Medical Device Daily™
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Uptake gets Australian approval for InterVapor, eyes U.S. market

By OMAR FORD
***Medical Device Daily* Staff Writer**

Just a few short weeks after **Uptake Medical** (Tustin, California) reported the first commercial use in Europe for its InterVapor System – the small med-tech company is revealing that it has garnered approval for the device in Australia.

The overseas use and approval of the device form the building blocks that will eventually help the company to bring the technology to the U.S.

"We have CE mark approval and have begun what we would call targeted charter accounts," said R. King Nelson, president/CEO, Uptake Medical, told *Medical Device Daily*. "We expect to have 10 to 20 of these over the next few months in Germany alone. So the objective is to build and continue to get good clinical data and adopters that you can turn into

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Washington roundup

Attorney says Roberts tough to predict in Prometheus case

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

The patent case of *Prometheus v. Mayo* arrived at the U.S. Supreme Court earlier this month, and while many of the justices' questions seemed to reflect positions they were expected to hold, questions posed by Chief Justice John Roberts have prompted at least one patent attorney to speculate that Roberts might find the application ineligible for patent protection. While the court is not expected to render a decision before spring, a majority opinion that dilutes the claims found in *Prometheus* could have a profound – and potentially catastrophic – impact on diagnostics and on personalized medicine.

Denise DeFranco of the law firm of **Finnegan** (Cambridge, Massachusetts) told *Medical Device Daily* that

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Report from Europe

SonoSite receives CE mark for its EDGE ultrasound system

A *Medical Device Daily* Staff Report

SonoSite (Bothell, Washington), a developer of hand-carried ultrasound for the point-of-care, said it has received CE marking to market its next generation point-of-care product: EDGE ultrasound system. The EDGE system is currently available for sale in the U.S., following receipt of FDA premarket notification 510(k) clearance in November. SonoSite is now commencing international customer deliveries. The EDGE ultrasound was formally introduced this fall at medical meetings and congresses in Europe and Australia.

"As a faithful SonoSite user, I want the company's products to remain true to its core elements, namely user friendliness, simplicity of use and rapid acquisition of a great

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FDA clears Chocolate PTA catheter from TriRemeMedical

A *Medical Device Daily* Staff Report

The FDA has cleared a device for the treatment of occluded peripheral arteries that sounds rather tasty.

TriRemeMedical Medical (Pleasanton, California) said it has received 510(K) clearance to market its Chocolate PTA balloon catheter for the treatment of occluded peripheral arteries. The device was developed in collaboration with

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Holiday notice

Medical Device Daily's offices will be closed Friday, Dec. 23, and Monday, Dec. 26, in observance of the Christmas holiday. No issues will be published those days. The next issue of *MDD* will be dated Tuesday, Dec. 27.

Don't miss today's MDD Extra: Orthopedics

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Agreements/contracts

Spacelabs to provide monitors to two Southeastern hospitals

A *Medical Device Daily* Staff Report

OSI Systems (Hawthorne, California) said its healthcare division, **Spacelabs Healthcare** (Issaquah, Washington), received orders for almost $2.3 million from two hospitals in the Southeast region to provide new patient monitors, including Spacelabs' Xprezzon patient monitor.

Deepak Chopra, OSI Systems CEO, said, "We look forward to providing our very top of the line Xprezzon patient monitoring system, paired up with our advanced connectivity solution, the ICS G2, easily facilitating remote and secure access to critical patient data."

OSI says the Xprezzon provides clinicians with visually rich custom trends that can be accessed with a single touch, as well as unique high-visibility alarm presentation capabilities. For instance, visually rich custom trends can be accessed with a single touch, or they can be displayed continuously to enable faster and better informed patient assessment. Also, highly visible alarm lights illuminating front and back aid the caregiver's ability to identify which monitor is alarming in the busy care area. In addition, the sleek, frameless display makes cleaning easier in order to minimize the risk of infection, the company said.

OSI Systems is a vertically integrated designer and manufacturer of specialized electronic system and components for critical applications in the homeland security, healthcare, defense and aerospace industries.

In other agreements/contracts news:

• **Mindray Medical International** (Mahwah, New Jersey), a maker of medical devices worldwide, has entered into an agreement with **Novation** (Irving, Texas) allowing its more than 65,000 members and affiliates to purchase Mindray's M7 and M5 ultrasound systems.

"We are pleased to enter into this agreement with Novation and look forward to partnering with the members it serves in supplying state-of-the-art ultrasound technology," said Michael Thompson, VP of ultrasound sales, Mindray North America. "Now these members can take advantage of Mindray's upgradeable architecture, which provides a significant price-to-value ratio."

Thompson added, "Mindray has been widely noted for its high-quality imaging and innovation over the years. Both the M7 and M5 systems can be used in a wide array of clinical applications. In addition, each system comes with numerous choices of transducers and options. We look forward to helping Novation's members find the right solutions for every facility's specific imaging needs."

Novation is a supply contracting company, serving members and affiliates of VHA, UHC, and Provista.

Mindray makes medical devices across three primary business segments, namely patient monitoring and life support, *in-vitro* diagnostic, and medical imaging systems.

• The **Premier** (Charlotte, North Carolina) healthcare alliance reported a new agreement for electric vehicles has been awarded to **Club Car** (Evans, Georgia).

Premier maintains a comprehensive repository of clinical, financial and outcomes information and operates a healthcare purchasing network. ■

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Financings roundup

Catasys to sell 3.3 million shares of its common stock

A *Medical Device Daily* Staff Report

Catasys (Los Angeles) said that it has entered into agreements to sell about 3.3 million shares of its common stock at a price per share of 30 cents to accredited investors pursuant to a registered direct offering, representing gross proceeds of about $1 million.

Investors will also receive warrants to purchase about 3.3 million shares of the company's common stock. The warrants have an exercise price of 30 cent per share and are exercisable at any time after the closing of the transaction and before the 5th anniversary of such initial issuance date.

The closing of the offering is expected to take place on or before Dec. 23, 2011, subject to the satisfaction of customary closing conditions, including the receipt of all necessary regulatory approvals. Pursuant to the agreement with the institutional investors, the company will not offer any additional securities off the registration statement and accordingly, until the offering is completed. ■

Deals roundup

Futuremed, Cardinal Health Canada, push offer deadline

A *Medical Device Daily* Staff Report

Futuremed Healthcare Products and **Cardinal Health Canada** (both Toronto) have extended the offer deadline for Cardinal Health Canada to acquire all outstanding common shares of Futuremed for CAD $8.15 a share in cash until Feb. 6, to allow the Canadian Competition Bureau to complete its review of the proposed acquisition. All other terms and conditions of the offer remain as described in Cardinal Health Canada's offer and take-over bid circular dated Nov. 14.

The companies have filed pre-merger notification filings with the Competition Bureau. On Nov. 24, Futuremed and Cardinal Health Canada received supplemental information requests for additional information required by the Competition Bureau to complete its review of the proposed acquisition pursuant to the Competition Act (Canada). The requests, which extend the waiting period applicable to the proposed acquisition until 30 days after the Competition Bureau receives the requested information, were not unexpected, the companies noted.

In other dealmaking activity:

• **Agilent Technologies** (Santa Clara, California) said it has acquired the **BioSystem Development** (Madison, Wisconsin) business. BioSystem Development is a privately held company that makes the AssayMAP Microchromatography platform to meet the analytical needs of the life sciences industry. Financial details were not disclosed.

BioSystem Development's AssayMAP platform, based on disposable microchromatography cartridges, enables for the first time, automation of complex, multi-step sample preparation workflows, Agilent said. These include protein purification, characterization and analysis solutions for bioprocess development, biomarker identification and analysis, as well as a variety of other life science research applications.

• **American Realty Capital Healthcare Trust** (New York) said it has acquired a ground leasehold interest in a three-story outpatient center, **Methodist North Medical Office Building** (Peoria, Illinois) for about $24.6 million, exclusive of closing costs.

The company also closed on an acquisition of a ground leasehold interest in an on-campus medical office building, **Odessa Regional Medical Center** (Odessa, Texas) for about $7.4 million, exclusive of closing costs.

The company said the two acquisitions increase the total size of its portfolio to roughly $161.2 million comprised of 11 properties. The two acquisitions total 112,522 square feet.

• **KRG Capital Partners** (Denver), a private equity firm, said it completed its sale of **Avizent** (Dublin, Ohio) to **York Risk Services Organization** (Dublin, Ohio). The all cash sale is a fully integrated national risk management provider serving the workers' compensation, auto and general liability segments.

Avizent's service offering includes third-party claims administration, medical managed care services, network PPO access (including diagnostic scheduling services) and alternative risk solutions.

William Blair & Co. acted as exclusive financial advisor to Avizent in connection with the transaction and Morrison & Foerster served as legal counsel for Avizent. ■

HIT roundup

etHIN selects Axolotl HIE platform from OptumInsight

A *Medical Device Daily* Staff Report

The **East Tennessee Health Information Network** (etHIN; Knoxville) has selected **OptumInsight**'s (Eden Prairie, Minnesota) health information exchange (HIE) technology to help physicians, hospitals and other healthcare providers in the region improve patient care coordination and quality.

etHIN is a collaborative group composed of eastern Tennessee's major health systems. The network will use the Axolotl HIE platform from OptumInsight to create a secure clinical network that connects participating physicians, hospitals, laboratory services providers and pharmacies in the region. This will enable medical professionals to access and share critical health information, including electronic medical records, to support faster, more effective clinical decision-making and coordination with other care providers.

Further, through the Axolotl HIE platform, participating physicians and hospitals will be able to connect to the state Health Information Partnership for Tennessee Network to coordinate patient care and access clinical data from Immunization Services, Public Health Reporting, Lab Reporting Services and other qualified organizations across the state.

The Axolotl HIE platform from OptumInsight connects hundreds of thousands of health professionals across nine statewide exchanges and 25 regional health information organizations, as well as beacon communities, accountable care organizations and independent delivery networks.

OptumInsight provides health information, technology and consulting services.

In other HIT activity, **Certara** (St. Louis), a provider of software and services designed to improve productivity and decision-making from discovery through clinical development, said it has released D360 version 6.0, with key enhancements that enable users to access data from clinical and preclinical data sources in addition to discovery.

D360 is an enterprise class solution that provides scientists with the ability to readily access all their research data, analyze that data, and easily share their findings and work with their colleagues. D360 6.0 provides significant enhancements to user workflows and collaboration capabilities and extends the ability to easily configure and customize the application for the specific needs of an organization, according to Certara.

The heart of D360 6.0 is a completely rewritten data access infrastructure in which data queries are represented by high level query objects (QObjects). QObjects provide improved query and data transformation performance and substantially more flexibility in end user data presentation, as well as improved support for a wider range of applications where data from different scientific disciplines is merged into single views. The introduction of QObject based querying greatly improves support for scientists using D360 in drug discovery, preclinical and clinical applications. Additionally QObjects simplify the configuration required to connect D360 to data sources, further lowering administration burden. ■

Restructuring roundup

Medical Connections reports increase in travel division

A *Medical Device Daily* Staff Report

Medical Connections Holdings (Boca Raton, Florida), a provider of healthcare staffing services, reported its travel headcount has increased more than 43% since completing the restructuring of its operations. In addition, the company has maintained its gross margin for its travel division at 22% as the company has continued to control costs and obtain higher margin contracts.

Anthony Nicolosi, company president, said, "We continue to make progress towards our goal of building a strong company. Our focused efforts on increasing our travel revenue and related margins have really paid off. We are getting much closer to our breakeven point. With all these factors working together we can now renew our efforts towards looking at acquisitions. We will continue to work hard to improve our business." ■

Med-Tech Notes

Philips, Steris expand into Ohio

Philips Healthcare (Eindhoven, the Netherlands), a designer of medical imaging devices, is expanding its Global Nuclear Medicine headquarters by moving 100 R&D jobs from Silicon Valley to Cleveland; the company's Global CT business is also headquartered in Cleveland and together the units employ 1,200 in the region.

Steris (Mentor, Ohio), a provider of hospital technologies, is adding a new manufacturing operation and 100 new positions to its global headquarters where it employs more than 1,000.

Both companies were assisted in their expansions by the State of Ohio, JobsOhio, regional governments and economic development organizations.

Uptake

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real zealots for the product. Secondary to that we have TGA in Australia. In our plan in Australia our plan is to build off two key opinion leaders and the most experienced users of our product in the world and that's at the Alfred Hospital in Melbourne, and Prince Charles Hospital in Brisbane."

"Our involvement with Uptake Medical and InterVapor goes back to the first usage in patients, and we are delighted to see the TGA approval," commented Professor Gregory Snell, head of lung transplant services at the **Alfred Hospital** (Melbourne, Australia). "InterVapor has continued to demonstrate clinical efficacy and safety and we look forward to offering InterVapor to our patients."

Launch plans for the device in Australia could come around the February or March time frame, the company said.

Nelson added, "the primary focus of the company in 2012 is commercially outside the U.S."

The company claims that InterVapor is the first non-surgical, endoscopic lung volume reduction system for the treatment of severe emphysema that uses the body's natural healing processes without leaving implants or foreign materials in the lung.

Clinical efficacy of InterVapor has been established by the multi-center VAPOR trial which showed a reduction in lung volume as well as statistical and clinical significance in lung function improvement (FEV1) and health-related quality of life (SGRQ) at six months.

The trial saw 44 patients completed in Germany, Australia and the U.S. with additional sites in Dublin and Vienna.

The company said that efficacy was consistently demonstrated across all endpoints. Secondary endpoints demonstrated that patients treated with the InterVapor procedure have significant physiologic improvements (including decreased hyperinflation and gas trapping) as well as clinical improvements (reduced breathlessness and improved exercise capacity). All treatments were performed successfully without intra-procedural complications. Adverse events related to treatment included a temporary increase in respiratory symptoms in some patients, which generally resolved with standard medical management. Clinical data supports a favorable risk/benefit profile for the use of InterVapor in the treatment of patients with heterogeneous severe emphysema.

Earlier this month, the small med-tech firm reported the first commercial use the system for endoscopic lung volume reduction in a patient with severe emphysema (*Medical Device Daily*, Dec. 1, 2011). The patient successfully underwent treatment with InterVapor, the first endoscopic lung volume reduction system for the treatment of severe emphysema that uses the body's natural healing processes without leaving foreign materials in the lung. The patient was treated by the team at **Thoraxklinik** (Heidelberg, Germany).

Uptake is billing the device as an alternative to far more invasive procedures used in the past.

"The next step for us is that we're going to be in discussions about larger randomized clinical trials," Nelson said. "We would guess that in 2012, we would hopefully be in a position to conclude our discussions and get into an agreement with the FDA on what a trial would look like."

Nelson did give some details about some of the upcoming trials particulars.

"It's going to be U.S. and Canada sites in the trial because of Geography," he told *MDD*. "We aren't using any other countries for this particular trial."

"We look forward to working with our distributor partner, **Aurora BioScience** [Sydney, Australia], as we introduce InterVapor in Australia in 2012," added Nelson.

Uptake was founded in 2005 with the specific focus of treating emphysema patients. Since its inception, the firm, with a full time staff of 25, has had about $45 million invested in it primarily by traditional venture capital groups, which include, GBS Venture Partners, Maverick Capital, Onset Ventures, Arboretum Ventures, Affinity Capital Management, and WRF Capital. ■

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Washington

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as she saw it on the day of the Dec. 7 hearing, Roberts seemed skeptical of the firm's claims. "I'm concerned that he's having a hard time getting himself there," she said of Roberts, adding that if the court goes against **Prometheus** (San Diego), the damage to diagnostic patents and to personalized medicine could be substantial.

A transcript of the hearing indicates that much of the discussion at the court revolved around the question of whether the eligibility of the patent was attenuated by a failure to limit the range of measurements of metabolites of thyropyridine in the Prometheus patent. DeFranco said, "Mayo's theory is that because there is no limit on the range" of readings, "the claim should not be patent eligible because it pre-empts the entire field."

The transcript indicates that Justice Steven Breyer remarked at one point, "discovering natural laws [that underlie a patent] is often a very expensive process," which could be interpreted as indicating that Breyer is more attuned to the views of industry than he perhaps might have been in the past, especially given his minority opinion in *LabCorp*. DeFranco did not see this as the case. "I don't think his opinion has changed at all," she said, remarking that the question may have been Breyer's way of trying to get Mayo's counsel to help him articulate "what I need to say is a standard as to why this claim is not eligible."

Chief Justice John Roberts posed the question of whether a patent could be obtained for a process in which "you take wood, you put it on a grate, you light it and you get heat." Roberts was testing the notion that a patent could be had when one recites "a series of acts in the physical world that transforms the subject of the process to achieve a useful result," which Roberts indicted was part of the filing for the government's case. The case as it stands pits **Mayo** (Rochester, Minnesota) against the U.S. Patent and Trademark Office for having allowed Prometheus' patent.

DeFranco said, "I think Justice Scalia is in the opposite camp from Justice Breyer," who is part of a group she said includes Justice Elena Kagan. A reversal of the outcome at the Court of Appeals for the Federal Circuit (CAFC), which found for Prometheus, "could have major implications," DeFranco said, adding, "if they say this claim is invalid, no matter how narrowly they state that, there are a lot of claims like this one" that would be affected.

Robin Feldman, a professor of law and the director of the Law and Bioscience project at the **University of California Hastings College of the Law** (San Francisco) told *Medical Device Daily* that while the court spent little time indeed on the machine-or-transformation (MoT) test, "I wouldn't say the justices ignored" MoT. "Their focus was on pre-emption" of natural processes and pre-emption of other inventions, which is tied to the failure to specify the range of measurements in the diagnostic. "That's a concept that came up repeatedly," Feldman observed.

Feldman said that she saw the questions from the bench as indicative of a group of justices who by and large were "trying to get a sense of whether there's a line at which they can say whether these inventions are patentable." Unlike DeFranco, however, Feldman was not entirely sure that Scalia was fond of the patent. "I read a number of Scalia's questions as [indicating] skepticism about allowing any types of patents" akin to this one.

Regarding Breyer's remarks about the cost of researching and developing life science products based on natural processes, Feldman said, "I would be surprised if an opinion from Justice Breyer said that because it's incredibly expensive to discover laws of nature that we should allow this" patent to stay on the books. She opined that Breyer, Justice Elena Kagan and Justice Anthony Kennedy "were all searching for something" that would allow personalized medicine, albeit with greater limits than are in place today. Feldman said Breyer touched on the question of "how much do you need to add" to nature to obtain a patent in some of his remarks.

"It will be interesting to see if you see an opinion signed by the three of them. That would be consistent with what we've seen with Kennedy across time," Feldman said, stating that the court may decide on a fine point of law that did not necessarily seem conspicuous during the hearing. She said the court may decide "there are things we'll allow protection for, even if we don't see it in front of us now."

Feldman said the outcome of this case will affect patents for therapeutic devices, even if it will influence them less routinely and less extensively than patents for diagnostics. "One of the things that may come out of this opinion – and one not necessarily intended by the justices – is the question of how to structure claims." She said "you could end up seeing language that moves you to drafting things that are more therapeutic than diagnostic" in terms of descriptions, and perhaps in terms of designs.

Regarding the possibility that the court will indeed come out with a very limited decision, Feldman gave an example. "I think the court was right in not giving more guidance in *Bilski*," the well-known business method patent case the court heard in 2008. The court, she said, "understood there were a lot of ramifications" of any hard-and-fast rules coming out of the court in *Bilski*. "I can see the same thing happening here" assuming the sense of the court is indeed that "they don't have a solution yet," which sends the issue back to CAFC "with limited guidance." That guidance may embody the message that "we don't want to see pre-emption of an entire field or a natural phenomenon," Feldman remarked, but also that the court wants to hear more from CAFC "about where that line should be." ■

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Europe

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image," said Amit Pawa, MD, Anesthesiologist Consultant, **Guy's and St. Thomas' NHS Foundation Trust** (London). "The EDGE system clearly accomplishes this while looking futuristic, sleek and sophisticated. Physicians will also benefit from the back-lit screen and wipe-able keypad. Overall, the image quality is superior and I can't wait to use it in clinical practice."

For overall improved detail and contrast resolution, the EDGE ultrasound system is engineered with new proprietary imaging algorithms that reduce speckle noise. The system also boasts a high luminance LED, high resolution 12 inch display, making it easier for clinicians to see the ultrasound image from across the bed during procedures.

The system also features a sealed silicone keypad for a new level of clean-ability – reinforcing SonoSite's ongoing commitment to assist medical facilities in the reduction of hospital spread infections.

For departmental flexibility, the EDGE system's transducers are compatible with SonoSite's M-Turboand S Series systems. At introduction, the EDGE ultrasound is available with a complement of thirteen transducers to support a wide range of examinations and procedures including thoracic assessment for pathology, vascular access, needle aspirations and injections, as well as abdominal, cardiac, nerve, OB/Gyn, musculoskeletal, small parts and vascular scanning.

Tryton receives German DRG reimbursement code

Tryton Medical (Durham, North Carolina) reportedthat the **German Institute for Medical Documentation and Information** (DIMDI, Cologne) has revised the procedure code for the treatment of coronary bifurcations lesions, distinguishing dedicated side branch stent systems from conventional technique and providing for additional reimbursement for use of the Tryton side branch stent.

"This favorable reimbursement decision in Germany is evidence of continued market acceptance of the Tryton stent, which has now been used to treat more than 3,500 patients worldwide," said Shawn McCarthy, president/CEO of Tryton. "The expanded reimbursement validates our commitment to providing data supporting Tryton's use in this problematic lesion subset."

Clinical data presented on more than 800 patients treated with the Tryton stent has demonstrated consistent target lesion revascularization rates of less than 4% at greater than six months follow up.

In addition, the Tryton stent is also being studied in the first and only randomized IDE clinical trial evaluating dedicated bifurcated stents. More than one-third of the 704 patients have been enrolled to date in the Tryton IDE study. The results of the trial will be submitted to the FDA for approval to market the device in the U.S.

The Tryton side branch stent system is built for bifurcation using proprietary Tri-zone technology to offer a dedicated strategy for treating bifurcation lesions. Tryton's cobalt chromium stent is deployed in the side branch artery using a standard single-wire balloon-expandable stent delivery system. A conventional drug-eluting stent is then placed in the main vessel. The stent system has received CE mark and is commercially available throughout Europe, Russia and the Middle East. It is approved in the United States for investigational use only.

More than one third of the patients have been enrolled to date in the landmark Tryton IDE study, a multi-national randomized trial that compares a Tryton stent in the side branch vs. the use of balloon angioplasty in the side branch, with both arms of the trial utilizing a standard drug eluting stent in the main vessel. The study, which is the first and only randomized IDE clinical trial, will enroll 704 patients at up to 75 centers in North America, Europe and Israel. Martin Leon, MD, **Columbia University** (New York) serves as principal investigator for the study and Patrick Serruys Thoraxcenter (Rotterdam, the Netherlands) is leading IVUS and three-dimensional angiographic analysis.

Privately held, Tryton is backed by Arnerich Massena & Associates, Spray Ventures, PTV Sciences, and RiverVest Ventures. ■

People in the News

• **Impact Corelab** (Sacramento, California) has named two new members to its board, both from affiliated company **Radiological Associates of Sacramento** (RAS), with key specialties and sub-specialties relevant to the company's focus areas. Vipin Bansal, MD, currently chair of the RAS finance committee, and Mark Leibenhaut, MD, an executive committee member for RAS, have both joined the Impact Corelab board. Impact Corelab combines cloud-based data on demand with experienced doctors, project managers, and clinicians to deliver guaranteed transparency, reliability, and query reduction for sponsors and CROs in image-based trials.

• **Integra LifeSciences Holdings** (Plainsboro, New Jersey) said its board has made the following changes, all effective Jan. 3. The board named Peter Arduini as president/CEO. In addition, the board elected Arduini to a newly-created position on the board. Stuart Essig was named executive chairman. Richard Caruso, founder of Integra LifeSciences and its chairman since its inception, will remain as a director of the company. Arduini joined Integra in November 2010 as president and COO. Integra makes products for orthopedics, neurosurgery, spine, reconstructive and general surgery.

TriRemeMedical

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TriReme's subsidiary, **Quattro Vascular** (Singapore). As far as *Medical Device Daily* was able to discern, the device does not have anything in common with the sweet sugary substance of the same name.

According to the company, Chocolate's design incorporates a constraining structure over a semi-compliant balloon to facilitate the formation of small modules (or, pillows). Through this advance mechanism of action, Chocolate minimizes shear stress and allows for uniform inflation and rapid deflation, TriRemeMedical said. The Chocolate pillows can expand locally to facilitate plaque modification and are designed to lower the strain and trauma induced on the vessel wall.

"I am very excited to be the first physician to use Chocolate PTA in the U.S." said Jihad Mustapha, MD, director of Endovascular Interventions and Research at **Metro Health Hospital** (Wyoming, Michigan). "We treated complex occlusions with outstanding results, no elastic recoil and no dissections which are the most feared complications in patients with critical limb ischemia. This product will be a crucial tool in the battle against critical limb ischemia and major amputations."

Attempts to reach TriRemeMedical by press time were unsuccessful and no information was found about the device on the company's web site about Chocolate.

Quattro Vascular reported winning CE mark approval for the Chocolate PTA balloon catheter earlier this year. Chocolate is the subsidiary's first product.

According to Quattro, more than 12 million Europeans suffer from peripheral vascular disease, with less than 25% undergoing treatment.

Current device-based treatment with atherectomy products, conventional balloons, cutting and other specialty balloons result in unpredictable results, substantial vessel trauma, high dissection rates, severe elastic recoil, and abrupt vessel closure. Even with peripheral stenting, outcomes are disappointing due to high rates of restenosis and stent fracture.

Quattro noted that the device's design is intended to minimize vascular overstretch and thus reduces injury during angioplasty procedures. In addition, Chocolate's innovative shaft technology consists of a braided shaft and an atraumatic tapered tip designed for greater push performance, Quattro said.

"Chocolate was developed for the treatment of complex lesions and represents the next generation in treatments of PAD," said Foo Fatt Kah, MD, managing director at Luminor Capital, which has invested in Quattro Vascular. "We have been very impressed by the pace that the company is progressing in its effort to commercialize this novel technology."

"We are pleased to receive U.S. regulatory approval for Chocolate PTA," Eitan Konstantino, PhD, president/CEO of TriReme, said in a company statement. "Chocolate is a great addition to our line of proprietary peripheral PTA catheters already available in the U.S., Europe and Asia. We are thrilled with Dr. Mustapha's initial U.S. experience and believe that Chocolate will provide substantial clinical benefits to patients suffering from peripheral vascular disease, both above and below the knee."

The company does make a similar device, the GliderXtreme PTA balloon catheter, which the FDA cleared for an expanded matrix of sizes last year (*Medical Device Daily*, May 28, 2010).

GliderXtreme is now approved for the percutaneous transluminal treatment of lesions in the peripheral vasculature in balloon diameters from 2.0 mm to 5.0 mm and in balloon lengths up to 200 mm. The GliderXtreme has a configuration that allows exceptional push, even in very long balloons that traditionally suffer from limited performance. Combined with its a-traumatic tapered tip and shaft construction reinforced for torque transmission, GliderXtreme is designed to cross distal, long, tight lesions to restore blood flow in complex peripheral anatomy, according to TriRemeMedical. ■

Product Briefs

• **Bio-AMD** (London) reported an update on progress on a digital strip reader, one of the three core point-of-care diagnostic device technologies owned by its 63% owned subsidiary, Bio-AMD Limited. The company believes that DSR can be applied to semi-quantitatively read lateral flow test strips for multiple diagnostics, particularly in established pregnancy and women's wellbeing tests market, where there is a shift toward digital devices. In response to discussions with potential commercial partners Bio-AMD Limited has further developed its single test DSR device to include a proprietary sensor array element. This improves sensor sensitivity, reliability and output matching. Bio-AMD Limited has also further refined its multi test DSR technology to address specific commercial needs. Bio-AMD intends to make a further patent application for its multi-test cartridge/reader mechanism.

• **Response Genetics** (Los Angeles) reported the addition of new anaplastic lymphoma kinase (ALK) testing capabilities. Using fluorescence *in situ* hybridization (FISH)-based technology – which complements the company's current PCR-based EML4-ALK test – Response Genetics can better detect gene variants in patients with non-small cell lung cancer (NSCLC) who may be candidates for Xalkori (crizotinib) treatment. Almost 3%-5% of NSCLC tumors have a rearrangement of the ALK gene, which can lead to impaired programmed cell death and abnormal cell growth. Using the new ALK Break Apart FISH Probe Kit, Response Genetics can detect rearrangements of the ALK gene on the 2p23 chromosome in tumors. The ALK Break Apart FISH Probe Kit is the only available diagnostic assay clinically validated to predict response to the targeted therapy Xalkori.

MDD's Ortho Extra

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

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Keeping you up to date on recent developments in orthopedics

Variations in spinal cervical Fusion Reflect Lack Of Evidence . . . If you're having surgery for degenerative disc disease of the cervical (upper) spine, the technique your surgeon uses may depend on what part of the country you live in, suggests a study in the January issue of *Spine*. Persistent regional variations highlight the need for solid scientific research on the techniques and outcomes of cervical spine surgery, according to the new report by Dr Kevin McGuire of **Beth Israel Deaconess, Boston**, and colleagues. The researchers analyzed data from a quality improvement project of the American Board of Orthopedic Surgeons, in which board-certified surgeons provided information on all surgeries performed over a six-month period. Data from 1999 to 2008 were analyzed to track trends in the rates and types of surgery for degenerative cervical disc disease.The study focused on a procedure called cervical spinal fusion, or anterior cervical discectomy and fusion (ACDF). In this procedure, the diseased disc between two vertebrae is removed and the vertebrae are fused together using bone grafts, hardware, or other techniques. Alternatively, an artificial disc may be implanted between vertebrae, without fusing the vertebrae. During the decade studied the number of cervical fusions performed by board-certified orthopedic surgeons increased by two-thirds, while the number of surgeons performing these procedures increased by nearly half. The number of surgeons who described themselves as spine surgeons increased by about one-fourth, while the number who said they were general orthopedic surgeons decreased by one-fourth. As in previous studies, the techniques used to perform ACDF varied between different U.S. regions. For example, surgeons in the South and Southeast were more likely to use artificial disc implants than Midwest surgeons. The use of metal plates was lower for surgeons in the Northeast but higher in the Southeast. Midwest surgeons were more likely to use bone substitutes (allograft) than the patient's own bone (autograft). Complications were more common when autograft was used. Overall rates of spine surgery in the United States have increased substantially in recent years. While spinal fusion is more commonly performed in the lower (lumbar) spine, about 40 percent of fusion procedures are done in the cervical spine. Previous studies have reported "enigmatic regional variations" in the rates of cervical spine surgery significant differences in rates and techniques, with no apparent basis in research evidence. The new study suggests that these variations persist while the number of cervical fusion surgeries increases. Since there has been little change in the population rates of cervical disc disease, "[O]ne must question the increase in surgical rates among orthopedic candidates, and continued regional variations in the types of procedures," Dr McGuire and colleagues write. These trends underscore the need for more evidence on the effectiveness of cervical spinal fusion surgery especially since studies suggest that about half of patients will improve without surgical treatment. There is also a lack of comparative data on which surgical technique provides the "best" results.

Introducing a new knee replacement model increases the chance of early revision surgery . . . Orthopaedic surgeons face a steep learning curve to get used to new prostheses, and the instruments and methods that go with them, before new total knee replacement procedures are as safe and effective as conventional methods. Patients who undergo the first 15 operations using a new device in a hospital are 48% more likely to need early revision surgery, than patients undergoing an operation to fit a prosthesis previously used in the hospital. The work by Mikko Peltola from the **National Institute for Health and Welfare** in Finland, and colleagues, is published online in *Clinical Orthopaedics and Related Research*. Total knee arthroplasty, or replacement, is an established treatment for patients with severe osteoarthritis of the knee. There are numerous brands and models of endoprostheses (a prosthesis used internally) available and new models continue to emerge as a result of a combination of new technology, marketing efforts and the increasing number of patients requiring the surgery. Hospital staff makes important decisions when choosing the implants and instruments they use, and these decisions carry consequences for patients' health. According to the research team, however, new equipment

and techniques are often used in clinical practice, occasionally without evidence of effectiveness and safety. Peltola and team looked at the risk of early revision surgery following the introduction of a new endoprosthesis model for total knee arthroplasty. They studied data from the Finnish Arthroplasty Register to identify centers that had performed total knee replacement operations for primary osteoarthritis between 1998 and 2004. Of the 23,707 total number of patients who underwent the surgical procedure, 22,551 were followed up for five years. The researchers found that the introduction of an endoprosthesis model in a hospital put the first patients at greater risk of revision surgery. The effect was substantial for the first 15 patients operated on with the new model, who were at 48% greater risk than patients having undergone an operation to implant a conventional endoprosthesis. Overall, the likelihood of needing revision surgery was greatest during the first two years after the surgery. The learning curve smoothed quickly, however, with no increased risk after the first 15 operations with the new model. The authors conclude: "Patients should be informed if there is a plan to introduce a new model and offered the option to choose a conventional endoprosthesis instead. Although introducing potentially better endoprosthesis models is important, there is a need for managed uptake of new technology."

Healing serious bone injuries faster than ever before . . . A human-made package filled with nature's bone-building ingredients delivers the goods over time and space to heal serious bone injuries faster than products currently available, Cleveland researchers have found. Tested on sheep in Switzerland, the surgical elastic "implant device," essentially a wrapping that mimics bone's own sock-like sheath called periosteum, delivered stem cells, growth factors and other natural components of the periosteum to heal a defect that would not heal on its own if left untreated. In experimental groups exhibiting best outcomes, a dense network of new bone filled the defect, from the surgical elastic wrapping on the outside towards the steel intramedullary nail that stabilized the bone on the inside, bridging old with new bone. Melissa Knothe Tate, a joint professor of biomedical engineering and mechanical & aerospace engineering at **Case Western Reserve University** (Cleveland); Ulf Knothe, an orthopedic surgeon at the **Cleveland Clinic**, as well as Hana Chang and Shannon Moore, graduate students in Knothe Tate's lab, report their work in a recent issue of *PLoS ONE*. "We're trying to use the methods Mother Nature uses to generate bone," Knothe Tate said. The device is modeled after the periosteum, the sock-like covering of bone, which is filled with stem cells and growth factors that, given the right cues, grow bone. Knothe Tate and her husband, Knothe, reported last year that bridging a bone injury with periosteum healed bone faster than any currently used methods, in testing on sheep and in limited clinical cases. But, often there is too little of the periosteal covering left to fully cover the gap after a traumatic injury. Based on what they'd learned, Knothe Tate built a version of periosteum out of two elastic sheets, approved by the FDA for surgery. She left one intact and perforated the other in a gradient with most holes across the center of the sheet and fewer the farther from the center. She sewed the sheets together using surgical sutures as thread, with the perforated sheet on the inside. The suture seams create a series of pockets, left open at what would be the top and bottom of the device. The device is sutured to the healthy tissue like a patch and provides a path for movement of cells and bone building materials upward, downwards and inwards. The researchers filled the pockets of one set of the devices with membranes made of collagen, which is a natural component of the periosteum; a second set was filled with collagen membranes seeded with cells that reside in the periosteum, and a third set with strips of periosteum. Both the collagen seeded sheets and the periosteum strips tucked into the pockets showed the most promising results for bridging of critical sized defects that do not heal on their own. The pockets filled with natural periosteal strips, although no longer connected to a blood supply, provided the ingredients to grow bone quickly, densely, and completely in a group of five adult sheep, Knothe Tate said. In addition to providing the ingredients at the right place and time, the device, along with the nail, act as a template for the new growth. "This really blurs the line between an implant and a delivery system," Knothe Tate said. Beyond bone, the device is flexible enough to be used in a broad array of applications, Knothe Tate said. Potential uses include growing cartilage for orthopedics, to fuse vertebrae, as a delivery system for stem cells, antibiotics, transcription factors and more.

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