

Cardiovascular Research Technologies 2010

Shuren cites tension between predictability and adaptability

By MARK McCARTY

Medical Device Daily Washington Editor

WASHINGTON – Tuesday served as the last day of CRT (Cardiovascular Research Technologies) 2010, sponsored by the **Cardiovascular Research Institute** (Washington), and included a lunchtime discussion session offering views of how healthcare reform might affect the device industry, but a previous session gave Jeffrey Shuren, MD, the chief of the Center for Devices and Radiological Health, a chance to further explain where he expects to steer the center in the next couple of years.

Shuren observed that “the landscape of device evaluation is always moving,” but promised that “some steps CDRH is taking,” will result in “clear and predictable regulatory pathways.” He added that he sees “some challenges” as to how to ensure safety and effectiveness “when the sci-
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Study shows robotic technique trumps laparoscopic procedure

By OMAR FORD

Medical Device Daily Staff Writer

Robot-assisted surgery proved to be a more efficient and safer treatment option for patients who suffered from kidney blockages which prevent urine from draining normally to the bladder, according to a study published in the *Canadian Journal of Urology*.

The study looked at 60 patients who had a procedure known as pyeloplasty that involves reconstructing the narrow area where part of the kidney meets the ureter, the tube that carries the urine from the renal pelvis into the bladder.

Ashok Hemal, MD, a urologic surgeon from **Wake Forest University Baptist Medical Center** (Winston Salem, North Carolina), compared both laparoscopic procedures and robot-assisted surgery using the daVinci surgical system developed by **Intuitive Surgical** (Sunnyvale, California)
See Robot, Page 7

Breath test may detect pulmonary tuberculosis

By AMANDA PEDERSEN

Medical Device Daily Staff Writer

As a physician doing a fellowship in the 1970s at the **University of California San Francisco**, Michael Phillips, MD, became very interested in breath testing. He knew that the technology existed to detect the use of certain drugs using a breath test, so he thought surely it ought to be possible to detect diseases the same way.

So, with the “optimism of youth,” as he tells *Medical Device Daily*, Phillips went on to create a company called **Menssana Research** (Fort Lee, New Jersey) with the goal of developing tests capable of detecting diseases in their earliest, most treatable, states simply by analyzing breath samples. And, as Phillips says, “it only took me 20 years” to get somewhere with it.

In February 2004 the FDA approved the company’s Heartsbreath test for heart transplant rejection and it
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Study focuses on telemedicine to cut rehospitalizations, ED visits

By LYNN YOFFEE

Medical Device Daily Staff Writer

It stands to reason that most people would be more comfortable and receptive to healthcare instructions and monitoring at home. Two technology giants along with **Mayo Clinic** (Rochester, Minnesota) are using this as a premise for a study to investigate a new model of healthcare delivery for patients at increased risk of rehospitalization or emergency department visits. Telemedicine is being put to the test in a year-long experiment focused on reining in costs and improving patient outcomes through personalized care and ongoing disease management.

“The ultimate goal of the study for most patients, providers and payers is to promote safe independent living,” Gregory Hanson, MD, Mayo Clinic Department of Primary Care Internal Medicine, one of the principal investigators in the study, told *Medical Device Daily*. “That’s the ultimate goal.”
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Don’t miss today’s MDD Extra: Orthopedics

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AHC Media LLC

*International report***Vicor, USFQ Ecuador in pact for HRV diagnostic awareness****A Medical Device Daily Staff Writer**

David Fater, CEO of **Vicor Technologies** (Boca Raton, Florida) said it has entered into a collaborative agreement with the **Universidad San Francisco de Quito** (USFQ; Cumbayá-Quito, Ecuador) to further awareness and use of the measure of heart rate variability (HRV) as a medical diagnostic.

Vicor uses its PD21 nonlinear algorithm and software to stratify patients at risk of sudden cardiac death and autonomic nervous system dysfunction, and trauma victims in need of lifesaving intervention. According to the company, its PD2i Analyzer displays and analyzes electrocardiographic data to provide a measure of heart rate variability in patients at rest, and during controlled exercise and paced respiration.

The company said it would collaborate with USFQ to: develop academic programs that advance awareness and use of the measure of HRV to diagnose various medical disorders within a variety of health-challenged and/or at risk populations; promote continued research into the uses of HRV in USFQ clinics; and stimulate assistance from Ecuador's public and private health sectors with the goal of preventing disease with appropriate intervention/treatment based on early diagnosis using HRV.

Additionally, Vicor will serve as the sponsor of the Vicor Technologies, Inc. **Heart Rate Variability Institute** at USFQ, with the express purpose of furthering throughout Ecuador HRV research and its use as a medical diagnostic as measured with Vicor's PD2i Analyzer.

This effort may also include study of HRV as measured

Today's MDD food for med-tech thought

"Why is there reform coming? Because we cannot afford to continue to do this and insure all our citizens." Reimbursement "is what drives over-utilization,"

— Steve Nissen, MD, of the **Cleveland Clinic** (Cleveland), discussing the inevitable need for more radical healthcare reform and the role reimbursement currently plays in escalating the problem, "Shuren cites tension between predictability and adaptability," pp. 1, 4.

by the PD2i Analyzer to identify autonomic nervous system dysfunction in diabetics, the need for lifesaving intervention in trauma victims as a means of facilitating triage efforts, imminent mortality in those with brain injury, and the risk of sudden cardiac death in target populations, including young athletes, the company said.

"Science and technology have propelled knowledge and practical applications in medicine at a fantastic speed," said Enrique Noboa, dean of the USFQ School of Medicine. "The collaboration of several universities for the purpose of investigating the risk of sudden death in certain special groups will definitely broaden the spectrum of routine procedures that will result in the prevention of these events and the salvage of precious human lives."

LabCorp acquires interest in Ontario j-v

Laboratory Corporation of America (LabCorp; Burlington, North Carolina) said it completed a transaction to acquire the partnership units from the holder of the noncontrolling interest in its Ontario, Canada joint venture. The purchase price of the noncontrolling interest's units was C\$147.8 million. On Feb. 17, LabCorp completed a transaction to sell the units acquired from the previous noncontrolling interest holder to a new Canadian partner

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*Deals roundup***Merge clarifies proposal to Amicas, responds to investors****A Medical Device Daily Staff Report**

Questions already surround **Merge Healthcare's** (Milwaukee) move to acquire **Amicas** (Boston). The company reported that it had received numerous calls from investors regarding a proposal to acquire Amicas for \$6.05 cash per share.

In response Merge said that it is providing additional information to clarify certain questions raised by investors. Merge's proposal, for an aggregate of \$248 million, represents a 13% premium to the previously-reported offer from a newly-formed affiliate of **Thoma Bravo** (Chicago) for \$5.35 cash per share (*Medical Device Daily*, Dec. 30, 2009).

Amicas expressed its doubt about Merge's commitment and ability to close its proposed acquisition of Amicas. But Merge said that it is fully committed and is prepared to complete the Amicas transaction.

Merge also said that it has not requested a financing "out" in its proposed merger agreement, and under the terms of that agreement, Merge would be liable to Amicas for almost \$18.6 million in cash if it breached its obligations due to its inability to fund the transaction.

The company also added that there has been some confusion regarding when Merge entered the proposal process.

Although characterized by Amicas as an "eleventh hour attempt," as noted in Amicas' proxy statement supplement, Merge said it approached Amicas almost 18 months ago to strike such a deal and has continued that effort ever since. Merge said it "remains ready to finalize a definitive merger agreement with Amicas that would provide for the commencement of a negotiated tender offer promptly after Thoma Bravo has waived its match rights and various other conditions are met."

Merge said it believes it is in the best interest of each company's stockholders, customers and employees to bring Merge and Amicas together and build a stronger future. Merge said "it looks forward to working with the Amicas board, subject to the provisions in the Thoma Bravo agreement, to commence a \$6.05 cash per share negotiated tender offer for all Amicas shares and to close the acquisition as quickly as possible thereafter."

In other dealmaking activity:

- **Millipore** (Billerica, Massachusetts) confirmed that its board is evaluating strategic alternatives to enhance shareholder value, including by pursuing a process with potential bidders to explore a possible merger or sale of the company.

The company has engaged Goldman Sachs as its financial advisor and Cravath, Swaine & Moore as its

legal advisor to assist the board in its evaluation. Millipore has not set a definitive timetable for completion of its evaluation and there can be no assurances that the process will result in any transaction. The company does not intend to disclose developments regarding this process unless and until the board has approved a specific transaction.

- **Royal Philips Electronics** (Amsterdam, the Netherlands) reported that it has acquired the Somnolyzer 24 x 7 automated scoring solutions business of the **Siesta Group** (Vienna, Austria).

This FDA-cleared solution will help improve the productivity of sleep centers and is based on the most advanced and clinically validated automated-scoring technology on the market.

The Siesta Group is a research and clinical software company specializing in polysomnography scoring solutions for sleep centers. The acquired business will become part of the sleep diagnostics business within Philips Home Healthcare Solutions. Financial details of the agreement were not disclosed. ■

*Grants roundup***Cigna helps MTeHC expand EMR offerings with \$150K in funding****A Medical Device Daily Staff Report**

Cigna (Nashville) reported that it has contributed \$150,000 to the Middle Tennessee eHealth Connect (MTeHC) toward its work to develop a regional health information organization for exchanging electronic medical records to help improve health care quality and reduce costs.

"Cigna's \$150,000 contribution is an investment for improving the health and reducing health care costs of Tennesseans," said John Sorrow, president of Cigna Health-Care of Tennessee. "We at Cigna are proud that Tennessee is a national leader in electronic health information exchange and that we are able to help our state create a network of electronic medical records so that physicians can better coordinate care, avoid redundancies and strengthen the care provided to individuals across the state."

MTeHC will allow healthcare professionals in its health information network access to patient medical records in one safe, secure location.

Tennessee's Office of e-Health Initiatives was created in 2006 as the state's coordinating authority for the exchange of electronic health information, and works with other regional health organizations, such as the Mid-South e-Health Alliance in Memphis and CareSpark in Kingsport, to increase the adoption of health information technology. ■

Wall Street firms' 2010 outlook spotty

What goes around in regulatory terms comes around in financing terms in the world of medical devices and diagnostics. However, the same can be said for healthcare reform, an idea that received some support by an analyst for an investment bank during the CRT 201 sessions concluded earlier this week (see accompanying story).

Rick Wise, an equity research analyst with the investment bank of **Leerink Swann** (Boston), gave a Wall Street perspective on healthcare reform. "It won't come to you as a major surprise that bad news and uncertainty are not good for stock prices," he said.

Discussing the device makers who trade shares on Wall Street, Wise said, "historically these stock sold at a significant premium compared to" the Standard & Poor's 500 series of stocks, although these large cap firms' returns in 2009 aligned more or less with the S&P.

Wise said that as of three or four months ago, "I thought 2010 might be a better environment" due to a variety of factors, including the expectation that "sales growth should accelerate." He said that "earnings per share growth are expected to grow faster than sales" for a lot of Wall Street firms next year mainly thanks to management's emphasis on leaner operations.

All the same, "healthcare reform is still an overhang,"

Wise observed, adding that industry is "going to be on the hook for some kind of tax" if any sort of healthcare reform proposal makes its way to the Oval Office.

Another very prominent factor is that "the FDA environment is growing more complicated," but device makers – indeed U.S. firms in general – are starting to lose exports thanks in part to how the dollar is trading against foreign currencies. The dollar, "which I thought was going to be a positive, is going the wrong way again," Wise stated, a dynamic that may in part reflect the inability of some European economies to move into positive economic growth.

Addressing cardiovascular devices, Wise said, "The major large market . . . has stabilized, but growth is slow," an observation he said extends to orthopedics. And while the Massachusetts special election has thrown healthcare reform for a temporary loss, he said he is "fascinated that some people are convinced that nothing is going to happen on healthcare reform."

Wise said that the number of 510(k) clearances is down and that one industry source says clearance times have doubled of late. He also noted of mergers and acquisitions that there is "lots going on and more to come." One way or another, "companies are still going to grow," he said, including by "marketing more vigorously in other nations," but said it is difficult to predict how the market would behave between now and 2015.

– Mark McCarty, Washington Editor

CRT

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ence is continually evolving [and] devices are becoming more complex," adding that devices "are evolving faster than people are."

This high pace of evolution makes devices and diagnostics "unique among medical products" and forces CDRH to "change our course accordingly," Shuren said. Hence, CDRH will not change its approach to regulatory review "on an *ad hoc* basis," but Shuren seemed to forecast at least some continued unpredictability with the remark that he sees an "unavoidable tension between predictability and adaptability."

Among the speakers during the lunchtime session addressing issues related to healthcare reform was Sean Salmon, VP and general manager for **Medtronic Cardiovascular** (Minneapolis), who noted that the firm had prepared for reform only to watch it crumble last month. Still, he said, the idea is not necessarily kaput. "It certainly looks like a tall hurdle for anything to pass in the near term," he acknowledged, adding that even industry realizes that "the system we have today is unsustainable."

Salmon cited both the numbers of uninsured and the share of GDP that goes to healthcare as imperatives for reform, but described the current crop of healthcare reform proposals as "health insurance reform, largely." The issue of

how to pay for it all "gets into some interesting NIMBY [Not In My Back Yard] issues," he observed, adding that for the device industry "that excise tax . . . on top of Medicare cuts" will force lower prices, which he said is an almost a certain outcome in the long run in any event.

Another point of pressure for industry, Salmon added, is that "it doesn't appear that the increased number of patients coming into the insured pool will offset" the device tax and the proposed Medicare cuts.

Salmon said that bundling is a practice Medtronic supports "as long as we don't have a disincentive" to use the appropriate technology, and said that most devices offer a good economic argument, even if a couple of iterations have to pass before some of those values surface in a particular design. He said that the cost of therapy for implantable cardioverter defibrillators "has come down dramatically," even as those units shrank physically as well.

As for physician payment sunshine, Salmon said, Medtronic supports federal government involvement even if only because "it's going to preempt state level reporting."

Salmon observed that the driver for innovation has traditionally been "necessity or unmet need," but that innovation was always fueled by capital. "We can see record declines in venture funding," which he said translates into an environment in which "getting funding . . . is nearly impossible." He added that the **National Venture Capital**

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Association (Arlington, Virginia) recently reported a 27% reduction in venture capital for devices.

"I believe that medical devices can be part of the solution" Salmon said of the healthcare spending problem, closing with the remark, "it's just a matter of using your imagination."

Steve Nissen, MD, of the **Cleveland Clinic** (Cleveland), highlighted "how bad a pickle we're in" where U.S. healthcare spending is concerned. The frequent critic of the pharmaceutical industry said that a comparison with other OECD (Organization for Economic Cooperation and Development) nations shows that the U.S. spends \$650 billion too much, adding that if healthcare reform "does put a chill in innovation, you have to understand we put ourselves [in this situation] by our behavior."

Life expectancy comparisons do not suggest that Americans are getting much bang for the buck, Nissen hinted, adding, "we're a little better than Greece and Mexico" in terms of longevity, but otherwise the U.S. still compares poorly to most other nations in the spending/outcomes dynamic.

Nissen said drug overspending comes to \$90 billion a year and pegged the figure for devices at \$26 billion a year. "It's primarily over-utilization" that drives excess healthcare costs, "and medical devices are part of the problem," he said, adding that Americans are "twice as likely to get" percutaneous interventional treatments than the European average and "more likely to get knee replacements." As for how innovation is financed, he said "it's our patients who are supporting it."

"Why is there reform coming? Because we cannot afford to continue to do this and insure all our citizens," Nissen charged. Reimbursement "is what drives over-utilization," he said, adding that cuts to Medicare spending are the only mechanism that can trim the Medicare budget. The U.S. government, he claimed, "really has no other options."

On insurance and administration, Nissen claimed, "we spend \$85 billion more than we should," which "amounts to about 29 cents on every dollar." By comparison, Medicare's administrative overhead is about 3%, he stated, a figure that has been disputed recently. "I think that the regulatory system needs an overhaul," Nissen argued, claiming that "the vast majority of 510(k) approvals" do not meet the regulatory standards for approvals, but offered no explanation for this statement other than to note that Congress "never intended the 510(k) program to be used the way it's used today."

"Fundamentally, they have a back-door approval process," Nissen alleged, which he said has evolved "to the point where it's the primary way devices get approved." He said that intravascular ultrasound was cleared rather than approved via a PMA "because it was [purportedly] just like measuring pressure in the coronary arteries" via another

technology. He argued that there is "considerable evidence that 510(k) devices are much more likely to be recalled" than PMAs, and made the case for an approach to new device development that would result in devices that are good enough rather than superlative.

Panelist Bill Maisel, MD, of **Beth Israel Deaconess Medical Center** and the **Medical Device Safety Institute** (both Boston) said of Nissen's remark about devices that are good enough: "The concept of [such devices] being the future of U.S. healthcare is not going to fly." He argued that no doctors "will purposely pick up a device that offers less for that patient," asserting, "we need to get better at bringing products" to markets with less expense. "We need to do better with bench testing," for example, which will require "figuring out where it's useful and where it's not."

Nissen said in response, "I think it's great to have fancy and expensive devices that do more," but "where's the evidence? That's the reason for CE research." He called for "more studies on 'are there patients who will do just as well?'" with the less expensive devices. ■

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Court report

Medtronic hit with whistleblower suit for off-label use of stents

A Medical Device Daily Staff Report

A lawsuit has been filed in the U.S. District Court for Massachusetts against **Medtronic** (Minneapolis), which accuses the company of purposefully promoting the off-label use of biliary stents to treat cardiovascular conditions, according to the *Massachusetts Medical Devices Journal (MMDJ)*.

"Medtronic is aware of the complaint and intends to vigorously dispute its allegations, including filing a motion to dismiss at the outset of the case," Charles Grothaus, senior manager, corporate public relations at Medtronic, told *Medical Device Daily*. "We don't comment on any specific allegations, but William Hawkins [chairman/CEO] is well known in the industry for his leadership in advocating and supporting ethical business practices."

According to the *MMDJ* report, two former Medtronic employees filed what is being labeled a whistleblower suit on behalf of the U.S. government, 22 states and the District of Columbia. The lawsuit alleges that Medtronic retaliated against the two employees – Tricia Nowak, a sales representative, and Enda Dodd, a senior research manager – and fired them after they objected to the off-label promotions.

Late last year several lawsuits against Medtronic, stemming from the October 2007 recall of the company's Sprint Fidelis defibrillator leads, were dismissed (*Medical Device* See Court, Page 7

Tuberculosis

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appears that Menssana is well on its way to developing a similar test to detect active pulmonary tuberculosis (TB). A study that will soon be published in the journal *Tuberculosis* shows that the new breath test can detect active pulmonary TB.

Phillips said the breath test was 85% accurate in detecting patients with active pulmonary tuberculosis in a study of 226 patients in San Diego, London and the Philippines. The patients in the study were symptomatic patients at high risk for TB, he noted. The **National Institutes of Health** funded the study, said Phillips, who in addition to being the founder/CEO of Menssana is also a professor of clinical medicine at **New York Medical College** (Valhalla, New York).

This wasn't the first time the NIH had supported Menssana's research in this area. Prior to the most recent study, the agency awarded the company a Phase I SBIR grant to test the feasibility of the idea. During that study, the company analyzed breath volatile organic compounds (VOCs) in hospitalized patients who were being screened for pulmonary TB at **New York University Medical Center**. Menssana also analyzed the VOCs made by Mycobacteria grown in the laboratory at **Saint Vincents Medical Center** (New York). The feasibility study showed that breath biomarkers of oxidative stress clearly distinguished between the "sick" hospitalized patients and normal controls. Also, breath VOCs accurately identified the patients whose sputum samples grew Mycobacteria – the VOC biomarkers in breath and in sputum cultures were very similar, according to the company.

"We were delighted and surprised to see" such results, Phillips said. It was based on these findings that the NIH awarded Menssana a Phase II SBIR grant to validate the breath test for pulmonary TB in this most recent, larger multicenter international study.

Phillips said the test appears to detect volatile organic compounds made by the infecting organism that causes the disease, Mycobacterium tuberculosis. He said the test detects a signal from Mycobacteria in the lungs, and thus is "probably a better test than skin tests or a blood test for tuberculosis that measures the body's immune response to infection."

Another advantage is that the breath test is safe, painless, and non-invasive, as a patient breathes gently for two minutes for a sample collection, Menssana noted.

According to the study, the researchers used a portable breath collection apparatus (BCA) to capture the VOCs in 1.0 liters breath and 1.0 liters room air on to separate sorbent traps. The geometry of the breath reservoir of the BCA ensured that the sample comprised greater than 99% alveolar breath. Subjects wore a nose-clip and respired normally for 2 minutes through a disposable and previously unused valved mouthpiece with a bacterial filter to prevent

Mycobacterial contamination of the instrument. The mouthpiece and filter presented low resistance to respiration, ensuring that samples were collected without discomfort to patients, the authors wrote.

The company said the breath test might offer a new way to detect tuberculosis, a major cause of death, especially in developing countries.

"Essentially the diagnosis of tuberculosis has not really changed in the last 50 years, which is amazing when you think about it," Phillips told MDD. He said one reason the technology for TB has not advanced much in recent history is because it is not a very common disease in developed countries, such as the U.S. However, he noted that the disease is making somewhat of a comeback because of the immigrant population and others who are high risk for TB, such as those with HIV or AIDS.

"For years doctors have diagnosed tuberculosis with a chest X-ray or sputum culture or sputum microscopy," Phillips said. "These are okay as far as they go, but they've got severe limitations."

He added that these tests often produce false negative results and, especially with chest X-rays, a lot of false positives as well. "So you can't always trust the results," he said.

Phillips emphasized the urgent need for better diagnostic technology for TB, especially in less developed countries, because the treatments for the disease exist. It's just a matter of determining accurately whether or not a patient has it, he said.

Menssana has been developing its breath test technology since the 1980s and has been working on the TB indication for about five years, Phillips said.

One limitation with the breath test techniques Menssana has been using so far is that they are laboratory-based and use expensive instruments, Phillips said. "The methods we're using are really too slow and too expensive for clinical use," he said.

But that will hopefully change soon, he added. The U.S. Air Force recently awarded Menssana a contract to evaluate a new point-of-care breath test for pulmonary TB, studying patients in Africa, Great Britain and the Philippines. If successful, a patient could learn within minutes whether they are infected with tuberculosis, the company said.

Phillips hopes that physicians and patients will eventually consider a breath test in the same way as they now think of a chest X-ray or a blood test: as an inexpensive and convenient screening test which can detect several diseases in their earliest and most treatable stages.

Menssana is also developing breath tests for several other diseases, the company noted, including lung cancer, breast cancer, and ischemic heart disease.

"The platform of breath testing can be applied right across the board for many type of diseases," Phillips said. ■

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Robot

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nia) for repairing the blockage.

"What we found was that for patient's that underwent the robotic assistance the hospital stays were shorter, and recovery periods were much faster," Hemal told *Medical Device Daily*.

Hemal said that following the patients for 18 months showed that both options were equally successful, but the robot-assisted technique had several advantages.

The first advantage was the time it took for the procedure to be completed.

In the study, procedures using the robotic assistance tool were done within 98 minutes with blood loss of about 40ml. The laparoscopic procedure took 145 minutes with an estimated blood loss of 101 ml.

But Hemal said perhaps the biggest advantage for surgeons is the relative ease of the robot-assisted procedure.

"The number one advantage for this procedure is that the learning curve is very small for surgeons," Hemal told *MDD*. "It's also faster and more efficient to use."

According to Hemal's report, the robotic pyeloplasty was performed using a transperitoneal transmesocolic approach on the left side and via retrocolic access on the right side by reflecting the ascending colon. Robotic pyeloplasty was performed through 4 ports. A 12 mm port was placed at the umbilicus or periumbilically for the stereoscopic robotic camera, and two 8 mm robotic ports were placed in the midclavicular line. A 5 mm trocar port for retraction, suction, and suture cutting was placed infraumbilically in the midline or on the contralateral side.

The type of repair depended on the size of the pelvis, length of the UP structure, presence of a crossing vessel, and the degree of renal function.

Robotic assistance was used from the outset to dissect and mobilize the colon, ureter, and renal pelvis. It was also used for reconstruction of the flaps, for neo-UPJ anastomoses, and for antegrade double-J stenting.

In one case, a retrograde stent was placed beforehand, and in three cases, anastomosis was done without a stent. A drainage tube was placed in all cases prior to port closure.

Hemal added that the 3-dimensional view the daVinci surgical system gives the user is more accurate and precise which is one of the reasons the robot-assisted technique yielded far greater results.

"It gives you a depth perception that you were unable to have in previous techniques," Hemdal said. "That's what makes the procedure easier to use."

Researchers in the study are saying this is one of the first in which a surgeon with expertise in both options compared the two procedures.

Previously the repair required a large incision. New technology led to minimally invasive approaches that require only small incisions – laparoscopic surgery, in

which the surgeon directly manipulates a viewing device and operating instruments inserted into the abdomen, and robot-assisted surgery, in which the surgeon sits at a console and uses hand and finger movements to control centimeter-size instruments while viewing the surgical site on a screen.

"There are no real disadvantages to using the daVinci," Hemal told *MDD*. "The robot is expensive, that might be a disadvantage. But for the most part this is a very beneficial procedure for patients." ■

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Court

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Daily, Oct. 29, 2009). Earlier in the year, a Massachusetts district court dismissed a government fraud case that alleged device distributors of giving kickbacks to doctors who used Medtronic products (*MDD*, April 6, 2009).

The whistleblower claims are brought under the False Claims Act in 2007

In other legal news, **Robbins Umeda** (San Diego) has begun investigating possible mismanagement of **Stryker** (Kalamazoo, Michigan).

Robbins Umeda's investigation of Stryker concerns questionable statements issued by the company between Jan. 25, 2007 and Nov. 13, 2008, regarding its business success and profitability as well as whether the company cut corners on its operational costs by failing to document and maintain adequate quality controls over the products it manufactured. Company insiders allegedly took advantage of the stock's 52-week high of \$75 per share (split-adjusted) in November 2007, when they sold their personally-held shares generating more than \$300 million in proceeds prior to the stock's 52% decline to \$36.11 on November 20, 2008, according to Robbins Umeda.

A lawsuit alleging violations of the Securities Exchange Act of 1934 has been filed on behalf of shareholders who purchased or otherwise acquired Stryker stock between Jan. 25, 2007 and Nov. 13, 2008, seeking recovery from Stryker and certain of its officers for the damages they have suffered as a result of the officers' mismanagement of the company. Securities class actions like this can potentially cause additional damage to the company. ■

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Telemedicine

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mate goal for changing the healthcare system. We hope as we do this that we'll also improve clinical outcomes. If we can do that and reduce unnecessary medical expenses, then that's the grand prize."

The study centers on the use of a computer tablet-like device designed to promote patient engagement and more efficient care by combining the in-home patient device with an online interface allowing clinicians to monitor patients and remotely manage care.

"We brought the Intel Health Guide to the marketplace in 2008; it's a remote patient monitoring technology for the home. We're trying to find ways for technology to reduce the cost of care and improve the quality of healthcare," Ray Askew, **Intel** (Santa Clara, California) Health Guide marketing manager told *MDD*. "There have to be ways to reduce the number of hospital visits and bring care to places where patients are more comfortable."

The Intel Health Guide was FDA cleared and commercially launched in 2008.

"Intel Health Guide allows users to receive messages from care providers and includes medication or other reminders, as well as the ability to visually interact with care providers," Askew said. "The care programs can be as specific as weight measurements, or it can issue a survey, such as 'How are you feeling?' or as basic as diet reminders, such as 'Eat an apple today and avoid Twinkies.'"

Patients with heart failure, for example, may get reminded to check their weight and blood pressure each day. The standalone computing device then automatically relays that data to the healthcare provider. It can also play patient education videos.

The 12-inch computer tablet has a touch screen that rotates and can be installed on virtually any type of surface. After that, no maintenance is required by the user.

GE Healthcare (Waukesha, Wisconsin) also is a partner in this effort to develop new patient-centered delivery care models. With the number of seniors expected to rise dramatically and increasing numbers of patients experiencing chronic disease, the current focus on face-to-face clinic interaction with the provider is not a sustainable delivery model, according to GE. Technology could enable new care models to help rein in costs and improve patient outcomes through personalized care and ongoing disease management at home and in the community.

Mayo Clinic will conduct a year-long study to determine if home monitoring of patients with chronic diseases will reduce hospitalizations and emergency department (ED) visits. The study will include 200 high-risk Mayo Clinic patients over the age of 60 who receive care in Rochester, Minnesota. The goal is to evaluate the effectiveness of daily in-home monitoring technology in reducing hospitalizations and ED visits compared with

usual medical care.

Hanson said that patients were chosen from a database that was developed to track previous hospitalizations. They have a mix of health problems ranging from heart failure to chronic obstructive pulmonary disease. The top 10% of patients at risk for rehospitalization were chosen. In addition to tracking the patients' care, the study will examine the economic impact of telemedicine.

"It's going to be challenging," he said. "We're interested in summing up the economic costs of the technology and the clinical infrastructure needed for monitoring balanced against reduced hospitalizations and emergency department visits. We'll look at both sides of the equation."

Mayo built a special practice to support the study by hiring three mid-level nurse practitioners who specialize in geriatrics from within the Mayo staff along with several RNs with geriatric experience. The group is housed in a room that's outfitted to monitor the patient.

Patients will be instructed to measure their vital signs such as blood pressure, pulse and weight, and respond to questions specific to their diseases on a daily basis, with all data reviewed by the clinical care team working with their primary care provider.

The technology, which includes videoconferencing capability, allows the care team to assess the patient for signs and symptoms suggesting clinical deterioration to facilitate early medical intervention. The hope is that early recognition and treatment of a change in clinical status will reduce the need for ED visits and hospitalizations.

GE Healthcare and Intel first reported their joint efforts to market and develop technologies for independent living and chronic disease management and to extend care from the hospital to the home in April 2009. The two companies plan to invest \$250 million over the next five years for the research and product development of home-based health technologies. In addition, GE Healthcare is selling and marketing the Intel Health Guide in the U.S. and the UK.

Telemedicine, both the idea and ensuing technologies have been around for a long time, but they have yet to reach the mainstream. Hanson said it's going to be important to demonstrate that the technology and efforts improve outcomes, and do so in a cost-efficient manner.

The 40 patients who have been enrolled so far are doing a good job of adapting, Hanson said.

"Once they get used to the equipment, they enjoy it," he said. "They like the extra contact and the reassurance that 'Someone is keeping an eye on me.' I suspect at the end of study, some folks will be disappointed because they do become enamored of it." ■

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International

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for the same price. Upon the completion of these two transactions, the company's financial ownership percentage in the j-v partnership remained unchanged at 85.6%. Concurrent with the sale to the new partner, the partnership agreement for the Ontario, Canada j-v was amended and restated with substantially the same terms as the previous agreement, LabCorp noted.

PPD opens offices in Philippines and India

PPD (Wilmington, North Carolina), a contract research organization (CRO), said it has opened offices in Manila, Philippines, and Bangalore, India, expanding its Phase II-IV clinical development services in response to growing client demand in Asia Pacific. PPD said it would provide clinical management services in key therapeutic areas from both locations.

PPD noted that it recently expanded in this region through its acquisitions of **Excel**, a CRO in China, and **Bio-Duro**, a drug discovery outsourcing company.

"With 90 million people living in the Philippines and more than 20 million in Manila, there is enthusiasm for local expansion and involvement in clinical trials," said Lesley Gerrard, director of clinical management in PPD's Melbourne, Australia, office. "The recent opening of the Manila office demonstrates PPD's commitment to the growth and development of emerging markets in Southeast Asia and to further exploration of the opportunities that exist within this region."

Denzel Benjamin, director of clinical management in PPD's Bangalore office, added, "India is expected to conduct nearly 5% of global trials by 2010, and the opening of our Bangalore office advances our plans for expansion in India. This office provides us easy access to all of our sites across south India, which means cost savings for our clients and greater efficiencies for PPD."

Sanmina-SCI's Hungary facility gets ISO

Sanmina-SCI (San Jose, California), a global electronics manufacturing services company, said its Tatabanya, Hungary facility has received ISO 13485 certification for medical device manufacturing.

ISO 13485 is an internationally recognized standard developed to ensure that companies provide medical devices that consistently meet regulatory requirements. In order to obtain the certification, Sanmina-SCI demonstrated the ability to consistently meet strict requirements for quality management systems applicable to medical device manufacturing and related services, the company noted.

"Sanmina-SCI's Tatabanya manufacturing facility has more than 10 years experience serving medical, industrial and telecommunications customers," said Dietmar Gunther, executive VP of the company's European operations.

"Receiving this key certification for medical device manufacturing opens new opportunities for our strategic customers looking for lower-cost and quality solutions in this region." ■

Financings roundup

MicroTransponder in \$7 million funding round; gets U44 grant

A Medical Device Daily Staff Report

MicroTransponder (Austin) reported a \$7 million Series B round of funding. MicroTransponder is developing a wireless neurostimulation platform for the treatment of chronic pain and other neurological indications.

In addition, the company is reporting that it has been awarded a \$2.6 million NINDS SBIR FastTrack U44 grant, which is a milestone-driven cooperative agreement to support pre-clinical validation of devices for the treatment of neuropathic pain and manufacturing scale-up. "The support from the NINDS has been essential to the bringing this technology closer to regulatory clearance," said CEO Will Rosellini.

The company said this funding has allowed it to hire premier clinical and regulatory expertise and to prepare a series of clinical trials and regulatory filings on their initial product, the Saint System for chronic pain. Evan Rosenfeld, MD, joins the company from Bioness, where he was chief medical officer and VP of medical & regulatory affairs. He directed all clinical, regulatory, and reimbursement activities for various external and implantable neurostimulation devices. Brent Tarver brings more than 20 years of experience in clinical studies focused on medical devices. Most recently, he oversaw the product development and clinical study efforts at OrthoAccel Technologies.

"We continue to focus on hiring the top neurostimulation talent," said Rosellini. "Dr. Evan Rosenfeld has extensive clinical and regulatory expertise in the field of neurostimulation and chronic pain. Brent Tarver was part of the initial core team that brought neurostimulation therapy for the treatment of epilepsy from concept to bedside. Both individuals will drive our aggressive clinical and regulatory program to demonstrate the clinical utility of wireless neurostimulation." The Series B round of funding consisted of existing Series A investors and new angel investors. ■

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Product Briefs

- **MedQuist** (Mt. Laurel, New Jersey) has introduced the MedQuist Performance Monitor (MPM). The MPM reporting tool provides MedQuist customer facilities with physician, worktype and facility detailed reporting to monitor, track and optimize their clinical reporting process. Medquist says the MPM offers a value-added benefit for transcription outsourcing customers who use the DocQment Enterprise Platform, and is robust and relevant enough to meet The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards. As a reporting tool, the MPM produces meaningful, actionable information, including turnaround time compliance, worktype and dictator statistics, performance trends, and quality indicators. MedQuist COO Michael Clark said, "Consistent with MedQuist's leadership in driving toward transparency within the industry, customers who contract with us for transcription work can see, clearly and concisely, how their outsourced service and physicians are performing. MedQuist's assigned Customer Care Managers review the MPM reports with their customers on a regular basis, and offer best practices, continuous process improvement advice, information and tools to help maximize document quality, data efficiency, and service delivery consistency and compliance, for optimal patient care."

- The Enterprise Mobility Solutions business of **Motorola** (Schaumburg, Illinois) said that Peleton Systems, a systems integrator and member of Motorola's channel partner program, has deployed its enterprise mobility solution at ArchCare, the Continuing Care Community of the Archdiocese of New York. Motorola's solution combines wireless LAN (WLAN) infrastructure with its field-proven MC70 Enterprise Digital Assistants (EDA) to support ArchCare's transition to an electronic medical record (EMR) system. ArchCare provides a wide range of managed care and community services for over 5,000 nursing home residents in the Greater New York City area. Motorola's WLAN infrastructure enables ArchCare staff to leverage MC70 EDAs for mobile access to EMR software and patient data at the bedside.

- **Small Bone Innovations** (SBI; New York) said that it has received FDA clearances for the Mini-Rail Fixation System and large Cannulated Screw System for use in lower limb reconstruction and repair procedures. SBI expects its Mini-Rail System to be used in common procedures such as first MTP (metatarsophalangeal) joint arthrodesis and distraction, subtalar fusion, and Jones fracture management. The Mini-Rail System is a highly adjustable fixation system that lets surgeons quickly achieve optimal placement in the bones of fixation "half" pins. The system's ease of use can decrease OR time. The

Mini-Rail System was launched following a series of extensive evaluations by U.S. foot and ankle surgeons.

- **Teleflex Medical** (Research Triangle Park, North Carolina) reported the introduction of the Teleflex ISIS HVT, the first convertible endotracheal tube. The Teleflex ISIS HVT features an integrated suction port and separate suction line allowing for subglottic secretion suctioning on demand. When needed, the suction tube attaches to the Teleflex ISIS HVT via a secure locking connection. Both connection ports can be sealed upon disconnection, reducing the risk of cross-contamination when not in use. This design allows for use of one endotracheal tube to meet the needs of patients requiring both short- and long-term ventilation. Teleflex says the ISIS eliminates many of the common objections to using traditional subglottic secretion suctioning (SGS) tubes, which can be up to seven times more expensive than standard tubes. Patients who need access to SGS often are not intubated with the appropriate tube, and approximately 20% of patients will require long-term ventilation. It is difficult to predict which patients will require long-term intubation, and if a SGS tube is not used at initial intubation, the patient must be extubated and reintubated, which disturbs the airway. ISIS solves this problem in a cost-effective manner. The attachment for subglottic suctioning is used—and paid for—only when needed.

People in the News

- Richard Falcone has been named president/CEO of **Aquamer Medical** (Lawrence, Massachusetts). Falcone was previously the CFO of Bed, Bath & Beyond. Aquamer is a company focused on early stage innovative technology development.

- **Medtronic** (Minneapolis) said that William Hawkins, chairman/CEO, has been elected a Fellow of the American Institute of Medical and Biological Engineering (AIMBE). AIMBE Fellows are recognized for their outstanding achievements in medical and biological engineering. Hawkins was named CEO of Medtronic in 2007 and assumed the additional role of chairman in 2008. He joined Medtronic in 2002 as senior VP and president of the company's Vascular business before serving as president and COO. The AIMBE was founded in 1991 to establish a clear and comprehensive identity for the field of medical and biological engineering.

- **NxStage Medical** (Lawrence, Massachusetts) said that Elise Tordella was named VP/GM of Critical Care Therapies. Previously, Tordella was VP of global marketing for patient care at Covidien. NxStage Medical makes dialysis products.

MDD'S ORTHO EXTRA

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

THURSDAY, FEBRUARY 25, 2010

PAGE 1 OF 2

Keeping you up to date on recent developments in orthopedics.

Controversial studies trigger drop off in osteoporosis treatment . . . Angelo Malamis, MD, an assistant professor in the Department of Radiology at **Loyola University Chicago** Stritch School of Medicine, says that 90% of his patients who have undergone a treatment called balloon kyphoplasty for vertebral fractures report significant reductions in pain and disability. But the number of kyphoplasty referrals Malamis has received from primary care doctors has dropped sharply since two controversial studies were published last year in the *New England Journal of Medicine*. In findings that have been disputed by two medical societies, researchers reported that a procedure related to kyphoplasty was not significantly better than a placebo-like procedure in reducing pain and disability. The **North American Spine Society** (Burr Ridge, Illinois) and the **Society of Interventional Radiology** (Fairfax, Virginia) have pointed to flaws in both studies. And earlier studies, published over 15 years, found major benefits to kyphoplasty and a related procedure called vertebroplasty. "We're missing opportunities for patients to receive a safe and effective treatment that can significantly reduce their pain and disability," said Malamis, an interventional radiologist. The procedures are used to treat vertebral compression fractures in patients with osteoporosis and other conditions that result in brittle bones. In a vertebroplasty, an acrylic cement is injected into a fractured vertebra. In a kyphoplasty, a balloon-tipped catheter first is inserted into the fracture. The balloon is inflated to restore the height and shape of the vertebra before the cement is injected. In the controversial studies, patients were randomly assigned to receive a vertebroplasty or a placebo-like "sham" procedure. In the sham procedure, patients received an injection of anesthetic, but no cement. However, patients in severe pain are reluctant to enroll in a trial where there's a 50% chance of receiving a sham treatment. In one of the studies, researchers had to screen 1,813 patients to enroll just 131 subjects. In the other study, only 78 of 219 eligible patients were enrolled. This low enrollment rate raises the possibility that the patients who did enroll were not representative. Patients experience the greatest pain during the first three months after a compression fracture. Thereafter, pain gradually subsides. Thus, a vertebroplasty or kyphoplasty provides the greatest benefit when performed within a week or two of the fracture. But the studies enrolled patients up to 12 months after fractures. In addition to reducing pain and disability, a kyphoplasty can reduce the risk of subsequent fractures by improving the angle and height of the spine. The studies evaluated vertebroplasty alone, and did not include the more innovative and very different kyphoplasty procedure.

BioMimetic Therapeutics completes Augment bone graft PMA submission. . .

BioMimetic Therapeutics (Franklin, Tennessee) reported that it has submitted the third and final module of its PMA application for marketing of Augment bone graft in the U.S. This final module, containing a comprehensive review of the clinical data related to Augment, completes the PMA application to the FDA. The company previously reported the filing of both the pre-clinical pharmacology/toxicology and quality/manufacturing modules with the FDA in June of 2009. Upon receipt of the clinical module, the FDA begins its 45 day filing process as the first step in the formal review of the PMA. The company expects the agency to schedule an advisory panel review sometime later in the year. "The Augment PMA submission is an important milestone for BioMimetic and our commitment to advance first-in-class, innovative biologics that stimulate tissue regeneration in bone, ligaments and tendons," said Dr. Samuel Lynch, president/CEO of BioMimetic. "We are very encouraged by the results seen to date in Augment's clinical development program and look forward to working with the FDA to facilitate the review and approval of this novel therapeutic."

Multi-Center data show vertebroplasty provides pain relief for vertebral compression fractures . . .

The results of a study of more than 4,500 patients from six Italian EVEREST (European Vertebroplasty Research Team) Centers (Dr. G.C. Anselmetti-Candiolo Torino, Dr. G. Bonaldi-Bergamo, Dr. P. Carpeggiani-Pisa, Dr. S. Masala-Roma, Dr. M. Muto-Napoli,) confirms the effectiveness of vertebroplasty in treating vertebral compression fractures (VCFs), finding that the procedure provides significant and sustained pain relief. Patients had immediate relief of back pain and were able to discontinue taking analgesics immediately following the procedure. Vertebroplasty is indicated for painful VCFs that fail to respond to conventional medical therapy, such as minimal or no pain relief with medication or narcotic doses that are intolerable. "In our large series of patients, vertebroplasty proved to be a safe and effective treatment, resulting in same day, dramatic improvement in pain," said Stefano Marcia, M.D., interventional radiologist

at **San Giovanni di Dio Hospital** (Cagliari, Italy). In the study, Marcia and his colleagues retrospectively evaluated the clinical outcomes of vertebroplasty in 3,211 women and 1,336 men treated in six different EVEREST centers. The patients were affected by severe painful osteoporosis, painful vertebral tumors (metastases or myeloma) with high risk of fracture and symptomatic vertebral angioma. Inclusion criteria were VCF with bone edema on MRI, local back pain with single-point pressure on examination, and poor or no response to medical therapy. The average number of VCFs treated with vertebroplasty in the same patient was three, for a total of 13,437 fractures. Within 48 hours, 4,004 of the 4,547 patients (88.06%) experienced clinically significant pain relief, with an average VAS score of 2 and an average difference from baseline of 5.5 to 6. The mean difference in VAS scores was $P < .0001$. The pain remained improved at each follow-up evaluation up to 12 months. No major neurologic complications were encountered. Venous leakage was the most frequent mild one (20.5%). The data add to the growing body of evidence that demonstrates vertebroplasty is a safe and effective treatment with a low complication rate. Vertebroplasty is widely available in the U.S. and is covered by Medicare and most private insurers. Marcia noted that the study demonstrates that vertebroplasty does not increase the risk of fracture in nearby vertebra. Of the 4,547 patients treated, only 430 (13%) were retreated for a subsequent fracture. In 302 of those 430 patients (70.2%), the new fracture occurred in the contiguous vertebra.

New pain management approaches reduce pain, speed recovery for knee or hip replacement . . .

Patients undergoing knee or hip replacements recover more quickly when treated with targeted pain-blocking medications that may eliminate the need for general anesthesia during surgery and intravenous narcotics drugs after surgery. The February issue of *Mayo Clinic Health Letter* explains the newer pain management options and their benefits. A decade ago, patients undergoing hip or knee replacements were almost exclusively given general anesthesia during surgery and intravenous narcotic pain medications afterward. This approach works for most people and still is commonly practiced. But both general anesthesia and intravenous narcotic drugs can cause nausea, vomiting, grogginess, decreased bowel function and other side effects. In the early 2000s, Mayo Clinic anesthesiologists began developing new anesthesia protocols for joint replacement surgery that used known anesthetic and pain relief techniques in new combinations. Their goal was to eliminate the need for general anesthesia and intravenous narcotics and the resulting side effects. The new procedures may vary but typically involve:

A choice: Even with the new protocols, patients may choose regional anesthesia, where the lower half of the body is numbed, or general anesthesia.

Oral pain medications early on: A combination of oral narcotic pain medications are given prior to surgery. Oral narcotics have fewer side effects than narcotics given intravenously. This technique is helpful for recovery whether general or regional anesthesia is used.

Sedation: Sedative drugs given before surgery help patients using regional anesthesia nap during the procedure, but not lose consciousness.

Nerve blocks: Through a catheter, a continuous infusion of numbing medicine is pumped near the surgery site for 48 hours. Nerve blocks are performed in conjunction with general or regional anesthesia.

Oral pain medications after surgery: For more than 95% of patients, pain that occurs after the nerve blocks are removed can be managed with oral pain medications such as acetaminophen (Tylenol, others), tramadol (Ultram, others) or oxycodone. Intravenous narcotic medications are used as a last resort.

Patients who receive regional anesthesia report significantly less pain after surgery than those receiving general anesthesia and intravenous narcotics. These patients are out of bed sooner, begin physical therapy sooner and leave the hospital one to two days before patients who were given general anesthesia and intravenous narcotics. With the newer protocols, patients may still experience typical side effects including nausea and vomiting, but to a lesser degree than with the older anesthesia methods.

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