



## WebOps designs software to monitor device inventory

By OMAR FORD

Medical Device Daily Staff Writer

Even though hospitals and healthcare institutions are moving toward or have already adopted electronic health records (EHR) to monitor patients, few have established an electronic tracking system capable of identifying and cataloging devices used to treat these same patients. Instead many organizations find themselves in a scenario, where they are using an old-fashioned cataloging system – pen and paper – which is prone to tremendous error.

But one small firm is seeking to give orthopedic device manufacturers and distributors an alternative to what it calls an outdated cataloging system, through its software platform.

**WebOps** (Atlanta) recently spoke with *Medical Device Daily* and said that its WebOps Logistics software can help  
*See WebOps, Page 4*

## superDimension on track for big growth year with ENB

By AMANDA PEDERSEN

Medical Device Daily Senior Staff Writer

The Electromagnetic Navigational Bronchoscopy (ENB) system from **superDimension** (Minneapolis) has really started to come of age in the past year as a more modern, minimally invasive way of diagnosing and treating lung cancer. CEO Dan Sullivan tells *Medical Device Daily* the company is on track to see another “substantial growth” this year.

Since its commercial launch, a total of 20,000 patients have been treated with the ENB system, superDimension noted.

On the heels of a record-breaking first quarter, the FDA has cleared a marker delivery kit designed for use with the ENB system. The ENB system provides a 3-D virtual roadmap of the lungs that enables a physician to  
*See superDimension, Page 5*

### Report from Europe

## NICO gets CE mark for Myriad brain tumor removal device

A Medical Device Daily Staff Report

**NICO** (Indianapolis) reported at the **American Association of Neurological Society** (AANS; Rolling Meadows, Illinois) annual meeting in Denver that it has received CE mark approval for its automated minimally invasive brain tumor removal device, the NICO Myriad. The approval allows NICO to sell the Myriad system in the 27 countries that make up the European Union. The device has been commercially available in the U.S. since 2009 with more than 1,000 procedures performed with adults and children, sometimes in cases that would have previously been considered inoperable.

“The CE mark approval for the Myriad in Europe is a significant accomplishment that validates the impressive  
*See Europe, Page 6*

### Washington roundup

## GAO study of device approvals to take center stage at hearing

By MARK McCARTY

Medical Device Daily Washington Editor

Yesterday’s hearing in the Senate Special Committee on Aging had controversy sown into it before the hearing began, thanks to a report by the Government Accountability Office that was leaked to the *New York Times* even before FDA had a chance to look at it.

A story appeared in the online edition of *NYT* late Tuesday evening that indicated that the GAO report will criticize FDA for its device approval processes, a claim GAO will likely find backing for, given the Democratic majority in the Senate. As of yesterday morning, the committee had not posted a notice of the hearing at the committee website, let alone a witness list (the hearing will be covered in  
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Don’t miss today’s MDD Extra: Orthopedics



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*Deals roundup***Shrink to buy Nanopoint in stock exchange****A Medical Device Daily Staff Report**

**Shrink Nanotechnologies** (Irvine, California) says it has executed a binding letter of intent to acquire 100% of **Nanopoint** (Honolulu, Hawaii), a biomedical instrumentation and microfluidics company with global distribution for its suites of life sciences products. Shrink will exchange 25,750,000 shares of its common stock for 100% of the equity interests in Nanopoint.

Closing is set for May 31 or sooner, Shrink noted. Also, additional stock payments of up to 40 million shares will be made upon Nanopoint meeting certain sales and EBITDA targets by June 30, 2012 and December 31, 2013, respectively.

Shrink says that all critical Nanopoint employees will be retained, and at closing, Nanopoint will operate as a wholly owned subsidiary of Shrink. Nanopoint will have at least \$500,000 of cash on its balance sheet.

"Nanopoint has built an award-winning platform of products in the life sciences space, as well as a network of global distribution for its products," said Shrink CEO Mark Baum. "Nanopoint's product line will extend Shrink's portfolio of opportunities in the drug discovery, live cell imaging, assisted reproductive sciences, stem cell research and cell culturing businesses. We believe that there is tremendous synergy between our respective products – StemDisc and Cell Align, in particular, along with work that we are doing with the Corning modular microfluidics platform, and we believe that the Nanopoint distribution group is a terrific way for Shrink to leverage on the relationships that Nanopoint has been able to build."

Nanopoint CEO Cathy Owen said the acquisition will provide the capital and liquidity necessary to rapidly accelerate sales of Nanopoint's cellTray Imaging system,

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

*"It's 7 a.m. do you know where your implants are, WebOps does,"*

– Slogan for WebOps, a company that has developed an electronic tracking system capable of identifying and cataloging devices, "WebOps designs software to monitor device inventory," pp. 1, 4.

cellTray Microfluidics system, cellTray Mini-Microscope system, and associated consumables including the cellTray slide and cellTray Dish. ■

*Patent watch***Celsion wins patent for drug delivery technologies****A Medical Device Daily Staff Report**

**Celsion** (Columbia, Maryland), an oncology drug development company, reported that the U.S. Patent and Trademark Office (USPTO) has granted an additional patent in the Needham patent family covering temperature-sensitive Liposomal technologies, including the ThermoDox formulation.

Celsion holds a license agreement with **Duke University** (Durham, North Carolina) under which the company received exclusive rights to commercialize products using Duke's temperature sensitive liposome technology in the Needham patent family. The new patent, U.S. Patent No. 7,901,709, provides coverage for a new method of loading active agents (such as doxorubicin or other active chemotherapy drugs) into liposomes which, with USPTO patent term adjustment, provides protection through Feb. 13, 2021

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Agreements/contracts**SUTIMCo enters venture acceleration with Capwave****A Medical Device Daily Staff Report**

**AquaStar Holdings** reported its subsidiary, **SUTIMCo**, has signed a venture acceleration agreement with **Capwave Sensor** (all Santa Ana, California), valued at \$2.79 million. Capwave is the maker of a revolutionary portable Enzyme-Linked ImmunoSorbent Assay (ELISA) test platform. According to the terms of the Agreement, SUTIMCo will assist Capwave with development and commercialization of its technology for a period of three years at \$77,500 per month.

Capwave is a rapid, sensitive, and portable Enzyme-Linked ImmunoSorbent Assay (ELISA) platform for use anywhere antibody based testing can be done and is capable of detecting Bioweapons (anthrax, bacillus globigii), Biomarkers (cancer, stem cells), Toxins (*E. coli* and salmonella in foodborne illness), contaminants and diseases (both viral and bacterial). According to the Centers for Disease Control and Prevention (CDC), about 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases. The ability to detect the foodborne pathogens responsible for these illnesses in a timely fashion has the potential to offer faster treatment, reduce hospital stays and prevent deaths.

SUTIMCo operates as a venture accelerator, offering development services to start-up companies for up to three years. The company launches and manages businesses in health & wellness, energy/environmental, advanced materials, sensors and electronic technology ventures to build upon the research of a host of universities across the U.S. AquaStar says it uses a unique and established platform to launch new technology enterprises based on world-class university research discoveries.

In other agreements/contracts news:

- **Cellular Dynamics International** (CDI; Madison, Wisconsin), a maker of tissue cells derived from human induced pluripotent stem cell (iPSC) lines, said it has strengthened its intellectual property (IP) portfolio by licensing patented definitive endoderm differentiation technology from **ViaCyte** (San Diego), a stem cell company focused on diabetes therapy. CDI will apply this methodology in the development and production of iCell Hepatocytes, iPSC-derived liver cells.

ViaCyte's technology covers cell cultures containing specific amounts of definitive endoderm. Definitive endoderm gives rise to organs and tissues such as the liver, pancreas, lung, intestine, thymus and thyroid. Separately, CDI has agreed to supply iPSC lines to ViaCyte.

Nick Seay, chief technology officer of CDI, acknowledged the importance of this technology to CDI's IP portfolio. "ViaCyte has developed and filed patents on useful methodologies for differentiating into definitive endoderm, which is the

normal intermediate in the subsequent manufacturing of hepatocytes. The right to incorporate this technology into our industrial pipeline assures our pharmaceutical customers that they will receive hepatocytes in the quantity, quality and purity that they require. In addition, this brings us a step closer toward developing hepatocyte line extensions, including panels with multiple iPSC starting materials. This step enables our customers to compare responses of tissue cells based on genetic diversity."

- **BD** (Becton, Dickinson and Company; Franklin Lakes, New Jersey) and **Waste Management Healthcare Solutions**, a subsidiary of **Waste Management** (Houston), reported an agreement to recycle medical sharps waste from hospitals and other healthcare facilities. The companies are jointly launching the BD ecoFinity life cycle solution, a service that will recycle medical sharps waste and utilize the material to manufacture new products.

"Our unique integrated environmental solutions increase value by managing materials more efficiently to help lower the costs for our healthcare customers, while maintaining safety and compliance standards," said Mike McInerney, VP of WM Healthcare Solutions.

Based on results of a pilot program at Rady Children's Hospital-San Diego, BD believes that more than 70% of its overall sharps waste may ultimately be recovered and recycled rather than be permanently disposed of in landfills. This program builds upon BD's sustainability commitment, which has been recognized for achievements in environmental stewardship. ■

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## WebOps

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precisely track inventory movement, implant usage and surgery schedules.

With a slogan on its web site that says “it’s 7 a.m. do you know where your implants are, WebOps does,” the company stands by its promise to keep better records of devices. Historically companies would track their devices using manual methods such as phone, fax and forms. One such firm, according to WebOps manually tracked inventory of more than 100,000 implants, and numerous sets of instruments for the support of hundreds of surgeries weekly. The correct combinations of implants and instruments for a wide variety of types of cases had to be available for each surgical case while providing the best possible patient care and service to surgeons. Manually accomplishing this volume of high pressure tasks exacted excessive costs as well as extreme stress on the people charged with unfailing support for surgical cases.

“One problem, when you don’t have a system like [WebOps Logistics] in place, is communicating between the sales rep in the field and the back end of operations,” Amin Rahme, CEO of WebOps told *MDD*. “Problems come when they use a fax, e-mails or cell phones requesting products. Either they make mistakes in what products they requested or they may miss some products they need. The last thing you want is a doctor in the operating room with a patient on the table and have either no products, missing products, or the wrong products.”

The privately held firm, which has a little more than 30 members on its staff, was founded in 2005, and primarily up until this point has focused on the orthopedics sector. The customer base is growing, according to Rahme and many who have been using the software, since it was released on the market, are still using it.

“First of all the biggest evidence [of success] is we haven’t lost a customer,” Rahme said. “And we’ve had customers since day one who have been using the technology. Like they say the proof is in the pudding. When they save money; streamline their operations; and have best practices in their operations enabled by WebOps; they are very happy.”

He cited that one med-device distributor in Boston was able to save \$151,000 in the first year of implementing WebOps Logistics.

Although outright FDA approval of the software wasn’t required, the company said that it still is subject to some of the same regulations that device manufacturers face from the agency.

“We are subject to audit as a subcontractor or a service provider to manufacturers from the FDA...,” he said. “So we have to adhere to FDA rules very much similar to the same FDA rules that device manufacturers follow in order to design, build and manufacture medical devices.”

The company said that the technology has the capability to interact with electronic health records (EHR).

“The same way that we are able to integrate the warehouse management systems that are used, we can electronically integrate into the EHR, providing the details of the implants used in the surgery,” Rahme said.

Most recently the technology has been boosted by the addition of the smart phone. Earlier this year, the company reported an iPhone application for WebOps Logistics. It said that there are plans to migrate toward other smartphone technologies later in the year. The move to smartphones is a measure that the firm said has revolutionized the way it can do business and provide almost instantaneous results to customers.

“Without the link that the smartphones provide, you’re really not getting a 360 degree view of what’s going on,” he said. “You can scan a product, convey it electronically and be aware of all products relevant to your cases while you’re in the operating room. I don’t think the power of our system would be realized if that piece (the smartphone) was missing.”

In the future the firm said that it was going to migrate beyond orthopedics and perhaps hit other key segments, that have been demanding the product.

“The same application could be used for cardiovascular, and other industries such as blood banks, tissue banks,” he said. “It’s anything you want to give visibility, tracking and compliance to.” ■

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## Patents

*Continued from Page 2*

“This additional patent coverage adds significant, long-term value to our drug pipeline, as it extends both the term of our ThermoDox patent estate, supporting our multifaceted portfolio development strategy, as well as the breadth of patent protection around temperature-sensitive liposomal formulations, Celsion’s core technology platform,” said Michael Tardugno, Celsion’s president/CEO. “In addition to the market exclusivity provided by ThermoDox’s U.S. and European Orphan Drug Designations in primary liver cancer, today’s announcement is an example of the deliberate and comprehensive strategy being pursued by the company to maximize the value of our drug delivery platform. We will continue to invest in strengthening our patent portfolio, both in the U.S. and globally, to allow us to pursue a variety of difficult-to-treat cancers using multiple, well-established chemotherapeutic agents.”

ThermoDox is a heat-activated liposomal encapsulation of doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of cancers. ■

## superDimension

*Continued from Page 1*

maneuver catheters, extending beyond the capabilities of the traditional bronchoscope to distant, previously inaccessible regions of the lungs. If the targeted lesions are determined to be cancerous, the physician can use ENB to place radiosurgical markers in and around lung tumors to help radiation oncologists treat patients with external beam radiation. These radiosurgical markers can also be enhanced with dye injected markers that facilitate a minimally invasive surgical procedure.

Previously the gold standard to diagnose lung cancer consisted of two invasive surgeries: wedge thoractomy (open chest partial lung removal) to biopsy the lung and mediastinoscopy (invasive lymph node surgery) to biopsy the lymph nodes. Patients with poor lung function who could not tolerate these more invasive procedures were left with the “watchful waiting” approach as their only option.

“Marker delivery and the method to do it is really important,” Sullivan told *MDD*. “Here’s what happens: let’s say you’re a patient with a spot on your lung and you want to know if that spot’s cancer; let’s say you have some comorbidities like emphysema or COPD so you can’t biopsy it surgically . . . in the past your only one choice was watchful waiting – hope it didn’t grow and get a CT scan every year. Now, with ENB, you can go in and biopsy it and if it’s positive you can go in and place a radiosurgical marker in that lesion . . . they can zap and cure stage one lung cancer without ever opening you up.”

That’s pretty remarkable considering the five-year survival rate for lung cancer is a dismal 15% unless it is caught early in which case the survival rate leaps to 90% at 10 years, according to Sullivan. He says lung cancer is considered the biggest cancer killer in the world.

“Our procedure is really starting to gain some traction in the hospital,” Sullivan said.

Larry Haimovitch, a contributing writer for *MDD*, noted in a recent column that superDimension is rapidly being accepted as an alternative to highly invasive and risky older procedures. He said the company’s revenue grew 82% in 2010, reaching about \$16 million (*Medical Device Daily*, Jan. 4, 2011). Sullivan says the company is expecting “substantial growth” in 2011 after having just completed a record-breaking first quarter.

“Overall the procedure is beginning to come of age,” Sullivan said. “When a new medical technology comes out you have the early adopters, the pioneers.” When the second generation of that technology is released there is usually a new wave of adopters, and he noted that superDimension did launch a significant new version of its ENB system in 2010. “It’s been growing at a rapid pace; it’s an exciting time,” he said.

In November 2009 the company launched iLogic (*MDD*, Nov. 3, 2009) an advanced version of the earlier generation device launched in 2007 called inReach (*MDD*, Sept. 10,

2007). iLogic improves on the earlier design, offering a simplified positioning and navigational system that improves ease of use and further enhances visualization for the pulmonologist, the company noted at the time.

The company places heavy emphasis on physician training of its device. While it is a “pretty extensive” training program, he said the procedure is fairly easy for physicians to get the hang of. “They spend two days in Minneapolis doing hands on with some experienced users, then they’re ready to go [do the procedure on their own].”

Sullivan also mentioned that the company is really starting to emerge into therapeutic applications of ENB. “We already sell a . . . line of biopsy tools, now we have a maker delivery tool . . . we’re being able to provide physicians with a whole variety of tools . . . for diagnosing and treating lung cancer.”

According to the **Centers for Disease Control and Prevention** (Atlanta) roughly 200,000 patients are newly diagnosed with lung cancer in the U.S. each year and an additional 160,000 die from the disease.

“This kit will enable both pulmonologists and surgeons to place radiosurgical markers deep in the lungs, facilitating the treatment of early stage lung cancer through external beam radiation and minimally invasive video assisted surgeries,” said David Wilson, MD, of **Columbus Regional Hospital**. “This is an exciting time in the diagnosis and treatment of early stage lung cancer. The preliminary results of the National Lung Screening Trial (NLST), combined with the ability that superDimension gives us to access the deep lungs, has changed the game for diagnosis and treatment of early stage lung cancer.” ■

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### *Financings roundup*

## Brainsway says it is seeking to raise \$30 million in an IPO

**A Medical Device Daily Staff Report**

**Brainsway** (Jerusalem) reported has filed with the US Securities and Exchange Commission its prospectus to raise \$30 million in an initial public offering. Brainsway will use 70%-75% of the proceeds to bring its non-invasive Deep TMS (transcranial magnetic stimulation) device for neurological disorders to new markets and to mass produce the device. Brainsway plans to hold the offering by the end of May.

Last week, Brainsway obtained the CE mark to use Deep TMS for the treatment of Parkinson’s disease and as a supplemental treatment for patients taking antidepressants. The company is also conducting clinical trials of the device for treatment cocaine, smoking and other addictions, autism and Asperger’s syndrome, and other neurological problems. ■

## Europe

*Continued from Page 1*

clinical and patient results that have been achieved throughout the U.S.," said Jim Pearson, president/CEO of NICO. "This device is pushing the frontier of progressing minimally invasive neurosurgery. The Myriad is allowing neurosurgeons to advance corridor surgery by providing improved access to tumors and shortening surgical resection times that result in shorter patient recovery times and hospital length of stays. It can provide the opportunity to significantly reduce patient trauma by reaching tumors located deep within the brain through much smaller openings."

The Myriad is about the size of a pencil and is completely automated, making it the first device that operates in open and endoscopic surgical approaches without using a heat source or ultrasonic energy that can potentially damage delicate critical structures in the brain. Its slender design and malleable tip allow surgeons to operate through narrow surgical corridors to aggressively remove large masses or highly fibrotic tissue, or work with precision to remove difficult to reach tumors that may be located near or on top of structures like optic nerves and carotid arteries.

The Myriad is also able to collect tissue removed during the surgical process in a viable (intact) format. This is significant because it can be sent for pathological and oncological evaluation to determine post-surgical therapeutic treatment regimens that improve patient outcomes.

The company said that more than 200,000 people in the U.S. and 2 million people worldwide are diagnosed with a brain tumor every year. They are the leading cause of solid tumor cancer deaths in children under the age of 20, the second leading cause of cancer deaths in male adults ages 20-29, and the fifth leading cause of cancer deaths in females ages 20-29.

### Wellcome gives GE Healthcare research award

The **Wellcome Trust** (London) has awarded a Strategic Translation Award to **GE Healthcare** (Chalfont, UK) for research into the potential use of MRI for newborns at high risk of brain injury. This marks the first time GE Healthcare will collaborate with Wellcome Trust to extend the reach of MRI technology.

In the UK, approximately five in every thousand babies born suffer brain injury and of those, approximately one-in-five die. Babies that survive early brain injury are at high risk of developing long-term neurological problems. Improving the speed and accuracy of diagnosis into brain problems in babies is essential for improving clinical outcomes.

Ultrasound technology is most commonly used to image newborns that are at high risk of developing brain injury, largely because the technique can be performed within the Neonatal Unit at the hospital. MRI is widely accepted as being a better diagnostic tool; however in many centers it

is not practical to take babies to an MRI scanner, which is usually located in another part of the hospital or sometimes at another center. As a result, the risk of removing a baby from the protective environment of the Neonatal Intensive Care Unit usually outweighs the potential benefit to be gained from MRI as a more sensitive imaging technique.

The Wellcome Trust award will initially be used to investigate how MRI could be placed within the neonatal unit itself, removing the need to transfer the infant. This research will lead to a better understanding of the technology required to care for infants in a Neonatal Intensive Care environment.

Commenting on the award, Paritosh Dhawale, general manager of Specialty MR, GE Healthcare said, "As we continue to push the boundaries of discovery using specialty MRI in novel ways, we're always mindful of the significant impact innovative technology may have on the diagnosis and treatment of even the smallest patients. In our Specialty MR business we are committed to making technology more accessible by using dedicated small bore superconducting magnets which produce uncompromised image quality."

### Delcath gets CE mark for Hepatic Chemostat

**Delcath Systems** (New York) has been notified of CE mark approval for its Hepatic Chemostat delivery system. The product has been approved with an indication for the percutaneous intra-arterial administration of a chemotherapeutic agent (melphalan hydrochloride) to the liver.

"Receipt of our CE mark represents the first regulatory approval for this product, and marks the beginning of the company's transition into a fully commercial enterprise," said Eamonn Hobbs, president/CEO of Delcath. "With its rising liver cancer rates, Europe represents a large opportunity for this product. With the CE mark in hand, we will now begin to build inventory and establish the commercialization infrastructure in Europe, including assembling a direct sales organization to cover countries in Northern Europe and establishing a network of third party distributors in Southern Europe. We will also begin establishing and training initial sites in select European countries as Centers of Clinical Excellence for the chemosaturization procedure."

Delcath is a specialty pharmaceutical and device company focused on oncology. Its initial focus is on the treatment of primary and metastatic liver cancers.

### XDx reports CE mark for AlloMap test

**XDx** (Brisbane, California), a molecular diagnostics company focused on developing noninvasive gene expression tests to monitor immune-mediated conditions, reported that its AlloMap molecular expression test has been CE marked under the In Vitro Diagnostics Directive.

AlloMap is a noninvasive FDA-cleared test that has been on the market in the U.S. since January 2005. It provides

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## Washington

*Continued from Page 1*

tomorrow's edition of *Medical Device Daily*), but the witness list is said to include Diana Zuckerman, PhD, President of the **National Research Center for Women and Families** (Washington) and Bill Maisel, MD, deputy director for science at FDA's Center for Devices and Radiological Health.

Another witness is Katie Korgaoker of Denver, Colorado, said to have had an ASR hip implant, a device with much higher than anticipated rates of failure. The unit is made by **DePuy Orthopaedics** (Warsaw, Indiana), although a witness list distributed to the media did not include a representative of DePuy or the firm's parent company, **Johnson & Johnson** (J&J; New Brunswick, New Jersey). Any representative of either J&J or DePuy might find the atmosphere in Washington this week uncomfortable, given the recent agreement J&J signed with the U.S. Securities and Exchange Commission and the U.S. Department of Justice over bribes alleged to have been paid to physicians in Eastern Europe and Iraq (*MDD*, April 12, 2011).

This hearing, however, is not the only one that will take up the question of the device approval process. A subcommittee of the House Oversight and Government Reform Committee will also take up the process, although that panel may strike a more friendly tone than is likely to be found in the Senate hearing. One of the witnesses scheduled to appear at that panel is Rep. Erik Paulsen (R-Minnesota), the author of the most widely supported device tax repeal legislation in the House. *Medical Device Daily* will cover that hearing as well as a markup of the patent reform legislation in the House Judiciary Committee, also scheduled for April 14.

### HHS revs up \$1B patient safety initiative

The Patient Protection and Affordable Care Act included a lot of ambitious and well-funded programs, one of which deals with patient safety, and the U.S. Department of Health and Human Services announced earlier this week that it has authorized the release of half of \$1 billion in funds for patient safety programs designed to reduce rehospitalizations and hospital-acquired conditions.

In an April 12 statement, the Centers for Medicare & Medicaid Services states that the Partnership for Patients program is intended to "help save 60,000 lives by stopping millions of preventable injuries and complications in patient care over the next three years," which could "save up to \$35 billion in healthcare costs, including up to \$10 billion for Medicare." CMS said the program could reduce Medicare spending by roughly \$50 billion over 10 years, and claimed that "more than 500 hospitals, as well as physicians and nurses groups, consumer groups, and employers have pledged their commitment to the new initiative."

The \$500 million bolus of funding, CMS states, "was made available through the Community-based Care Transitions Program," which will finance coordination of care between

"community-based organizations partnering with eligible hospitals to help patients safely transition between settings of care." Those organizations must apply for the program, although CMS states that applications "are being accepted on a rolling basis."

### FDA announces guidance for process changes

FDA announced in yesterday's edition of the *Federal Register* that it has posted a guidance for industry addressing notifications to the agency for process or manufacturing method changes as well as the fee schedule associated with such notifications.

While the government website at [www.regulations.gov](http://www.regulations.gov) did not yet have the guidance posted yesterday morning, the *FR* notice states that the guidance affects 30-day notices, 135-day PMA supplements and 75-day humanitarian device exemption supplements for manufacturing changes. The guidance will supplant a guidance released in 1998 and will go into effect immediately, bypassing the usual open public comment period prior to implementation. FDA states that it is taking this route because it has "determined that prior public participation is not feasible or appropriate," a conclusion the agency arrived at "because statutory provisions regarding medical device user fees ... are in effect and being implemented, and guidance is needed to help effect such implementation."

While the *FR* notice makes no mention of the potential effect on user fees, FDA states that the Food and Drug Administration Amendments Act of 2007 "added 30-day notices to the types of premarket submissions subject to user fees." However, the agency said the new guidance will also "clarify the process for submitting a 30-day notice" and provides "additional information on the types of changes that may be submitted." FDA adds that the 1998 guidance "did not include certain information on HDEs, even though certain modifications to a manufacturing procedure or method of manufacture are subject to the 30-day notice provisions."

### FDA announces workshop on ortho registry

FDA has announced a date for the upcoming workshop dealing with an international consortium of orthopedic registries. According to the April 13 edition of the *Federal Register*, the workshop will take place at FDA's main campus at 10903 New Hampshire Ave. in Silver Spring Maryland on May 9.

The title of the workshop is "International Consortium of Orthopedic Registries," which is designed to "facilitate discussion among FDA and worldwide orthopedic registries that have orthopedic implant information and create a research network to advance the methodology and conduct of research related to orthopedic device performance."

FDA states that no fee will be charged, but that prior registration is required by April 25. Those interested in

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## Product Briefs

- **Bruker** (Billerica, Massachusetts) reported the introduction of the CryoProbe Prodigy. The broadband CryoProbe Prodigy uses nitrogen-cooled RF coils and preamplifiers to deliver a sensitivity enhancement over room temperature (RT) probes of a factor of 2-3x across the board for X-nuclei from <sup>15</sup>N to <sup>31</sup>P. The sensitivity gain on the proton channel exceeds RT probe performance by a factor of 2x or more. The CryoProbe Prodigy is compatible with Avance III NMR spectrometers. The product is available at 400 and 500 MHz.

- **Cerapedics** (Westminster, Colorado) reported the results of a prospective, randomized, controlled trial of its i-FACTOR biologic bone graft for patients undergoing posterior lumbar interbody fusion (PLIF) spine procedures. The objective of the study was to evaluate the safety and efficacy of Cerapedics' novel i-FACTOR biologic bone graft compared to autologous bone delivered via interbody fusion cages in single- and multi-level PLIF surgery. All patients served as their own control and also received posterior pedicle screw instrumentation. Outcomes included VAS for pain, Oswestry Disability Index (ODI) and radiographic images. The occurrence of complications or adverse events was also recorded. In addition to X-rays, the study utilized CT scans taken at 6-month and 1-year intervals. The company claims the i-FACTOR is the only biologic bone graft that utilizes a small peptide as an attachment factor intended to stimulate the natural bone healing process resulting in safe, predictable bone formation at a fraction of the cost of growth factors.

- **Ikaria** (Clinton, New Jersey) reported the introduction of its next-generation drug-delivery system, the Inomax DSIR, in neonatal intensive care units (NICUs) within hospitals throughout the U.S. The Inomax DSIR is a drug-delivery system that delivers the drug, Inomax (nitric oxide) for inhalation, the only drug approved by the FDA to treat hypoxic respiratory failure (HRF) associated with pulmonary hypertension in term and near-term infants, which includes infants born at a gestational age of at least 34 weeks. HRF is a serious condition in which blood vessels in the lungs constrict, making it difficult to oxygenate blood. Inomax relaxes pulmonary blood vessels, improves oxygenation and treats HRF in this delicate newborn population. The Inomax DSIR uses infrared technology to link the device and cylinder allowing expanded informatics on use of Inomax therapy. The Inomax DSIR is compatible with more than 45 makes of ventilation devices and anesthesia machines to offer flexibility of use with patients at many ventilator settings.

- **MiMedx Group** (Marietta, Georgia) reported the launch of the EpiFix, a biologic implant specifically processed to offer a wide variety of wound healing and

wound care options. MiMedx reported that EpiFix is the wound care branded tissue resulting from the company's Purion process. The amniotic tissue produced using the Purion Process has generated a growing demand for minimally manipulated allografts and has experienced increased growth in the areas of ophthalmology, dental, spine and sports medicine.

- The FDA has cleared the **SpectraShield** (Silver Spring, Maryland) 9500 N95 surgical respirator, a device that kills 99.99% of three different kinds of bacteria when exposed to its outer surface. The SpectraShield is cleared as a single-use, N95 surgical respirator for use in healthcare settings by healthcare personnel to protect against microorganisms, body fluids and particulate material. Data from laboratory tests demonstrated that the respirator is effective against the following bacteria: *Streptococcus pyogenes*, Methicillin-resistant *Staphylococcus aureus*, also called MRSA, and *Haemophilus influenzae*. N95 surgical respirators are different than regular facemasks, which are designed to help block large-particle droplets, splashes, sprays, or splatter that may contain viruses and bacteria from reaching the mouth and nose. The N95 designation means that the respirator blocks at least 95% of very small particles when subjected to careful testing. If properly fitted, the capabilities of N95 respirators exceed those of regular facemasks.

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## Europe

*Continued from Page 6*

transplant physicians with a tool to aid in the determination of the probability of acute cellular rejection for post-cardiac transplant patient management.

AlloMap's CE marking is a critical accomplishment for XDx in its strategy to make AlloMap available to heart transplant patients and healthcare practitioners in the EU, and eventually in other markets around the world, the company said. The potential EU market for heart transplant surveillance monitoring is substantial and nearly identical in size to the U.S. market, with approximately 2,000 new heart transplants performed annually and 20,000 living heart transplant recipients. ■

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## Washington

*Continued from Page 7*

registering should send their name, title, organizational affiliation, address, and contact information to Kaiser Permanente's Betty Jo Alfstad (betty.jo.alfstad@kp.org). Alfstad can be reached by phone at 858-581-8272. Registration will be closed before April 25 if registration reaches maximum capacity before that date. ■

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# MDD'S ORTHO EXTRA

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

THURSDAY, APRIL 14, 2011

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

**Newer surgery for neck pain may be better . . .** A new surgery for cervical disc disease in the neck may restore range of motion and reduce repeat surgeries in some younger patients, according to a team of neurosurgeons from the **University of California, San Francisco (UCSF)** and several other medical centers that analyzed three large, randomized clinical trials comparing two different surgeries. More than 200,000 Americans undergo surgery every year to alleviate pain and muscle weakness from the debilitating condition caused by herniated discs in the neck. For some, the team found, arthroplasty may work better. The results do not suggest that the older surgery is ineffective or unsafe, but that arthroplasty is a viable option for some. "For people younger than 50 who have cervical disc disease, arthroplasty is a good option," said Praveen Mummaneni, MD, of the Department of Neurosurgery at UCSF. Neck surgery is not cheap and requires a patient to be placed under general anesthesia and a surgical team to perform the operation in a sterile room. They are typically reserved for patients who have failed to respond to other measures such as physical therapy or drugs, such as steroids. For decades, the standard of care in this country was a procedure called anterior cervical discectomy and fusion. In this surgery, a surgeon cuts through the front of the neck, accessing the spine and removing the herniated disc, then replacing it with a piece of bone and a plate in the neck. That creates a solid union - or fusion - between two or more vertebrae to strengthen the spine. Arthroplasty also begins with a surgery to remove the herniated disc. But instead of fusing the spine, the surgeon replaces the missing disc with an artificial one made of steel, plastic or titanium. The idea is that the artificial disc will provide more spine mobility after surgery and less stress on adjacent discs. While arthroplasty has become more widely used in the U.S. since the FDA approved several models of artificial discs in the last few years, it is still performed less often than in Europe, where the procedure has been available for more than a decade. Here in the U.S., the older, surgical fusion technique remains more common - in part because not all insurance companies pay for the newer procedure, as is the case in California. Both techniques have occasional failures. In the fusion surgery, the bone may not heal, requiring further fusion surgery months or years later. In the arthroplasty surgery, the artificial disk may loosen or not fit well and may need to be replaced. The new analysis looked at three randomized clinical trials that enrolled 1,213 patients with cervical disc disease at medical centers across the U.S.- including UCSF. In the trials, 621 patients received an artificial cervical disc and 592 patients were treated with spinal fusion. The analysis looked at outcomes two years after surgery. The results were surprising, Mummaneni said: "While the two-year surgical results for both techniques were excellent, the rate of repeat surgery is lower for arthroplasty than for fusion at the two-year timepoint."

## **IOF calls for more research into changes in fracture rate incidence . . .**

Osteoporosis constitutes a major public health problem through its association with age-related fractures, most notably those of the hip. As life expectancy rises around the world, along with the number of elderly people in every geographic region, the incidence of hip fractures is estimated to reach 6.3 million in 2050 - assuming a constant age-specific rate of fracture in men and women. A new review paper by a scientific working group of the **International Osteoporosis Foundation (IOF)**; Nyon, Switzerland) shows however that age-specific hip fracture rates have changed during recent decades - decreasing in some countries or regions while increasing in others. The review examines some possible reasons for these trends and calls for further research. The authors examined published literature which addressed trends in the incidence of hip and other fragility fractures around the world and concluded that studies in western populations (including North America, Europe and Oceania) have generally reported clear increases in hip fracture incidence until around 1980, with rates then reaching a plateau or decreasing during the following decades. In contrast, the fewer studies in Asia suggest that age-specific rates may be increasing in the region. Published in *Osteoporosis International*, the review also examines the mechanisms which might explain the worldwide trends in fracture incidence. What demographic or environmental factors have caused changes to trends in age-adjusted hip fracture rates in Western countries? The potential contributors could be a

change in the frequency of risk factors for fracture which affect people in later life; a change in the frequency of risk factors influencing bone strength in early life; and changes in the demographic structure of the population. For example, the increase in age-adjusted hip fracture rates in the second half of the last century seen in certain countries may be explained by changes in pattern of physical inactivity, vitamin D insufficiency and increasing survival of the frail elderly. However the reasons for a plateau or decrease in rates are still not clear and require further investigation. Professor Cyrus Cooper, director of the MRC Lifecourse Epidemiology Unit at the University of Southampton and Professor of Musculoskeletal Science at the NIHR Musculoskeletal Biomedical Research Unit at the **University of Oxford** (Oxford, UK) emphasized the importance of the review and the need for further research. "It is interesting to see that, in recent decades, the incidence rate of hip fractures have been reported to increase, plateau or decrease in different countries. There is evidently a need for further research to pinpoint the reasons for the decline in rates observed in some regions, as this may help us understand ways to reduce rates of hip fracture worldwide. Data on continuing trends in fragility fracture need to be collected and evaluated as the trends will impact on worldwide economic evaluations of the future burden of osteoporosis and its related fractures."

**Modern surgery for scoliosis has good long-term outcomes . . .** Teenagers who undergo spine fusion for scoliosis using the newest surgical techniques can expect to be doing well 10 years after surgery, according to a **Hospital for Special Surgery** (New York) study published online ahead of print in the TK issue of the journal *Spine*. Researchers had thought that the surgery would cause damage to the spine just below the fused discs, but the study showed that this was not the case. "Fusion for adolescent idiopathic scoliosis using the newer generation spine implants appears to spare junctional disc degeneration and allows patients ten years out to have a relatively normal pain free lifestyle," said Daniel Green, MD, a pediatric orthopedic surgeon at Hospital for Special Surgery who led the study. Scoliosis is a condition in which a person's spine is curved. Starting in the early 1960s and up until the late 1990s, scoliosis was treated with surgery with so-called Harrington rods that were implanted along the spinal column. Starting in the late 1990s, surgeons started using newer techniques to fuse the spinal column together and these straight rods became obsolete. Spinal fusion is basically a procedure where doctors "weld" parts of the spine together, so the vertebral column heals into a single, solid rigid unit. The modern surgery is superior to the Harrington rods surgery because it allows the spine to be corrected in a much more natural, physiologic way, but there haven't been many studies evaluating how patients who undergo the surgery fare years down the road. To remedy this, HSS investigators conducted a pre- and post-operative MRI analysis in patients undergoing the surgery with modern techniques. The investigators reviewed all spinal fusions performed by four senior scoliosis surgeons at HSS between 1991 and 1997. Patients were included in the study if they had idiopathic scoliosis, were 21 years or younger and had surgery that had the surgeon approach the patient's spine from the patient's back vs. the front or side. Patients had to have fusion of the spine in their lower back (between vertebra T12 and L3). Thirty-three potential study participants were located and 20 agreed to participate. These patients returned for a physical examination by an orthopedic surgeon that included an MRI. Doctors recorded their medical history with special attention to level and location of pain and whether or not the patient was taking pain medication. Doctors compared the new MRIs to the ones taken ten years prior, before the surgery. "We wanted to see how the patients were doing ten years down the road, specifically focusing on the part of the spine that didn't have surgery. The standard belief was that the area of the spine just below the surgery would wear out, because of the increased stress that the surgery or the fusion would put on that part of the spine," Green said. "That isn't what we found. We found that the area of the spine adjacent to the fusion was pretty healthy and didn't show any major degeneration ten years later. While mild degenerative changes were noted in almost every patient, the severe changes that we were concerned that we might find were not there at all." The investigators also found that patients had good functional scores and maintenance of balance. No patients reported significant lower back pain. No patients took analgesic medications for their pain, with the exception of four patients (20%) who took occasional non-prescription non-steroidal anti-inflammatory drugs.

– **Compiled by Holland Johnson, MDD Managing Editor**  
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