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UEGW 2008

Evidence-based approach buoys Barrx's expansion in Europe

By JOHN BROSKY

Medical Device Daily European Editor

VIENNA – A California company secured its expansion into Europe with the release of a multi-center European study highlighted in the opening plenary session as United European Gastroenterology Week 2009 (UEGW) got under way here.

With 11,700 participants from 126 countries attending the meeting, **Barrx Medical** (Sunnyvale, California) reported it has launched a follow-on to the three-center EURO I trial it presented that will involve 10 reference medical centers, which “reads like a Who’s Who for endoscopy in Europe,” according to Darin Wilson, who heads up the nascent international marketing effort.

Roos Pouw, MD, from the **Academic Medical Center** (AMC; Amsterdam) presented the results from EURO I, a val-

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JACC publishes MIV's VESTAsync trial results

By AMANDA PEDERSEN

Medical Device Daily Staff Writer

A company that believes removing the polymer from drug-eluting stents (DES) is at least one way of addressing the safety concerns surrounding the technology reported that the *Journal of the American College of Cardiology Intervention* (JACC) published preliminary results from its first human trial.

The VESTASync I trial, which evaluated **MIV Therapeutics'** (Atlanta) polymer-free DES, appears in the Oct. 21 issue of JACC and is available online at <http://interventions.onlinejacc.org>. Author J. Ribamar Costa Jr., MD, describes the results from the four-month follow-up of a multicenter, 15-patient, first-in-man study led by principal investigator Alexandre Abizaid, MD, PhD, chief of coronary intervention at the **Institute Dante Pazzanese of Cardiology** (Sao Paulo, Brazil).

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Report from Europe

InfraScan receives CE mark for brain hematoma detector

A Medical Device Daily Staff Report

InfraScan (Philadelphia), a device firm specializing in brain injury diagnostic products, reported receiving the CE mark for the Infrascanner handheld brain hematoma detector. The company said it plans to launch international sales this fall.

The Infrascanner is a small, completely portable device, which can detect the presence and location of a brain hematoma based on differential NIR light absorption of a hematoma and normal brain tissue.

InfraScan will present the results of a pivotal, 400-patient, multi-center study to the FDA later this year to support its 510(k) application and a subsequent U.S. launch of the device.

It said a pilot study with an earlier Infrascanner prototype involving more than 300 patients demonstrated high sensitivity for detecting bleeding in the brain and for rapidly detecting the onset of delayed hematomas.

See Europe, Page 7

New in basic science

Group eyes benefits, risks of nanotechnology in pediatrics

By DON LONG

Medical Device Daily National Editor

Nanotechnology and personalized medicine – two relatively new concepts that would seem to go arm in arm.

But exactly how early in the individual's life can personalized medicine be used – and how soon should that relatively uncharted territory of nanotechnology be used?

“That’s one of the things we want to investigate – when is it appropriate?” says Edward McCabe, physician-in-chief at **Mattel Children's Hospital** at the University of California Los Angeles (UCLA).

He hopes that this and related questions will be answered by a new effort at the hospital, the Mattel UCLA NanoPediatrics Program, to explore personalized medicine's applications for children, including both the opportunities and the risks of applying nanomedicine for this group.

The hospital says that the program is one of the

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INSIDE:

BARD IS WARNED FOR HERNIA PATCHES RECALLED IN 20052

CARDINAL HEALTH/CAPSULE PACT CONNECTS VENTILATORS WITH IT3

 **AHC Media LLC**

*Washington roundup***Bard is warned for hernia patches recalled in 2005**By **MARK McCARTY****Medical Device Daily Washington Editor**

A November 2007 FDA inspection of the plant operated in Humacao, Puerto Rico, by **C.R. Bard** (Murray Hill, New Jersey), netted the firm a heavily detailed warning letter describing a series of miscues that may have left surgeons with the incorrectly sized surgical accessories and implants, including the Kugel line of hernia patches that were recalled in December 2005 and which are the subject of ongoing lawsuits.

Holly Glass, a spokeswoman for Bard, referred *Medical Device Daily* to a July 28 investor relations statement on the company's site that states that the company is facing "approximately 735 federal and 1,100 state lawsuits involving claims by approximately 1,940 plaintiffs" in addition to three "putative class actions" in connection with a December 2005 recall of the "Composix Kugel." The statement also notes that Bard "intends to fully implement corrective actions to address the concerns identified" in the warning letter, but cannot "give any assurances that FDA will be satisfied with its response to the warning letter or as to the expected date of resolution of matters included in the warning letter."

The lead citation – which was for lack of procedures for identifying products "during all stages of receipt, production, distribution and installation" – states that a procedure dealing with lot size "allowed excess finished units from up to three different batches of product to be added to another batch with a new lot number." According to FDA, "once the units were added to the new batch, your firm was unable to identify and trace the individual units back to their original lot numbers."

This finding was tied to an incident in which one lot of Bard's line of Kugel hernia patch kits ended up with

Today's MDD food for med-tech thought

"From our perspective the one way to try and solve these issues is to eliminate the polymer and then once and for all we know if it's a drug issue or a polymer issue."

— Mark Landy, MD, president/CEO of MIV Therapeutics, commenting on reported results from the stent developer's first human trial, "JACC publishes MIV's VES-TAsync trial results," pp. 1, 6.

patches with a different size monofilament, but the firm's internal investigation is said to have concluded "there was no impact on distributed products" because Bard was "able to segregate the affected units before they were distributed."

FDA states that this conclusion was unwarranted because of a similar complaint from March 2007 in which a product labeled "medium Ventralex" mesh, also a hernia patch, was in fact a small mesh. The warning letter also indicates that Bard "became aware of this situation only as a result of FDA's inspection." The agency states further that "we find it objectionable that after acknowledging the potential for mix-ups and deficiencies" related to the SOP in question, the corrective and preventive action report for the products with incorrect monofilament sizes "did not include an impact assessment for distributed products." The letter states that the company's responses dated March 18 and May 19, 2008, were inadequate and requests that the company provide updates on corrections.

The second citation notes an absence of procedures for control of non-conforming products, and lists two complaints regarding carotid artery shunts that were of an incorrect size. FDA states that the firm "took no further action" because it was deemed unlikely "that the known adverse effects of placing a bypass shunt would be increased by the use of a slightly larger device." The warning letter did not describe Bard's proposed corrections for this finding, but states that "they are inadequate" and

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*Agreements/contracts***Cardinal Health/Capsule pact connects ventilators with IT****A Medical Device Daily Staff Report**

Cardinal Health (Dublin, Ohio) and **Capsule** (Andover, Massachusetts) reported an agreement that promotes connectivity between Cardinal Health ventilators and hospital information systems using Capsule connectivity solutions.

The agreement ensures that Cardinal Health's AVEA and VELA ventilators have the most current connectivity software and creates a foundation for all future Cardinal Health ventilation products to connect to any hospital information system.

"The connectivity between ventilators and information systems is vital to our customers," said Pete Goulding, director of marketing for conventional ventilation at Cardinal Health. "Capsule's DataCaptor serves as a bridge that translates the digital output from our ventilators into a format compatible with all hospital information systems."

Capsule's DataCaptor features one of the largest device interface libraries in the world supporting more than 370 different types of medical devices, including patient monitors, ventilators, and infusion pumps. It automatically converts the medical device data to HL7 or XML format and integrates it with any electronic medical record, clinical information system, or alarm and event management system to help improve clinical documentation, enhance workflow and save thousands of nursing hours.

*Grants roundup***Study eyes use of cooling device to treat MI victims****A Medical Device Daily Staff Report**

Life Recovery Systems (Waldwick, New Jersey) has received a competitively awarded \$700,000 grant from the National Institutes of Health (NIH) to conduct a clinical study to investigate the feasibility of cooling heart attack patients with its ThermoSuit System, the only cooling device using cold-water immersion to rapidly lower patient temperatures.

The grant was awarded through the Small Business Innovation Research (SBIR) program of the **National Heart, Lung and Blood Institute** (NHLBI) of NIH. This is the third SBIR grant for Life Recovery Systems from NHLBI. The two previous grants totaling \$1.3 million were to develop the ThermoSuit System.

Twenty patients will be enrolled in the study, which will be conducted under an Investigational Device Exemption that was previously granted to Life Recovery Systems by FDA. The study is a cooperative effort between Life Recovery Systems and the **Ochsner Clinic** a division of **Ochsner Health System** (New Orleans) a non-profit academic and healthcare delivery system with seven hospitals and more

In other agreements/contracts news:

- **Active Implants** (AIC; Memphis) said it has signed an exclusive agreement with **Joint Replacement Instrumentation** (JRI; London) to expand distribution of its polymer TriboFit Hip System in the UK.

JRI will market its flagship product, the Furlong H-A.C. hip stem, alongside AIC's TriboFit acetabular system, a soft-bearing articulation product. TriboFit employs a low-wear, medical-grade, polycarbonate-urethane buffer.

AIC and JRI are launching a post-approval collaborative market study in the UK with leading orthopedic surgeons.

Under this new arrangement, AIC has agreed to manufacture certain components of the TriboFit Hip System at the JRI facilities in Sheffield, UK.

- **Premier Purchasing Partners** (San Diego) reported that it signed new agreements for vascular closure devices with **Abbott Laboratories** (Abbott Park, Illinois) and **Cardiva Medical** (Mountain View, California).

Effective Nov. 1, the 36-month agreements are available to acute-care and continuum-of-care members of the Premier healthcare alliance.

- **NxStage Medical** (Lawrence, Massachusetts) said that its Medisystems Division has signed a long-term product supply agreement with **Renal Advantage** (RAI; Brentwood, Tennessee), the fourth-largest provider of dialysis services in the U.S.

NxStage will supply the Streamline airless blood tubing set as well as MasterGuard and other products to RAI's dialysis center network. ■

than 35 health centers in Southeast Louisiana.

The trial will explore the feasibility of cooling heart attack (ST-elevation acute myocardial infarction) patients with the ThermoSuit System before blood flow is restored to the heart. Patients will be sedated and cooled after entry into the emergency room and prior to percutaneous coronary intervention in the catheterization laboratory.

It is expected that the ThermoSuit System will enable cooling of the patient to 34 degrees C after a treatment of 30 minutes or less and within the 90-minute door-to-balloon time requirement for treating ST-elevation acute myocardial infarction patients.

A successful result of the study will lead to a pivotal clinical study to investigate the potential for the ThermoSuit cooling treatment to reduce the severity of the heart attack. Previous research has suggested that cooling of some types of heart attack patients before coronary reperfusion could result in a significant reduction in the amount of injury the heart suffers.

The ultimate goal of these studies is to obtain FDA clearance for the use of the ThermoSuit System in treating heart attack patients. Life Recovery Systems said it believes that this would contribute to better outcomes for such patients and thus substantially increase the potential uses and market for its cooling technology. ■

Washington

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observed “it seems that you do not appreciate the criticality of your mislabeling issues.” FDA also cited the firm for similar problems in connection with the Vacora line of biopsy probes.

Toward the end of the warning letter, FDA acknowledges the firm’s intent to create a “dedicated quality assurance group,” hire a consultant and perform “other additional corrections.” The warning letter was not posted at FDA’s web site until last week despite bearing a date of July 22.

Steris warning cites RI plant

FDA tagged contract sterilizer **Steris** (Mentor, Ohio), for several problems in connection with several loads of products that were shipped from the company’s plant in Coventry, Rhode Island, after undergoing sterilization for times and temperatures that were out of predetermined parameters. While the firm offered the agency two responses to the situation, the warning letter indicates FDA’s dissatisfaction with those responses.

The warning letter states that Steris released part of one lot of an unspecified product for less than the prescribed duration (the parameters were redacted from the warning letter) at a higher temperature than indicated. Another load taken from a different lot, also sterilized with ethylene oxide, was in the autoclave for longer than the specified duration, but again, the parameters were redacted.

FDA states that Steris’ July 16 response to the inspection findings was inadequate because “your corrective actions did not address any product that was processed prior to the initiation” of the corrective/preventive action.

Another citation states that Steris sterilized a load with a software module that had not been approved. The company is said to have opened a corrective action to deal with the “server migration of unapproved cycles into the [redacted] software,” but that at the time of the incident, Steris had not “initiate[d] any preventive action to ensure that this problem does not recur.”

The company’s second response drew no praise from FDA, which states that the company had not “provided any evidence that demonstrates that the process controller replacements will address the migration of unapproved ethylene oxide sterilization cycles.”

In other instances, operators were said to have removed loads from autoclaves “without properly identifying the product,” which in one instance led to the shipment of a load “19 hours before scheduled completion.” That load, according to FDA, was shipped to the customer, although the letter does not address what became of the load after that point.

The company’s director of corporate communication, Steve Norton, told *MDD* that the problems are restricted to the Steris Isomedix plant in Rhode Island and that “the

issues being raised are due primarily to documentation and record-keeping practices” and have resulted in no quality or product problems. He said the plant has received no warning letters in the past.

LabCorp warned for homebrew Dx

A Sept. 29 FDA warning letter to **Laboratory Corporation of America** (LabCorp; Burlington, North Carolina), dealt specifically with the firm’s web site, which FDA stated contained information about the OvaSure diagnostic. The warning letter indicated that the diagnostic “is a test that was designed, developed, and validated by investigators at **Yale University** (New Haven, Connecticut) and not by LabCorp.” The warning letter went on to essentially state that the diagnostic was still under home-brew rules and as a consequence, LabCorp’s description of the OvaSure at its web site violates regulations. ■

Deals roundup

Sorin receives binding offer for Vascular Therapy Business

A Medical Device Daily Staff Report

The Sorin Group (Milan, Italy) reported that it has received a binding offer for the acquisition of its vascular therapy business from Italian investment fund **Investimenti e Partecipazioni** (IP).

Closing of the transaction is subject to completion of regulatory procedures involving employee representatives of the vascular therapy business in Italy and France. Upon the conclusion of that process, and approval by Sorin’s board of directors, the company will provide full financial information resulting from the transaction.

Upon completion of the transaction, IP would become the new owner of the entire Sorin coronary vascular therapy business worldwide, including its unique intellectual property portfolio.

“We believe this transaction will offer a significant opportunity for our vascular therapy business to further develop and to exploit its full potential for the benefit of our employees, the patients and the physicians who have demonstrated their continuous support to this innovative technology,” said CEO André-Michel Ballester.

He added, “The completion of this transaction will allow Sorin Group to better focus on the global expansion of its three leading core cardiovascular franchises.”

The Sorin Group is a developer of technologies for cardiac surgery, cardiac rhythm dysfunctions, interventional cardiology and the treatment of chronic kidney diseases. ■

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UEGW

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ablation trial conducted at the AMC, **Evangelisches Krankenhaus** (Düsseldorf, Germany), and **Erasme University Hospital** (Brussels, Belgium).

Pouw described a "stepwise" study based on a series of procedures where patients with the most advanced stages of Barrett's esophagus, including dysplasia and early cancer, underwent endoscopic mucosal resection (ER) and then were treated with the endoscopic radiofrequency (RF) ablation using the HALO Ablation System.

The study is similar to validation trials Barrx has conducted in the U.S. with similar results.

In Europe, among the 24 patients in this first trial, all but one were cured of all diseased tissue after a one-year follow-up, or 96%.

Because the patients are well advanced in the development of cancerous tissue, the first stage of endoscopic resection both confirms absence of a more invasive cancer and clears the field for the HALO radio frequency therapy that radiates down to a 1,000-micron depth.

The two-step HALO process is described by the Barrx product names, the HALO 360 and HALO 90 indicating the scope of the ablation.

Six weeks after the resection, the patient undergoes the first Barrx procedure where a balloon-based ablation device applies a controlled heat over the entire surface of the targeted segment, or 360-degrees.

At two-month intervals following this procedure the patient receives, where necessary, a more focused ablation using the HALO 90 device mounted on the endoscope to treat smaller, residual areas of Barrett's esophagus.

While the procedure seems protracted, it is as close to a magic bullet as a cancer patient is likely to receive. The treatment is non-surgical, so after shaking off the sedatives, the patient can go home rather than spending the five days in the hospital required by other remedies to Barrett's esophagus.

"Preliminary data of this European study suggests this treatment modality effectively removes dysplasia without serious adverse events and therefore compares favorably with radical ER or photodynamic therapy," Pouw said in her presentation.

AMC will lead the second European multi-center cohort study, EURO-II that targets ten patients at each of the 10 tertiary referral centers for endoscopic treatment.

Barrx's entry into Europe was boosted in part by a \$27.8 million financing in 2006 that also underwrote the development of the HALO 90 (*Medical Device Daily*, July 21, 2006).

The international strategy for Barrx is twofold, according to CEO Gregg Barrett: "To win the support of key opinion leaders, and then to get reimbursement."

"We have now demonstrated in Europe that we can

tightly control ablation, reverse Barrett's disease and that new, healthy tissue grows back," he said.

On the ground, Wilson, who runs the Barrx European operations from Switzerland, said the two primary markets in Europe for Barrett's disease are the UK and France, especially the UK, which is the top market.

His goal is to continue winning more procedures in countries where Barrx has inroads, and then to win reimbursement.

"In Europe the health technology assessment authorities demand evidence, and we have the evidence," he said.

In the UK, he said Barrx has submitted necessary documentation to the **National Institute for Clinical Excellence**, which allows the device to be used under research conditions while awaiting guidelines for clinical practice and reimbursement.

In France he said a study is planned for 2009 with the **Société Française d'Endoscopie Digestive**, a necessary step for winning reimbursement.

In Germany, another important European market, he said the company has filed procedures for 2009 that should lead to reimbursement approval in 2010.

Wilson said the international groups expects to double sales year-to-year before winning reimbursement and after that sales targets "are much more aggressive."

More than 250 centers use Barrx technology worldwide for an accumulated total of 20,000 procedures to date, he said.

The company has established operations in 10 European countries as well as Australia and Canada, he said.

The complete Barrx HALO assembly sells for about €45,000 (\$60,000) according to the Dutch team at the UEGW event, which includes the two generators and the endoscope-mounted RF applicators that can be mounted on the gastro endoscope of any manufacturer. ■

MED - TECH NEWS AND NOTES

Wound Management hires IM

Wound Management Technologies (Fort Worth, Texas) said it has engaged International Monetary (IM) as its investor relations & strategic advisory firm to provide investor relations services, public relations services, and advise the company's management on other strategic decisions.

"IM has a direct connection to the investment community which will help us quickly move forward with our strategy," said President/CEO Scott Haire. "Their vast experience will aid in our overall market support, which is where we have needed some more substantial professional help in the past."

MIV

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“The publication of the preliminary VESTASYNC I trial results in such a prestigious, peer-reviewed journal as *JACC* is clearly a vote of confidence in the soundness of our science,” said Mark Landy, MD, president/CEO of MIV. “We are very proud to be included and to receive this tremendous recognition by the scientific community.”

DES makers have been in a race to address the safety issues surrounding DES ever since it became associated with a higher rate of thrombosis, or blood clotting. Before a company can truly solve the problem, however, it will have to get to the bottom of what is causing the higher rate of thrombosis – is it the drug itself or the polymer used to attach the drug to the stent?

“From our perspective the one way to try and solve these issues is to eliminate the polymer and then once and for all we know if it’s a drug issue or a polymer issue,” Landy told *Medical Device Daily*.

In the VESTASYNC I trial, MIV said, the VESTAsync DES was successfully implanted in all cases, and there were no procedure and in-hospital complications. Life-long aspirin and five-month clopidogrel therapy were prescribed for all patients. At four months, in-stent late lumen loss was 0.30 + 0.25 mm and percent of stent obstruction was 2.8 + 2.2%.

The VESTAsync DES late loss of 0.30 mm situates this new device among the highest-efficacy DES, with the advantage of a polymer-free system using less drug than first-generation equivalents, MIV said. After up to six months of clinical follow-up, no major adverse cardiac event was registered, the company added.

“The VESTAsync stent’s been designed to address the safety issue that has arisen with polymer-based stents,” Landy said.

Giving *MDD* an overview of what makes the stent unique – or, as he put it, “a 30,000-foot view putting it into three buckets” – Landy said the VESTAsync stent’s benefits fall into three broad categories: biocompatibility, accelerated healing, and a more efficient drug-delivery system.

First, Landy said, MIV removed all polymers and other unnatural materials and replaced those with a drug-delivery system comprised of materials that occur naturally. Second, he said, “we’ve made sure that we accelerate healing and don’t interfere with the normal healing process.” So MIV came up with what it considers a more efficient drug-delivery system and were able to reduce the amount of drugs required to get the desired results. Third, Landy added, the coating is “much, much thinner” which also ensures that the stent heals in a “very normal and we believe expedited manner.”

MIV hopes its VESTAsync also will reduce the length of time the patient requires anti-platelet therapy after the procedure. In the VESTASYNC I trial, for example, patients received anti-platelet therapy for five months, and in the VESTASYNC II trial patients were given anti-platelet therapy

for just three months. The current anti-platelet standard is a minimum duration of one year and in many cases is life-long therapy, the company noted.

MIV said its VESTASYNC II trial is a 120 randomized controlled study designed to demonstrate the safety and efficacy of the VESTAsync where patients are given anti-platelet medication (Plavix) for only three months.

“That’s the thing about peer-reviewed articles, while they’re fantastic they’re kind of always about a year behind where you really are,” Landy said, noting that the *JAAC* article only reported results from the VESTASYNC I trial even though the company is already working on the second trial.

He told *MDD* that MIV was the first company to prove there is a direct correlation between the amount of drug used and the efficiency of the drug-delivery system. Also, he said, while other companies have tried to develop a polymer-free DES, Landy says MIV has the lead data.

“We’re really the first company that is taking a bold step and addressing the concerns we have with polymer-based stents,” Landy said. ■

MED - TECH NEWS AND NOTES

PLC Systems to be delisted from AMEX

PLC Systems (Franklin, Massachusetts) said that it has not submitted a plan to the American Stock Exchange (AMEX) that would demonstrate its ability to regain compliance with the exchange’s listing standards. Accordingly, the company anticipates that its common stock will be delisted from the AMEX in the next several weeks, and begin to trade on the over-the-counter bulletin board.

PLC received a notice of failure to meet listing qualifications dated Sept. 17 from the Listing Qualifications department at the AMEX. The notice said that the company was not in compliance with Section 1003(a)(ii) of the AMEX company guide because shareholders’ equity was less than \$4 million as of June 30, and it incurred losses from continuing operations and net losses in three out of its four most recent fiscal years.

Kindred Healthcare opens Florida hospitals

Kindred Healthcare (Louisville, Kentucky) reported the opening of Kindred Hospital the Palm Beaches in Palm Beach County, Florida, and reported plans for a new free-standing hospital in Melbourne, Florida.

“We are excited about these new hospitals in Palm Beach County and Melbourne, Florida,” said President/CEO Paul Diaz. “These hospitals will further our strategic growth plans and provide new opportunities to expand in markets that need our high-quality, post-acute services.”

Kindred Healthcare is a healthcare services company.

Europe

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“Receiving our CE mark represents significant progress toward InfraScan’s strategic goal of providing our potentially life-saving technology to patients in some of the world’s top established and emerging markets,” said President/CEO Baruch Ben Dor, PhD.

He noted that the company had passed a British Standards Institute audit and received ISO 13485:2003 quality certification earlier this year. “This facilitated our obtaining the CE mark for the Infrascanner and allowed us to sign our first distributors in the UK, Spain, Israel, India and Africa,” Dor said

Infrascan says the Infrascanner is “the first hand-held device of its kind designed to assist first responders and emergency room personnel in identifying life-threatening brain hematomas, allowing expedient assessment of patients and potentially facilitating crucial treatment.”

It added, “Intracranial hematomas resulting from a traumatic brain injury are life-threatening and patient outcomes can improve significantly if treated within an hour after an injury – known as the ‘golden hour.’”

The company noted that, “while most hospitals have a computer-aided tomography scanner, which is viewed as the state-of-the-art technology for diagnosing a brain hematoma, many facilities lack the neurosurgical capabilities to treat the condition.”

It said the early identification of a brain hematoma “can play a significant role in facilitating transportation of critically injured patients to facilities, which can both verify Infrascanner’s early diagnosis and offer surgical intervention.”

An estimated 1.5 million individuals seek medical treatment for head trauma in the U.S. each year, and a total of 10 million individuals seek head trauma treatment annually worldwide, the company said.

In addition to the Infrascanner’s first application for detecting brain hematomas, the company will pursue future applications for the product, including the monitoring of stroke victims using the same NIR technology.

InfraScan has received early-stage funding from the Office of Naval Research, BioAdvance, the Biotechnology Greenhouse of Southeastern Pennsylvania, Ben Franklin Technology Partners of Southeastern Pennsylvania, and from the Philadelphia Industrial Development Corp.

Norwegian hospital installs new Leksell Knife

Haukeland University Hospital (Bergen, Norway) has installed the Leksell Gamma Knife Perfexion from **Elekta** (Stockholm, Sweden), which the company describes as “the latest technology for treatment of brain disorders.”

This new-generation Leksell Gamma Knife is fully automated and has the ability to treat patients with multiple brain metastases in much shorter times compared to other technologies, the company said.

Gamma Knife surgery is used to manage numerous neurosurgical conditions, including brain tumors such as metastatic cancer, as well as vascular malformations and certain functional disorders. Elekta said this method “provides pinpoint accuracy, is highly efficient and produces outstanding results.”

The company added, “Patients benefit from fast, painless treatment, often conducted in an outpatient surgical setting without the need for general anesthesia or even convalescence.”

To date, more than 500,000 patients worldwide have undergone Gamma Knife surgery.

“Leksell Gamma Knife Perfexion technology represents a major advance in brain radiosurgery,” said Olof Sandén, executive vice president, Elekta Europe, Africa & Latin America. “It also offers enormous opportunities to treat lesions all over the brain in a single treatment, while also ensuring excellent patient comfort.”

Leksell Gamma Knife Perfexion was introduced two years ago and the company has about 30 systems around the world.

ISO certification for Cardiac Dimensions

Cardiac Dimensions (Kirkland, Washington) said it has received ISO 13485:2003 certification from **KEMA Quality BV**, a European Union Notified Body from the Netherlands. The company noted that ISO certification is a key requirement in obtaining the CE mark.

Paul Cornelison, vice president of regulatory affairs & quality assurance at Cardiac Dimensions, said, “This certification validates the company’s efforts to establish, document and maintain an effective quality management system. The entire company has been committed to achieving and maintaining this status.”

President/CEO Rick Stewart said, “The ISO certification . . . represents a validation of our high standards in terms of product design along with our manufacturing and distribution processes. We are also working toward gaining the CE mark for our Carillon system; this ISO certification provides a foundation to meet the specific quality requirements for the countries that accept CE marking.”

The Carillon Mitral Contour System combines an implantable device and delivery system. The implant consists of a shaping ribbon between distal and proximal anchors. It is delivered percutaneously via jugular access under fluoroscopic guidance. The implant is designed to be positioned, adjusted and gently anchored in the coronary sinus/great cardiac vein to reshape the annulus around the mitral valve, thereby reducing mitral regurgitation.

Pre-clinical and early clinical data have suggested both a reduction in mitral regurgitation and improvements along other key parameters, including New York Heart Association class, 6-minute walk times and quality of life. ■

Neopediatrics

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world's first dedicated solely to the use of nanomedicine for pediatric patients.

As founding director of the program, McCabe rhetorically asks another question: "Why develop a nanopediatrics program?"

"Because," he told *Medical Device Daily* in answer, "one of our mantras in pediatrics is that children are not small adults."

He cites the evidence that drugs work differently in children – "they metabolize, excrete and may even utilize, developmentally, specific receptors differently than adults." And he emphasizes that an adult-only approach as a priority for research in this area is a "flawed strategy" that could put children at risk as nanotechnology reaches maturity.

McCabe says that while the potential dangers of nanotechnology have been overblown "with no evidence," it is clearly necessary "to look at the risk side, not bury our heads."

He adds: "One of our founding members is Dr. Andre Nel. He has done a lot of work with nanotoxicology to look at this — not only at the risks to adults, but also to animal models, [this research] fitting into the pediatric period."

Nel is founder and chief of the Division of NanoMedicine at UCLA's Department of Medicine, which defines its mission as educating "physicians and scientists in the principles and application of nanoscience and nanomaterial applications and safety in medicine."

The Mattel NanoPediatrics Program was officially formed in May of this year but rolled out at a special symposium this past Friday for the purpose of announcing a \$1.8 million grant from the **Mattel Children's Foundation** to fund its research work.

Using the personalized medicine/nanomedicine approach early in an individual's life is an obvious basic target for this field, McCabe says.

As one example of nanomedicine's potential benefits, he cites premature infants "that are exposed to antibiotics associated with hearing loss in individuals who have a mutation in their mitochondrial DNA. Wouldn't it be great to take DNA from that neonate and in 15 minutes . . . check to see if this is a baby at risk?"

He cites also the development of a pilot program in Wisconsin, through a partnership of sub-specialists at Mattel Children's, to identify the presence or absence of small, circular DNA structures generated by normal cells, by revealing severe combined immunodeficiency (known also as "Bubble Boy disease"), much more common than average among Navajo neonates. He notes that this disease afflicts one in 50,000 to 100,000 babies in the general population, but one in 2,000 Navajo babies.

He says this represents the use of microarrays at the nanoscale level to apply an existing therapy to help these infants.

Friday's symposium to announce program funding also featured presentations on nanomedicine, a majority of them focusing on pediatric oncology. And McCabe told *MDD* that cancer is likely to be a primary focus of the initial research work by the NanoPediatrics Program.

Mattel Children's says that it already is working to develop nanodevice procedures for the treatment of children with genetic diseases and cancer, and investigate the use of nanoparticles for diagnostic imaging both during pregnancy and after birth. McCabe says that the NanoPediatrics Program will partner with the **California NanoSystems Institute** at UCLA, an integrated research center established in 2000 to encourage university collaboration with industry and enable the rapid commercialization of discoveries in nanosystems.

The \$1.8 million funding for the program is essentially start-up funding, seed financing that will offer a platform for developing research targets and applications that will be used to leverage grant support, several-fold, McCabe says, from the National Institutes of Health. One possibility he predicts is an application for funding a program to train clinicians in the use of nanomedicine for pediatric applications.

Kevin Farr, CFO of Mattel Children's and chairman of the Mattel Children's Foundation, said that the foundation "is excited to support this groundbreaking program in nanopediatrics, which can potentially revolutionize the research and treatment of illnesses that affect young patients." ■

MED - TECH NEWS AND NOTES

Scient'x adds U.S., international facilities

Scient'x (Maitland, Florida), a maker of spinal implants and instrument systems, reported changes and additions to its U.S. and international facilities.

Scient'x is relocating its U.S. headquarters to West Chester, Pennsylvania, from Maitland, Florida, effective at the end of October. The new, larger facility will house both the commercial and operational components of the U.S. business. It will also have a dedicated laboratory and training facility capable of hosting surgeon and sales training, as well as supporting product development and testing.

"I am very excited about expansion of the U.S. operation," said President/CEO Michael Huggins. "Not only does it help us to better support our customers, it also provides us the opportunity to expand capacity and allows us to educate and train surgeons and sales professionals on both our technology and surgical solutions."

Scient'x also is adding a new educational facility in Beaurains, just north of Paris. This facility provides the ability to train up to 50 people at a time. It is anticipated to open before the end of the year.

PRODUCT BRIEFS

- **CSR** (Cambridge, UK) said its BlueCore Bluetooth silicon provides wireless connectivity for the Team2 heart-rate monitoring system from Polar. The system comprises of up to 28 Bluetooth heart-rate monitors that link up to a PDA, PC or laptop to log and process the data via a Bluetooth Access Server platform from Bluegiga. The system is designed for sports teams, research centers and universities to monitor and improve the performance of athletes. The Bluetooth connectivity in the Polar Team2 system is provided by Bluegiga's WT11-A Class 1 module which uses CSR's BlueCore4 silicon and Bluegiga iWRAP Bluetooth connectivity firmware. Bluegiga's Access Server which is based on multiple CSR BlueCore4 chipsets, allows the system to wirelessly collect and analyze data from up to 28 players simultaneously. This enables the heart rate monitors to achieve a battery life of up to 30 hours when using Bluetooth and a range of up to 100 meters – ideal for monitoring the players in field sports. The Team2 heart-rate monitors are water-resistant down to 30 meters, fully shock resistant and each system comes complete with PDAs and PC software for uploading the data and providing analysis.

- **Endologix** (Irvine, California) reported FDA approval of the PMA supplement for its Powerlink XL system, which includes new suprarenal stent grafts as well as the new Powerlink XL stent graft. The approval broadens the company's treatment indications for the Powerlink system, used in the minimally invasive treatment of abdominal aortic aneurysms (AAA). The system was evaluated in an IDE clinical study and approved for the treatment of AAA patients with proximal aortic necks between 23 mm and 32 mm. The Powerlink and Powerlink XL systems are available with proximal extensions offered in both infrarenal and suprarenal configurations.

- **Energizer Battery** (St. Louis) said it is replacing its current hearing aid batteries with equally-performing zero-mercury batteries. Currently, it said, all other zinc air hearing aid batteries sold in the U.S. contain mercury. Through a combination of new product designs, purer raw materials and new manufacturing processes, Energizer said that its scientists have developed batteries that can now be produced without added mercury, after more than a decade of development and testing. The zero-mercury product is now widely available throughout the U.S., Energizer said.

- **Pioneer Surgical Technology** (Marquette, Michigan) reported the human implantation of its new biologic inter-body spacer, the nanOss-Cervical cage. The device is machined from nano-crystalline hydroxyapatite (HA) and is designed to function as bone, Pioneer said. The nanOss-Cervical cage is intended to facilitate spinal fusion procedures, by maintaining decompression and serving as a

Artes completes enrollment for ArteFill treatment study

A Medical Device Daily Staff Report

Artes Medical (San Diego) said enrollment has been completed in the 1,000-patient post-marketing study required by the FDA. The study follows patients treated with ArteFill, the company's non-resorbable dermal filler, for a five-year period.

Artes reported that study participants have now been screened and entered into the study which includes a skin test, ArteFill injections and follow-up evaluations for safety and duration of treatment effects of their facial wrinkles, known as nasolabial folds or smile lines. An ArteFill skin test is required before initial treatment.

The most common adverse events associated with ArteFill treatment, similar to those observed with other dermal fillers, are lumpiness, persistent swelling or redness and increased sensitivity at the injection site.

ArteFill is a formulation comprised of polymethylmethacrylate, or PMMA, microspheres and bovine collagen, and is the only PMMA-based injectable product that has been approved by the FDA for the treatment of facial wrinkles. Artes Medical is the sole manufacturer of ArteFill.

graft containment device in conjunction with traditional rigid fixation.

- **SunTech Medical** (Morrisville, North Carolina) reported launch of the Advantage A+ OEM Non-invasive Blood Pressure (OEM NIBP) module. The module is the size of a business card, its features including internal automatic modes, low-voltage communication protocols and the lowest power consumption in the industry, making this platform ideal for portable and hand-held applications, SunTech said. The Advantage A+ also offers a motion-tolerance option with an R-wave-gated method of acquiring oscillometric blood pressure readings.

PEOPLE IN PLACES

- Sarah Adkins was named VP of marketing for **Immersion** (San Jose). Adkins was most recently strategic marketing manager for Cook Medical. Immersion makes computer-based surgical simulation training systems.

- Dorin Panescu, PhD, has been named chief technical officer/VP of R&D at **NewCardio** (Santa Clara, California). Panescu most recently was director of technology development at St. Jude Medical. NewCardio is a cardiac diagnostic and services company.

BioWorld® China Biotech 2009

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