

## FDA clears St. Jude's five-column neurostimulation lead for pain

By LYNN YOFFEE

*Medical Device Daily Staff Writer*

**St. Jude Medical** (St. Paul, Minnesota) continues to expand and refine its portfolio of neurostimulation offerings with FDA approval of the Penta surgical lead, the first five-column lead on the U.S. market using the smallest available electrodes.

Unveiled at the annual **North American Neuromodulation Society** (Glenview, Illinois) meeting in Las Vegas, "The Penta lead is designed to increase targeting of the lead so that physicians can more specifically address multifocal pain," Tom Hickman, VP of Product Management for St. Jude Neuromodulation, told *Medical Device Daily*. "The lead itself is probably best used for our patients with failed back surgery syndrome. That's the largest patient population that we have in the chronic pain niche. Those patients have low back and leg pain, which is multifocal pain. There  
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## MicroPhage gets CE mark for MRSA/MSSA diagnostic test

By OMAR FORD

*Medical Device Daily Staff Writer*

The issue of methicillin-resistant *S. aureus* may have taken a backseat to current reports of H1N1, but the spread of this antibiotic resistant bacterium is still prevalent and continues to be a strong market, according to **MicroPhage** (Longmont Colorado) – a small startup company developing rapid diagnostic tests.

The company said that it makes a transition of sorts this week as it finally receives CE mark approval to sell its Microphage MRSA/MSSA Blood Culture Test designed to rapidly identify *Staphylococcus aureus* bacteria as well as determine methicillin resistance (MRSA) or susceptibility (MSSA) in suspected cases of bacteremia— bacteria in the blood— in as little as five hours.

"We consider [getting the CE mark] a major milestone, Steve Lundy MicroPhage, CEO told *Medical Device Daily*.  
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### *International report*

## NIMS gets Canadian patent for Exer-Rest platform technology

A *Medical Device Daily Staff Report*

**Non-Invasive Monitoring Systems** (NIMS; Miami) reported that the Canadian Patent Office issued Patent number 2,534,302 to NIMS on Oct. 20, 2009. The patent, titled "Reciprocating Movement Platform for the External Addition of Pulses to the Fluid Channels of a Subject," relates to the comprehensively researched technology underlying NIMS' Exer-Rest acceleration therapeutic platform. The Canadian patent that expires Aug. 4, 2024 incorporates 55 claims dealing with treatment of acute and chronic inflammatory diseases and is the Canadian counterpart to U.S. Patent No. 7,404,221, the fifth patent issued for this technology.

NIMS is authorized to sell the Exer-Rest in Canada as a class II medical device with CE certification. The Exer-Rest is intended as an aid to improve circulation, increase joint  
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### *Washington roundup*

## FDA suggests hospitals get rid of Steris SS1 sterilizers

By MARK McCARTY

*Medical Device Daily Washington Editor*

FDA continues its crackdown on the medical device industry, the latest being a recommendation to healthcare providers that they jettison any System 1 sterilizers made by **Steris** (Mentor, Ohio). The Dec. 3 letter takes the unusual step of urging providers to replace their SSIs "as soon as possible to ensure continued patient safety."

FDA's action comes on the heels of an Aug. 15 warning letter to Steris citing the firm for changes to the SSI that the agency deemed significant, but for which the company did not obtain clearance. According to the warning letter, those changes include a replacement for a circulation pump undertaken in 1999 to improve flow of sterilant through the device lumen.

Other changes include those to a high-pressure pump, to  
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**Don't miss today's MDD Extra: Neurology**

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**AHC Media LLC**

*Deals roundup***Hospira reports buying clinical informatics company TheraDoc****A Medical Device Daily Staff Report**

**Hospira** (Lake Forest, Illinois), a provider of clinical information and medication delivery technologies, reported that it has acquired **TheraDoc** (Salt Lake City), a clinical informatics company that develops hospital surveillance systems. TheraDoc's two leading products, Infection Control Assistant and Antibiotic Assistant, join Hospira's expanding portfolio of medication safety and infection management products.

As part of the agreement, Hospira acquired additional assets related to the TheraDoc business, including the headquarters in Salt Lake City, and the TheraDoc employees are now a part of Hospira. Financial details of the agreement were not disclosed.

"The acquisition of TheraDoc aligns well with Hospira's focus on improving the clinical outcomes, caregiver productivity and safety of patient care," said Philip Settmi, MD, VP, Global Marketing, Devices, Hospira. "TheraDoc is the gold-standard in enterprise-wide clinical surveillance and decision support. Hospira now offers a truly comprehensive solution for medication safety and infection management, which are two of providers' most pressing healthcare challenges."

According to the Centers for Disease Control, there are 99,000 deaths due to hospital-acquired infections (HAI) and 1.7 million HAIs annually. Careful monitoring of infections is critical with the Centers for Medicare & Medicaid Services' emphasis on avoiding "Never Events," and hospitals facing reduced funding and coverage based on infection rates.

**Today's MDD food for med-tech thought**

*"Hospital-acquired infections (HAIs) are a colossal problem, killing more than 15 million persons worldwide each year and costing the U.S. \$29 billion in unnecessary healthcare expense. We believe that our initial test will be extremely well received in Europe as well as in the U.S. MRSA is still here and it's still a prevalent issue."*

— Steve Lundy, CEO of MicroPhage, on why he isn't concerned about raising the required capital for the company's next financing round, "MicroPhage gets CE mark for MRSA/MSSA diagnostic test," pp. 1, 6

TheraDoc's Infection Control Assistant provides continuous infection monitoring, intelligent alerts and timely analysis of hospital infections. The product joins Hospira's portfolio of infection management tools, including the LifeShield TKO and Antimicrobial CLAVE, devices that are designed to help address potential infection-related contamination.

A key advantage of the TheraDoc technology for OSF and other multi-hospital systems is the ability to access information about infections across all facilities from one central location. As a result, TheraDoc provides a system-wide picture of what is happening with infections.

TheraDoc's Antibiotic Assistant provides real-time point-of-care screening to arm clinicians with timely and relevant information about antimicrobial resistance trends. This allows clinicians to effectively monitor and analyze the spread of infectious diseases so that the right antibiotic treatment can be prescribed. Antibiotic Assistant complements Hospira's medication safety products like Symbiq and Plum A+ smart infusion pumps and Hospira MedNet safety software, which were also designed to support safe

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*Court report***Arthrex wins appeal against S&N in patent infringement case****A Medical Device Daily Staff Report**

Arthrex (Naples) reported that it has won an appeal in federal court over a patent infringement lawsuit filed by a **S&N Endoscopy Division** (S&N; Andover, Massachusetts), reversing a \$23 million judgment stemming from a trial last year (*Medical Device Daily*, June 13, 2008).

The favorable ruling means that no injunction is pending against Arthrex's SutureTak or PushLock products, anchors used during arthroscopic shoulder surgery.

John Schmieding, general counsel for Arthrex, said he expects the plaintiffs, S&N and John Hayhurst, to pursue a new trial again in federal court in Portland, Oregon.

"I do expect that," Schmieding said, adding that a new trial will be based on patent claims proposed by Arthrex and not by S&N. "We are now fighting on our own terms."

S&N spokesman Joe Metzger offered a different interpretation of the appeals' court decision.

"The court of appeal did not enter a judgment of non-infringement in Arthrex's favor," Metzger said. "It was a claims' interpretation and because of that, they are sending it back for a new trial."

In June 2008, a Portland jury found Arthrex had willfully infringed on a patent held by Hayhurst, which is under exclusive license to S&N. At issue are suture anchors marketed by S&N as Tag Wedge, Tag Rod and Bioraptor. S&N filed the lawsuit in 2004.

The jury awarded \$14.7 million in damages to S&N and the judge ordered damages and payment of royalties that brought the total to more than \$23 million that Arthrex would have faced paying.

Arthrex argued that the patent originally issued to S&N is a method patent for inserting a resilient, winged suture anchor into bone to reconnect tissue to the shoulder socket.

Schmieding said last year that S&N argued the patent also applied to any surgical technique involving any anchor device that is resilient. Arthrex countered that its anchors don't rely on resiliency to lodge in the bone.

The case had gone to trial twice before, with the first trial resulting in a hung jury and the second with a verdict favoring S&N.

In other legalities, **SMI** (Irvine, California) reported that it will recover \$6.5 million, including \$2.5 million in punitive damages, from **Staar Surgical** (Monrovia, California).

SMI was a former authorized independent sales company for Staar. Staar manufactures and sells specialized lenses for surgical vision correction, such as replacement lenses for the eye's natural crystalline lens in cataract surgery. SMI prevailed against Staar for intentional and negligent interference with SMI's prospective economic advantage to sell the products of one of Staar's competitors. ■

**Deals***Continued from Page 2*

and effective drug delivery.

"Hospira and TheraDoc share a dedication to advancing the quality and safety of care through advanced medical technology," said Stanley Pestotnik, co-founder, president/ CEO of TheraDoc. "TheraDoc's leadership in providing real-time clinical decision support, combined with Hospira's market-leading position driving medication safety and infection management, will result in expanded access to technologies that are integral to patient care."

TheraDoc has about 85 employees and prominent customers across the U.S. The company's products are also under evaluation by hospitals in Canada, the UK and Australia.

In other dealmaking news, **Healthcare Trust of America** (HTA; Scottsdale, Arizona), a self-managed, non-traded, real estate investment trust, reported the execution of a purchase and sale agreement to acquire a long-term acute care hospital (LTACH), located in Dallas, for about \$27.35 million. The closing of the acquisition is subject to the satisfaction of a number of conditions.

The roughly 52,300 square foot LTACH contains 60 private, licensed beds and is located between **Presbyterian Hospital of Dallas** and **Medical City Dallas Hospital**, each located north of downtown Dallas in an area which is considered the north central medical district. The LTACH is subject to a long-term lease with **RehabCare** (St. Louis), a national provider of post-acute services.

The 4-story LTACH was developed two years ago by the seller, which is a partnership between local physicians and Gulf States Health Services who are the Sellers. ■

**Med-Tech Notes****Spine Pain Management has new symbol**

**Spine Pain Management** (Houston) has officially changed its name from Versa Card and has changed its trading symbol from IGLB to SPIN.

William Donovan, MD, the company's CEO, said: "We believe the new name better reflects the Company's current business model within the healthcare industry."

The company's mission is to deliver turnkey solutions to spine surgeons, orthopedic surgeons and other health care providers for necessary and appropriate treatment for musculo-skeletal spine injuries resulting from automobile and work-related accidents. The company says its goal is to become a leader in providing care management services to spine surgeons and orthopedic surgeons to facilitate proper treatment of their injured clients.

*Agreements/contracts***Biomagnetics inks agreement with Los Alamos National Security***A Medical Device Daily Staff Report*

**Biomagnetics Diagnostics** (BD; San Francisco) discussed the company's acquisition of intellectual property rights from **Los Alamos National Security** (Los Alamos, New Mexico) and how it plans to use it for the development of a handheld integrated optical biosensor capable of highly accurate and rapid HIV/AIDS, malaria, tuberculosis and other pathogen detection and disease diagnosis.

BD reported last month that it had finalized a patent license agreement with Los Alamos National Security. Under that agreement, Biomagnetics will have access to the Triggered Optical Biosensor and Integrated Optical Biosensor System (IBOS) technology developed at Los Alamos National Laboratory. The agreement was recently enhanced to include the intellectual property for "Quantitative Multiplex Detection of Pathogen Biomarkers," which was recently protected through a U.S. patent application filed in October.

When used with the IBOS, it is capable of detecting multiple pathogens from a single blood sample. BD plans to integrate these technologies into a handheld blood diagnostic device that can be utilized by relatively unskilled personnel to screen potential blood donors for various pathogens at the point of collection.

In other agreements/contracts news:

- The **National Cancer Institute** (Bethesda, Maryland) has awarded a \$55.4 million, multiple-year contract to **Fred Hutchinson Cancer Research Center** (Seattle) to become the nation's sole operator of its Cancer Information Service Contact Center. The move will create 60 new jobs at the Hutchinson Center, nearly tripling the size of its current CIS workforce, once the consolidated center is fully operational, which is scheduled for March 15, 2010. The Seattle CIS center will remain in its existing location on the Hutchinson Center campus.

The CIS is a free public telephone and Internet-based resource for personalized information about cancer prevention, screening and treatment. The Hutchinson Center has operated a CIS contact center since 1981.

- **Dynatronics** (Salt Lake City) has signed a sole-source vendor agreement to provide therapy equipment and rehab supplies to **Benchmark Physical Therapy** (Ooltewah, Tennessee) with 65 clinics located in Tennessee and Georgia. Dynatronics has been actively seeking contracts with large chains of clinics, hospitals and group purchasing organizations.

- **Steris** (Mentor, Ohio) and **NeoForce Group** (Ivyland, Pennsylvania) have agreed to jointly market the world's first surgical system designed just for newborn babies. The system is made up of NeoForce's neonatal surgical table,

and lighting, visualization and connectivity technology from Steris, and it's designed to be located near fragile babies, rather than transport the babies to a modified operating room for adults.

In 2008, NeoForce started working with **University Hospitals Rainbow Babies and Children's Hospital** (Cleveland) to design a surgical table system that would meet the needs of surgeons who operate on newborns. Steris was called into the project to integrate lighting, visualization and connectivity technologies with the table.

"As we developed our Rainbow Flex surgical table, we had to assure that our designs would harmonize with the other devices in the [operating room]," Otho Boone, president of NeoForce, said. "Steris caught our attention with their superior lighting, integration and casework solutions." ■

*Financings roundup***MedClean Technologies enters stock deal for up to \$7.5M***A Medical Device Daily Staff Report*

**MedClean Technologies** (Bethel, Connecticut) has entered into a preferred stock purchase agreement with Socius Capital Group, a Delaware limited liability company, doing business as Socius Life Sciences Capital Group. Pursuant to the purchase agreement, MedClean will receive up to \$7.5 million in capital.

The company agreed to sell up to 750 shares of its Series C preferred stock, in one or more tranches from time to time. The tranches will be sold at the company's sole discretion, at a purchase price of \$10,000 per share, for an aggregate purchase price of up to \$7.5 million. With each tranche, Socius will also receive five-year warrants to purchase that number of shares of the company's common stock equal to 135% of the value of preferred stock delivered in such tranche. The exercise price of such warrants will equal the closing bid price of the company's common stock on the date the company provides notice of such tranche.

Pursuant to the purchase agreement MedClean will pay a commitment fee to Socius equal to 5% of the total commitment and will use its best efforts to file a registration statement within 30 days with the SEC for the resale of all shares of common stock issuable pursuant to the agreement.

Scott Grisanti, the company's chairman, said, "This transaction provides MedClean with the capital required to accelerate execution of its growth and expansion strategy. The investment will enable MedClean to accelerate development plans for new product lines that target new market segments, especially the non-hospital small quantity generator market for regulated medical waste treatment." ■

## St. Jude

*Continued from Page 1*

are different fibers running to address leg pain and back pain. This lead enables physicians to optimize stimulation in very specific areas and create small programs that run together to create a very specific stimulation pattern for each patient.”

Failed back surgery syndrome is reported to affect nearly 30% of all people who have spinal surgery. Treatment options are limited. Short of having another surgery, neurostimulation has offered at least a 50% reduction in pain and 47% of treated patients report satisfaction with the therapy, according to research by St. Jude. Hickman said the company has no specific data ready to disclose on the effectiveness of the Penta.

St. Jude already has five neurostimulation leads on the market. The Penta is not a replacement, but an enhancement specifically for use in multifocal pain. This lead provides the broadest lateral electrode span of any neurostimulation lead on the market with a paddle configuration of 10.9 mm wide. The smaller size is enabled by a micro-texturing process which allows for greater amounts of current to be delivered via the small electrodes. The result is a lead that can more specifically focus current over a greater lateral area of the spinal cord, which may provide better coverage for managing hard to control chronic pain.

“Neurofibers running up through spinal cord lay out in a lateral fashion,” Hickman said. “The ability to provide more columns of electrodes placed at an optimum distance allows for the physical capability to specifically target pain fibers and create pain release in a specific and focused manner.”

The leads aren’t just smaller; new technology is incorporated.

“The electrodes are gated by the amount of charge density they can provide to the body,” he said. “The propriety micro-texturing enables high-charged density with small electrodes. We couldn’t have created a five-column lead without smaller electrodes. And those smaller electrodes weren’t possible without the surface optimization with micro-texturing.”

Micro-texturing enables the surface area of electrodes to be greater. That greater surface area allows charge to be more concentrated.

To treat the pain of failed back surgery, a lead – basically a small insulated wire with multiple electrodes – is placed in the epidural space near the spine. Mild electrical pulses are carried from the neurostimulator to the lead’s electrodes to interrupt or mask the transmission of pain signals to the brain. The whole system can be customized to meet each patient’s needs.

The neurostimulator is enabled by another new product release from St. Jude: MultiSteering Technology software for Rapid Programmer is a programming platform used to optimize neurostimulation therapy. The software is

designed to help healthcare professionals program devices for patients with complex pain patterns to manage chronic pain of the trunk and limbs, and pain from back surgeries that have failed. The software:

- Allows more than 10 times the number of electrode configurations to be evaluated in the same amount of time as conventional programming.
- Captures multiple painful areas by enabling the clinician to evaluate stimulation patterns in real time.
- Provides control of multiple stimulation fields for optimal pain coverage.

“The amount of stimulation is provided on a patient-by-patient basis,” Hickman said. “They are given an external device that controls how it’s provided. Physicians optimize the program and then give a prescribed program to patient with a handheld device.”

St. Jude reports that more than 60,000 patients in 35 countries have been implanted with St. Jude Medical neurostimulation systems. ■

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### *Grants roundup*

## Texas A&M gets \$9.9M to develop blood loss therapies

**A Medical Device Daily Staff Report**

As part of Pentagon efforts to dramatically reduce battlefield deaths, the **Texas A&M Institute for Preclinical Studies** (TIPS; College Station) has been awarded a \$9.9 million grant from the Defense Advanced Research Projects Agency (DARPA) to develop frontline treatments for U.S. military personnel injured in combat and suffering from massive blood loss.

It is estimated that half of U.S. military personnel killed in action die because of severe blood loss from injuries such as gunshot wounds or improvised explosive devices. When such a severe blood loss occurs, it is critical for the injured person to receive emergency trauma care within the first hour (the golden hour) to provide the highest chances of survival. Unfortunately, many combat casualties occur in inaccessible locations where rapid evacuation is impossible.

The goal of the research to be carried out by TIPS is to develop and test small volume medications that can be given rapidly on the battlefield to extend the golden hour by as much as six hours. If successful, these medications would give injured troops a much higher chance of survival.

The DARPA grant is the first multi-million dollar award for TIPS, and among the largest single competitive federal awards received by Texas A&M University. ■

## MicroPhage

*Continued from Page 1*

"With the ability to now market our product in Europe, we're now a commercial company as opposed to a developmental company."

Since its inception in 2003, MicroPhage has been vying for the commercialization of its diagnostics tests. Armed with only 16 employees, a number that is soon sure to grow, MicroPhage is now reportedly eyeing to get a foothold into the U.S. market.

The company has already had some exposure in the states. In August, it reported the start of a multi-site clinical trial to support its FDA premarket notification 510(k) submission, which is expected to be filed shortly. The clinical study involves four major medical centers throughout the U.S. and is expected to test more than 1,000 specimens with the Microphage MRSA/MSSA Blood Culture Test to demonstrate its safety and performance.

"Our initial product, as well as the family of tests we intend to offer based on our Bacteriophage Amplification platform, represents a new paradigm for the effective, cost-effective testing of hospital patients," Lundy said.

The test itself requires no instrumentation and begins with two small reaction tubes for incubating blood culture specimens.

After only five hours, the incubated samples are added to a dual dipstick-like detector, which looks much like a home pregnancy test. One part of the test will identify if the blood sample is infected with *S. aureus* bacteria and the other shows whether it is susceptible or resistant to methicillin-type antibiotics.

Delivering this diagnostic information quickly will enable physicians to determine more effective and precise antibiotics that could shorten hospital stays, lower healthcare costs and, ultimately, save lives. *S. aureus* bacteria typically has a mortality rate of more than 20%.

Another upside according to MicroPhage, is that the results derived from the assay cost about \$15-\$40 per test—significantly lower than some other tests on the market.

With the anticipation of getting into the regulatory path from the FDA and riding off the coat tails of the CE mark, Lundy said the company is poised to raise nearly \$15 million in financing.

"Because of the amount of money we've raised in the past and where we're at in the regulatory pathway, I would say this is like a hybrid B and C series financing," Lundy said. "We didn't go the traditional VC route; most of our money was raised from private investors."

MicroPhage last reported completing a financing round that brought the total money secured for the company up to \$11 million (*Medical Device Daily*, Nov. 24, 2008).

Lundy said that he isn't concerned about raising the required capital for the next financing round, because the issue of MRSA is still a big problem that many hospitals face.

"Hospital-acquired infections (HAIs) are a colossal problem, killing more than 15 million persons worldwide each year and costing the U.S. \$29 billion in unnecessary healthcare expense. We believe that our initial test will be extremely well received in Europe as well as in the U.S.," Lundy told *Medical Device Daily*. "MRSA is still here and it's still a prevalent issue." ■

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## Med-Tech Notes

### Lifeline close on software development

**Lifeline Biotechnologies** (Reno, Nevada) reported that management has recently returned from Singapore where meetings were conducted with Nanyang Technological University's (NTU) School of Mechanical & Aerospace Engineering to receive the final report on the software development of Lifeline's First Warning System.

Louis Keith, MD, Lifeline's VP and medical director said, "The report clearly displayed that the system of obtaining physiological measurements of the dynamic changes in the breasts of women was valid, and that such data could be efficiently and effectively classified into four reproducible classes which then could be transmitted to examining physicians for use as an adjunct to the early detection of breast cancer. Of equal importance, the report showed that the noninvasive First Warning System was more efficient than mammography without exposure to radiation and compression while providing indications of tissue irregularities at much earlier stages."

### Arrayit Diagnostics retains Elite Financial

**Arrayit Diagnostics** (Houston) reported the appointment of Elite Financial Communications Group, a fully integrated marketing and communications firm, as the company's investor and public relations counsel of record.

Dodi Handy, president/CEO of Elite, said, "Given Arrayit Diagnostics' near term strategy to commercialize a series of proprietary diagnostic tests using microarray technology capable of detecting specific disease states in their early stages, the coming year promises to be one defined by potentially remarkable growth opportunities for the company. As such, Elite looks forward to ensuring that due attention is focused on Arrayit Diagnostics as it progresses its compelling business plan and earns distinction for the important role it intends to play in the fast evolving genomic and proteomics industry."

## International

*Continued from Page 1*

mobility, and to provide temporary relief of minor aches and pains.

Marvin Sackner, NIMS' founder/CEO, said "this Canadian patent builds on the company's global intellectual property and provides protection in our efforts to market in Canada."

The Exer-Rest is currently being marketed and sold in the U.S., Canada and other major international markets. It has been cleared by FDA as an aid to temporarily increase local circulation, to provide temporary relief of minor aches and pains, to reduce morning stiffness and to provide local muscle relaxation. The Exer-Rest is also approved for sale in Europe as an aid to increase mobility.

### Microcap chosen by Bavarian Red Cross

**Oridion Systems** (Jerusalem/Needham, Massachusetts) reported that the Bavarian Red Cross has chosen Microcap portable capnographs for its RTW (Rettungswagen) medical vehicles. The use of capnography can help paramedic teams to assess the ventilation status of a patient as well as alert them to issues that affect respiratory status such as displaced endotracheal tubes, episodes of respiratory depression as well as the status of resuscitative efforts. Immediate treatment of these developing conditions can improve the patient's status and limit the danger of further serious complications.

Since 2007, the DIN 1789 Norm and Rules for German Ambulance Vehicles of the type "RTW" mandated the use of capnometers when transporting emergency patients. The Bavarian Red Cross has been looking for a standalone capnograph unit to fulfill the requirements of DIN 1789, as it believed the utility vs. cost to be better than incorporating capnography into existing defibrillators or respirators. Additionally, a significant graph of the CO<sub>2</sub> curve was a requirement.

The Bavarian Red Cross tested four different competitive units at four different sites and after a thorough analysis, chose the Oridion Microcap capnography monitor. Their selection of the Microcap was based on several criteria including: ease of use, reliability, portability, ruggedness and stability of the device. Microcap monitors are one of the Oridion family of portable monitors employing Microstream capnography technology to provide accurate, continuous monitoring on intubated and non-intubated patients from neonate to adult patients in hospital and pre-hospital environments, including emergency transport.

The ability to accurately monitor CO<sub>2</sub> levels in a patient's breathing is vital for ensuring patient safety - especially in emergency transports.

Capnography is increasingly being used by paramedics worldwide to help in their assessment and real-time treatment of both intubated and non-intubated

patients in the pre-hospital setting. This is one of the reasons why the London Ambulance Service and several states in the U.S. have mandated capnography for intubated patients in Emergency Medical Services (ambulances).

Oridion develops proprietary medical devices and patient interfaces, based on its patented Microstream(R) technologies, for the enhancement of patient safety through the monitoring of the carbon dioxide in a patient's breath. These products provide effective, proven airway management and are used in various clinical environments, including procedural sedation, pain management, operating rooms, critical care units, post-anesthesia care units, emergency medical services, transport, alternate care and other settings where patients' ventilation may be compromised and at risk.

### Visage in deal to provide PACS to Lake Imaging

**Visage Imaging** (Andover, Massachusetts), a wholly owned subsidiary of **Pro Medicus** (Richmond, Australia), signed a deal to provide **Lake Imaging** (Geelong, Australia), one of Australia's largest independent diagnostic imaging groups, with Visage 7 - its next generation, thin client streaming digital imaging technology (PACS) solution.

Lake Imaging is one of the fastest growing radiology groups in Australia. In 2002 it was among the first private practices in Australia to adopt a fully digital imaging solution which has helped power its growth from two practices to today's network of seventeen fully digital campuses.

Visage 7 will be installed and fully integrated with the existing Pro Medicus Radiology Information System (RIS) at all Lake Imaging sites. In addition to being used for all primary diagnosis, the system will handle the long term image archiving needs of the group. The Visage solutions also provide Lake Imaging referring physicians with the ability to remotely access, view and manipulate their patients' images in both 2-D and 3-D, another first being native support for both Windows and Mac OS X.

"Visage 7 is a revolutionary new product that sports a number of industry firsts. It is truly thin client which provides rapid access to extremely large datasets without having to download them. This creates new opportunities for sharing images, regardless of location, that are not feasible using standard image transfer technology. The new Visage 7 Universal Viewer allows radiologists to view conventional 2-D as well as advanced 3-D and 4-D (moving) images all within the one application," said David Chambers, CEO, Visage Imaging/Pro Medicus. "Up to 30 % of Australia's referring specialists use the Macintosh platform so we see this as a significant strategic advantage," he added. ■

## Washington

*Continued from Page 1*

the system's connectors, and to the sterilant used in the SSI. The warning letter states that each of these individually would have necessitated the filing of a 510(k), although the letter does not state whether this is intended to mean a traditional 510(k) or one of the alternates, such as an abbreviated or special 510(k).

According to the letter to healthcare facilities, the agency is in possession of "some reports of malfunctions of the SSI that had the potential to cause or contribute to serious injuries to patients, such as infections." FDA states that infections associated with a device reprocessed in the SSI "may be difficult to attribute to the SSI and may go unreported." FDA states further that it has received reports of injuries, "mostly burns from exposure to the sterilant solution."

Sterilization generally speaking seems to be of concern at the agency as demonstrated by a Nov. 19 communication to healthcare facilities regarding sterilization of endoscopes during reprocessing. On the other hand, the Aug. 15 warning to Steris was the second warning to the firm in less than a year. FDA wrote the company a Sept. 25, 2008, warning letter to the firm regarding operations at its plant in Coventry, Rhode Island (*Medical Device Daily*, Oct. 22, 2008).

FDA's letter to healthcare professionals advised that if facilities "have an acceptable alternative to the SSI to meet your sterilization and disinfection needs," the facility "should transition to that alternative as soon as possible to ensure continued patient safety." If no alternative is immediately available, the agency states, the facility should "take steps to obtain legally-marketed substitutes for the SSI."

Steris had not responded to a call for comment by press time Friday.

### HealthSouth associate fined \$3 million

The Department of Justice announced recently that a sports medicine orthopedic clinic operating in Los Angeles, the **Kerlan Jobe Orthopaedic Clinic**, has agreed to shell out \$3 million to settle charges that the clinic accepted kickbacks from **HealthSouth** (Birmingham, Alabama).

According to the Dec. 1 DoJ statement, HealthSouth gave Jobe a number of inducements including stock option grants, forgiveness on equipment loans, and "a disproportionately high ownership interest in a jointly owned ambulatory surgery center" for referrals to HealthSouth facilities. HealthSouth is said to have also made donations to the **Kerlan Jobe Foundation** in exchange for referrals.

DoJ states that Jobe was required to enter into a corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services "as a condition of continued participation in government healthcare programs." The action, according to DoJ, is associated with a settlement between HealthSouth and DoJ that cost the company almost \$15 million "for improper financial relationships with Kerlan Jobe and an [unnamed] Alabama

sports medicine clinic," which DoJ acknowledges was reported by the new management team that took over at HealthSouth in 2007.

HealthSouth's founder and then-CEO Richard Scrusby was indicted and eventually convicted in 2006 for a range of charges, including money laundering, and was ordered to pay damages of roughly \$2.8 billion. Neither the HealthSouth nor the Kerlan Jobe web sites list any press statements on the matter.

### IRB cited for lack of quorum

Conflict of interest still occupies a large place on the regulatory radar screen, including where institutional review boards (IRBs) are concerned. This was made clear in the Nov. 20 warning letter to **Centra Health** (Lynchburg, Virginia), which cited the IRB for counting a board member who had a conflict of interest as a qualifying voting member in reviews of ongoing studies.

The first citation states that Centra had used a retroactive re-approval of an ongoing study, the name of which was redacted, rather than review the study on schedule. The IRB's proposed correction, FDA states, was inadequate because Centra did not include documentation of the proposed fix, which is said to include "a spreadsheet and an e-mail calendar . . . to remind the IRB when a study is due for renewal."

The stickiest part of the warning letter, however, was that Centra voted in January 2007 to approve a study despite not achieving a quorum. According to FDA, the board counted toward the quorum a member of the IRB who was conflicted, and FDA asserted in the warning letter that this member "should have been excluded in the total count of voting members." The warning letter states further that a similar situation arose in May 2007 involving two board members who were conflicted but who were nonetheless counted toward the quorum.

Centra's response to this finding on the 483 apparently indicated that the IRB was of the view that "an abstention does not break a quorum." FDA states that according to the pertinent regulations, "a majority is defined as more than 50% of the total voting members of an IRB (excluding alternates)." Hence, the agency argues, Centra "did not maintain the required majority to review" studies. FDA also asked for proof of corrective action.

Centra was also cited for failure to document "the actual numbers of members who voted for, against and abstained" from votes" in reference to two IRB meetings held in May 2007. The warning letter states that the IRB's minutes noted only "unanimous approvals." The IRB's response was said to assure FDA that future notes would be more exhaustive, but the agency requested "evidence of the corrective actions." ■

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## Product Briefs

- **ExonHit Therapeutics** (Paris) reported that AclarusDx Alzheimer's test (formerly known as EHT Dx21), its blood-based test for the detection of Alzheimer's disease (AD), is now available as a Research Use Only (RUO) product for pharmaceutical companies and leading academic centers conducting clinical trials in Alzheimer's disease. AclarusDx Alzheimer's test is a reproducible, objective, and non-invasive test. A blood sample is all that is required from the patient, no special equipment or medical facilities are required and the ease of the procedure should enhance volunteers' willingness to participate in trials. When used in combination with neuro-cognitive tests, AclarusDx Alzheimer's test could help pharmaceutical companies running clinical trials to include patients fulfilling clinical criteria for AD and who share a common transcriptional profile that has been correlated to AD. Hence, AclarusDx Alzheimer's test could lower the trial's "background noise" and potentially lead to a better study outcome by selecting a more homogeneous study population.

- **MAKO Surgical** (Ft. Lauderdale, Florida) reported the commercial availability of the Lateral Unicompartamental Knee Resurfacing Application for its RIO Robotic Arm Interactive Orthopedic System. The new application complements MAKO's existing unicompartamental and bicompartamental knee applications targeting the medial and patellofemoral compartments. The RIO is a surgeon-interactive tactile surgical platform that incorporates a robotic arm and patient-specific visualization technology and prepares the knee joint for the insertion and alignment of MAKO's resurfacing Restoris implants through a minimal incision.

- **Orthofix International** (Boston) reported that its sports medicine division, BREG, has expanded its successful line of Fusion functional knee braces by introducing the Fusion Lateral OA Brace, which features an ultra-thin low-profile hinge designed for individuals suffering from lateral compartment osteoarthritis (OA). The Fusion Lateral OA Brace was developed to off-load knee stress for individuals suffering with osteoarthritis, and the low-profile hinge is designed to reduce interference during the wearer's movement specifically on the inside, or medial, part of the knee. As the newest member of the Breg family of Fusion functional knee braces, the new Lateral OA Brace is designed to provide support for the anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL), as well as protection for collateral ligaments, without hindering the wearer's activity.

- **Revolutions Medical** (Charleston, South Carolina) producers of the RevVac safety syringe, RevColor, RevDisplay and Rev3D MRI Technology, reported that it introduced its proprietary suite of MRI software products with great success. Radiologists and universities world-wide received presentations at the RMCP booth. A number of these contacts could play an important role in the company's ongoing efforts to clinically validate specific applications of its MRI tools prior to the 2010 commercial launch.

- **Stentys** (Princeton, New Jersey) reported that the first patient has been enrolled into the APPOSITION II clinical study — a randomized trial comparing the Stentys self-expanding stent with a conventional balloon-expandable stent in AMI patients. The primary endpoint of the APPOSITION II study is stent strut apposition at day three post-procedure via extremely high-resolution optical coherence tomography imaging. The self-expanding feature of the Stentys platform, unrivaled in the stent industry, is designed to insure optimal apposition of a stent in the critical initial hours and days after an AMI procedure, by being continuously applied to the vessel's internal surface even during thrombus and vessel spasm relief—thereby avoiding malapposition, a significant concern to cardiologists.

## People in the News

- **Owens & Minor** (Richmond, Virginia) a distributor of national name-brand medical and surgical supplies and a healthcare supply-chain management company, reported that its Corporate VP & Controller, Olwen Cape, intends to retire from the company in April 2010. Cape has served the company as chief accounting officer since 1997, after working more than 20 years in public accounting and corporate finance. Owens & Minor simultaneously reported the appointment of D. Andrew Edwards, as Corporate VP, Finance of Owens & Minor, effective Dec. 14. Upon Cape's retirement, Edwards is expected to assume the title of Corporate VP Controller & Chief Accounting Officer of Owens & Minor. He will report to Corporate Senior VP & CFO James Bierman.

- **Suneva Medical** (San Diego) a privately-held aesthetic device company, reported the appointment of Philip Ranker as VP and CFO. In this role, Ranker will lead all Suneva Medical's general and administrative functions including finance, accounting, IT, IR, administration and human resources. He will also serve on the company's senior management team.

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# MDD'S NEUROLOGY EXTRA

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

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*Keeping you up-to-date on recent headlines in neurological science:*

**Stomach hormone could boost resistance to Parkinson's . . .** U.S. researchers report finding that ghrelin, a hormone produced in the stomach that regulates appetite and how the body deposits fat, may be used to boost resistance to or slow the development of Parkinson's disease. The study is the work of Tamas Horvath, chair and professor of comparative medicine and professor of neurobiology and obstetrics and gynecology at the **Yale University School of Medicine** (New Haven, Connecticut), and colleagues and was published recently in *The Journal of Neuroscience*. Parkinson's disease is a neurodegenerative disorder where dopamine neurons in an area of the midbrain known as the substantia nigra, which is responsible for dopamine production, start to die off. As less dopamine is produced, the symptoms become more severe, so that eventually people with the disease have difficulty walking, have restricted and delayed movements, get tremors in their head and limbs, lose their appetite, can't eat properly, and have periods of immobility or "freezing." In this study, Horvath and colleagues discovered that ghrelin also protects the neurons that make dopamine. "We also found that, in addition to its influence on appetite, ghrelin is responsible for direct activation of the brain's dopamine cells," said Horvath. He explained that because the hormone is made in the stomach, it circulates normally in the bloodstream, "so it could easily be used to boost resistance to Parkinson's or it could be used to slow the development of the disease." Horvath et. al. gave one group of mice extra ghrelin, and while another group were genetically engineered to lack the hormone and its receptor. When compared to a group of control mice, the mice that had impaired ghrelin action in the brain had more dopamine loss. They concluded that their study supports the idea that ghrelin could be a new therapeutic strategy to fight neurodegeneration, loss of appetite and body weight linked with Parkinson's disease.

**Naked mole rats could hold stroke survival clues . . .** Blind, nearly hairless, and looking something like toothy, plump, pink fingers, naked mole rats may rank among nature's most maligned creatures, but their unusual physiology endears them to scientists. Two **University of Illinois at Chicago** researchers report in the Dec. 9 issue of *NeuroReport* that adult naked mole rat brain tissue can withstand extreme hypoxia, or oxygen deprivation, for periods exceeding a half-hour — much longer than brain tissue from other mammals. The findings may yield clues for better treatment of brain injuries associated with heart attack, stroke and accidents where the brain is starved of vital oxygen. John Larson and Thomas Park studied African naked mole rats — small rodents that live about six feet underground in big colonies of up to 300 members. The living is tight and the breathing even worse, with the limited air supply high in carbon dioxide and low in oxygen. The air they breathe is so foul it would be fatal or lead to irreversible brain damage in any other mammal, Larson and Park said. But naked mole rats studied were found to show systemic hypoxia adaptations, such as in the lungs and blood, as well as neuron adaptations that allow brain cells to function at oxygen and carbon dioxide levels that other mammals cannot tolerate. "In the most extreme cases, naked mole rat neurons maintain function more than six times longer than mouse neurons after the onset of oxygen deprivation," said Larson. "We also find it very intriguing that naked mole rat neurons exhibit some electrophysiological properties that suggest that neurons in these animals retain immature characteristics." Park added: "The trick now will be to learn how naked mole rats have been able to retain infant-like brain protection from low oxygen, so we can use this information to help people who experience temporary loss of oxygen to the brain in situations like heart attacks, stroke or drowning."

**New source found for nerve cell generation in brain . . .** Until recently, neurogenesis the process of nerve cell development was considered to be impossible in the adult brain. The textbooks asserted that dead nerve cells could not be replaced. Then researchers discovered regions in

the forebrain in humans in which new nerve cells can be generated throughout life. These so-called GABAergic cells use gamma-aminobutyric acid (GABA), a neurotransmitter of the central nervous system. A research team of scientists led by Magdalena Gotz, director of the Institute of Stem Cell Research at **Helmholtz Zentrum Munchen** and **Ludwig-Maximilians-Universitat** (both Munich, Germany) has now taken a closer look at this brain region in the mouse model. Their findings: Even in the forebrain, there are other nerve cells that are regularly generated the so called glutamatergic nerve cells, which use glutamate as neurotransmitter. The stem cell researchers could prove this by means of a specific transcription factor: *Tbr2* is only present in progenitor cells of glutamatergic nerve cells. Particularly in Alzheimer's disease, nerve cell degeneration plays a crucial role. In the future, new therapeutic options may possibly be derived from steering the generation and/or migration mechanism. These findings have been published in the current issue of *Nature Neuroscience*. The newly generated nerve cells in the adult organism are located in the olfactory bulb, the region of the brain involved in the sense of smell. Nerve cells that use glutamate as a neurotransmitter are also responsible for memory storing and retrieving information. In Alzheimer dementia, alterations in the signal transduction pathways of these special cells play a significant role. Gotz explained the reason why this finding is so important: "Neural progenitor cells can generate these newly discovered glutamatergic nerve cells for the neighboring cerebral cortex for example after brain injury." The research group was able to demonstrate this on the mouse model: There the cells migrated into the damaged neighboring cerebrum tissue and generated mature neurons. Accordingly, progenitor cells could then replace degenerate nerve cells.

**Study shows glial cells can 'cross over' . . .** Glial cells, which help neurons communicate with each other, can leave the central nervous system and cross into the peripheral nervous system to compensate for missing cells, according to new research in the Dec. 2 issue of *The Journal of Neuroscience*. The animal study contributes to researchers' basic understanding of how the two nervous systems develop and are maintained, which is essential for the effective treatment of diseases such as multiple sclerosis. The nervous system is divided into the central nervous system (the brain and spinal cord) and the peripheral nervous system (sensory organs, muscles, and glands). A major difference between the systems is that each has its own type of glial cells. In a healthy body, glial cells are tightly segregated and aren't known to travel between the two systems. The peripheral nervous system also regenerates more than the central nervous system, due in part to its glial cells – a characteristic that, if better understood, might be used to improve the regenerative capabilities of the central nervous system. Glial cells serve nerve cells by insulating them with layers of fats and proteins called myelin. Myelin coatings are necessary for nerve signals to be transmitted normally; when the sheaths are lost, disorders involving impairment in sensation, movement and cognition such as multiple sclerosis or amyotrophic lateral sclerosis develop. Glial cells named oligodendrocytes produce myelin around nerves of the central nervous system, while those named Schwann cells make myelin that insulates peripheral nerves. This study shows that in the absence of Schwann cells, oligodendrocytes migrate from the central nervous system along motor nerves and form myelin on peripheral nerves, indicating that glial cell movement across the border is controlled by a self-policing mechanism. "Past studies have hinted that Schwann cells can cross into the central nervous system after peripheral nerves near the border are damaged, or after central nerves lose their myelin sheath," said Bruce Appel, PhD, of the **University of Colorado Denver** Anschutz Medical Campus, one of the study's authors. "However, migration across the border has never been observed directly, nor was there any evidence that oligodendrocytes can move in the opposite direction."

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