Medical Device Daily™
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# MASPP physician touts St. Jude's Epiducer system as 'pretty cool'

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

It's hard to miss the enthusiasm Frank Falco, MD, has for the new Epiducer lead delivery system from **St. Jude Medical** (St. Paul, Minnesota) when he talks about the unprecedented access the technology provides to the epidural space.

Falco, founder/CEO and principal at **Mid Atlantic Spine and Pain Physicians** (MASPP; Elkton, Maryland), performed the East Coast region's first procedure using the Epiducer lead delivery system and has been selected by St. Jude to train other physicians nationwide to use the device, MASPP said.

The purpose of the Epiducer lead delivery system is to offer a less invasive option for introducing multiple leads and/or S-Series paddle leads. Rather than requiring a needle

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*NewCo on the Block*

# Bluegrass Vascular focuses on Surfacer 'inside out' catheter

**By ROBERT KIMBALL**
***Medical Device Daily* Staff Writer**

Medical technology incubator **Therix Medical** (Lexington, Kentucky) reported the launch of spin-out **Bluegrass Vascular Technologies**, a stand-alone company specializing in life-saving devices and methods that address shortcomings in vascular access procedures. Bluegrass Vascular Technologies' flagship product is the Surfacer inside-out access catheter system, an instrumentation set that allows physicians to perform a novel "inside-out" approach to gain venous access.

The Surfacer was developed to provide a new option for patients with upper extremity venous occlusion (or blockage in the vein) that makes the vein impenetrable by a guidewire or standard access techniques. This condition

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*Report from Europe*

# Neovasc receives CE mark for Reducer angina treatment

**A *Medical Device Daily* Staff Report**

**Neovasc** (Vancouver, British Columbia), reported that it has received the CE mark designation for its Reducer product for the treatment of refractory angina.

The Reducer is designed to treat patients who suffer from refractory angina, a painful and debilitating condition that occurs when the coronary arteries deliver an inadequate supply of blood to the heart muscle. Refractory angina currently affects an estimated one million patients in Europe, who often lead severely restricted lives. The incidence of refractory angina is growing, yet current treatment options are limited.

The Reducer is implanted in the coronary sinus vein using minimally invasive techniques that are similar to

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*Washington roundup*

# House, Senate call for $50M boost in FDA's 2012 funding

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

The ongoing budget struggles are presumed to offer a potentially sharp cut to the budgets of a number of federal agencies and programs, but the lobbying on behalf of FDA seems to have paid off with the announcement that FDA will not only avoid a loss of appropriated monies, but will see a net increase of $50 million in taxpayer dollars. Most of that increase will go toward food safety and bioterrorism programs, but the development at least takes the pressure off device user fee negotiators as they work toward a settlement on user fees for the next five-year fee schedule.

The **Alliance for a Stronger FDA** (Washington) listed the details of the agreement between House and Senate

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**Don't miss today's MDD Extra: Oncology**

INSIDE:



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*Deals roundup*

# Alcon to pay $1.5M plus royalty fees for Iridex GreenTip rights

**A *Medical Device Daily* Staff Report**

**Iridex** (Mountain View, California) has struck a license and distribution deal with **Alcon** (Fort Worth, Texas) covering the Iridex GreenTip Soft Tip Cannula family of products and license rights to the patented technology.

Alcon will pay $1.5 million in upfront royalties, purchase Iridex branded products for distribution in the U.S. and pay an ongoing royalty to license and manufacture related Alcon branded products for distribution overseas.

The Iridex GreenTip Soft Tip Cannula products are used in vitrectomy procedures and allow retina surgeons to effectively visualize and access the proximity of the retina, the company noted. Benefits include: optimal contrast against the retina, maximized visualization and greater protection of the retina with its unique atraumatic silicone tip.

"An important part of our growth strategy is to develop and identify unique consumable products that bring clinical value to retina surgeons and their patients, and we are very pleased to be working with Alcon in distributing a key product family in that category," said Dominik Beck, PhD, president/CEO of Iridex. "Working with Alcon, the market leader in ophthalmology devices, underscores the value of our enhanced visualization cannula products and may lead to additional opportunities for collaboration in the future."

In other dealmaking activity:

• **Samsung Electronics** (Piscataway, New Jersey) said it has acquired the Nexus division of **ITC Nexus Holding** (San Diego, California), a provider of cardiac point-of-care testing solutions.

Nexus develops the Cardiac STATus, Decision Point and Vyent line of rapid test kits that aid in the diagnosis and monitoring of several cardiovascular diseases.

"This investment represents an exciting opportunity to strengthen Nexus' technological capabilities while enabling Samsung to compete in the cardiac point-of-care testing market," said Yong-chu Bang, VP of Samsung Electronics' Health and Medical Equipment (HME) business team. "We welcome the expertise that Nexus brings and believe this partnership will play a vital role in helping Samsung to position itself as a global leader in healthcare technology."

Nexus will continue to operate from its San Diego headquarters and become part of Samsung's HME division which focuses on developing technological solutions for the healthcare industry.

As part of long-term plans to develop next-generation growth engines, Samsung reported last year its goal to invest $12 trillion through 2020 in healthcare equipment. Its first major move into electronic diagnostics tools began early this year with the acquisition of a controlling stake in diagnostic ultrasound manufacturer Medison, now renamed Samsung Medison.

• **Conmed Healthcare Management** (Hanover, Maryland), a provider of correctional facility healthcare services to county and municipal detention centers, said it has received notice from **Ayelet Investments** that Ayelet does not in good faith believe it will be able to obtain the necessary financing sources to agree on certain post-closing covenants, including post-closing financial covenants.

Conmed is now considering the various options available to it based on such notification.

In July, Conmed reported a definitive merger agreement to be acquired by Ayelet Investments, an affiliate of James Desnick, MD, for $3.85 a share in cash, or about $57.2 million. Conmed's board had already unanimously approved the transaction at that time (*Medical Device Daily*, July 13, 2011). ■

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*Agreements/contracts*

# Volition to earn revenues for blood profiling technology

**A *Medical Device Daily* Staff Report**

**Volition** (Singapore) said its wholly owned subsidiary, **HyperGenomics**, has signed a contract which is expected to provide Volition with its first revenues. Volition has been commissioned to develop epigenetic profiling signatures from blood.

Volition's HyperGenomics technology will be used to determine specific epigenetic signatures from biopsies and blood. The HyperGenomics range of tests will be used as a second line once cancer (and potentially other conditions) has been diagnosed, to accurately determine the specific subtype of disease and to help decide the most appropriate therapy.

"Our HyperGenomics technology is a cutting-edge method of epigenetic profiling. We believe that epigenetic profiling is set to make a significant impact in the area of personalized medicine – selecting the correct treatment on an individualized basis. We're delighted that others are beginning to see the potential of our HyperGenomics platform. The funded study will contribute to our ability to identify unique, epigenetic signatures from blood and thus support our internal cancer-profiling program. In addition, data analysis will help validate the biostatistical algorithms we are developing," said HyperGenomics chief scientific officer Mark Eccleston.

The agreement provides for staged payments of up to $55,000 to be paid to HyperGenomics based on successful milestone completion over the next eight months. HyperGenomics will partner with **Biomedicum Genomics OY** (Helsinki, Finland) to fulfil sequencing and bioinformatics requirements.

Volition makes non-invasive blood tests for cancer as common and simple to use as existing diabetic and cholesterol tests on similar formats.

In other agreements/contracts news:

• **BSD Medical** (Salt Lake City) said the Cancer Treatment Centers of America (CTCA) at **Midwestern Regional Medical Center** (Zion, Illinois) has purchased a BSD-500 Hyperthermia System (BSD-500). CTCA Midwestern Regional Medical Center is a cancer care facility that provides therapeutic resources in cancer treatment in one location. This will be the sixth BSD Hyperthermia system purchased by CTCA.

The BSD-500 Hyperthermia System is used to deliver therapeutic heating (hyperthermia) using either noninvasive (external) hyperthermia, which is delivered using antennas placed over the tumor, or interstitial hyperthermia, which is delivered using antennas that are inserted into the tumor, or a combination of both. The BSD-500 has received FDA pre-market approval for the use of hyperthermia in conjunction with radiation therapy to treat certain tumors.

• **Misonix** (Farmingdale, New York), a company that makes therapeutic ultrasonic products for surgical applications, has entered into a new, two-year, exclusive distribution agreement with **Sarl Excellence Sante** (SES; Algiers, Algeria) for the distribution of the SonaStar Ultrasonic Surgical Aspirator and the BoneScalpel Ultrasonic Bone Cutter. The agreement provides SES with the rights to sell throughout Algeria. Included in the agreement are annual minimum purchase requirements. Initial product training is complete and open market sales are underway.

SES is a distributor of medical devices and has launched multiple new products into Algeria, including capital equipment-based surgical systems, and is known for their commitment to service and physician training, particularly in the fields of spine surgery, orthopedic surgery and neurosurgery.

The SonaStar is used by Neuro and General Surgeons for quick and efficient removal of both hard and soft tumors while sparing most vessels. The BoneScalpel is a tissue specific osteotomy device capable of making precise cuts through bone and hard tissue while largely preserving delicate soft tissue structures. It offers the convenience and speed of a power instrument without the danger associated with rotary sharps. ■

*Financings roundup*

# Echo's shareholder commits to warrant exercise of $2M

**A *Medical Device Daily* Staff Report**

**Echo Therapeutics** (Philadelphia) said it has received a commitment by its largest shareholder, Platinum Partners, for a warrant exercise of $2 million, in addition to the previously disclosed $1.7 million warrant exercise by Platinum.

"We are very pleased with this warrant exercise as it will allow us to continue the accelerated pace of product development finalization and clinical validation necessary for FDA clearance of the Symphony tCGM system," said Patrick Mooney, MD, chairman/CEO of Echo Therapeutics. "The exercise of these warrants by our lead investor will demonstrate Platinum's confidence in Echo's strategy and product potential. We are grateful for the ongoing support that Platinum has exhibited."

Echo is developing the Symphony tCGM system as a non-invasive, wireless, transdermal continuous glucose monitoring system for patients with diabetes and for use in hospital critical care units. Echo is also developing its needle-free Prelude SkinPrep system as a platform technology for enhanced skin permeation for delivery of topical pharmaceuticals.

In other financing activity:

• **Athersys** (Cleveland) has entered into a common stock purchase agreement with Aspire Capital Fund, whereby Aspire Capital has committed to purchase up to $20 million of Athersys' common stock in multiple transactions over the next two years at a modest discount to the then prevailing market price. At closing, Aspire Capital purchased 666,667 shares of common stock for $1.50 per share.

As part of the purchase agreement, Athersys will control the timing and amount of any sales of common stock to Aspire Capital and will know the sales price before giving notice directing Aspire Capital to purchase shares. Aspire Capital has no right to require any sales by the company, but is obligated to make purchases as the company directs, in accordance with the terms of the purchase agreement. The purchase agreement may be terminated by Athersys at any time, at its discretion, without any additional cost or penalty.

Athersys is a specialist in regenerative medicine and cell therapy research and development.

• **Kindred Healthcare** (Louisville, Kentucky) reported the full results of its registered exchange offer for all of its outstanding 8.25% senior notes due 2019, which were not registered under the Securities Act of 1933, as amended, for an equal principal amount of its 8.25% senior notes due 2019, which have been registered under the Act.

Wells Fargo Bank, National Association, acting as exchange agent for the exchange offer, advised the company that all of the $550 million aggregate principal amount of the initial notes have been validly tendered for exchange, representing 100% of the principal amount of the outstanding initial notes. The company accepted all of the initial notes validly tendered and not withdrawn.

• **HealthStream** (Nashville, Tennessee) said it has launched a tender offer of 3.25 million shares of its common stock, consisting of 3.1 million shares to be sold by the company and 150,000 shares to be sold by certain selling shareholders. William Blair & Co. is serving as the sole book-running manager of the public offering and Avondale Partners, and Craig-Hallum Capital Group are serving as co-managers of the public offering. The company intends to grant the underwriters a 30-day option to purchase up to an additional 487,500 shares at the public offering price, less the underwriting discount, to cover over-allotments, if any.

HealthStream says it intends to use the net proceeds from the public offering for working capital and general corporate purposes and/or to acquire or invest in strategic businesses, products, or technologies.

• **Laboratory Corporation of America** (Burlington, North Carolina) said it is extending until Nov. 30 its cash tender offer for all outstanding shares of the common stock of Orchid Cellmark.

On May 17, 2011, LabCorp received a request from the Federal Trade Commission for additional information under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, applicable to the acquisition of Orchid by LabCorp. LabCorp previously extended its tender offer to Nov. 14. LabCorp says it is continuing to cooperate with the FTC's request for additional information and is consequently further extending the expiration of the tender offer. To allow more time to consummate the transactions contemplated by the offer to purchase, LabCorp, OCM Acquisition, and Orchid have amended their previously announced agreement and plan of merger dated April 5, as amended, to extend the extended outside date by an additional 30 calendar days, or until Dec. 14.

In April LabCorp, through its subsidiary OCM Acquisition, launched a tender offer for all outstanding shares of Orchid at a price of $2.80 a share net to the seller in cash without interest and subject to applicable withholding taxes. The tender offer was made pursuant to the merger agreement.

• **Babson Capital Management** (Springfield, Massachusetts), an investment management firm, said it provided $16 million of mezzanine debt financing and $2 million of equity for **Compass Investment Partners**' (New York) acquisition of **Dantom Systems** (Wixom, Michigan).

Dantom provides outsourced document management services and customized data solutions to the accounts receivable management industry, with customers across the healthcare, financial, home services and government end-markets. Established in 1997, Dantom's core service offering includes secure document creation and delivery,

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*HIT roundup*

# Happyneuron offers MemTrax online memory-screening test

**A *Medical Device Daily* Staff Report**

**Happyneuron** (Mountain View, California), a maker of online cognitive cross-training solutions, reported the release of MemTrax, a new memory-screening test for consumers. MemTrax offers a screening for the early detection of memory issues, available as an online service or iPhone/iPad app.

MemTrax was developed after 10 years of research by Wes Ashford, MD, chair of the memory screening advisory board of the Alzheimer's Foundation of America and clinical editor of the *Journal of Alzheimer's Disease*.

MemTrax has been shown to be sensitive to the clinical memory problem that affects patients with Alzheimer's disease, therefore providing early indications of mild cognitive impairment, dementia and Alzheimer's disease. Through Ashford's research, The MemTrax memory test was found to reliably indicate the presence of significant memory impairment, and poor performance (below 75%) seen in 100% of dementia patients taking the test.

"Memory is something that every person cherishes, but most people neglect the mind as a part of their overall health screenings," said Ashford. "It's our hope that making a memory screening so readily accessible will encourage more people to take responsibility of their own brain health."

MemTrax is available as both an online service and mobile application. The online screening provides one free test for first-time visitors and then is less than one dollar per month, with a new test offered each month. Users are sent a reminder when each new test is available and an assessment is provided after each test to show potential decline in certain cognitive areas.

In other HIT news:

• **Carestream** (Rochester, New York) received FDA clearance for the use of its Vue Motion medical image viewer with mobile devices such as Apple iPads. The zero-footprint, web-based viewer enables on-demand access to patient imaging data by clinicians.

Since the independent Vue Motion viewer can be integrated with other vendors' PACS systems, DICOM archives or XDS repositories, clinicians and referring physicians gain much faster and easier access to radiology images stored in various locations throughout a healthcare system, the company said.

Vue Motion does not require downloading of dedicated applications or software. There are no storage or technology requirements for users' mobile devices, PCs or workstations.

The viewer can be embedded in a HIS or EMR portal to allow authorized users across the enterprise to quickly and easily view patient data and images with a single log-in.

Carestream Health is a provider of dental and medical imaging systems and healthcare IT solutions.

• As 46 million seniors nationwide rush to make their health insurance selections by the Dec. 7 annual enrollment period (AEP) deadline, a new online resource has emerged that helps make these decisions easier and more information based.

The new **Joppel** (Orange, California) 3.0 website has been expressly designed to help consumers and brokers evaluate, compare and enroll in private insurance plans participating in the nation's Medicare program.

Through Joppel, seniors and others on Medicare can view all of their options side by side and go through a needs assessment that narrows down hundreds of plans through criteria that are specific to them – such as what medications are covered, cost of co-payment and plan premiums.

"This new site puts control squarely in the hands of the users by giving them access to powerful information they can manipulate quickly and easily to get down to what's most important to them," said VP Gregg Ratkovic. "We've taken all of the data we've collected and all of the experience we've gained over the years and compiled it into a very user-friendly tool that gives people control and flexibility."

• **InterSystems** (Cambridge, Massachusetts), a specialist in software for connected care, said that **Pronger Smith Medical Care** (Tinley Park, Illinois ) rolled out InterSystems Ensemble as its core enterprise integration platform. The strategic decision to build application interfaces with in-house staff on the Ensemble platform has already generated tens of thousands dollars in cost savings over any other development approach, according to Craig Cypress, network system manager at Pronger Smith. "Now that we've been trained and have experience working with Ensemble, it sometimes requires less than 10 minutes to build an interface . . . maybe an hour if the interface is complex," Cypress said.

After a successful rollout this year of Ensemble interfaces that provide connectivity between Pronger Smith's legacy EHR and the regional HIE, the organization is perfectly positioned to move forward with additional integration projects.

• **LexisNexis Risk Solutions** (New York) has introduced Social Network Analytics, a new analytic tool, at the National Health Care Anti-Fraud Association (NHCAA) Institute's Annual Training Conference in Atlanta.

According to the company, healthcare fraud is on the rise. Organized crime is finding the big money, access to electronic records and low penalties just too tempting to pass up. Social Network Analytics can bring visibility to hidden relationships using a company's internal data, but also leveraging "big data" outside what the company already knows. Public records data and derived and risk scored data sets can reveal hidden relationships between people, assets, entities, property and medical providers. This information can be used to stop collusion within a payer's network that might otherwise remain hidden, costing untold amounts and endangering patient safety. ■

## St. Jude

*Continued from Page 1*

stick for each percutaneous lead or requiring a laminotomy for S-Series paddle leads, the Epiducer system enables physicians to gradually dilate the *ligamentum flavum* through a percutaneous approach.

"You're talking about safety, you're talking about efficiency, and you're also talking about the ability for the first time to put in a paddle lead or paddle leads without having to do a more invasive procedure," Falco told *Medical Device Daily* as he described the many advantages he sees in the Epiducer system. "How cool is that?"

St. Jude reported in July that it had received FDA approval for the Epiducer lead delivery system for neurostimulation therapy (*Medical Device Daily*, July 14, 2011).

Designed to reduce procedural complexities and enhance efficiency, the Epiducer lead delivery system reduces the need for multiple incisions typically required to place more than one neurostimulation lead utilized in spinal cord stimulation (SCS) therapy for the management of chronic pain, according to St. Jude.

"We are always looking for new methods to help treat our patients' spine and chronic pain related disorders," Falco said. "We have offered the most advanced options for spinal cord stimulation treatments in the region for some time now. With the introduction of this cutting edge procedure using the Epiducer device, we're now able to implant surgical paddle leads in a minimally invasive way. This is a great alternative for patients looking for a long term solution."

Falco was recently involved in the first training session on the East Coast to 40 pain physicians and neurosurgeons. He will continue to provide training to other surgeons and pain physicians on the Epiducer device and how it is used for the implementation of leads and paddles.

"I think it's a much safer approach," Falco told *MDD*. "You still have to place the needle initially, that part is the same . . . but it is much safer than leaving the needle in there for the entire time." He added that physicians, while doing these procedures via the traditional method, "are always concerned about the needle causing injury to the [spinal] cord."

Being able to implant surgical paddle leads in a minimally invasive way is a "huge, huge, huge, advantage" of using the Epiducer system, Falco said.

"The biggest thing that everyone was surprised to find was how easy it was to steer the paddle leads once they were placed there," Falco said, noting that in Germany and Australia, where the device has been approved for more than a year, physicians have been able to place the paddle leads all the way up into the cervical spine. Again he expressed notable enthusiasm for the device's steerability saying, "how cool is that?" ■

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*Patent watch*

# Awarepoint wins four U.S. patents for mesh-based location algorithm

**A *Medical Device Daily* Staff Report**

**Awarepoint** (San Diego)a developer of real-time wireless location systems (RTLS) for hospitals, reported that the U.S. Patent and Trademark Office has awarded it four additional patents.

The new patents broadly cover Awarepoint's most accurate mesh-based location algorithm to date, methods for detecting improperly sterilized medical equipment, and wireless technology architectures that drive enterprise wide visibility applications.

Patent 8,033,462 is for a wireless tracking system and method of automatically determining if medical and surgical supplies and equipment have been properly sterilized, helping to improve patient safety and quality of care.

Patents 8,031,120 and 8,040,238 provide a process to enhance the detection of the exact location of hospital equipment and medical and surgical supplies.

Patent 8,041,369 describes multiple wireless technologies that precisely track hospital workflows, improve enterprise-wide visibility, and optimize revenue cycle management.

"Our latest patents protect the investment we've made in providing the best technology for our customers," said Matt Perkins, chief technology officer at Awarepoint and one of the inventors named in the patents. "Not only are we the most effective solution for driving enterprise workflow and enterprise visibility, but we continue to be the only company that has demonstrated tags that can survive a full sterilization cycle and alert on decontamination and sterilization violations prior to patient usage."

"From the beginning, we recognized that a one-size-fits-all approach to RTLS technology would not work for hospitals," Perkins said. "Our continuous innovation strategy enables us to deliver multiple technologies to meet our customers' specific needs." ■

## Financings

*Continued from Page 4*

data hygiene and analytics, electronic archival services and online payment portals, all while ensuring compliance with regulatory guidelines.

• **Fulcrum Equity Partners** (Atlanta) said it has funded the $3.2 million acquisition of **AAA Home Health** by **Partners Healthcare Group** (PHG). Founded in 2011, PHG will serve as the platform upon which CEO Rob Radics and his management team will build a home health and hospice company that will provide patients throughout the Southeast with best-in-class care. ■

## Bluegrass

*Continued from Page 1*

develops most frequently in patients treated with central venous catheters, access devices that are used to deliver dialysis or nutrition, to implant pacemakers, and to administer intravenous chemotherapy for cancer. Bluegrass Vascular anticipates completion of a first-in-man study using the Surfacer by the end of the year. "The company expects to complete the ten-patient feasibility study in 2Q12," James Clifton, CEO of Therix Medical and president of Bluegrass Vascular Technologies told *Medical Device Daily.*

Explaining the importance of the product, Clifton told *MDD* that "when a central venous occlusion forms, it can develop into a chronic occlusion that is impenetrable by a guidewire or standard access techniques. When this occurs, the vein becomes compromised and unusable for further access, requiring the physician to seek an alternative vein. If all four central veins become occluded and compromised, more invasive surgical access through the chest or torso is required, both with greater cost and morbidity. Risks of these alternate access options include arm/face edema, infection, thrombosis, catheter failure/dislodgement, punctured lung, collapsed lung, and blood that seeps into the cavity containing the lungs and heart [hemothorax]. The Surfacer was designed to offer an alternative to these invasive techniques with its unique 'inside-out' approach," Clifton added.

Using the system, physicians insert a guidewire through the femoral vein in the groin area and, using fluoroscopy, navigate it up through the torso with an exit point in the jugular vein in the neck or the subclavian vein under the collar bone. The procedure is performed while the patient is under conscious sedation, as with other vascular access procedures.

"The idea for the Surfacer was born from seeing many patients with obstructed central venous systems who needed life-saving vascular access therapies, whether that be pacemakers or defibrillators or dialysis access," said John Gurley, MD, practicing interventional cardiologist at the **University of Kentucky Albert B. Chandler Hospital**, chief medical officer of Bluegrass Vascular Technologies and inventor of the Surfacer. "Our unique system offers physicians an innovative yet simple solution. If the veins are obstructed and you can't put a needle in from the outside, you can now go inside the body and direct the needle out."

The company says the potential market size and need for the Surfacer is substantial. Bluegrass Vascular estimates that more than three million patients require central venous access for medical treatment in the U.S. alone.

Bluegrass Vascular Technologies estimates the market opportunity for the Surfacer and related products to be in excess of $1 billion, with the total market opportunity for general venous access approaching $2.5 billion.

"We believe the Surfacer has the potential to bring tremendous clinical and economic benefit to the healthcare community, as it offers a totally novel approach for venous access that is intended to address a significant unmet clinical need among a very sick patient population," said Clifton. "The launch of Bluegrass Vascular marks a very exciting achievement for Therix Medical, which is singularly dedicated to taking ideas for novel, high-value therapeutic concepts like the Surfacer from the bedside to the commercial market."

The launch of Bluegrass Vascular Technologies follows Therix Medical's $2.5 million Series A financing, which closed in August. Select proceeds of the funding round have been dedicated to support the new spin-out company.

Bluegrass Vascular Technologies is a medical technology company dedicated to developing and commercializing life-saving devices and methods that address shortcomings in vascular access procedures. Therix Medical is a medical technology company focused on enabling the transfer of novel, high-value therapeutic concepts from the bedside to the commercial market. ■

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## Med-Tech Notes

### Vibra opens Texas hospital

**Vibra Healthcare** (Mechanicsburg, Pennsylvania), an operator of specialty hospitals and outpatient physical therapy centers, said it will open a long-term acute care hospital in DeSoto, Texas. The company will transfer the operations of its current Dallas facility to the new DeSoto location.

Vibra Specialty Hospital in DeSoto is located at 2700 Walker Way and will open with the completion of regulatory approvals. The new 37,790-square-foot DeSoto facility features 40 private licensed long term acute care beds, including 12 ICU rooms and 28 private medical surgical suites, a CT scanner, Fluoroscopy suite and a dedicated three-station dialysis unit.

The decision to transfer the operations and provide critical services in the southern Dallas County market is good for patients and the community, according to Brad Hollinger, founder, chairman/CEO. "While we have been quite successful working with key referral sources in the Dallas Medical District, we recognized it was a solid business opportunity to expand Vibra Healthcare in the rapidly growing market of southern Dallas County," Hollinger said. "We were able to reposition our operations in a way that strengthens the healthcare delivery system and provides the best quality care to our patients and community."

## Europe

*Continued from Page 1*

implanting a coronary stent. By modulating blood flow from the coronary sinus, the Reducer acts to increase the perfusion of oxygenated blood to certain areas of the heart muscle, thereby reducing the pain and disability caused by the condition.

"The Reducer's CE mark designation is good news for European refractory angina patients, who previously had exhausted available treatment options but who will now have access to this novel treatment for relieving their symptoms and improving their quality of life," said Dr. Shmuel Banai, medical director of Neovasc. "In addition, the Reducer is implanted using a procedure that is minimally invasive and requires less than 20 minutes to complete."

Results of a published prospective three-year clinical study have demonstrated that the Reducer is safe and effective at providing relief of angina symptoms in refractory angina patients. Neovasc is presently enrolling patients in the COSIRA Coronary Sinus Reducer for Treatment of Refractory Angina (COSIRA) trial, a multicenter, sham-controlled, randomized, double-blinded study. COSIRA has been designed to provide additional controlled, statistically significant data to further demonstrate the clinical efficacy of the Reducer and to support physician education and marketing efforts. It also will support additional regulatory applications to make the Reducer available to the millions of refractory angina patients worldwide who could potentially benefit.

"We are very pleased to have received CE mark designation to treat this critical patient population with high unmet need," said Alexei Marko, CEO of Neovasc. "In the immediate term we will continue to focus on completing enrollment in the COSIRA trial in order to obtain additional data that we expect will be very valuable in supporting medical education and marketing activities for the Reducer. We are currently evaluating a number of options for European commercialization and look forward to distributing the Reducer in select European markets beginning in 2012."

### Midatech begins nanoparticle clinical trial

**Midatech** (Oxford, UK), a developer of nanomedicines, reported that it has received Swissmedic approval to start the first-in-man clinical trial with insulin-coated gold nanoparticles, which will be coordinated through its Swiss subsidiary **PharMida**.

The trial is designed to assess the safety profile of insulin-coated gold nanoparticles when applied in transbuccal film to healthy volunteers. The study will be performed in a clinical research unit near Basel, Switzerland and results of the trial are expected during 1Q12.

Midatech has developed ultra-small gold nanoparticles (GNP, < 2 nm) that act as artificial atoms that are covalently surface-passivated with a mixed carbohydrate/organic layer (corona). The corona is designed to non-covalently bind and stabilize multiple copies of bioactive peptides like insulin and glucagon-like peptide-1 (GLP-1). Extensive pre-clinical studies with GNP and peptide-GNP have demonstrated favorable PK properties and a clean safety profile in studies with single and multiple dosing by oral, intravenous, subcutaneous and transbuccal route in various animal species.

"This is the first time that solid core nanoparticles of this size and nature will enter human clinical trials," Thomas Rademacher, chairman/CEO of Midatech said. "Based on the excellent preclinical and toxicology results obtained for Midatech's gold nanoparticles in multiple animal models, we are pleased to move to the next stage of development and test the safety of our nanoparticles in human clinical trials. We are also pleased that our Spanish-based IMP Licenced manufacturing subsidiary, Midatech Biogune SA, will be able to provide clinical-grade material for these studies."

Midatech has a collaboration with **MonoSol Rx** (Warren, New Jersey) to develop products by combining its proprietary gold-nanoparticle technology with MonoSol's PharmFilm drug delivery technology and a joint venture with **Immunotope** (Doylestown, Pennsylvania) to develop nanoparticle based immunotherapeutic cancer vaccines for the delivery of peptide antigens.

### Torax receives CE mark for Fenix system

**Torax Medical** (St. Paul, Minnesota) has received CE Mark for its Fenix continence restoration system, a new approach to the treatment of fecal incontinence (FI). While studies suggest FI is more prevalent in women and increases with age, men and women of all ages can be affected and for these people there are few treatment options. Torax anticipates first commercial implants in November at specialized medical centers in Europe.

"The Fenix continence restoration system represents a promising new treatment option for patients suffering from this debilitating problem. We plan to work with medical centers which specialize in the treatment of fecal incontinence as we introduce the Fenix system in European markets," said Todd Berg, CEO of Torax. ■

## Washington

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conferees, which would put $323 million into operations at the Center for Devices and Radiological Health at FDA for fiscal 2012, an increase of $1 million over the amount provided in fiscal 2012 via the continuing resolution. Nancy Bradish Myers, President of the Alliance and President of **Catalyst Healthcare Consulting** (McLean, Virginia), said the Alliance's members are "grateful to the conferees for assuring that FDA has the funds to continue its mission." She noted further that FDA "must continue to be a national priority so we can advance medical progress, improve patients' lives, and assure Americans have a safe food supply." The user fee schedule for the years 2013-2017 is still the object of negotiations, and one of the sticking points for FDA is the concern that appropriated monies would drop substantially, leaving CDRH with a potential personnel problem in its efforts to keep pace on PMA approvals and 510(k) clearances (*Medical Device Daily*, July 18, 2011). Industry and FDA have closed the gap on several other issues, however, and the news regarding appropriated funds might make it easier for all concerned to arrive at some consensus on device user fees and other issues.

### FDA inks IDE guidance for public comment

FDA's Center for Devices and Radiological Health published a draft guidance for investigational device exemptions, and indicates that much of the intent behind the guidance is to provide industry and agency with an adaptive mechanism for device trials that allows tweaks to both device and study designs. The accompanying notification in the *Federal Register* states that responders have until Feb. 8, 2012 to make their views known.

In the overview section of the draft, which mentions no predecessor guidance, FDA says that the document "introduces new approaches to facilitate timely device and clinical protocol modifications during an early feasibility study while still requiring compliance with the IDE regulations." Among the provisions to be found in the guidance is a greater range of "types of modifications that can be made under a five-day notification without prior FDA approval as compared with other types of studies," as well as "a contingent approval process that permits changes contingent upon acceptable nonclinical test results without requiring additional FDA action." However, FDA apparently would like to also engage industry in an "interactive review of IDE supplements" as well.

The guidance explicitly acknowledges one of the pivotal elements of device flight, namely that the agency "intends for this policy to facilitate initiation of clinical studies in the United States earlier in the device development process than has historically occurred."

One of the routine complaints heard in Washington and at medical conferences recently is that even as device lag allows residents of other nations access to devices unavailable to Americans, pivotal studies have increasingly commenced outside the U.S., a trend that has even captured some of these earlier clinical studies. This particular passage implicitly acknowledges some of the pressure behind a new piece of legislation, the Premarket Predictability Act of 2011 (H.R. 3209), which was introduced earlier this year by Rep. John Shimkus (R-Illinois) in an effort to force FDA to streamline the IDE process (*Medical Device Daily*, Oct. 20, 2011).

The draft specifies that other than pivotal trials, device makers can avail themselves of three trial types, including an early feasibility study intended to provide "initial insights" into device features such as safety associated with implant procedures and challenges associated with operator technique. FDA states that this kind of study can be deployed "when device changes are expected and when, due to the novelty of the device or its intended use, a clinical study is expected to provide information that cannot be readily provided through additional non-clinical assessments."

FDA states that early feasibility studies need not include definitions of success or a data analysis plan, but an application for such a study should include reports of prior investigations, including any data that supports "an expectation of acceptable clinical use." Among these data are bench and animal testing, but data on basic device safety should also be included and may cover biocompatibility, sterility and electromagnetic compatibility.

The draft mentions computational modeling as one way to support an early feasibility analysis, including durability analyses for chronic implants when "the boundary and loading conditions are known," although computer modeling may also serve to simulate iterative design modifications in the absence of compelling data on boundary and loading conditions. FDA gives the example of the use of computer modeling for magnetic resonance compatibility to simulate worst-case scenarios "that cannot be replicated in an animal model and cannot be tested ethically in humans."

### PTO announces med-tech partnership meeting

Med-tech firms that have grown leery of the U.S. federal government of late might wonder what's next, but the U.S. Patent and Trademark Office announced a fairly benign event recently that should give patent holders in industry at least less reason to prefer decaf.

According to a Nov. 8 statement at the PTO website, the agency intends to host the "Medical Device Technology Partnership Meeting" Nov. 29 at PTO headquarters, located at 600 Dulaney St. in Alexandria, Virginia. The meeting is intended to "bring industry stakeholders and patent examiners and directors" from one of the agency's technology centers together "to share ideas, experiences, and insights on best practices in advancing prosecution" of patents as well as "provide a forum for discussion on how

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## Product Briefs

• **BioMedical Enterprises** (BME; San Antonio), a maker of small bone implants, reported the U.S launch of Speed. It is the first fully disposable continuous compressive bone fixation system made available to orthopaedic and podiatric surgeons, the company claims. The Speed system is a series of shape memory bone fixation staple implants, in combination with single-use instruments. The disposable design prevents loss of instrumentation before and after surgery. Instrument cleaning and sterilization is completely eliminated, simplifying the entire surgical process and significantly reducing operating room costs.

• **DFine** (San Jose, California) reported the initiation of a prospective randomized clinical study to evaluate the clinical effectiveness of minimally invasive augmentation procedures to treat debilitating, painful vertebral compression fractures (VCFs). PRIORi-T (Prospective Randomized Investigation Of Radio Frequency Targeted Vertebral Augmentation) is a post-market, clinical study that will compare the radiofrequency targeted vertebral augmentation (RF-TVA) procedure to non-operative management (conservative care) in properly diagnosed osteoporotic VCFs within six weeks of onset. The DFine StabiliT Vertebral Augmentation system is designed for the treatment of vertebral compression fractures (VCFs). During the RF-TVA procedure, a small tube is placed into the fractured vertebra and a cavity is created. Ultra-high viscosity StabiliT ER2 Bone Cement fills the cavity and permeates the surrounding bone to stabilize the fracture. With StabiliT, physicians are able to navigate within the vertebral body to target the spinal fracture with greater precision and control, while also sparing the bone – two unique benefits of RF-TVA over older, conventional therapies such as balloon kyphoplasty.

• **Parascript** (Longmont, Colorado) reported the release of AccuDetect 5.0, the next generation of its computer-aided detection (CAD) software, aimed at helping radiologists improve breast cancer detection. AccuDetect 5.0 makes significant performance improvements over its predecessor and further reduces the potential for false-positive rates when detecting suspicious lesions on mammograms, the company said. AccuDetect is tuned to work with many Full Field Digital Mammography and Computed Radiography systems. AccuDetect is intended to assist radiologists in the early detection of breast cancer during mammography screening exams. The technology has been developed using a broad database of digital images from leading digital mammography systems. It uses complementary algorithms to detect the presence of suspicious lesions on mammogram images.

• **Royal Philips Electronics** (Andover, Massachusetts) has introduced Philips HeartStart FR3 automated external defibrillator (AED) in the U.S. for professional responders who treat victims of sudden cardiac arrest (SCA). As the smallest and lightest professional-grade AED among leading global manufacturers, the HeartStart FR3 is Philips' most advanced professional-grade AED. The rugged and reliable HeartStart FR3 is designed to help make lifesaving faster and easier for professional responders. The HeartStart FR3 includes several innovations designed to make it easier for professional responders to treat SCA, including a bright, high-resolution, color LCD that provides visible prompts for easier use in noisy environments; a CPR metronome that keeps the beat for consistent chest compressions; and bilingual configurability so that voice and text prompts can be clearly understood by a variety of responders.

## People in the News

• **Digital Insurance** (Atlanta) has named Annette Bechtold as senior VP of operations and strategic development. With more than 30 years of experience, Bechtold currently serves as Digital's senior VP of operations. Digital Insurance is an employee benefits agency.

• **Health Net** (Los Angeles) has named Scott Law as chief Medicare officer. Previously, Law was senior VP of healthcare delivery for WellCare Health Plans. Health Net is a managed care organization.

• **Imprivata** (Lexington, Massachusetts) has named Sean Kelly, MD, as the company's chief medical officer. In addition to his role as Imprivata CMO, Kelly will continue to practice as an emergency physician at Beth Israel Deaconess Medical Center, a level-one trauma center and academic teaching hospital in Boston. Imprivata makes single sign-on and access management for healthcare.

• **Photocure** (Oslo, Norway) reported the resignation of chief financial officer Christian Fekete. Fekete has served as CFO of Photocure since November 2004. Photocure makes photodynamic technology.

## Washington

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the agency can improve and expand its relationship with the medical device technology community."

Among those scheduled to appear at the meeting are Bruce Kisliuk, PTO's assistant deputy commissioner for patents for mechanical disciplines, and Sharon Gibson, group director for the agency's med-tech technology center.

Interested parties should RSVP to Brian Casler (Brian.Casler@uspto.gov, 571- 272-4956 or Tom Hughes (Tom.Hughes@uspto.gov, 571-272-4357). ■

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# MDD's Oncology Extra

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

Wednesday, November 16, 2011


*Keeping you up to date on recent developments in oncology*

**Phthalocyanine dye may enhance photoimmunotherapy . . .** Matching a therapeutic modality with a targeting agent is a priority in cancer research these days, and the National Cancer Institute announced recently that one of its efforts in photoimmunotherapy (PIT) has demonstrated a sufficiently robust response in animal testing to rate an entry into the peer-reviewed literature. According to a Nov. 7 NCI statement, an article appearing the previous day in the online edition of *Nature Medicine* offers details into an evaluation of a pairing of monoclonal antibodies for three types of cancers with IR700, one of the phthalocyanine class of dyes, a combination that averts some of the traditional problems with PIT, namely damage to healthy tissues adjacent to the cancer. The article states that the larger class of photodynamic therapies as yet are "not specific for cancer cells," but the researchers had combed through "a large number of photosensitizers" before coming upon IR700, which is said to have had "the most favorable chemical properties." The NCI statement indicates a high degree of efficacy in animal testing with the statement, "even a single dose of near-infrared light resulted in dramatic tumor shrinkage in mice that had been given" the combination therapy. Hypothetically, this construct could be applied to three different monoclonal antibodies, NCI notes, including antibodies built to attach to HER2 (human epidermal growth factor receptor-2), which is over-expressed by some breast cancers. Another potential target is an unspecified member of the family of epidermal growth factor receptors, which is associated with a number of lung, pancreatic, and colon cancers; and prostate-specific membrane antigen, which the statement reminds is over-expressed by prostate cancers. One of the advantages to this particular effort, NCI states, is that the use of near-infrared portions of the spectrum can penetrate more deeply than the 0.8 cm (.3") depth limit seen in most conventional photosensitizer technologies while this NIR spectrum "can penetrate tissue to a depth of several centimeters." Another factor for optimism with this development is that it can scan for cancer at lower doses than are needed for treatment, but even the treatment dose levels may indicate a need for less monoclonal antibody levels than commonly see in this kind of research. Better yet, the statement notes, "because the MAb-IR700 compound also emits a small amount of light, it can be used to monitor therapy as well." Hisataka Kobayashi, MD, chief scientist in the Molecular Imaging Program at NCI's Center for Cancer Research, said in the statement, "although more testing will be needed, we believe this PIT method has the potential to replace some surgical, radiation, and chemotherapy treatments."

**Can exercise stave off cancer? . . .** Regular physical activity offers many benefits, but recent research indicates that keeping the metabolism moving may help ward off cancer via lower levels of several fundamental biological mechanisms. According to a Nov. 3 statement by the the **American Institute for Cancer Research** (AICR; Washington), as many as 49,000 annual diagnoses of breast cancer and 43,000 diagnoses of colon cancer in the U.S. "are linked to a lack of physical activity," a conclusion offered by the authors of a paper presented at AICR's recent annual meeting. Christine Friedenreich, PhD, of **Alberta Health Services Cancer Care** (Calgary, Canada) presented the findings from the Alberta Physical Activity and Breast Cancer Prevention (ALPHA) Trial, the latest results from which explore the role of C-reactive protein in cancer risk levels, which appear in the October edition of *Cancer Prevention Research*. The statement notes that moderate to vigorous exercise each day tamped down on levels of this biomarker for inflammation, and while a definitive link has not been established, the statement points out that cytokines are a routine part of the inflammation cycle and that macrophages and neutrophils are known to release reactive elements such as oxygen and nitrogen, which can damage the DNA and produce the mutations that give rise to cancer. Friedenreich said in the statement that moderate activity, such as brisk walking, can significantly reduce the risk of certain cancers. "In breast and colon cancers, for example, we're seeing overall risk reductions of about 25%-30% associated with higher levels of physical activity. With prostate cancer the evidence isn't as strong but it's still there - about 10%-20% lower risk," she said, while for

endometrial cancer, "we are finding about 30%-35% risk reduction with more physical activity." AICR spokesperson Alice Bender said the sum total of research into this area "suggests that every day, we're each given numerous opportunities to be active and protect ourselves from cancer," adding, "we need to start thinking in terms of make time and break time." What they are suggesting does not seem too onerous, either. AICR suggests that those who are sedentary at work engage in a mere one to two minutes of activity each hour, which need consist of nothing more than "walking to a colleague's office instead of sending an e-mail, or going to the kitchen to get a glass of water."

**A miniature X-ray system called MAX . . .** Legend has it that Theophrastus, who succeeded Aristotle as the headmaster at the Lyceum, was the first to describe anything related to the property of pyroelectricity in 314 BC, but this principal of electrical generation via whole-crystal heating is behind a proposed laptop computer-sized X-ray machine that could revolutionize field diagnostics. According to a Nov. 4 statement by the **Science and Technology Facilities Council** (Swindon, UK), two entities located in California has been working to develop and commercialize "an innovative X-ray source on a chip" known as the micro-emitter array X-ray, the underlying technology for which was originally developed at the University of California at Los Angeles (Los Angeles) for aerospace applications. The MAX X-ray machine, as it is now called, is in the hands of **Radius Diagnostics** (Los Angeles) and the **California nanoSystems Institute** (CnSI), and will "be 20 times lighter than any existing portable X-ray system," given that it will weigh in at about 10 kilograms (22 lbs.) compared to the current state of the art, which comes in at a hefty 250 kg. Mark Evans, CEO and co-founder of Radius, said this system "will transform many applications of X-rays, and we are thrilled that one of its first applications, allowing truly portable X-ray systems to travel to the patient, will improve patient comfort, prevent unnecessary hospital admissions and save lives." Evans also claimed that the difference between MAX and currently available portable X-rays is "as great as the shift from old-style TVs to today's flat screens," asserting further that many of the potential applications in healthcare and other fields of endeavor "have not even been envisioned yet." The statement claims that production costs for these miniature MAXes "will be less than half the cost of any current equivalent, making widespread use affordable." Another advantage of this system, however, is that the energy source the system uses allows for pixellation, a feature that will allow a physician "to selectively control the emission of X-rays and enable the patient's radiation burden to be reduced."

**Stanford team trains software to diagnose cancer . . .** Those horrible movies about humans being elbowed aside by machines are probably starting to resonate with radiologists with the news that a team of scientists at **Stanford University** (Stanford, California) have trained a computer to diagnose breast cancer more accurately than humans can. According to a Nov. 9 story at the website for the Stanford School of Medicine, the Computational Pathologist (C-Path) program incorporates more than 6,000 factors to evaluate a breast mass whereas the traditional approach has been to assess three factors "to stratify breast cancer patients into three groups that predict survival rates." A factor of great interest to the program at this point is the stroma, which the C-Path program found more powerful a predictor of survival than the traditional assessment of epithelial tissue in tumors. The software is not static, however, and incorporates new information into its computational matrix to improve its diagnostic and prognostic capability, but this software is also prompting physicians to take a different perspective on tumors. Matt van de Rijn, MD, a professor of pathology and co-author of the study appearing in the Nov. 9 edition of *Science Translational Medicine*, said "through machine learning, we are coming to think of cancer more holistically, as a complex system rather than as a bunch of bad cells in a tumor." He also said computers and their software are "pointing us to what is significant, not the other way around."

**– Mark McCarty, *MDD* Washington Editor**
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