

## MDxHealth shifts focus from research to commercialization

By OMAR FORD

Medical Device Daily Staff Writer

Sometimes change can be difficult.

In the case of **OncoMethylome Sciences**, which saw itself transform from a research firm to **MDxHealth** (Liege, Belgium) a company that develops and commercializes cancer assessment tests, the change was not only an easy one, but necessary for the viability of the firm.

MDxHealth reported the decision to change its business model this past summer and said that it was going to reap the “full benefits” of its methylation platform by developing DNA-biomarkers as stand-alone cancer diagnostics.

Previously the company out-licensed these biomarkers to third party developers and distributors and depended on royalties derived from the licenses as profit.

“You’re completely relying on payment to come when

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## Robots are ‘sexy’ but not always most cost effective

By AMANDA PEDERSEN

Medical Device Daily Senior Staff Writer

Robot-assisted surgery has become increasingly popular among both patients and surgeons as it has received a hefty amount of media attention in recent years and even appeared on “Grey’s Anatomy” in 2009. While there is certainly a lot to be said for the technological advancements of using a robot for some procedures, a new study suggests that it might not be the most cost effective choice for hysterectomy cases.

The study, sponsored by **Ethicon Endo-Surgery (Cincinnati)** and published in the November/December issue of the *Journal of Minimally Invasive Gynecology*, found that robot-assisted hysterectomy procedures cost \$2,667 more, on average, for inpatient procedures and \$1,971 more for outpatient procedures than traditional

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*Report from Europe*

## Mederi receives CE mark for new Stretta/Secca systems

A Medical Device Daily Staff Report

**Mederi Therapeutics** (Greenwich, Connecticut) reported that it has received a CE mark authorizing the European distribution and use of its second generation of the Stretta and Secca systems. The Stretta system is for treatment of gastric reflux disease, commonly known as GERD, and the Secca system is for treatment of bowel control disorder, or BCD. These latest systems include a streamlined user interface, significant improvements in ease of use, and are smaller, lighter, and highly portable.

“Mederi is very pleased to offer the Stretta system for the treatment GERD and the Secca system for treatment of BCD. Mederi has made a substantial capital investment which has resulted in numerous improvements to these

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*Washington roundup*

## FDA releases special controls for wound closures, NPWTs

By MARK McCARTY

Medical Device Daily Washington Editor

The Center for Devices and Radiological Health at FDA has published two special controls documents for therapeutic devices, bringing to five the number of such guidances the center has released in recent weeks. The latest additions to the list of devices CDRH has reclassified are negative pressure wound therapy (NPWT) devices and tissue adhesives with adjunct wound closures.

The agency recently released the long-awaited special controls guidance document for full-field digital mammography (FFDM) systems (*Medical Device Daily*, Nov. 5, 2010), after four years, a delay which fed concerns among those in the radiological devices sector about the premarket

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

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**AHC Media LLC**

*Financings roundup***Stereotaxis prices public offering of 4 million shares****A Medical Device Daily Staff Report**

**Stereotaxis** (St. Louis) reported that it had priced the public offering of four million shares of its common stock at a price to the public of \$3.65 per share. Stereotaxis has granted the underwriters of the offering an option to purchase up to an additional 600,000 shares of common stock to cover any over-allotments.

All of the shares in the offering are being offered by Stereotaxis. Stereotaxis expects the offering to close on Nov. 16, 2010, subject to the satisfaction of customary closing conditions.

Oppenheimer & Co. is acting as sole book-running manager for the offering. JMP Securities, Barrington Research Associates, and Madison Williams and Co. are acting as co-managers for the offering.

Earlier this week, the company said that it received a commitment letter from Silicon Valley Bank for an amended credit agreement that extends its revolving \$30 million credit facility to March 31, 2012.

The revolving line of credit commitment includes a sublimit of \$10 million for advances guaranteed by two current shareholders. The commitment also provides an additional \$10 million term loan that matures on Jan. 1, 2014.

The commitment is contingent upon the company raising \$10 million in additional equity, completion of definitive loan documents and other typical closing conditions as well as the recently completed extension of the \$10 million guarantee from two shareholders.

In other financings activity:

• **Health Care REIT** (Toledo, Ohio) reported that it has priced an offering of \$450 million in aggregate principal

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

*"The robot is sexy. It really is, it's a sexy technology, and I think that in certain procedures it absolutely has its place."*

– Matt Moore, director of reimbursement and healthcare economics at Ethicon Endo-Surgery, pointing out that surgical robotic systems may only be useful in special cases for hysterectomies, "Robots are 'sexy' but not always most cost effective," pp. 1, 7.

amount of 4.95% Senior Notes due January 15, 2021. The notes were priced at 99.349% of their face amount to yield 5.03%. Subject to customary closing conditions, the offering is expected to close on November 16, 2010.

The company intends to use the net proceeds from this offering for general corporate purposes, including investing in health care and senior housing properties.

• **Yale University** (New Haven, Connecticut) spinout **NovaTract Surgical** (New Haven) is the first company to land financing from Connecticut Innovations' \$4 million pre-seed fund, launched in September. The company has taken in \$150,000 from the fund and from LaunchCapital's matching funds.

The company has previously received financial support from Connecticut Innovations, the state's quasi-public agency focused on technology investments, in the form of a May pre-seed infusion of \$20,000. It was the 13th company chosen as part of CI's Pre-Seed Support Services Program, which helps startups receive business support and market and intellectual property assessments.

Co-founded in 2010 by CEO Eleanor Tandler and Yale School of Medicine assistant professor of gastrointestinal and general surgery Kurt Roberts, NovaTract develops a device designed for use in single-incision laparoscopic surgery and natural orifice transluminal endoscopic surgery. The company plans to use the device for gall bladder removals and appendectomies. ■

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**AHC Media LLC**

*Deals roundup***Caprius to be acquired by Vintage Capital Group****A Medical Device Daily Staff Report**

**Caprius** (Paramus, New Jersey) has entered into a definitive merger agreement to be acquired by Vintage Capital Group (Los Angeles). Caprius' common and preferred stockholders will receive \$0.065 per share on an as-converted basis. The price represents a premium of about 157% over the trailing 30-day weighted average closing price of the company's common stock.

Caprius' board, acting on the recommendation of a special committee of independent directors, unanimously approved the merger agreement and recommends that Caprius' stockholders adopt the merger agreement at a special stockholders meeting.

Vintage is the company's senior secured lender. To date, Vintage has advanced approximately \$4.3 million in cash to the company, exclusive of an additional \$1.4 million of capitalized obligations owed to Vintage. Pursuant to the terms of the merger agreement, Vintage has agreed to exercise its warrant into no more than 40% of the company's voting stock as of the record date of the special stockholders meeting.

Under the merger agreement, Caprius has the right to solicit competing acquisition proposals from third parties during a period ending on Dec. 15. KPMG Corporate Finance has been engaged by Caprius' special committee in connection with the solicitation. In addition, Caprius may, at any time, subject to the terms of the merger agreement, respond to unsolicited superior proposals. Caprius does not intend to disclose developments regarding this process. There is no assurance that this process will result in a superior proposal.

Caprius is engaged in the infectious medical waste disposal business, through subsidiaries which developed, market and sell the SteriMed and SteriMed Junior compact systems that simultaneously shred and chemically disinfect regulated medical waste using a proprietary, EPA registered, bio-degradable chemical known as Ster-Cid.

In other deals news:

- **Osteotech** (Eatontown, New Jersey), a specialist in the field of biologic products for regenerative healing, said that at a special meeting of stockholders, Osteotech's stockholders approved **Medtronic's** (Minneapolis) acquisition of Osteotech for \$6.50 in cash for each share of Osteotech common stock outstanding, which per share amount is subject to decrease in certain limited circumstances described in the agreement and plan of merger, dated August 16 (*Medical Device Daily*, Aug. 18, 2010.)

The closing of the merger remains subject to certain closing conditions as specified in the merger agreement. Osteotech expects that the closing of the merger will take place on or about November 6, assuming satisfaction or waiver of all such conditions to closing.

- **IPC The Hospitalist Company** (North Hollywood, California), a hospitalist physician group practice company, has acquired **Zenith Hospitalists** (Las Vegas). The acquisition represents an expansion in the Nevada market, where IPC already has a presence. Zenith has an annualized volume of approximately 40,000 patient encounters.

Jeffrey Taylor, president/COO of IPC, said, "Zenith is a well-known and highly respected acute care practice in the Las Vegas market. Our partnership with Zenith reinforces our reputation for the high quality of care that we are committed to in the Las Vegas market, and throughout our organization."

- **St. Jude Medical** (St. Paul, Minnesota) and **AGA Medical Holdings** (Plymouth, Minnesota) said that St. Jude Medical's request for early termination of the waiting period has been granted with respect to all filings made under the HSR Act and foreign antitrust laws, and therefore such waiting periods with respect to the previously announced exchange offer and proposed merger have ended. Under the HSR Act, the merger may not be consummated unless certain filings have been submitted to the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice, and certain waiting period requirements have been satisfied. ■

*Grants roundup***Replication Medical gets \$244K in QDTP funds****A Medical Device Daily Staff Report**

**Replication Medical** (Cranbury, New Jersey) a developer of hydrogel-based products for spine and other surgical applications, reported said that it has been awarded a Qualifying Therapeutic Discovery Project (QTDP) grant from the U.S. government in the amount of \$244,479 based on Replication Medical's 2009 GelStix related research expenditures.

The GelStix product is intended to treat chronic lower back pain which impacts nearly 10-15% of adults and is associated with a condition known as degenerative disc disease.

Early stage treatments for degenerative disc disease (DDD) include non-surgical pain management such as anti-inflammatory medications and exercise programs. Traditional surgical interventions include spinal fusion and disc replacement, which can be debilitating and risky for patients, especially the elderly.

The Replication Medical GelStix device is a matchstick-sized implant placed into the intradiscal space using a small needle and doesn't require surgery.

Once implanted, GelStix absorbs bodily fluids and expands many times in volume to rehydrate and repressurize the disc. The product represents an important step in filling the continuum of care gap for DDD. ■

*Agreements/contracts***Milestone, Ordway combine drug delivery technology****A Medical Device Daily Staff Report**

**Milestone Scientific** (Livingston, New Jersey), a maker of computer-controlled drug delivery technologies, and **Ordway Research Institute** (Albany, New York), a research and drug development organization, have agreed to develop drug formulations for precise targeted delivery of drugs to affected body parts, organs and cancerous tissue through Milestone's CompuFlo injection technology. Collaboration of the two organizations will facilitate the development by Ordway of nanoparticulate and other drug reformulations suitable for dispensing through specialized CompuFlo instruments which Milestone will develop. Drugs being developed by Ordway include those for treatment of arthritic joints, healing of wounds and destruction of tumoric and multisite cancers.

Precise and targeted delivery of Ordway's drug reformulations through Milestone's instruments is believed by the parties to offer enhanced therapeutic benefits unavailable through systemic delivery and may lead to new patents being granted for reformulations of drugs in the public domain by Ordway and others. Under the agreement, Milestone will provide Ordway with prototype CompuFlo instruments to assist Ordway in its continuing development of its drug reformulations.

The company says its CompuFlo system is a computer-controlled drug delivery injection system that incorporates Dynamic Pressure Sensing technology for safer and painless delivery (and fluid aspiration) of all medicaments. Dynamic Pressure Sensing technology provides visual and audible in-tissue continuous real-time pressure feedback, differentiating and identifying tissue types to the healthcare provider. Dynamic Pressure Sensing technology empowers healthcare providers to accurately identify tissues of the body, allowing for the injection of medication at an intended, precise location, the company said.

The Ordway Research Institute was formed in 2002 to facilitate inter-institutional and interdisciplinary collaborations in basic and translational biomedical research. Research is focused on drug development in cancer, emerging infections and signal transduction/endocrinology. Milestone Scientific is engaged in pioneering advanced computer-controlled drug delivery technologies for the medical and dental markets.

In other agreements news:

- **Flexible Stenting Solutions** (FSS; Eatontown, New Jersey), a designer of peripheral arterial and biliary stents, reported the signing of an exclusive agreement with **Goodman Co.** (Nagoya, Japan). Goodman will be responsible for overseeing the regulatory and clinical

process in Japan. Ultimately, Goodman will seek Shonin approval from the Japanese Ministry of Health, Labor and Welfare (MHLW) as a pre-requisite to their marketing and distributing the FlexStent femoropopliteal and biliary self expanding stent Systems in Japan.

FSS believes that this femoropopliteal stent and delivery system can significantly improve patient care in the high growth peripheral vascular segment. The fully connected flexible FlexStent provides an atraumatic, highly durable, fatigue resistant stent. It has superior radial stiffness, as well as excellent conformability to and mobility with the treated vessel. The delivery system provides simplicity, ease-of-use and accurate, uniform stent placement for the vascular interventionalist, FSS claims.

- **Roche Diagnostics** (Indianapolis) and **CapitalBio** (Beijing) reported their intention to initiate a strategic partnership targeting molecular diagnostic applications and the development of technologies. This new development builds on the genomics and diagnostics expertise of the two companies and will focus on furthering microarray technologies and complementary products for molecular diagnostic applications.

"This agreement is a significant step for Roche in forming closer relations with China's premier biochip development company," said Manfred Baier, head of Roche Applied Science. "The agreement formalizes a closer relationship with CapitalBio, formed since it joined the Roche NimbleGen Certified Service Provider (CSP) Program in January 2010."

The partnership plans to focus initially on the research and development of instruments and products to enhance and automate the Roche NimbleGen microarray workflow and the application of this workflow in preventive and personalized diagnostics. Roche said special focus will be placed on cooperation in education on the benefits and use of molecular diagnostics that exploit novel technologies involving microarrays and their related products and next-generation sequencing in both the greater China and international markets. The partnership also plans to establish educational facilities across China for molecular R&D and the application of clinical molecular diagnostics.

- **MedClean Technologies** (Bethel, Connecticut), a provider of onsite technology for the treatment and disposal of medical waste and the destruction of confidential documents and related media, has signed an agreement with **Gamma HealthCare/Danner Medical Waste Management Services** (Poplar Bluff, Missouri), for the purchase of a MedClean 4500 fixed-based sterilization system.

The agreement includes the purchase of the equipment plus additional recurring consumable orders for the life of the equipment, estimated over 10 years. Gamma HealthCare

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*HIT roundup*

## MHIS project provides South African nurses resources

*A Medical Device Daily Staff Report*

**Qualcomm** (San Diego), through its Wireless Reach initiative, reported the Mobile Health Information System (MHIS) project. According to the company, 3G wireless technology and in Internet-capable mobile device, pre-loaded with a clinical library, are providing nurses in hospital settings with access to medical resources.

Striving to enhance the quality of patient care delivery in South Africa, the AED-SATELLIFE Center for Health Information and Technology, supported by grants from Qualcomm's Wireless Reach initiative and the Henry E. Niles and John M. Lloyd Foundations, designed, planned and implemented the MHIS project. The project is a collaborative effort by participating organizations, including the **Eastern Cape Department of Health** (Eastern Cape, South Africa), the **Port Elizabeth Hospital Complex** (South Africa), **MTN-South Africa**, **Nelson Mandela Metropolitan University** (Port Elizabeth, South Africa) and the project funders.

The company said the MHIS project was designed to improve the ability of healthcare workers in urban and rural settings to care for their patients by providing them with locally relevant, reliable and accurate clinical information accessible using a commercially available mobile device. Each device provides access to a pre-loaded library of clinical and educational resources developed by AED-SATELLIFE as well as dynamic Internet content accessed through wireless broadband connectivity provided by MTN-South Africa.

The project provides training sessions which teach nurses how to use their smart phones to access information and share it with their colleagues. A comprehensive evaluation of the system, carried out by the Nelson Mandela Metropolitan University, showed that enabling nurses to access health resources wirelessly significantly improved their ability to provide care for their patients.

In South Africa, only 10.8% of the population has Internet access and only 0.09% has broadband Internet access. As a result, many public health workers do not have access to important health information and tools. The MHIS project allows nurses, through the use of 3G wireless technology, to share information within their health community when rare and complex cases are encountered, to keep abreast of the latest information on epidemics and to look up information they cannot otherwise access while in the field. Due to limited availability of skilled health professionals, the duty of providing health care to the poorest populations falls on nurses. Enhancing their access to relevant and accurate clinical information is vital to improving health service delivery.

"The Mobile Health Information System project is made

possible because of the collaboration and dedication of all project participants," said Elizabeth Migwalla, senior director of government affairs for Qualcomm. "Qualcomm believes wireless broadband can play a key role in delivering critical clinical data to public health care workers – not just in South Africa, but throughout the world."

In other HIT news:

• **MobileHelp** (Boca Raton, Florida) introduced its new Solo system, a mobile, personal emergency response system (M-PERS). Solo operates on AT&T's nationwide cellular network and is enabled with GPS location technology. According to MobileHelp, the system provides the flexibility of a wireless device with the convenience and capability of a PERS system. The company noted that consumers who use voice over Internet protocol phone lines or cellular service, emergency calls may not be as dependable as dialing 911 on a landline. Unlike traditional medical alarm systems, Solo does not require a phone line. A single press of the button immediately connects users directly to a 24-hour staffed emergency call center where an operator will have instant access to the user's location, medical history and emergency contacts, according to MobileHelp.

The system includes a wireless device, a portable charging cradle, and choice of a waterproof neck pendant or wrist button which may be worn at all times. Also incorporated in the system is MobileHelp's Caregiver Tools intended to enable caregivers to locate the user anytime online or through their smartphone.

• **Harris** (Melbourne, Florida) said it has been awarded a contract by **MED Trends** (Rockville, Maryland) to continue developing national patient registries for U.S. military veterans. The new contract, with a 12-month base period and two 12-month option periods, is a follow-on to the original contract awarded to Harris in October 2008.

For the original contract, Harris developed three new registries: Traumatic Brain Injury Registry, Defense and Veteran Eye Injury Registry, and Embedded Fragments Registry. Under the new contract, Harris will maintain and improve the existing registries' infrastructures and develop new registries based on other veteran-centric conditions.

• **Portico Systems** (Philadelphia) reported a new solution for provider and member identity management. Portico's Master Data Management product is engineered to deliver an accurate, reliable and consistent integrated identity management platform, the company said.

According to Portico, the lack of consistent and accurate provider identification has led to proliferation of duplicate records as well as wrongful attribution of provider data elements within records. The company noted that there is an increased need by health plans and hospitals to integrate large amounts of information that come from different systems that pertain to provider networks, provider services/clinical encounters, patient profiles and claims information. ■

## MDxHealth

*Continued from Page 1*

these companies [that use our biomarkers] bring their products to market," Jan Groen, MDxHealth's president/CEO told *Medical Device Daily*. "In some cases money comes in five to ten years out. Cancer screening is a very tough business. Outsourcing wasn't very profitable."

The name change is particularly important for the company's direct sales to treating physicians who want healthcare solutions. The company believes that MDxHealth captures its new aspirations. MDx, short for molecular diagnostics, has rapidly become one of the key areas of healthcare innovation and progress; an area where diagnostics and therapeutics converge.

For years now the firm has licensed out its biomarkers to other companies.

One such example was when the firm worked with **Laboratory Corporation of America Holdings** (LabCorp; Burlington, North Carolina) and granted LabCorp an exclusive license on certain IP technology to perform commercial MGMT methylation laboratory testing services in the U.S. and Canada (*Medical Device Daily*, April 2, 2008).

Another such collaboration was with **Rubicon Genomics** (Ann Arbor, Michigan). Rubicon said it would use its MethylPlex platform to carry out an analysis of MDxHealth's biomarkers. Additionally, Rubicon granted the firm an option to license markers resulting from the collaboration (*MDD*, Jan. 24, 2008).

Groen said that the new shift in focus allows the company to take greater ownership of their applications.

Currently, these applications are focused on three major cancer areas: prostate, colorectal and lung cancer.

In prostate cancer, MDxHealth is developing a biopsy test for use as a confirmation for those who have been identified by a PSA as possibly having cancer. The launch of this test, called Confirm MDx is planned for 2012.

"The test will take biopsies and will confirm if yes or no [if the patient has cancer]," Groen said. "We're hoping to bring the product to the market in 2012. By 2011 we are aiming for a CLIA Lab in the U.S."

The company said results from ongoing validation studies show excellent performance of its prostate test compared to technologies and products currently on the market. The firm added that it plans to launch a lung cancer recurrence assay for which data has already been published in the *New England Journal of Medicine*.

Groen said that lung cancer represents a large underserved market, in which MDxHealth's methylation profiles may have a positive impact. In addition, he said that MDxHealth is developing a methylation test to predict response to therapy in colorectal cancer.

The firm said that its first companion diagnostic test is currently in a Phase III FDA trial with **Merck Serono's** (Geneva, Switzerland) drug cilengitide for brain cancer.

MDxHealth has several other co-development projects in place with pharmaceutical companies for the development of companion diagnostic tests. The combined products of MDxHealth will be addressing a market with a revenue potential of more than \$1 billion per year.

In 4Q10, the firm said that it expects continued financial improvement from commercial revenue increases and cost reductions.

However it noted that the full effect of the change in strategy will not be seen until 2011. Excluding one-time restructuring charges, the 2010 operating costs are expected to be nearly 25% lower compared to 2009. The full year 2010 revenues are expected to be similar to 2009.

The company has hired an advisor to examine potential commercial distribution targets and is evaluating new fund raising opportunities to support the company's growth ambitions.

Groen told *MDD* that while it was challenging to move away from the past business model, it made the best sense for the company.

"We've achieved a lot in a very short amount of time," he said. ■

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## Med-Tech Notes

### Cyberbond gets ISO certification

**Cyberbond** (Batavia, Illinois) said it has become the first adhesive manufacturer in the world to be certified to the ISO 13485:2003 standard. Certification to this standard allows makers of medical devices and their components to ensure the effectiveness of their manufacturing processes, helping in turn to ensure their compliance with the requirements of medical regulations worldwide.

"Cyberbond is among the leading domestic manufacturers of industrial adhesives, but we've been able to expand our focus and now do business in many countries, each of which has their own set of rules and regulations," said Cyberbond's president, Jim East. "Being certified to this standard will allow us to provide to medical markets around the world, and do so as easily as we have for the past several years in the US. That we are the first adhesive company in the world to gain this certification hopefully shows the dedication we have to leading this market into the 21st century."

Cyberbond makes a full line of industrial adhesives – including cyanoacrylates, UV-curable, anaerobics, epoxies and acrylics – and specializes in custom formulations and innovations.

## Robot

*Continued from Page 1*

laparoscopic hysterectomy surgery. However the robot-assisted procedure offers no significant improvement in clinical outcomes, the study authors note.

"The robot is sexy," Matt Moore, director of reimbursement and healthcare economics at Ethicon Endo-Surgery, told *Medical Device Daily*. "It really is, it's a sexy technology, and I think that in certain procedures it absolutely has its place."

But Moore's team sought to find out if it is economically responsible to broadly use the robot-assisted technology for procedures such as hysterectomy that can be done laparoscopically without the use of a robot. He added that there has been a lot of research to prove the clinical benefits of robot-assisted surgery compared to open surgery, but not as much has been done to compare the robot procedure to traditional laparoscopic procedures.

"The purpose of the study was to understand the value proposition of a robotic GYN procedure compared to a straight stick or laparoscopic GYN procedure and understand if there was some huge benefit that you were getting from the robot versus straight stick and also what the costs were," Moore said.

The study was a retrospective review of 36,888 patient records from 358 hospitals of which 95% of laparoscopic hysterectomies were performed without robot assistance.

What the researchers found was that there is "very little difference," in the clinical outcomes of the robotic hysterectomies compared to traditional laparoscopic hysterectomy. The fact that both methods produced very similar clinical results was not a surprise, Moore said, "because both of them would be considered laparoscopic."

However the cost of performing a hysterectomy with a robot is considerably higher, the researchers found, than doing the surgery without the robot. These costs are specific to the episode of care, Moore said, and do not include the initial cost to purchase the robot, annual maintenance, or any operating room build-out to accommodate the size of the robot. Surgery time was also significantly less for non robot-assisted procedures, the study authors noted.

"Hospitals, in this current environment, are struggling for margin and struggling to keep costs as low as possible without compromising care," Moore said.

The study examined data from the Premier hospital database of cases involving women 18 years or older who had a minimally invasive hysterectomy – traditional or

robot-assisted – performed between 2007 and 2008. The investigators examined the association between robot-assisted hysterectomy and adverse events, hospital costs, surgery time, and length of stay.

Moore said he expected there to be more of a difference between the robot and pure laparoscopic procedures for complex cases, or cases involving cancer patients. "Honestly, the results were a little bit in favor of the robot, but they weren't anywhere near what I thought that they would be," for such cases, he said.

So far, Moore said he has spoken with two or three surgeons about the study results and that they were "happy, quite frankly, to get this information." He explained that the surgeons have had patients come into their office and ask for a robot-assisted hysterectomy. "Up until now it's been very difficult for the surgeon to say 'I can do it laparoscopically, we really don't need to use the robot' . . . this allows them to have a good conversation with their patients," about the benefits and costs associated with both procedures.

The researchers acknowledge, however, that there are cases in which the robot might offer significant advantages over traditional procedures.

"Robot-assisted surgery can provide advancement in minimally invasive procedures for a very select, more complex type of procedure, such as laparoscopic prostatectomy or gynecologic oncology," said Resad Pasic, MD, PhD, of the **University of Louisville** (Kentucky), one of the lead investigators for the study. "However, our study showed that in routine hysterectomy procedures, where traditional laparoscopic approaches can achieve the same clinical outcomes at a much lower cost to hospitals and with shorter operating time, there is no value proposition to use the robot for routine hysterectomy."

Moore added that it is more important than ever before to be economically responsible in selecting which procedure to use for a particular surgery case.

"You don't want to squelch, if you will, new technology and advancements, but I think we just have to do a really good job – or a much better job – of being responsible not only from a clinical standpoint but from an economic standpoint," Moore said, rather than to use a robot "just because it's sexy and just because it's on Grey's Anatomy and just because it's out there on a billboard." ■

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## Europe

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novel technologies," stated Will Rutan, CEO and President of Mederi Therapeutics. "The Secca and Stretta systems are ultra-minimally invasive technologies that bridge a significant gap that exists between conservative therapies and invasive surgical options for GERD and BCD. Numerous clinical studies have shown Stretta and Secca to be effective therapeutic options."

The second generation Stretta and Secca devices were launched at UEGW 2010, the annual congress of the United European Gastroenterology Federation, which was held in Barcelona, Spain, October 23-27. "It was exciting to witness the overwhelming response to Stretta and Secca, resulting in numerous requests to purchase Mederi products at the recent European congress. As the only endoluminal therapies for GERD and BCD, the interest and demand for these novel technologies is extremely high," added Rutan. Concurrent with the EU launch activities, Mederi has engaged and trained a worldwide distribution network to drive demand and ensure safe and proper use of Stretta and Secca.

Mederi manufactures medical devices that deliver radio frequency energy to treat disease states affecting the human digestive system.

### SBi enters Netherlands distribution agreement

**Small Bone Innovations** (SBI; New York), a privately-held orthopedic company focused exclusively on technologies and treatments for the small bones & joints, reported that its Small Bone Innovations International unit has entered into an exclusive three-year distribution agreement in The Netherlands with Biomet Nederland (Dordrecht, The Netherlands), a subsidiary of **Biomet** (Warsaw, Indiana).

Roland van Esch, managing director of Biomet Nederland, said, "We are very eager to offer SBI's full product line in the Netherlands that both complements and supplements Biomet's European product line."

SBI was founded in 2004 by Viscogliosi Brothers (VB), a New York-based merchant banking firm that specializes in the musculoskeletal/orthopedics sector. VB created SBI as the first company to focus purely on small bones & joints.

### XStor completes ISO 13485 certification

**XStor Medical Systems** (Mountain View, California) reported the completion of its ISO 13485 certification. The ISO 13485 quality management system certification is a key step in obtaining CE markings and clearance to market medical solutions globally.

"XStor's software products are designed under robust process and strict quality controls, and this certification codifies our ability to deliver safe & effective solutions. There is an emerging need and strong demand for our products in the U.S., Canada, Europe and Japan. Our strategic partners

have a strong presence in these markets, and this certification enables us to provide our industry-leading solutions to our customers," said Syed Hamdani, CEO of XStor.

XStor develops software solutions for medical imaging connectivity and storage for the healthcare specialties such as radiology, oncology and pathology.

### Accentus completes manufacturing plant

**Accentus Medical** (Didcot, UK), a company that supplies advanced coatings and surface treatments to the device industry, reported that it has successfully completed the installation and initial demonstration of a prototype manufacturing plant for its Agluna anti-infective technology, following the award of a grant worth £330,000 from the Technology Strategy Board within the High Value Manufacturing call.

Accentus was awarded the grant in December 2009 in collaboration with **Stanmore Implants Worldwide**, an existing licensee and customer of Agluna in the field of custom made limb salvage devices and patient specific joint replacements, and academic partner **University College London**. Following the successful development and clinical proof of concept of Agluna, the principal objective of the grant project was to demonstrate commercial scale manufacture of the Agluna technology.

Philip Agg, CEO of Accentus, said, "The Technology Strategy Board grant has been crucial in demonstrating our ability to manufacture the Agluna technology on a commercial scale. This capability will add to the company's established manufacturing capability in supplying to global orthopedic device customers its Acusure range of plasma spray coatings for implant fixation." ■

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## Agreements

*Continued from Page 4*

will expand its operations to include a centralized waste sterilization processing center within their seven state Midwest region.

"The continued strengthening of MedClean's relationship with Gamma HealthCare further validates our approach to building a nationwide network of quality partners who provide high quality services at lower costs to the hospital market," said David Laky, president/CEO of MedClean. "The MC 4500 can process over one million pounds of medical waste annually. It is exciting for us to contribute toward Gamma HealthCare's goal of processing medical waste, expanding the Danner Medical Waste Management Services line of business, and assisting them with future expansion of their operations throughout the Midwest region. We look forward to continuing to develop other portions of the region as a partner to Gamma HealthCare."

Gamma HealthCare is a group of medical testing facilities. ■

## Washington

*Continued from Page 1*

process at CDRH. However, the center released special controls guidances for a pair of class III catheter types in September (*MDD*, Sept. 9, 2010), and published summaries for two *de novo* device applications (*MDD*, Nov. 9, 2010). The *de novo* channel, which is designed to deal with medium risk devices without a clear predicate, has been the target of remarks that it is underutilized over the past year or so, and even the previous center director, Dan Schultz, MD, had made similar remarks at a meeting of the **Medical Device Manufacturers Association** (Washington) last year (*MDD*, June 4, 2009).

The guidance for NPWT devices specifically addresses non-powered units and states that the agency “may recommend that you collect clinical data” to support the clearance application under some circumstances. Included in the list is when “indications for use [are] dissimilar from a legally marketed system of the same type” and when the design is “dissimilar from designs previously cleared under a premarket notification,” although the guidance offers little detail as to when “dissimilar” triggers a requirement for clinical data. However, the statement notes that the agency “will consider alternatives to clinical testing when the proposed alternatives are supported by an adequate scientific rationale.”

The special controls document for tissue adhesives with adjunct wound closures, which like the NPWT guidance is dated Nov. 10, states that the reclassification is limited to such device “intended for the topical approximation of skin.” This, the guidance states, “is a separate classification from the classification for tissue adhesives” found in chapter 21, subsection 878.4010 of the Code of Federal Regulations, which FDA states includes “tissue adhesive for the topical approximation of skin and tissue adhesive for non-topical use.” CDRH emphasizes further that the reclassification does not apply to “devices used as an adjunct to standard methods of achieving hemostasis in open surgical repair of large vessels such as the aorta, femoral and carotid arteries,” to “devices used as dural sealants,” or to “devices used as tissue adhesives for ophthalmic use.”

### OIG exonerates FDA over employee gripes

FDA has seen its share of disgruntled employees over the past couple of years, and the Office of Inspector General at the Department of Health and Human Services had investigated complaints made to the Obama administration and members of Congress about alleged pressure to change opinions on the approvability of device applications. However, outside groups continued to pressure Congress over those allegations, hence triggering a second OIG investigation.

The first OIG report was announced earlier this year while an FDA public hearing was underway (*Medical Device Daily*, April 1, 2010), and the second report, a summary

of which was obtained by *Medical Device Daily*, drew essentially the same conclusion.

According to the Oct. 14 summary document, which ran to only two pages, an independent assessment of the complaints of retaliation against reviewers by management led to the conclusion that there was “no evidence of retaliation . . . against complainants.”

*Medical Device Daily* obtained a copy of the text of a Nov. 5 all-hands letter from center director Jeff Shuren, MD, noting that the outside investigation “found no evidence of retaliation by CDRH management against complainants and no evidence of material violation of rules with respect to documenting significant decisions, such as product approval decisions, as alleged by complainants.” Shuren noted further, however, that the center “also hired an independent contractor to investigate allegations of other problems not reviewed by the OIG, such as failures of administrative processes.” He said he expects to receive “a report of their findings in the coming weeks and will” advise the agency’s employees as to “what the contractor found.”

### FDA, Health Canada, tout benefits of PMAP

As regulatory bodies across the globe approach harmonization more or less gingerly, the joint inspections programs that are in place seem to attain more importance as a blueprint for whatever level of harmonization might ultimately be achieved. FDA and Health Canada (HC) recently reported the results of their joint pilot multipurpose audit program (PMAP) and concluded that while only 10 such inspections were conducted, the results suggest that industry can shave off a substantial number of inspection/audit days from their calendars by taking part in such programs in the future.

According to the Nov. 8 FDA final report on the pilot program, the intent was to conduct only 10 inspections under the pilot and that device makers saved an average of 33% in terms of the number of inspectional days by participating in the pilot rather than going through separate inspections by HC and FDA. The savings in terms of time, FDA states, ranged from 25% to 58%. That outlier of 58% was a firm that had incurred a total of 19 days in dealing with both FDA and HC inspections in times gone by, and managed to get the joint inspection handled in only nine days under the pilot.

The ride was not entirely free of bumps, however, as FDA noted that in several instances, findings of non-conformities were not always accompanied by “a cause analysis, a clear statement of correction of the non-conformity or a clear statement of the corrective action” the manufacturer would undertake to correct the situation. Those who routinely read FDA warning letters would find this comment inconspicuous, and FDA acknowledges as much in the report. The agency indicates that it and HC intend to incorporate the relevant guidance by the Global Harmonization Task Force from study group three into their inspectional regimes in an

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## Product Briefs

- **Alma Lasers** (Buffalo Grove, Illinois) introduced its new medical laser technology with the Soprano(XLi) for laser hair removal and deep dermal heating. The Soprano(XLi) uses Alma's IN-Motion technology. The diode module has a 12x10 mm footprint and (up to) 10Hz repetition rate. The Soprano(XLi) can treat all skin types, including tanned skin. For hair removal, the Soprano(XLi) uses a 810 nm diode laser. Its low fluence, high repetition rate delivers energy to heat the dermis and hair follicles. Gradual heating combined with the contact cooled Sapphire tip ensures maximum patient comfort throughout the treatment, no analgesics are required. Alma Lasers makes laser, light-based, radiofrequency and ultrasound devices for aesthetic and medical applications.

- **Ethicon Endo-Surgery** (Cincinnati) said that the FDA has granted the appeal of the Center for Devices and Radiological Health's (CDRH) denial of the Sedasys System Premarket Approval Application (PMA). As a result, a new independent advisory panel will be appointed to reconsider the Sedasys System clinical trial data and application. The Sedasys is the first computer-assisted personalized sedation (CAPS) system designed to allow physician/nurse teams to provide minimal-to-moderate sedation with propofol during routine upper and lower gastrointestinal procedures in healthy adults. The Sedasys has the potential to benefit patients, physicians and nurses. If approved, it may help reduce sedation-related risks associated with endoscopic procedures, may improve the overall patient experience, and may encourage more individuals to be screened for colon cancer.

- **Mentor Worldwide** (Santa Barbara, California) introduced PDS Flexible Plate – the absorbable implant that provides structural support and streamlines cartilage management during nasal reconstruction procedures. Nasal reconstruction surgeries, such as rhinoplasty and septoplasty, can be difficult and time consuming – requiring the meticulous reconnecting of cartilage pieces to form a straight, solid plate that bridges and supports nasal structures. These procedures frequently result in disposal of valuable cartilage and complications requiring re-operation and secondary surgeries. PDS Flexible Plate is a biodegradable polydioxanone surgical material that can act as a scaffold for the assembly of the cartilage pieces and support newly reconstructed cartilage during the critical healing period following surgery. It can also reduce the need for secondary cartilage donor site surgery. PDS Flexible Plate remains intact during the critical healing process of the first 10 weeks after implantation but is absorbed completely within 25 weeks, leaving no residue and minimal fibrous scar tissue. This absorbability avoids some of the long-term problems associated with non-absorbable implants.

## People in the News

- **Halfpenny Technologies** (Blue Bell, Pennsylvania) has named Gai Elhanan, MD, as the company's chief medical information officer. Previously, Elhanan was chief of healthcare informatics at 3M Health Information Systems. Halfpenny Technologies is a clinical data exchange solutions provider specializing in laboratory, pathology and physician electronic medical record system interoperability.

- **Perceptive Informatics** (Boston) has named Vladimir Evilevitch, MD, PhD, to the position of associate medical director and head of cardiology and nuclear medicine in its medical imaging group. Evilevitch, formerly was regional medical advisor at Novartis Healthcare. Perceptive Informatics is an eClinical solutions provider.

- **SRI International** (Menlo Park, California) said that Joseph Perrone has joined SRI International's Center for Advanced Drug Research (CADRE; Shenandoah Valley, Virginia). Perrone will head CADRE's molecular diagnostic efforts, including its rare and neglected diseases program. Prior to joining SRI, Perrone was president of JBP Consulting. SRI is an independent nonprofit research and development organization.

- **Titan Spine** (Mequon, Wisconsin) has named Andrew Shepherd as VP of marketing. Previously, Shepherd was VP of sales & marketing for Impliant. Titan Spine makes bioactive interbody fusion devices for the spine.

## Washington

*Continued from Page 9*

attempt to standardize their respective approaches to such situations.

One other feature of the inspection/audit program that FDA indicates needs work is that some of the joint check-ups were for strictly auditing purposes for HC whereas that same visit had to cover a full GMP/QS inspection for FDA purposes. The document states that audits should be matched to audits and full inspections matched to full inspections in order to maximize time savings, but a natural question to pose is whether such alignments will regularly crop up in a normal state of affairs. ■

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# MDD'S DIAGNOSTIC EXTRA

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

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*Keeping you up to date on recent headlines in diagnostics*

## **Study shows 40% of scleroderma patients won't be correctly diagnosed with automated test . . .**

New research from **Georgetown University Medical Center** (GUMC; Washington) suggests that up to 40% of scleroderma patients will not be correctly diagnosed with the disorder using a new automated commercial screening test. The **American College of Rheumatology** (Atlanta) recommends immunofluorescence antinuclear antibody (IF-ANA) testing to help detect the presence of scleroderma specific antinuclear antibodies. Finding the antibodies is a helpful predictor of disease manifestations, clinical course and outcome in scleroderma. However, many commercial labs have recently adopted a newer, automated method that use non-immunofluorescence antinuclear antibody testing. This test is known as NEW ANA. To test the accuracy of the commercial method for detecting scleroderma antibodies, GUMC researchers evaluated the all test results performed through commercial laboratories of more than 200 scleroderma patients treated in the Georgetown scleroderma clinic between June 2008 and June 2009. Test results using NEW ANA were available in 58 scleroderma patients. Twenty-eight patients (48%) tested negative. Of these 28 patients, 22 had either positive results using IF-ANA or one of the scleroderma specific antibodies. "The NEW ANA testing, that is the ANA test without immunofluorescence, failed to identify patients with a particular subset of scleroderma specific antinuclear antibodies and other patterns that are picked up with IF ANA testing. This finding was significant," says Victoria Shanmugam, MBBS, MRCP, assistant professor in the Division of Rheumatology, Immunology and Allergy who presented the findings. NEW ANA test results were not available for the remaining 183 scleroderma patients. IF-ANA testing was conducted in these patients and the positive antibody results were divided by subtypes. "Given what we know about the subsets that are not detected by the NEW ANA testing, it appears that as many as 40% of the scleroderma patients would have tested negative using the new commercial testing method," Shanmugam says. "If a clinician has clinical suspicion for scleroderma, they should order the immunofluorescent ANA."

## **Solar powered blood pressure monitor could reduce cardiovascular disease in low income nations . . .**

A solar-powered blood-pressure measuring device that's reliable and affordable could help reduce rapidly rising rates of cardiovascular disease in low-income nations, according to a new study. Field tests at three medical centers in Africa - two in Uganda and one in Zambia - showed that the \$32 automated device is 94% in agreement with the standard blood-pressure testing method for systolic blood pressure, which is the top number in a blood-pressure reading and represents the maximum pressure when the heart contracts. It was less accurate for diastolic blood pressure (the lower number that shows pressure when the heart is relaxed), but that is something that should be easy to fix, the researchers said. They also noted that systolic blood pressure is the major contributor to cardiovascular events and tends to be the more important reading. The research is reported Nov. 8 in the journal *Hypertension*. It took about 15 minutes to train medical center staff to use the device. The staff then used the new device and a standard device to take blood pressure readings on about 716 patients. They repeated this one month later. Medical staff and patients said they preferred the solar device over the standard device. "Solar energy eliminates the need for expensive rechargeable batteries in remote areas where electricity and the availability of batteries might be scarce, but sunlight is plentiful. It can be run on batteries, but it can also be left in the sunlight to charge, making it ideal for rural areas and use out in the bush," lead author Eoin O'Brien, PhD, a professor at Conway Institute of Biomolecular and Biomedical Research of the **University College Dublin, Ireland**, said. He noted that the incidence of hypertension, or high blood pressure, has risen dramatically in low-income nations, many of which lack trained medical personnel. "Hypertension leads to stroke and heart attack as the major cause of death around the world. It is greater than malnutrition, cancer and AIDS," O'Brien said. "We have been able to provide an accurate, robust and inexpensive device to diagnose high blood pressure," O'Brien added. "It's a start. If we can't measure blood pressure, we certainly can't begin to treat hypertension."

## Screening for cervical cancer could be reduced thanks to vaccine

■ ■ ■ Girls who get cervical cancer vaccines may only need screening twice in their lifetime, medical experts have claimed. It is hoped that the disease will become “rare” as a result of the vaccine’s introduction, according to Professor Peter Sasieni of the **University of London**. “After youngsters have had the vaccine at the age of 12 or 13, they would only require screening for the illness when they are 30 and 45,” he said. The vaccine will protect girls against key strains of the papillomavirus (HPV), a sexually-transmitted infection behind most cases of cervical cancer. Professor Sasieni suggested that HPV testing could replace current smear testing programs, where women are invited for screening every three to five years. The HPV test can detect up to 13 strains of cervical cancer, although the infection can take more than 10 years to develop after infection takes place. “If you don’t have one of these 13 types of HPV then your chance of getting cervical cancer in the next 10 years is really incredibly low,” Professor Sasieni said. “You would capture virtually everybody with HPV testing. Vaccinated women would only need to be screened when they are 30 and 45.”

## Sweet 16, could detect cognitive impairment in patients . . .

A screening test that takes just two minutes could detect as many as eight in ten cases of cognitive impairment, a condition that is often a precursor to Alzheimer’s, according to an article in the *Archives of Internal Medicine*. Current screening tests take a minimum of 10 to 15 minutes, and require the patient to write with pen and paper, an impossibility for many people who are hospitalized. The new screening test is known as the “Sweet Sixteen,” because it involves 16 elements. There are eight questions on basic orientation, such as “where are you?” and “What day is it?” The person tested is also given three items to remember, asked to count a number sequence forwards and backwards and asked again about the three items. According to the new paper, the Sweet Sixteen did just as well as other common tests – including the widely used MMSE, or Mini-Mental State Examination, in finding mild cognitive problems. Tamara Fong, the lead author and an assistant professor of neurology at **Harvard Medical School** (Cambridge, Massachusetts), as well as an assistant scientist at the Aging Brain Center at the **Institute for Aging Research at Hebrew SeniorLife** in Boston, says the Sweet Sixteen is only meant to be a first step, a trigger for further testing. However, she said its speed and ease of use – it requires only minimal training to administer – could make it widely attractive. “One reason primary physicians don’t screen [for cognitive impairment] is because they don’t have time to do it,” says Fong. “If you only have 10 minutes for a visit, you’re not going to use a screening test that takes 10 or 15 minutes.” Ron Petersen, Director of the **Mayo Clinic** (Rochester, Minnesota) Alzheimer’s Disease Research Center, said that while the test might prove useful, it should not be used to diagnose cognitive impairment. “It’s important not to misuse it,” Petersen says. “But if it just means, ‘you’ve got to go and get checked by a physician,’ then, that’s a different story.” Screening tests for cognitive impairment are becoming a hot-button issue, partly because of the aging population and partly because of a change in Medicare rules.

## New test could give insight on drug therapy benefit for cancer patients . . .

Scientists have developed a new test to select which patients with ovarian cancer will benefit from new drugs called PARP inhibitors, according to research presented at the **National Cancer Research Institute** (Bethesda, Maryland) PARP inhibitors are the first targeted treatment to be developed for women with inherited forms of breast and ovarian cancer carrying faults in a BRCA gene. Early results from clinical trials are showing promise for patients with the rare inherited forms of these cancers. But this new test shows that even more patients – 60% of all patients with ovarian cancer - may benefit from PARP inhibitors. Inherited ovarian cancer accounts for up to 15% of all cases of the disease. Asima Mukhopadhyay, presenting the results, said: “Our results show that this new test is almost 100% effective in identifying which ovarian cancer patients could benefit from these promising new drugs.” “We have only been able to carry out this work because of the great team we have here which includes both doctors and scientists.”

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