and operated as a division of Halfpenny Technologies. The acquisition leverages Halfpenny's Integration Technology Framework platform for clinical data capture, aggregation and normalization to expand the company's interface services to the payer and health plan markets, the firm noted.

Halfpenny's expansion of services through the LMS acquisition will include: clinical data capture of all member data points within a plan or product; clinical data normalization through LOINC mapping; plan leakage management for health plans and laboratory service providers; and technology to manage shared capitation reimbursement.

Through the acquisition, Halfpenny will be able to facilitate the movement and normalization of clinical data from laboratories and hospitals to satisfy health plan reporting requirements. ■

People in the News

• **Concerro** (San Diego) has named Ken Roos as VP of sales. Most recently, Roos spent six years at Vital Images, where he led the transformation of the U.S. sales organization from workstation products to enterprise solutions and managed the global business relationship with Toshiba Medical Systems, Vital Images' largest reseller. Concerro is a healthcare Software-as-a-Service (SaaS) company that provides workforce and emergency management systems that facilitate real-time information access.

• **NextCare Urgent Care** (Mesa, Arizona) has named John Julian CEO for its network of urgent care clinics. Julian spent eight years as an entrepreneur, working with start-up companies in the pharmacy and personal services industries. NextCare Urgent Care operates 56 urgent care facilities in Arizona, Colorado, Georgia, North Carolina, Texas, and Virginia.

Product Briefs

• **Absorption Systems** (Exton, Pennsylvania), a specialist in testing drugs for ADMET (Absorption, Distribution, Metabolism, Excretion and Toxicity), reported the launch of Express Plus ADME Assays. The Express Plus ADME Assays are a series of *in-vitro* and *in-vivo* tools for the identification of promising drug-like leads at an early stage of drug discovery. Absorption Systems claim these services offer enhanced value across three critical elements: robust assay designs, timely project execution and data interpretation focused on the advancement potential of new drug candidates. "We work hard to make sure our customers get what they want and with the launch of the new Express Plus ADME Assays we are delivering just that," said Patrick Dentinger, President/CEO of Absorption Systems. "We pride ourselves on providing excellent service, rapid turnaround and high-quality data. With Express Plus ADME Assays, we further strengthen our commitment in helping our customers bring safer drugs to market by enabling them to profile the ADME properties of their compounds with confidence."

• **Royal Philips Electronics** (Andover, Massachusetts) introduced Philips VasoCT, an intra-vascular interventional configuration for the Philips Allura Xper interventional X-ray system designed to visualize vessel structure beyond a clot and help physicians identify and assess the size and extent of an ischemic stroke. This ensures angiography suite treatment as quickly as possible, thus helping to improve outcomes and quality of life for the patient. VasoCT is based on a 3-D rotational scan and a special injection protocol, the company said. VasoCT will be available in the near future as an interventional configuration to the Philips Allura Xper interventional neuro radiology suite.

• **Vital Images** (Minneapolis) reported availability of Vitrea Enterprise Suite 1.3 with new clinical capabilities including adult and pediatric cardiac applications, and an enriched set of workflow tools. New applications include cardiac multi-chamber analysis with adult and pediatric options that automate atrial and ventricular chamber analysis and leverage low-dose CT scanning protocols. Clinical enhancements to cardiac structural analysis tools, Vessel Probe and Vessel Walk, allow easy navigation through complex cardiovascular anatomy, according to the company. A host of additional workflow features make it easier to review CT and MR scans, while a new edge-detecting contouring tool, single-click volume segmentation and improved report access streamline case reviews and enhance communication between clinicians. Vitrea Enterprise Suite 1.3 also now enables web-based access to MeVis Visia CT Lung, the first clinically validated CAD system for chest CT. MeVis' CAD technology platform integrates within Vital Images' reading workflow.

• **W. L. Gore & Associates** (Flagstaff, Arizona) received FDA approval to market a 45 mm diameter version of the Gore Tag Thoracic Endoprosthesis for treatment of aneurysms of the descending thoracic aorta. The larger diameter device allows treatment of TAAs with proximal and distal neck diameters ranging from 37-42 mm. The 45 mm Gore Tag device is available in 10, 15 and 20 cm lengths. In addition, all Gore Tag devices, including the 45 mm device are delivered on a modified device delivery catheter that is designed for enhanced trackability and deliverability. The modified Gore Tag device delivery catheter is a simple, single-step deployment system engineered to optimize placement and control. The novel sheathless delivery catheter provides flexibility for navigating tortuous anatomy and low deployment forces. The Gore Tag device internally relines the thoracic aorta and isolates the diseased segment from blood circulation. The Gore Tag device is comprised of an ePTFE graft with a self-expanding nitinol support structure to combine both device flexibility and material durability. The device is inserted via a catheter delivery technique through a small incision in the patient's groin.

Court report

Cook's infringement case against Endologix to proceed

A *Medical Device Daily* Staff report

The U.S. District Court, Southern District of Indiana, has ruled in favor of **Cook** (Bloomington, Indiana) in its decision to lift the stay on Cook's patent infringement case against **Endologix** (Irvine, California). With this ruling, the case, filed by Cook on Oct. 6, 2009, will now proceed (*Medical Device Daily*, Oct. 12, 2009). The complaint claims infringement by Endologix of two Cook patents for endovascular technologies, one of Cook's leading technology portfolios.

"We are extremely pleased with the court's decision to lift the stay of this case. Given Cook's established, global leadership position in endovascular technologies, we are eager to move forward as swiftly as possible to obtain all available remedies based on Endologix's infringement of our two patents." said Cook general counsel Cynthia Kretz. "The court's decision brings to an end Endologix's defensive tactic to delay the case by initiating reexaminations of both patents."

The two patents in question are Cook's U.S. patent 5,755,777 and 5,035,706. The '777 patent is entitled "Expandable Transluminal Graft Prosthesis for Repair of Aneurysm," and was granted on May 26,1998.

The '706 patent is entitled "Percutaneous Stent and Method of Retrieval Thereof," and was granted on July 30, 1991. The Patent Office has issued a reexamination certificate for the '706 patent, as well as notice of intent to issue a reexamination certificate on the '777 patent. As a result, the court ruled that Cook's case was "now poised to move forward." ■

MDD's Oncology Extra

Additional Developments in One of Med-Tech's Key Sectors
Wednesday, June 9, 2010

Keeping you up to date on recent developments in oncology.

NovoCure reports successful trial results for glioblastoma device

. . . Data from the first phase III clinical trial of **NovoCure**'s (Haifa, Israel) NovoTTF device for treatment of patients with recurrent glioblastoma (GBM) were presented as a late breaking abstract during the Neuro-Oncology session at the **American Society of Clinical Oncology** (ASCO; Alexandria, Virginia) annual meeting in Chicago. Study results show that NovoTTF, a noninvasive, portable medical device, may be as or more effective than the best available chemotherapies for GBM, but without the toxicity usually associated with cytotoxic or targeted treatments. The study enrolled 237 patients with recurrent, late-stage GBM, the most malignant form of primary brain cancer. Using low intensity, alternating electric fields to disrupt tumor growth, NovoTTF is the first non-drug, non-radiation, non-surgical treatment approach to show promise of clinical benefit for the treatment of brain cancer. Philip Gutin, MD, primary investigator for the study, chair of the Department of Neurosurgery, co-executive director of the Brain Tumor Center, and Fred Lebow chair in Neuro-Oncology of **Memorial Sloan-Kettering Cancer Center** (New York), said, "Data from this non-invasive, non-chemotherapy option are encouraging, and could establish this device as another treatment option for this population." The randomized, controlled, phase III clinical trial compared NovoTTF monotherapy with the best available chemotherapy, as determined by the study physicians in the U.S. and Europe, in patients with recurrent, late-stage GBM. In the intent-to-treat population, patients treated with NovoTTF lived as long as those treated with the best available chemotherapy, including bevacizumab (median overall survival 6.6 months vs. 6.0 months). Overall response rate was higher for NovoTTF compared with chemotherapy (11.7% vs. 5.9%). In addition, NovoTTF treatment was associated with three to four times fewer infections, and less hematological and gastrointestinal side effects compared to standard chemotherapy. The NovoTTF is an investigational device in the U.S. and has CE mark in Europe.

Cardinal Health supports trials evaluating oncologic biotracers . . .

Researchers have long used non-proprietary imaging agents such as 18F-Fluoroumisonidazole (FMISO), 18F-Sodium Fluoride and Fluorothymidine (FLT-PET) to evaluate cancerous tumors. Now, with manufacturing and distribution support from **Cardinal Health** (Dublin, Ohio), the **American College of Radiology Imaging Network** (ACRIN; Philadelphia) is conducting nationwide clinical trials with positron emission tomography (PET) to determine if these agents can be used in new ways to assess the efficacy of cancer treatments. The ACRIN trials, funded by the **National Cancer Institute**, aim to better characterize cancerous tumors and to help oncologists select the most appropriate treatment for patients with cancer. The research also aims to help develop strategies to more quickly evaluate new cancer treatments and speed the delivery of effective drugs into clinical use. The four ACRIN clinical trials that Cardinal Health is supporting include:

- A trial to determine whether FMISO can be used as a biotracer to measure the oxygen level (or hypoxia) of a specific type of brain tumor called glioblastoma. Knowing how hypoxic a tumor is may help treating physicians determine the best course of therapy for their patients.
- A clinical trial to determine whether 18F-Sodium Fluoride, a bone imaging agent, can be used to gain information about how the drug dasatinib may work in treating castration-resistant prostate cancer that has spread to the bone.
- Two clinical trials assessing FLT-PET. One will evaluate its ability to assess whether chemotherapy treatments have been successful in reducing tumors prior to surgery in patients with locally advanced breast cancer. The other will use FLT-PET and advanced MRI sequences to assess whether imaging biotracers can be useful in predicting the likelihood of survival among patients with glioblastoma tumors.

Speeding up cancer diagnosis with MEMS microscope . . . Early detection is the key to the successful treatment of cancer. But not every lump turns out to be a malignant tumor. To find out whether cancerous cells are present, doctors usually perform a biopsy and examine the removed

tissue under the microscope. This process is not only very stressful for the patient but also highly time consuming. Research scientists at the **Fraunhofer Institute for Photonic Microsystems IPMS** (Dresden, Germany) are aiming to speed up cancer diagnosis. They have developed a microscope head with a diameter of just eight millimeters which can optically resolve and magnify tissue cells measuring just 10 to 20 micrometers. Fitted in the tip of an endoscope it will be used for in vivo cancer diagnosis, inserted in the body as in a minimally invasive surgical operation. The scientists envision that the MEMS (micro-electromechanical system) microscope head will eliminate the need for biopsies. Diagnosis in real time would enable doctors to decide on the necessary course of treatment more quickly. "Microscopic image recorders that can be used on endoscopes have not been available up to now. We have developed the first laser-based sensor for this purpose," said Michael Scholles, business unit manager at the IPMS. "In classic endoscopy using macroscopic imaging, the job can be done by CCD or CMOS image sensors, as used in digital cameras and cellphones. For endomicroscopy, however, MEMS-based image sensors are highly advantageous because they can magnify even the smallest object fields, such as cells, without the need for a large lens. We have combined the sensor with a microscanner mirror to achieve the required resolution of 10 micrometers and can therefore massively magnify the tiniest structures."

Breast tomosynthesis being compared with digital mammography

. . . In the U.S., one out of eight women will develop breast cancer in her lifetime. The earlier the breast cancer is found, the more likely a woman will live a normal life, said Stephen Rose, MD, a breast radiologist at **Memorial Hermann Memorial City Center** (Houston). Since April, the Bobetta Lindig Breast Care Center at Memorial Hermann Memorial City Medical Center has been participating in a clinical trial of a new imaging technology called breast tomosynthesis. The trial will compare breast tomosynthesis in combination with conventional digital mammography. There is no additional cost for the tomosynthesis research study. "Many women have dense breast tissue. On a conventional mammogram, it can look similar to cancer," said Rose, principal investigator for the Houston study. "Breast tomosynthesis allows us to see multiple slices of the breast, which improves our ability to see a malignancy that may be hidden by overlapping tissue." Breast tomosynthesis is a 3-D imaging technology that involves a small number of low dose images of a breast in a short (5 second) scan. A powerful computer is then used to reconstruct the images into a series of thin high-resolution slices. Reconstructed tomosynthesis slices reduce or eliminate the problems caused by tissue overlap and structure noise in conventional 2-D mammography. Breast tomosynthesis also offers a number of opportunities, including improved diagnostic and screening accuracy, fewer recalls, greater radiologist confidence, and 3-D lesion localization.

– Compiled by Lynn Yoffee, *MDD* Staff Writer
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