



### Washington roundup

## Shuren: user fee schedule to be affected by 510(k) review

By MARK McCARTY

*Medical Device Daily Washington Editor*

Negotiations between industry and FDA are about to commence for the next round of medical device user fees, but the process for this round is already different from that of the first two iterations in that the agency held a public meeting on the subject. Jeff Shuren, MD, director of the Center for Devices and Radiological Health at FDA, advised attendees that review times for 510(k) filings may be affected by the ongoing restructuring of the device clearance process, but he also said the agency is interested in feedback from all stakeholders, one of which argued that user fees are too low.

Shuren said the user fee program has allowed reviewers "to reduce the time it takes to review 510(k) submissions"  
*See Washington, Page 6*

### Agreements/contracts

## DSM continues Spinelab partnership for Bionate PCU

By AMANDA PEDERSEN

*Medical Device Daily Senior Staff Writer*

**DSM Biomedical** (Geleen, the Netherlands) and its operation **DSM PTG** (Berkeley, California) said it has extended its partnership with **Spinelab** (Winterthur, Switzerland), a company developing a dynamic stabilization system for the spine.

Spinelab's Elaspine implant system, a pedicle-screw based posterior motion preservation system for the degenerative lumbar spine, uses Bionate PCU, a proprietary DSM Biomedical polymer with optional built-in surface modification, designed for chronic implants and extensively used in orthopedic applications for its tough, load bearing qualities, the company noted. The implant system also marks the first clinical use of a PCU-only posterior rod.  
*See Agreements, Page 7*

### Report from Europe

## Varian proton therapy center treats 1st complex lung cancers

By JOHN BROSKY

*Medical Device Daily European Editor*

The **Rinecker Proton Therapy Center** (RPTC; Munich, Germany) reports encouraging preliminary results for a novel treatment of lung cancer using the proton therapy systems supplied by **Varian Medical Systems** (Palo Alto, California).

Delivering the advanced therapy marks a significant clinical milestone for the center and for the emerging business unit of Varian comes as a welcome validation for its long struggle to bring online Europe's first commercial proton therapy facility.

In Munich, a large tumor in the right upper lung of a 75-year-old patient was reduced by 50% thanks to 18 proton  
*See Europe, Page 8*

## Cardio3KG distinguishes between old, new LBBB

By OMAR FORD

*Medical Device Daily Staff Writer*

Patients who have signs of a myocardial infarction (MI) frequently have a 12-lead ECG abnormality known as left bundle branch block (LBBB). The condition makes it virtually impossible to read the ECG for signs of an acute heart attack and often result in the patient being taken for invasive interventional procedures.

In the LBBB condition, activation of the left ventricle is delayed, which results in the left ventricle contracting later than the right ventricle.

The problem is that if the LBBB is old and unrelated to the patient's current condition, then those invasive procedures can be avoided. But physicians find themselves in a difficult position since they don't have an accurate  
*See NewCardio, Page 9*

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TRYTON RAISES \$20 MILLION IN 'D' ROUND FOR U.S. TRIAL .....	2
MEDASSETS TO BUY BROADLANE GROUP FOR \$850 MILLION IN CASH .....	3



*Financings roundup***Tryton raises \$20M in 'D' round for U.S. trial****A Medical Device Daily Staff Report**

**Tryton Medical** (Durham, North Carolina) said it has closed a \$20 million Series D round of financing.

Arnerich Massena led the round, which also included current investors PTV Sciences, RiverVest Venture Partners and Spray Venture Partners.

Greg Davis, president/CEO of Tryton, said the new funds will enable the company to conduct its U.S. pivotal trial and drive product adoption internationally. Tryton's Side Branch Stent System is approved for sale in Europe for the treatment of bifurcation lesions.

"We are pleased to welcome Arnerich Massena to our distinguished investor group," Davis said.

The Tryton Side Branch Stent System is designed to offer a dedicated strategy for treating atherosclerotic lesions in the side branch at the site of a bifurcation. Tryton's highly deliverable balloon-expandable cobalt chromium stent is deployed in the side branch artery using a standard single-wire stent delivery system. A conventional drug-eluting stent is then placed in the main vessel.

The system demonstrated "excellent" six-month clinical and angiographic results in a first-in-man study of the system and excellent six-month clinical results from almost 200 patients in four different registries with a rate of target lesion revascularization of less than 4%, Tryton noted.

In other financing news:

- **NanoPass Technologies** (Rehovot, Israel), a company that develops microneedle solutions for "painless"

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

*"Imagine a door closed and that you might hear some voices behind it, but you really can't tell who's on the other side. You know there is someone there, but you don't know who. This is the mystery LBBB presents to physicians."*

– Ihor Gussak, MD, PhD, CMO and VP of NewCardio, on the difficulty of distinguishing old and new left bundle branch block, "Cardio3KG distinguishes between old, new LBBB," pp. 1, 9.

delivery of drugs and vaccines said it has recently secured a strategic investment and manufacturing agreement with **Elcam Medical** (Bar'Am Israel), a medical device maker. Existing investors including Ofer Hi Tech and D Partners, also participated in the round.

Ehud Raivitz, Elcam's CEO, and Ilan Neugarten of D Partners, will join NanoPass's board.

The company noted that the investment will allow it to develop additional pharmaceutical clients and prepare for market launch.

- **Laboratory Corporation of America** (LabCorp; Burlington, North Carolina) reported that for the period of Sept. 12, 2010 to March 11, 2011, its zero coupon convertible subordinated notes due 2021 will, subject to the terms of the notes, accrue contingent cash interest at a rate of no less than 0.125% of the average market price of a zero coupon note for the five trading days ended Sept. 8, 2010, in addition to the continued accrual of the original issue discount. Contingent cash interest, which the company has determined to be about \$1.24 a note, will be payable to holders of the notes as of the record date, which is Feb. 24, 2011. The payment of contingent cash interest is expected to be made on March 11, LabCorp said. ■

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*Deals roundup***MedAssets to buy Broadlane Group for \$850 million in cash****A Medical Device Daily Staff Report**

**MedAssets** (Atlanta) has entered into a definitive purchase agreement to acquire **The Broadlane Group** (Dallas).

Under the terms of the agreement, MedAssets will purchase The Broadlane Group for approximately \$850 million in cash, with \$725 million to be paid at closing and \$125 million to be paid in January 2012. To fund the transaction, MedAssets has obtained financing commitments from J.P. Morgan and Barclays Capital.

As part of this transaction, MedAssets expects to achieve at least \$20 million of expense-based synergies in 2011. When combined with the growth of both businesses, the company expects this transaction to be about 5 cents to 10 cents accretive to non-GAAP diluted cash earnings per share (EPS) in 2011, excluding acquisition-related amortization, acquisition-related expenses, acquisition-related revenue discounts and share-based compensation.

Together, MedAssets and The Broadlane Group would have reported non-GAAP combined net revenue of \$508.9 million and non-GAAP combined adjusted EBITDA of \$161.8 million for the year ended Dec. 31, 2009. The Broadlane Group serves more than 100 acute care hospitals and 50,000 non-

acute care facilities across the U.S., and MedAssets serves more than 3,300 hospitals (inclusive of 1,700 in its Spend Management segment) and 40,000 non-acute healthcare providers. The combined companies' client footprint will be calculated at closing.

"The Broadlane Group and MedAssets are an outstanding strategic fit, and this combination offers numerous benefits for our clients and stakeholders. We are bringing together some of the best contract pricing in the industry, with highly complementary technology and clinical consulting expertise from both companies," said John Bardis, chairman, president/CEO of MedAssets. "Our core strategy is to enable broader clinical and operating effectiveness throughout our nation's health system, and this transaction will further enhance our ability to help hospitals and other healthcare providers drive their operating and supply costs lower, while improving patient care.

The Broadlane Group is a provider of supply chain management, strategic sourcing of supplies and services, capital equipment lifecycle management, medical device or PPI cost management, centralized procurement, clinical and lean process consulting, and clinical workforce optimization.

MedAssets partners with healthcare providers to improve their financial strength by implementing integrated spend management and revenue cycle solutions that help control cost, improve margins and cash flow, increase regulatory compliance, and optimize operational efficiency. ■

**Med-Tech Notes****Scientia Advisors tout new POC tests**

Rapid medical tests that can be analyzed in close proximity to patients in professional settings comprise the fastest growing segment of the global \$37.5 billion in-vitro diagnostics industry, according to a new global review of the point-of-care (POC) diagnostics industry.

The review was released this week by Scientia Advisors (Boston), a management consulting firm specializing in growth strategies for companies in health care and life sciences.

"Growth in the POC market is fueled in part by a trend toward decentralization of health care – in which testing and treatment are migrating from hospital labs to settings such as emergency rooms, outpatient, doctor's offices, rapid and urgent care clinics, and homes," said Harry Glorikian, Scientia Advisors' managing partner.

However, Glorikian cautioned, "companies bringing POC tests to market must consider not only accuracy, reliability and ease of use, but also the challenges of gaining clinical acceptance and meeting sometimes-onerous regulatory and reimbursement requirements."

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*Patent watch***Vermillion's PAD research validated with patent grant****A Medical Device Daily Staff Report**

**Vermillion** (Austin, Texas), a molecular diagnostics company, reported the U.S. Patent and Trademark Office (USPTO) has issued a notice of allowance for a patent titled "B2-microglobulin as a biomarker for peripheral artery disease" to the company. The patent claims are directed to biomarker combinations that include B2-microglobulin for the diagnosis and management of peripheral artery disease and to the measurement of the biomarkers by a variety of methods, including mass spectrometry and immunoassay.

"The notice of allowance for this PAD biomarker patent is additional validation of our approach to intellectual property protection. This will play an important role as we continue efforts to develop and commercialize our Vasclir test for PAD," said Gail Page, CEO of Vermillion.

The studies underlying the patent were conducted with John Cooke, MD, PhD, a professor and associate director of the Stanford Cardiovascular Institute at **Stanford University School of Medicine** (Stanford, California).

Vermillion, along with its scientific collaborators, has

diagnostic programs in oncology, hematology, cardiology and women's health.

In other patent news, **Absorption Systems** (Exton, Pennsylvania), a specialist in testing drugs for ADMET (Absorption, Distribution, Metabolism, Excretion and Toxicity), said the U.S. Patent and Trademark Office (USPTO) issued U.S. patent number 7,795,019 covering its novel Breast Cancer Resistance Protein (BCRP) knockdown cell line within the company's CellPort Technologies brand. Absorption Systems' cell lines allow pharmaceutical and biotechnology companies to definitively predict clinical drug-drug interactions involving drug transporters.

CellPort Technologies is a suite of *in vitro* test systems designed to provide definitive data regarding interactions between drugs and specific transporter proteins. Specific transporter proteins, BCRP is one example, have been identified by regulatory agencies such as the FDA and the European Medicines Agency (EMA) as key mediators of unintended drug interactions.

"This patent further confirms the uniqueness of the approach that Absorption Systems has taken," said president/CEO Patrick Dentinger. "We believe that using CellPort Technologies gives pharmaceutical and biotech companies a significant advantage by providing, in a very efficient and definitive manner, the information required by the FDA. No other company is offering technology or service today that provides such conclusive results." ■

*Restructuring roundup***Response to cut 25% of staff after 3M cancels flu product****A Medical Device Daily Staff Report**

**Response Biomedical** (Vancouver, British Columbia) reported that the company is taking steps to strategically refocus its resources and has implemented a company-wide cost-cutting initiative. As a result, the company said it is expecting expense reductions of about \$2 million in 2011 based on current sales levels. This \$2 million savings will be recognized with an approximate 25% reduction in the company's workforce, with the potential for other cost-savings, moving forward, it said.

The company said it is prioritizing its resources and focusing its efforts on the growth of the cardiovascular business through its partnership with **Roche Diagnostics** (Basel, Switzerland) and through international distributorships in China, Japan, Europe and the Middle East. The restructuring and refocus of the organization was driven in part by **3M's** (St. Paul, Minnesota) decision not to proceed with development of the next generation flu product. While Response will continue to support 3M's efforts in the U.S., the company does not expect a significant negative impact on our near term revenue,

caused by their decision regarding not proceeding with the second generation flu product.

"We are determined to take advantage of the opportunity to accelerate sales growth and shorten the timeline to profitability by leveraging our emerging leadership in cardiovascular POCT," said S. Wayne Kay, CEO. "We offer customers a complete cardiovascular menu and with the launch of the RAMP 200 system overseas, we will focus our organization on commercial operations moving forward. We see immediate potential for further growth in China and we will be adding resources there. As well, we have added a sales manager for Europe, the Middle East and Africa, and we anticipate strong growth from these markets. We will continue to support 3M in their commercial operations efforts in the infectious diseases product line in the U.S., however, their decision not to move forward with the next generation flu product and market outlook for the coming months has caused us to refocus and restructure our business as we move toward profitability. While we do see further opportunities to grow the business in other diagnostic areas eventually, we want to first deliver on our promise to our shareholders to become cash flow positive and move to profitability."

Response develops rapid on-site diagnostic tests for use with its RAMP Platform for clinical and environmental applications. ■

*HIT roundup***Hayes to offer EMR conversion service to healthcare groups***A Medical Device Daily Staff Report*

**Hayes Management Consulting** (Newton, Massachusetts) reported a new service offering: EMR Conversion and Migration Management, designed to assist healthcare organizations to convert legacy data and migrate to a new electronic medical record system.

"We have had the opportunity to hone our methodology as more organizations are moving to new EHRs to meet future needs such as meaningful use and PQRI reporting requirements," said Peter Butler, president of Hayes. "Since we have subject matter experts on multiple systems, professional project managers and data extraction experts, we can manage the entire migration process. This close coordination is a critical success factor for conversions, which require diverse skill sets from participants across the organization."

The new offering includes the following services: Manual vs. automated conversion assessment; Project planning and project management; 24/7 legacy system support; Data mapping, extraction, and transformation; Conversion design; Design and build of the conversions; Data migration; Clinical workflow redesign; and Go-live planning and support.

In other HIT news:

- **Allied Telesis** (San Jose, California) and **Hosted PACS Solutions** (Wellington, Florida) reported a technology alliance offering managed cloud-based Picture Archiving and Communications Systems (PACS) services to enable the seamless and secure transfer and storage of bandwidth-intensive imaging and diagnostic studies. According to the companies, the partnership marks the first-of-its-kind cloud-based PACS service, hosting this software platform.

Hosted PACS Solutions and Allied Telesis will offer a completely managed PACS solution, including network design, implementation, configuration, and access to Hosted PAC Solutions' HIPAA compliant data centers, as well as maintenance, remote management and monitoring, and 24/7 support, according to the companies.

- **Prematics** (McLean, Virginia) reported a multi-year contract extension with **Availity** (Jacksonville, Florida). Availity offers Prematics' e-prescribing services under the CarePrescribe private label. Prematics will continue providing e-prescribing services to Availity through 2013, and add its Care Communication services for existing and future CarePrescribe users.

The e-prescribing partnership began in February 2008.

- **EDIMS** (Livingston, New Jersey) said it has appointed Christian Mueller as director of data operations and management. Prior to working for EDIMS, Mueller ran his own technology consulting firm, where he became familiar with EDIMS' technology by spearheading the redesign of a core

piece of its technology, developing many key components to its software and reengineering new, successful storage architecture processes.

- **Pitney Bowes Managements Services** (PBMS; Stamford, Connecticut) has established a strategic reseller agreement with **Imerge Consulting** to support PBMS consulting opportunities in records and information management as part of its document processing solutions offering.

Imerge will provide supplemental support to PBMS and its customers within a broad cross-section of professional and business challenges in the area of records and information management, focusing particularly on the healthcare and life sciences market. Imerge will assist PBMS in the definition of requirements, assessment of legal and compliance needs, development of records programs and strategies for PBMS customers, and specification and effective use of data, records and document management systems. ■

*Med-Tech Notes***Report shows high-tech industry on uptick**

**TechAmerica Foundation** (Washington) released a report based on U.S. Bureau of Labor Statistics data that shows the U.S. high-tech industry added 30,200 jobs between January and June of 2010, a 0.5% gain. The report looks at four sectors within the high-tech industry: tech manufacturing, communications services, software services, and engineering and tech services.

"Though the tech industry was among the last to feel the effects of the economic downturn of 2008 – 2009, it was not immune to job loss and is only slowly showing signs of climbing out of it," said Josh James, VP, Research and Industry Analysis, TechAmerica Foundation. "Tech employment as of June 2010 stood at 5.78 million, compared to 5.99 million in January 2009. So there is still a way to go before we've made up for lost jobs, and continued recovery is by no means certain. With job growth in three of the four tech sectors, we remain guardedly optimistic."

The technology industry continued to add jobs until the last quarter of 2008, by which time much of the rest of the private sector was already well into recession. Over the most recent six months, high-tech manufacturing in the U.S. once again added jobs, reversing the downward trend. Technology manufacturers added 9,000 net jobs in the first half of 2010, for a total of 1.24 million tech manufacturing jobs in June – a 0.7% gain.

TechAmerica Foundation educates industry executives, policy makers and opinion leaders on the promise of technological innovation to advance prosperity, security and the general welfare.

## Washington

*Continued from Page 1*

substantially, noting that about 70% of clearances were handled within 90 days before the program, but that “now more than 90% are.”

“This means nearly 500 more 510(k)s receive a timely review each year” than was the case prior to the Medical Device User Fee Modernization Act (MDUFMA), Shuren said.

On the other hand, Shuren said “we recognize the critical importance” of expediting those changes and that “to the extent they are successful if adopted, they could improve performance.” Still, he advised that the review of the 510(k) program could hold “other implications for MDUFA [Medical Device User Fee Act] reauthorization,” pointing out that the fees “currently account for less than 20% of funding for CDRH activities covered by user fee program.”

Shuren hinted that other parties will have a lot of influence on the user fee schedule. He said the agency “commit[s] to an open and transparent process” regarding user fees and that “we look forward to strengthening our relationship with all stakeholders throughout the reauthorization process.”

Malcolm Bertoni, assistant commissioner for planning at FDA, told the audience that Congress requested the public meeting, although he did not name the parties who made the request. “Transparency is a very important and robust part of this process,” he said.

FDA’s negotiations with industry will now be public as well, Bertoni indicated, noting that FDA will “be publishing for the first time the summaries of these meetings.” He backed up Shuren’s remark regarding stakeholder input, noting that CDRH managers are “also going to be holding monthly meetings with stakeholders.”

Regarding the time line for the draft user fee recommendations Bertoni said, “at this point we’re thinking this will start officially in the new calendar year,” to be completed by the end of next summer so the public can comment before presentation to Congress in January 2012. By that time, FDA is “hoping . . . there will be a minimal need to make revisions at that point” due to the monthly meetings with stakeholders. FDA is accepting preliminary comments on the subject for 30 days following yesterday’s meeting.

### User fees assailed from both ends

Two public health advocates spoke at the meeting, but while they both evidenced distaste for the 510(k) process, they had different views on user fees. Diana Zuckerman, president of the **National Research Center for Women and Families** (Washington) said “on some level, we would not care at all how high or how low user fees were if appropriations were higher,” but nonetheless opined, “we think the user fees are too low.”

“We also think there’s no good reason why some of the largest corporations in the world . . . that pay very large user fees” for drug applications “pay much-much, much-much, much-much less” for device applications, adding that the “fees

for the 510(k)s are especially egregious,” given the relatively low sums required. Zuckerman stated further that the largest firms should pay for “the entire cost of a 510(k) review.”

“We think they should also pay additional substantial user fees for every new advertisement they direct to consumers” for the agency’s review mechanism for direct-to-consumer ads,” Zuckerman said. “Even the much larger PMA user fees are disproportionately low compared” to fees charged for new drug applications (NDAs), she said, arguing that the fees and the quality of the reviews “should be similar” between the two application types.

Zuckerman asserted that the “vast majority of the recalls that FDA itself called high-risk recalls were 510(k) devices,” saying that a 510(k) device is categorically not life-sustaining. “It seems to us if a device can kill you if it fails or does not work accurately . . . that device should be a high-risk device” and should “go through the PMA process.” She said her organization wants to see legislation drafted to “ensure that FDA does not continue to approve dangerous devices just because they’re similar to other dangerous devices,” citing the case of luer lock connectors she described as responsible for “deaths across the country.”

“It seems to us that the big issue is not what was approved before,” but “how the device actually functions in the real world,” Zuckerman said, adding that in her view, “changes in the law and in user fees are needed to support post-market surveillance of all medical devices.” She further made the case that the lack of a requirement for a pre-clearance inspection is “something that has to change.”

Amy Allina, program and policy director for the **National Women’s Health Network** (Washington) said a user fee “undermines the agency’s independence and has interfered with FDA’s ability to allocate resources.” She said FDA should be fully funded by appropriated monies, stating that “even a doubling [of the FDA budget] would not be a great price to pay” to ensure food drug and device safety.

“We need to raise the standards for reviewing medical devices,” Allina said, noting that the difference in standards between drugs and devices allow some devices to go through with no clinical data. Even the PMA standard is not the same as that for drugs, she remarked, arguing that “this lower standard means that dangerous and ineffective devices are being approved.”

Regarding the notion of substantial equivalence, Allina argued that CDRH “should use a more limited interpretation of what it means to say that one device has the same intended use as another,” stating that the standard of “functioning in the same manner is not synonymous with having the same intended use.”

Allina said predicate creep is an issue as well, adding that “over time . . . this has led to pretty vast chasms between the medical and technological characteristics of the new device and the predicate.” She also made note of the resources issue associated with FDA, but said that

*See Washington, Page 7*

## Agreements

*Continued from Page 1*

With the use of this advanced technology, the viscoelastic material properties of the polymer rod allows the system to act comparably to a damper thus enhancing stability and reducing the effects of peak loads.

According to DSM, Bionate PCU has been a key material used by Spinelab in its Elaspine, which is designed to reduce pain for patients while still allowing limited range of motion in the spinal column. Introduced in 2009, Elaspine has experienced success with Spinelab customers, having most recently completed one-year performance assessment with its first patients, DSM said.

"Continuing to evolve our relationship with DSM Biomedical puts us in a unique position to leverage the impressive track record of their suite of biomedical materials," said Thomas Zehnder, president/CEO, Spinelab. "We selected Bionate PCU for its long and successful clinical track record. Working with a proven, unmatched implantable material for our spinal applications allows Spinelab to focus on delivering the desired biomechanics to ensure implant performance for our esteemed customers."

Rob Evans, VP of global marketing and sales at DSM PTG, said the opportunity to continue making and supplying Bionate PCU to Spinelab is a "catalyst" in growing the company's product sales and validates the company's mission to focus on growth by leveraging proprietary biomaterials technology and capabilities.

Evans told *Medical Device Daily* that the two companies have been working together since 2003.

"The new agreement is further evidence of the value placed on using Biomaterials with a proven track record. In the end, this equates to a shorter time to market and less complicated regulatory pathway," Evans said. "The agreement further validates DSM PTG's business model of licensing the right to use enabling materials in critical medical devices."

According to Evans, Bionate PCU is recognized as one of the most extensively tested polymers known for chronic implantation. "Bionate PCU bridges the performance gap between harder, more brittle thermoplastics such as PEEK and softer, less strong and abrasion resistant polymers such as Silicones," he said. Evans further noted that the polymer is the predecessor of the company's recently launched (mid 2009) second generation polymer, Bionate II PCU, which incorporates DSM PTG's SAME end group technology which delivers "unique surface properties to an implant without effecting bulk mechanical properties."

In other agreements/contracts news:

- **International Rehabilitative Sciences** (RS Medical; Vancouver, Washington) reported its first award of a federal supply schedule contract. The contract is in effect through June 14, 2015.

According to the company, millions of veterans and those with federal health benefits can now have access to RS Medical's non-drug, non-invasive pain management and

rehabilitation devices that are patient-administered home therapies to relieve acute and chronic pain, and improve function. The handheld stimulators, traction apparatus and advanced spinal bracing products include the RS-4i Sequential Stimulator and the Pronex Inline Cervical Traction.

RS Medical says it will leverage its national direct distribution and service staff of more than 250 to focus on the growing demand among veterans for cost-effective, patient-administered home therapies to relieve pain and improve function.

- **Cut Rite Instruments** (North Dighton, Massachusetts) said that **All Dental Prodx** (Galloway, New Jersey) will be the exclusive sales and marketing partner for the complete line of Cut Rite dental products including. These products include: the Kool Krystal diamond line, which uses the company's Kool Abrasive technology to cut at higher speeds, produce less heat, and last longer than traditional diamonds and carbides; the Terminator, dentistry's most aggressive instrument, according to Cut Rite, with the field's highest removal rate and shorter grinding cycles which shorten patients' time in the chair and reduce crown-and-bridge time; and the HQ Diamond series, which offers dentists multiple uses for the cost of a single-use product.

- **Oxford Nanopore Technologies** (Oxford, UK) reported a new agreement to strengthen its collaboration with the **University of Oxford**. The company will fund research in the laboratories of Professor Hagan Bayley and will partner exclusively with the university to develop "revolutionary" products for molecular analysis from these new discoveries, it said.

Research projects within the Bayley group include methods for the direct sequencing of single stranded DNA. This and other nanopore sequencing techniques may offer substantial performance benefits over currently-available sequencing technologies through improved cost and speed, according to the company. ■

## Washington

*Continued from Page 6*

an effective public safety resource is already in place. She claimed that "many of the disasters that have unfolded with medical devices were all the more tragic because they were not a surprise to the FDA staff who reviewed the products."

"We urge the agency to respect, support and empower the scientific staff to make decisions... based on evidence," Allina said, adding that FDA should "encourage the staff to identify the products for which a clinical trial is needed" and "to speak up when clinical data submitted fails to meet a standard of scientific rigor needed to protect the public health."

*Medical Device Daily* will review the comments made by representatives of three industry associations in tomorrow's edition. ■

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## Europe

*Continued from Page 1*

therapy treatments over three months, the Rinecker center reported.

Manfred Herbst, medical director at RPTC, said he expected to further reduce this tumor with subsequent treatments.

For a second patient with cancer in the left lung, Herbst reported a clear reduction of the tumor volume and a significant improvement in breathing after eight treatment days, while healthy tissue in the same lung and the right lung were unaffected by the high-energy treatment and free of radiation.

Unlike conventional X-ray radiotherapy that scatters a wider area, exposing healthy as well as cancerous tissue to radiation, proton therapy delivers heavier particles in a beam to destroy tumors in a highly controlled dose and exposure.

Patients are not in proximity to the source of radiation, and the greater precision of the prescribed doses, or fractions, with proton beam therapy results in fewer treatment sessions.

The advanced treatment technique used at RPTC - called pencil beam scanning - enhances precision by enabling clinicians to maximize dose to the tumor while minimizing dose to nearby sensitive organs and tissue.

The proton energy has a predictable drop-off which enables oncologists to deposit the peak of the energy within the tumor and reduce the exposure to the surrounding healthy tissue.

The center's operator, **ProHealth** (Munich, Germany), expects to treat 4,000 patients per year at RPTC and reports that from the moment the doors were opened earlier year it has been overwhelmed with inquiries that far exceeded capacity (*Medical Device Daily*, Feb. 5, 2010).

RPTC enthusiastically predicts that "under favorable conditions, this number may be increased to 5,000 patients a year," yet the center, which originally expected to open in 2005, has faced only unfavorable conditions.

Varian took over the troubled project in 2007 with the acquisition of **Accel Instruments** (Bergisch Gladbach, Germany) (*Medical Device Daily*, Jan. 30, 2007 and Feb. 5, 2008).

After untangling the complex engineering issues it inherited from Accel, Varian was then stymied in commissioning of the gantries for the five treatment rooms as problems cropped up in the software that drives the complex mechanical and electromagnetic forces capable of delivering a proton beam with one millimeter accuracy from a super conducting cyclotron located 92 meters away (302 feet).

"As a result we decided to limit press relations to a minimum and keep a low profile," said Joerg Hauffe, MD, CEO of ProHealth, adding that with its limited therapy capacity the center currently is offering medical appraisals

for inquiring patients to inform them whether they can hope for a timely treatment or should seek an alternative therapy.

As of July the €150 million (\$209 million) RPTC reported treating 250 patients from 23 countries.

A Varian spokesperson told *MDD* that gantries in three treatment rooms have been successfully commissioned.

A fourth treatment room with a similar 360-degree targeting gantry is "currently being commissioned and will be brought into use very shortly," the spokesperson reported.

The company said it expects to commission in November 2010 the fifth and final treatment room with a fixed-beam gantry to irradiate delicate head, neck and eye cancers or tumors close to the spinal cord.

ProHealth plans to construct new centers in Leipzig and Cologne, but has not yet announced whether it will contract with Varian, according to a company spokesman.

The Varian spokesperson said the company will "announce subsequent deals - ProHealth or otherwise - as soon as we can."

"I can say that Varian has been named as preferred supplier to proton projects that are being planned in Delft, the Netherlands, and in Maestra, Italy," said the representative.

### European centers report results from Varian

Varian's Oncology Systems group is making a strong showing this week in Barcelona, Spain at the annual meeting of the **European Society for Therapeutic Radiology and Oncology** (ESTRO; Brussels, Belgium), reporting both clinical and commercial successes for novel radiotherapy technologies.

Following the presentations of research findings for its RapidArc technology, Varian announced the first clinical evidence and a second installation of its newer TrueBeam system.

Introduced in April as the first fully-integrated system designed to treat a moving target tumor, the TrueBeam platform for image-guided radiotherapy and radiosurgery delivers specified radiation doses with greater precision in fewer, higher dose fractions than with conventional radiotherapy.

Results from treatments at **Zurich University Hospital** (Zurich, Switzerland), the first medical center to bring the novel technology online, were presented during an Emerging Technologies symposium at ESTRO.

In the same session, clinicians from the **Vrije Universiteit Medical Center** (Amsterdam, the Netherlands), which began clinical treatments the week previous using the TrueBeam system, discussed results for an 80-year-old lung cancer patient who underwent the radiotherapy using the new linear accelerator.

A second TrueBeam system is currently being installed at VU Medical Center and is expected to begin clinical

*See Europe, Page 9*

## NewCardio

*Continued from Page 1*

means of detecting whether the LBBB is new or old.

**NewCardio** (Santa Clara, California) a small med-tech firm that develops cardiovascular diagnostics products, thinks that it might have the answer to accurately distinguishing between old and new LBBB with its Cardio3KG software.

"Imagine a door closed and that you might hear some voices behind it, but you really can't tell who's on the other side, Ihor Gussak, MD, PhD, FACC CMO and VP of NewCardio told *Medical Device Daily*. "You know there is someone there, but you don't know who. This is the mystery LBBB presents to physicians."

The company reported that a clinical study of its Cardio3KG was found to distinguish between the two states of LBBB and has been published in the August 2010 issue of the peer-reviewed journal, *Heart Rhythm*, the official journal of the **Heart Rhythm Society** (Washington).

In the study titled, "Vectorcardiographic and Electrocardiographic Criteria to Distinguish New and Old Left Bundle Branch Block," clinicians obtained ECG data from 39 patients with new LBBB and 1,760 patients with old LBBB, and used NewCardio's Cardio3KG suite of 3-D based ECG analysis algorithms to identify a Cardio3KG marker called the QRS-T Loop ratio. This allowed highly accurate discrimination between new and old LBBB (100% sensitive and 96% specific for correctly assigning LBBB tracings to the "new" or "old" category).

"We can use this technology to diagnose new vs. old LBBB – something no one has ever done before," Gussak told *MDD*. "Based on an ECG physicians have to make the decision if patients go to the cath lab. If the ECG has signs of LBBB, then the physician has no choice but to send the patient to the cath lab. But for the majority of these cases, the LBBB is old and this results in a tremendous waste of resources and patients have to undergo unnecessary invasive procedures."

The company said that the Cardio3KG software is an important advance and is expected to provide a cost-effective solution to a long-standing and notoriously difficult diagnostic dilemma in acute MI diagnosis. Moreover, because the Cardio3KG uses standard 12-lead ECG input, its analytical results are available in minutes and require no change in standard ED practices or special training of the ED staff.

According to the company, Cardio3KG is a set of algorithms and tools that provide a comprehensive method to describe cardiac electrical activity in time and space. The application extracts additional information from standard 12-lead ECG signals and uses it to generate a 3-D representation of cardiac electrical activity as a function of time.

To further enhance understanding and ease of use, the program superimposes the diagnostically relevant electrical information on an intuitive, revolving 3-D anatomic model of the heart.

A typical Cardio3KG output that is easy to read and requires less training to interpret, when compared with the standard 12-lead display.

The company said that a key aspect of Cardio3KG is its suite of algorithms to correct the problem of variation in electrical attenuation across the chest wall. The problem usually leads to regional inconsistency and poor diagnostic sensitivity in remote regions of the heart. To correct this issue, Cardio3KG includes algorithms to normalize electrical attenuation, which results in a "virtual sphere" of normalized electrical activity, and ensures accurate and balanced representation of all heart regions.

While the company has yet to bring a 510(k) submission to the FDA, it said that it was gathering a growing body of evidence to give more support toward the efficacy of the diagnostics tool.

The company added that plans to gain CE mark approval weren't at the forefront - just yet.

The boost from this recent study, though could add more power to the company's arsenal.

According to Alexei Shvilkin, MD, the results are phenomenal and could certainly change the way doctors classify LBBB.

"We believe these study results have substantial clinical significance," he said. "The ability of Cardio3KG to identify old LBBB will help reduce unnecessary invasive procedures and lower the overall cost of medical care. On the other hand, the accurate identification of new LBBB by Cardio3KG will reinforce the need for aggressive management and urgent coronary intervention, and may thereby improve long-term clinical outcomes for acute MI patients." ■

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## Europe

*Continued from Page 8*  
operation in November.

Varian reports 10 European centers are installing the technology including the **Institut Catala d'Oncologia** in the ESTRO host city of Barcelona.

In addition to the new linear accelerator, TrueBeam integrates technologies that dynamically synchronize imaging, patient positioning, motion management, and treatment delivery. ■

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## People in the News

- **AngioDynamics** (Albany, New York) has named Scott Solano as senior VP and chief technology officer, and Scott Etlinger to the position of senior VP, global operations. Solano previously was president/CEO of Arterial Vascular Engineering. Etlinger previously was COO of Dental Services Group. AngioDynamics makes medical devices used by interventional radiologists, surgeons and other physicians for the minimally-invasive treatment of cancer and peripheral vascular disease.

- **ContextVision** (Stockholm, Sweden) named Anita Tollstadius as CEO. In addition to serving on the ContextVision board of directors since 2008, Tollstadius has counseled other medical technology companies on matters such as product research and development, production, and communications. ContextVision provides medical imaging enhancement, analysis and processing technologies, serving leading OEMs and distributors.

- **Isabel Healthcare** (Ann Arbor, Michigan) has named Donald Bauman, Jr. as CEO responsible for North American Operations. Bauman brings more than 25 years of field and leadership experience to Isabel. In past assignments, he has been successful in accelerating market penetration and commercialization of innovative technologies that have transformed healthcare practices and increased patient safety, the company said. Isabel Healthcare provides tools for diagnosis decision support solutions.

- **Prometheus Laboratories** (San Diego) has named Declan Doogan, MD, as executive VP and chief medical officer. Doogan most recently was interim CEO and head of R&D at Amarin. Prometheus makes pharmaceutical and diagnostic products that enable physicians to provide greater individualized patient care.

- **Total Medical Solutions** (TMS; Orlando, Florida) has promoted Aaron Hunziker to regional sales manager for the southwestern U.S. Hunziker joined the company in 2008 in a strategic planning position. TMS is a provider of home healthcare and complex care products and services for the workers' compensation industry.

- **Universal Health Services** (King of Prussia, Pennsylvania) said that Michael Marquez has resigned as president of the acute care division. Marquez was president of the acute care division since May 2009 and had previously served as co-president of the acute care division with Marc D. Miller. Universal Health Services is a hospital company.

- **Voalté** (Sarasota, Florida) reported five new team members, doubling the size of its staff since the beginning of the year. Chris Coffey was named project manager for hospital installations. Coffey brings with him nearly five years of experience with construction project management. Justin Kirby joins Voalté's engineering team as a server developer. Kirby has more than 12 years of experience in high-reliability design and development. Tricia Wren was named staff accountant. Jeff Antonio and Judy Thompson were named as Voalté care specialists. Voalté provides software solutions for healthcare institutions that solve communication problems at the point-of-care.

## Product Briefs

- **20/20 GeneSystems** (Arlington, Virginia) reported the launch of their technology for biomarker identification in tumors and other tissue samples. 20/20 is currently offering the technology to industry and academic researchers under service contracts. The technique – known as layered-Immunohistochemistry (L-IHC) – represents a major step forward in enabling personalized medicine and stratification of clinical trials to improve drug efficacy, the company said. L-IHC allows for the simultaneous detection of multiple biomarkers in a single tissue section while preserving its morphology and eliminating several limitations associated with the few current multiplex histology techniques. It is particularly useful for studies in which multi-parametric information is essential and tissue supply is limiting, a typical problem in clinical and translational research.

- **Roche Diagnostics** (Basel, Switzerland) received FDA clearance for the cobas 8000 modular analyzer series, a Serum Work Area solution designed for diagnostic laboratories with a workload of three million to 15 million

clinical chemistry/immunochemistry tests per year. The cobas 8000 has a peak throughput of up to 9,800 tests per hour and up to 280 reagents onboard. The cobas 8000 modular analyzer series features intelligent sample routing with fast transportation and return lines, independent processing lines within each module, and a modular sample buffer in each module for true random-access sampling. The series also uses the same operator interface and the standardized reagent cassette concept used on other cobas analyzer platforms. Tests run on the new platform give physicians important clinical information in a wide range of medical areas, such as cardiac and infectious diseases, bone disorders and cancer.

- **RSB Spine** (Cleveland) said that the InterPlate L-Ti has been cleared for an additional product code (KWQ). The L-Ti was previously cleared as an interbody fusion device. RSB Spine CEO John Redmond said, "Because of our Bridging Flush Fit design, we have always been of the opinion that the InterPlate L-Ti can function as an interbody fusion device and/or anterior lumbar plate. The new product code also simplifies coding surgeons, clarifying reimbursement for this type of zero profile implant." RSB Spine is a privately held medical device company focused on developing innovative spinal implants.

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# MDD'S ONCOLOGY EXTRA

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

WEDNESDAY, SEPTEMBER 15, 2010

PAGE 1 OF 2

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

**Another sponge may help clean up on cancer . . .** Oncology Extra reported recently that a nanosponge might be a useful tool in delivering antiproliferatives to the sites of cancers (*Medical Device Daily*, Aug. 11, 2010), but another sponge of substantially larger size, the Cytosponge, may prove invaluable in dealing with Barrett's esophagus, seen widely as a precursor to esophageal adenocarcinoma. In an article appearing last week in the *British Medical Journal*, a group of researchers including Sudarshan Kadri, a clinical research fellow at the **University of Cambridge** (Cambridge, UK), write that their device, a mesh that is delivered into the esophagus in a pill-like capsule that dissolves, leaving a sponge-like device attached to a string, returned diagnoses of Barrett's esophagus in numbers comparable to those found in the literature for other diagnostic methods. The researchers recruited nearly 2,700 patients and enrolled 504 into the trial, with 501 successfully gulping down the capsule and string and returning sufficient amounts of esophageal tissue to allow a biopsy performed with immunohistochemistry for trefoil factor 3, a protein that is commonly expressed in the gastrointestinal mucosa and which is commonly associated with the TFF3 gene, which is in turn associated with esophageal cancers. The paper notes that two Cytosponges did not fully deploy and returned smaller samples for study, and that no serious adverse events were noted in connection with the procedure. The impetus behind the research is that the incidence of esophageal cancer has risen "sixfold in the Western world since the 1990s" and that conversion to cancer is about half a percentage point per year for as many as 15 years after diagnosis of Barrett's esophagus. Early detection can ward off a mortality rate of 80% at five years, which means that the Cytosponge could play a vital role in pushing back against an increasing tide of esophageal cancer deaths. The paper states that the recruitment rate of almost 19% (about 500 of 2,700 recruited) "is consistent with the 16.3% reported in a previous endoscopic study in the primary care setting," and that the diagnostic rate of 3% is likewise "in keeping with previous published studies." Endoscopic screening for Barrett's esophagus is described in the paper as less than cost effective, but the Cytosponge could "prove a more cost effective approach" inasmuch as no special hardware is needed and the test can be administered by a nurse practitioner or physician's assistant. A future screening study will provide more cost data, the article states, adding that the Cytosponge "coupled with a single immunomarker is a promising tool to screen for Barrett's esophagus."

**Value of treating aggressively for low PSA levels eroded by Dutch study . . .** The debate over the value of testing for prostate-specific antigen (PSA) rambles on thanks to a recent article appearing in the journal *Cancer*, which states that the value of aggressive treatment for men between the ages of 55 and 74 based on PSA levels is "limited," according to the abstract. The article, penned by a team including Pim van Leeuwen, MD, of **Erasmus University Medical Center** (Rotterdam, the Netherlands) reviews the records for almost 44,000 men who had enrolled in the ERSPC (European Randomized Study of Screening for Prostate Cancer) study between 1993 and 1999, and were followed through 2006 to determine outcomes for PSA levels and treatment. The abstract states that the numbers needed to investigate for men with PSA levels of zero to 1.9 nanograms per milliliter (ng/mL) in order to save one life was more than 24,000, whereas the same measurement for men whose PSAs were in excess of 10 ng/mL was 133. Measuring the numbers needed to treat, the investigators said clinicians had to treat more than 700 patients with the lower PSA levels in order to save one life, whereas only 60 patients with the higher levels had to undergo treatment in order to stave off a death due to prostate cancer. The authors concluded that "for men with a low serum PSA level, the benefits of aggressive investigation and treatment may be limited because they are associated with a large increase in cumulative incidence and potential overtreatment."

**Maybe it's not safe to go back in the water after all . . .** Now that the summer swimming season is over, the cry of "shark" doesn't affect swimmers the way it did before Labor Day, but the ultimate bad news for those who enjoy swimming during the cooler months came in a recent edition of *Environmental Health Perspectives* (EHP) in which an article argues that the chemicals used to suppress pathogens in swimming pools may be carcinogenic. According to the EHP report, the underlying premise was predicated in part on the fact that human exposure to byproducts of disinfectants "has been associated with cancer risk" and a recent study is said to have found "an increased bladder cancer risk among subjects attending swimming pools relative to those not attending," although the abstract does not name or offer any numbers from this study. The researchers write that they collected samples of blood, urine, and exhaled air from 49 non-smoking adults prior to and just after a 40-minute splash in an indoor pool treated with chlorine, and drew estimates of associations between changes in four biomarkers and the concentrations of four trihalomethanes in exhaled breath. The abstract adds that the authors "also estimated associations and interactions with polymorphisms in genes related to DNA repair or DBP [di-butyl phthalate] metabolism." Phthalates have long been suspected of imparting damage to humans, but many of the alleged effects have yet to be confirmed via studies. The results were that swimmers presented seven times the trihalomethanes after swimming than before, but the duration of the effect was not addressed in the abstract. The authors also noted that the effect did not extend to DNA damage as detected by the comet assay. The authors conclude that their findings "support potential genotoxic effects of exposure to DBPs from swimming pools" and suggested that the benefits of swimming "could be increased by reducing the potential health risks of pool water."

**CAP inks MOU with counterparts in Canada, Australasia . . .** The **College of American Pathologists** (CAP; Northfield, Illinois) reported Monday that it had signed a memorandum of understanding with its counterparts in two other parts of the globe to align their datasets, described in this instance as protocols, in an effort to provide a common template for cancer reporting. According to a Sept. 13 statement at the CAP web site, the organization is partnering with the **Canadian Association of Pathologists** (CAP-ACP; Ottawa) and the **Royal College of Pathologists Australasia** (RCPA; Surrey Hills, Australia) on the project, one of the ambitions for which is to provide better defined parameters for staging of cancer specimens. Stephen Bauer, MD, president of CAP, said in the statement that the American organization's focus "is on enhancing and changing the face of cancer reporting through our collective ideas and resources," noting that the current approach "continues to challenge all pathologists in cancer centers." Bauer said the collaborative effort will "accelerate progress in countless ways." The statement notes that CAP started publishing guidelines for cancer reporting in 1986, an effort that morphed over time into full-blown protocols. Paul McKenzie, President of RCPA, said in the statement that the memorandum "formally recognizes the important collaboration we are undertaking with our pathology colleagues in North America," adding that the memo "represents a significant step forward in ensuring that the pathology report for every cancer patient around the world is standardized to the same high level of detailed information and in the same clear format." John R. Srigley, MD, head of the pathology and laboratory medicine program at **Cancer Care Ontario** (Ontario, Canada), said "a checklist-based synoptic pathology report is much easier to complete." Srigley noted "it is much easier for the clinician to read and understand the report with confidence" and that a standardized report "reduces the need for interpretation of narratives and helps surgeons and oncologists decide on the best treatment for their patients."

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