
MEDICAL DEVICE DAILY™

THE DAILY MEDICAL TECHNOLOGY NEWSPAPER

WEDNESDAY, MARCH 4, 2009

VOL. 13, No. 41

PAGE 1 OF 12

Study reveals 37% of LVAD patients later need RVAD

By AMANDA PEDERSEN

Medical Device Daily Staff Writer

It probably goes without saying that if a heart failure patient is going to develop right ventricular (RV) failure after receiving a left ventricular assist device (LVAD), that patient should have received bi-ventricular support from the start. The problem is, predicting post-LVAD RV failure requiring mechanical support is anything but easy.

Data published in the December issue of the *Journal of Heart and Lung Transplantation (JHLT)* highlights this problem, as one article in the journal finds that RV dysfunction develops in 20% to 50% of LVAD patients and a second article finds that 37% of LVAD recipients later require a RV assist device (RVAD).

What happens is when the LVAD is implanted it begins to assist the left side, which powers up the body and moves blood back to the right atrium, and the right ventricle can't

See Study, Page 7

With MAKO's robotic knee system, results are as planned

By JIM STOMMEN

Medical Device Daily Executive Editor

The premise behind **MAKO Surgical's** (Fort Lauderdale, Florida) approach to minimally invasive knee procedures is simple: What you plan is what you get.

And that's what the company highlighted at last week's annual conference of the **American Academy of Orthopaedic Surgeons** (AAOS; Rosemont, Illinois), where it debuted its RIO Robotic Arm Interactive Orthopedic System and Restoris MCK MultiCompartmental Knee System after receiving FDA clearance of the products in December.

Maurice Ferré, MD, president/CEO/chairman of the company, ebulliently told *Medical Device Daily* that the AAOS gathering "was kind of our 'coming out' party."

Ferré said the traffic at MAKO's booth on the exhibit floor was constant. "We have taken the floor by storm," he said in a phone interview from that busy exhibit area.

See MAKO, Page 8

International report

Canada approves Angiotech's Quill SRS suture products

A Medical Device Daily Staff Report

Angiotech Pharmaceuticals (Vancouver, British Columbia) said it has received 510(k) clearance to begin marketing the Quill SRS Polydioxanone (PDO), Monoderm and Nylon product lines in Canada.

"With the approval of the PDO, Monoderm and Nylon product lines in Canada, we can further extend the global reach of this next-generation suture product beyond the U.S. and Europe," said President/CEO Dr. William Hunter.

Quill SRS PDO is a longer-lasting absorbable suture, which is typically used for deeper tissue closures while Quill SRS Monoderm is made from a rapidly resorbing polymer and intended primarily for superficial wound closure applications and soft tissue approximation where use of an absorbable suture is appropriate.

The monofilament Quill SRS Nylon is a polyamide suture indicated for use in soft tissue approximation excluding closure of the epidermis.

See International, Page 10

Imalux's OCT system can ID early stage cervical dysplasia

By LYNN YOFFEE

Medical Device Daily Staff Writer

An annual trip to the gynecologist for a Pap smear to check for cervical cancer has become a standard regimen for millions of women. But the test is far from perfect, missing up to half of all early stage signs of cervical dysplasia.

Imalux (Cleveland) is in the process of refining an Optical Coherence Tomography (OCT) system that would allow physicians more precisely differentiate grades of pre-invasive cervical dysplasia prior to biopsy, providing the opportunity for earlier treatment.

"Cervical dysplasia is currently diagnosed in three steps," Nancy Tresser, MD, Imalux vice president and chief medical officer, told *Medical Device Daily*. "We do a Pap smear and then if it's abnormal, you have colposcopy and then a biopsy. If the biopsy shows early cancer or invasive cancer, we move on to treatment.

"We're trying to identify patients at earlier stages," she said. "Our eventual hope is that this would be cost-effective

See Imalux, Page 9

INSIDE:

HOUSE BILL WOULD PUT FEDERAL MONEY INTO CRC SCREENING2

VON ESCHENBACH: HEALTHCARE NEEDS TO BE REFORMED, TRANSFORMED3



*Washington roundup***House bill would put federal money into CRC screening****A Medical Device Daily Staff Report**

The prevalence of colorectal cancer (CRC), not to mention the high mortality rate associated with the disease, has the attention of both medical professionals and lawmakers, hence the reintroduction of a bill that would back the concerns with federal tax dollars.

Rep. Kay Granger, (R-Texas) has introduced the Colorectal Cancer Prevention, Early Detection, and Treatment Act of 2009 (H.R. 1189) to the House Energy and Commerce Committee that would essentially parallel a bill that made the rounds in the 110th Congress by the same name with the exception of the date designation, which was 2007. In its current form, the bill would provide \$50 million for programs that provide screening and treatment for the disease with a special emphasis on low-income Americans and those with no insurance or inadequate insurance. By 2013, the funding would rise to \$250 million.

The bill has the support of the **American Cancer Society Cancer Action Network** (ACSCAN; Atlanta), which issued a Feb. 27 statement by Robert Youle, chairman of the ACSCAN board of directors. Youle states that given that "colon cancer screening could actually prevent cancer by detection and removal of premalignant polyps, the programs initiated by this legislation could potentially save thousands of lives, avoid suffering due to cancer treatments, reduce the burden of cancer costs and prevent many colon cancer cases and deaths altogether."

Youle also states that with early diagnosis, the disease has a five-year survival rate of 90%, but survival at five years drops to 10% for late-stage detection. The association's numbers indicate that colon cancer is the third most commonly diagnosed type of cancer, with roughly 148,000 Americans diagnosed each year.

Granger's bill would help cover screening and treat-

Today's MDD food for med-tech thought

"When they put their hands on the robot, they have an epiphany."

— Maurice Ferré, MD, president/CEO of MAKO Surgical, discussing surgeons' reactions to trying out the company's RIO robotic system at AAOS, "With MAKO's robotic knee system, results are as planned," pp. 1, 8, 9.

ment for those aged 50 and over at typical risk for the disease and anyone under the age of 50 who has a demonstrated risk. H.R. 1189 would also give states the option of using Medicaid monies for residents under the age of 65 who lack sufficient coverage to deal with the cost of treatment and follow-up.

It is not clear if the bill includes funding for the screening of CRC with computerized tomography, which the Centers for Medicare & Medicaid Services proposed not to cover last month (*Medical Device Daily*, Feb. 13, 2009). This decision, CMS said, was due to, among other things, concerns of exposure to X-radiation as well as questions about the clinical study patient population which was considerably younger than the Medicare aged population

Beneficiary sues to avoid Medicare

Given all the *sturm und drang* over Medicare costs, one would think that the Centers for Medicare & Medicaid Services would be happy to allow a Social Security beneficiary to opt out of Medicare in favor of his own coverage. But a recent court case shows that one would be mistaken to think that.

After decades of service at the Department of Housing and Urban Development, Brian Hall retired in 2006 at the age of 62. Hall signed up to collect Social Security benefits, but opted to maintain the health coverage he'd had via the Federal Employee Health Benefits Program (FEHBP), which has often been touted as a model for nationalized health-care.

See Washington, Page 11

MEDICAL DEVICE DAILY™ (ISSN# 1541-0617) is published every business day by AHC Media LLC, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305, U.S.A. Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. MEDICAL DEVICE DAILY™ is a trademark of AHC Media LLC, a Thompson Publishing Group company. Copyright © 2009 AHC Media LLC. All Rights Reserved. No part of this publication may be reproduced without the written consent of AHC Media LLC. (GST Registration Number R128870672)

ATLANTA NEWSROOM: Executive Editor: **Jim Stommen**. Managing Editor: **Holland Johnson**. National Editor: **Don Long**. Washington Editor: **Mark McCarty**. Staff Writers: **Omar Ford**, **Amanda Pedersen** and **Lynn Yoffee**. Senior Production Editor: **Rob Kimball**.

BUSINESS OFFICE: Senior Vice President/Group Publisher: **Donald R. Johnston**. Senior Marketing Product Manager: **Chris Walker**. Marketing Coordinator: **Sonia Blanco**. Account Representatives: **Bob Sobel**, **Chris Wiley**.

REPRINTS: For photocopy rights or reprints, please call **Stephen Vance** at (404) 262-5511 or e-mail him at stephen.vance@ahcmmedia.com.

SUBSCRIBER INFORMATION
Please call **(800) 688-2421** to subscribe or if you have fax transmission problems. Outside U.S. and Canada, call **(404) 262-5476**. Our customer service hours are 8:30 a.m. to 6:00 p.m. EST.

EDITORIAL
Holland Johnson, **(404) 262-5540**
Fax: **(404) 814-0759**

SVP/GROUP PUBLISHER
Donald R. Johnston,
(404) 262-5439

INTERNET
www.medicaldevicedaily.com

AHC Media LLC

Former FDA chief von Eschenbach:

Healthcare needs to be both 'reformed and transformed'

By DONNA YOUNG

Medical Device Daily Washington Writer

Biomedicine's future is dependent on the new reality in healthcare of integrating the parts and pieces of product discovery, development and delivery, said former FDA Commissioner Andrew von Eschenbach, who recently joined **Greenleaf Health** as a senior adviser.

In an environment where science and medicine have moved rapidly from simply observations of the manifestations of disease to understanding of the mechanisms of disease, the FDA, industry and Congress all need to make adjustments if healthcare is going to be reformed and transformed, said von Eschenbach, who spent 25 years at the **University of Texas M.D. Anderson Cancer Center** (Houston) before becoming director of the National Cancer Institute in 2002 and later moving to the FDA in 2005.

Von Eschenbach noted that when he joined the FDA, his challenge was one of resuscitating the agency.

"It was like encountering a patient who was on life support," he told *Medical Device Daily's* sister publication, *BioWorld Today*, calling the agency one that had antiquated information technology systems and a shrinking work force, with 30% of its personnel set to soon retire.

"My first and foremost challenge and responsibility as commissioner was along the lines of resuscitation, developing the justification and rationale for additional resources, acquiring those resources and beginning to transform the infrastructure," von Eschenbach said.

However, the agency has recently received more funds to increase its staff and improve its technology and the FDA's move to its new White Oak headquarters in Silver Spring, Maryland, which began in 2003, has progressed smoothly, said von Eschenbach.

He left the FDA in January, and his new position for Greenleaf Health does not involve lobbying. Rather, he is advising organizations about long-term strategies involving product discovery, development and delivery.

The medical product industry, too, is now facing its own challenges, he noted. As with the computer industry, where the success of a laptop or hard drive is dependent on the microprocessor and other components and vice-versa, healthcare has become an industry in which the success of a therapeutic intervention is increasingly becoming reliant on the use of diagnostic tests, von Eschenbach said.

What used to define market share is no longer the case, he said, noting that drugs and devices in the future will not always be made for large populations, given the progress of personalized medicine and the knowledge of mechanisms of diseases.

"Industry has to rethink market share based on what are commonalities as it relates to fundamental mechanisms for which you are developing an intervention," von

Eschenbach said.

Firms should be developing their interventions against a mechanism rather than against the outcome of the disease, he said.

For instance, von Eschenbach said, when angiogenesis inhibitors were being developed as cancer treatments, no one had considered at that time that they also could be successful treatments for macular degeneration of the eye, as is now the case, with many doctors substituting **Genentech's** (South San Francisco, California) cancer drug Avastin (bevacizumab) for its much more expensive, but basically similar, drug Lucentis (ranibizumab).

From a mechanistic perspective, he explained, both cancer and macular degeneration "are diseases with abnormalities of angiogenesis operative."

Novartis's (Basel, Switzerland) Gleevec (imatinib mesylate), which is approved to treat chronic myeloid leukemia and gastrointestinal stromal tumors, is another example, von Eschenbach noted.

"Who in oncology would have ever said those diseases are the same," he said. "But from a mechanistic point of view, they can be thought of as the same."

While the medical products industry and the FDA currently are transforming their models for developing and regulating therapies, Congress also must transform its mindset, said von Eschenbach.

Lawmakers, he said, must understand that the FDA needs the ability to engage with device and drug makers. "You can't do this in a vacuum," von Eschenbach contended. "There is going to have to be consultation, corroboration and cooperation," he said.

However, he added, "That doesn't mean the FDA is going to stop being a strong regulatory agency and it doesn't mean the industry doesn't have to remain economically viable. The FDA should be and ought to be the strongest, most effective regulatory agency on the planet protecting and promoting public health of the people it serves. But that doesn't mean it doesn't do it in collaboration and cooperation with industry."

If the FDA and industry are forced to work in separate silos, new therapies will be delayed, von Eschenbach said.

"The more you isolate the FDA from the industry and isolate the industry from the FDA, the greater problems you are going to have," he said.

If personalized medicine is going to move forward, von Eschenbach said, "Why would we not want to do that in dialogue with each other so that we are aligning discovery and development with the regulatory pathway that is going to bring those things rapidly and efficiently to patients? Why are we going to create barriers or partitions between those rather than create this in a way that is much more seamless?"

The FDA, he said, must make a better case to Congress and reassure lawmakers about the necessity of communication between the agency and industry if regulation is going to be able to keep up with the scientific advances that lie ahead. ■

*Deals roundup***For up to \$20M, PhotoMedex acquires Photo Therapeutics****A Medical Device Daily Staff Report**

PhotoMedex (Montgomeryville, Pennsylvania), a developer of excimer lasers and products for other dermatological applications, said it has acquired **Photo Therapeutics** (Cheshire, UK). The initial purchase price of \$13 million was paid at closing, and up to an additional \$7 million of consideration will be paid if certain gross profit milestones are met by June 30, the company noted.

The acquisition was funded through a convertible debt investment of \$18 million by an investment fund managed by Perseus, which financed the \$13 million purchase price of the acquisition, and a further \$5 million in working capital at the closing of the acquisition.

Perseus will make up to an additional \$7 million convertible debt investment in PhotoMedex in the event the additional consideration is payable. After the payment of roughly \$2 million of transaction expenses associated with the acquisition and Perseus' investment, the company will have about \$3 million remaining for use as working capital.

"We are very excited about completing this acquisition which further solidifies our dermatological franchise. In addition, we are very encouraged with the future growth prospects of Photo Therapeutics' products," said Jeff O'Donnell, president/CEO of PhotoMedex. "We believe having Perseus' support as our financial partner will allow us to focus on continuing to build market share in both the medical and consumer dermatology space."

Photo Therapeutics develops non-laser light devices and associated skin care products for the treatment of a range of clinical and aesthetic dermatological conditions. The company operates out of three primary business segments: Professional Devices, Home Use Devices and Skin Care Consumables.

In other dealmaking activity:

- **Power Medical Interventions** (Langhorne, Pennsylvania) said Monday it has received a \$2.5 million payment from **Intuitive Surgical** (Sunnyvale, California) in connection with a license and development agreement the two companies signed in September.

The payment relates to a surgical stapling device being jointly developed by Power Medical and Intuitive, a company best known for its da Vinci robotic surgical systems.

The surgical stapling device being developed incorporates Power Medical's patented technology. It is being designed to attach to Intuitive's da Vinci surgical system for a broad array of surgical applications.

The companies have also entered into an exclusive reload supply agreement that calls for Power Medical to make and exclusively supply staple reload cartridges for the newly developed device.

- **Hansen Medical** (Mountain View, California)

reported an equity investment in **Advanced Cardiac Therapeutics** (ACT; Laguna Beach, California), and the securing of exclusive rights to certain ACT intellectual property for certain robotic applications. Details of the transaction were not disclosed.

ACT, a privately held company, is developing a technology designed to accurately measure the temperature in a lesion during cardiac ablation procedures.

Current manual technology used by physicians to control catheters in electrophysiology procedures can be limiting in several ways including, precise catheter control and stability, as well as the inability to accurately sense tissue temperature and its potential effect on lesion quality.

The Sensei Robotic Catheter System from Hansen has helped to advance the control of electrophysiologic mapping catheters by using flexible medical robotics technology to provide stable and predictable control of catheter movement inside the heart, according to the company.

- **Lab21** (Cambridge, UK), a provider of state-of-the-art diagnostic products and services, reported that it has purchased the majority shareholding of **Biotec Laboratories** (Ipswich, UK), a clinical diagnostic company with particular emphasis on infectious diseases, most notably tuberculosis (TB). Financial details of the transaction were not disclosed.

As part of the sale, Lab21 also acquired Biotec's South African subsidiary, **Biotec Laboratories SA** (Johannesburg, South Africa) which is a joint venture with the Cape Biotech Trust.

Commenting on the acquisition, Graham Mullis, CEO of Lab21 said, "Our goal is to grow Lab21 into a major international diagnostics business through both organic growth and acquisition – this transaction is an important step in that process. Our combined businesses, which have very complementary products, provide a great platform from which to build further our infectious disease and immunodiagnostic portfolio."

Biotec Laboratories has developed a portfolio of diagnostic products with a particular focus on infectious diseases. The two companies have had an ongoing commercial relationship, with Biotec Laboratories distributing some of Lab21 diagnostic products through its established global network of distributors in 80 countries worldwide. This will strengthen the Lab21 global reach, in particular in Africa and South America and will allow it to immediately access new markets for its products. Biotec Laboratories SA has developed proprietary phage amplification technology that is being used to develop rapid diagnostic and susceptibility tests for both active and Drug Resistant TB.

For the immediate future, Biotec Laboratories will continue to trade as a subsidiary of Lab21 group.

- **Bausch & Lomb** (B&L; Rochester, New York), the global eye health company, has entered into a licensing agreement with **Santen Pharmaceutical** (Osaka, Japan)

See Deals, Page 11

Agreements/contracts**HP, Partners extend alliance to develop genomics technology****A Medical Device Daily Staff Report**

HP (Palo Alto, California) and **Partners HealthCare** (Boston) reported the extension of a five-year, multi-million dollar agreement to develop software and implement hardware and services supporting Partners' efforts to accelerate clinical genomics and advance personalized medicine.

This phase of the collaboration focuses on extending Partners' technology infrastructure, especially data storage capabilities, to address the challenges posed by sequencing technologies. The increase in genetic and genomic data output from these sequencing technologies will require a cost-effective, high-performance computing storage environment.

"To turn the vision of personalized medicine into reality requires the convergence of IT, research and health-care," said John Glaser, chief information officer, Partners HealthCare. "We believe the vision of personalized medicine, where clinicians are able to make diagnostic, treatment and clinical management decisions based on a patient's genetic profile, can only be realized by leveraging IT infrastructure that can keep pace with the fast rate of change in the genomics field. The Partners HealthCare Center for Personalized Genetic Medicine (PCPGM) is uniquely positioned to deliver the promise of personalized medicine."

HP and Partners' collaboration builds upon a five-year relationship that has led to the development of a large multi-cluster computer facility to support genetics researchers at Partners HealthCare.

This infrastructure allowed HP and PCPGM to collaborate on the creation of the Gateway for Integrated Genomics-Proteomics Application and Data, a software environment that integrates disparate laboratory systems, provides a portal to submit and access biological samples and enables efficient management of analytical workflows and data repositories.

"As a result of this collaboration, we have been able to make genetic and genomic technologies more accessible for our researchers as well as our clinicians," said Sandy Aronson, executive director, Information Technology, PCPGM. "Now we will build support for the new forms of sequencing and genotyping that will accelerate the advancement of personalized medicine. It is exciting to envision the benefits that will accrue."

In other agreements/contracts news:

- **Pfizer** (New York) and **Bausch & Lomb** (B&L; Rochester, New York) reported a co-promotion agreement involving both companies' prescription ophthalmic pharmaceuticals in the U.S. The agreement will allow both companies to greatly increase the level of eye care industry support for the medications that treat serious ophthalmic

conditions. Both the Pfizer and B&L sales forces will promote Xalatan, Alrex, Lotemax, Zylet and besifloxacin (subject to FDA approval).

- **PDI** (Saddle River, New Jersey) and **Sequenom Center for Molecular Medicine** (SCMM; San Diego) reported that PDI has been selected to provide the sales infrastructure to launch and commercialize SCMM's noninvasive prenatal genetic screening tests based on its SEQureDx technology.

Under the direction of SCMM management, PDI will support the commercialization of SCMM's fetal Rhesus D genotyping test from a maternal blood sample. This test will reduce the risk to the mother and fetus by providing clinicians early and accurate information. PDI will also provide sales support to SCMM upon commercialization of its noninvasive Down syndrome (Trisomy 21) test which is expected to be launched in June of this year, as well as other laboratory developed tests.

Financial terms were not disclosed.

- **Laboratory Corporation of America** (LabCorp; Burlington, North Carolina) has signed a collaboration agreement with **Duke University** (Durham, North Carolina) related to LabCorp's Biorepository in Kannapolis, North Carolina. The deal focuses on the operation of the facility, as well as the management of samples deposited by Duke University, and its clients and collaborators, including samples from the MURDOCK study, which is applying technologies to identify genomic linkages across major chronic diseases and disorders.

"The Biorepository is an important addition to LabCorp's biomarker development capabilities and our service offerings for our commercial clients," said David King, CEO of LabCorp. "The Biorepository is also an important addition to our long standing relationship with Duke University and a new initiative for LabCorp at NCRC. The combined capabilities of our organizations through the Biorepository will further our leadership in personalized medicine and will lead to new discoveries and new diagnostic tests that will benefit patient care." ■

Patent watch**Therative gets patent for new acne clearing device****A Medical Device Daily Staff Report**

Therative (San Francisco) reported that the proprietary technology in its ThermaClear Acne Clearing Device is now patent-protected under the new U.S. patent No. 7,494,492.

The FDA-cleared ThermaClear Acne Clearing Device delivers a controlled, two-second pulse of targeted heat directly to individual pimples, attacking acne at its source. The advanced Thermal Pulse Technology delivers a pulse

See Patent, Page 6

*Financings roundup***Cardima raises \$20M gross proceeds in private stock sale****A Medical Device Daily Staff Report**

Cardima (Fremont, California) said it has completed the private sale of 18,518,518 shares of common stock at \$1.08 a share to an accredited investor for total gross proceeds from the sale of \$20 million. In addition, the company said it would issue to the investor warrants to purchase 5,555,555 shares of common stock at an exercise price of \$1.25 a share.

"The fact that Cardima is able to raise equity in the midst of the most challenging economic environment that we have faced in generations is a testament to the commercial potential of our ablation technology," said Tony Shum, chairman of Cardima. "We intend to use the proceeds to prudently continue to execute our commercial plans to support further product adoption and to repay outstanding loans."

Cardima describes itself as a device company focused on the treatment of atrial fibrillation (AF). The company has developed the Pathfinder, Tracer and Revelation series of diagnostic catheters, the Intellitemp energy manage-

ment device and the surgical ablation system. All of these devices have received CE mark approval and FDA 510(k) clearance, the company notes. The Revelation series of ablation catheters with Intellitemp EP energy management device, developed for the treatment of AF, has received CE mark approval and is marketed in Europe, the company added.

In other financing activity, **GetWellNetwork** (Bethesda, Maryland), a provider of interactive patient care (IPC) solutions, said it received \$10 million in a Series C financing round. Johnson & Johnson Development Corporation, as well as existing investors including Valhalla Partners, Grosvenor Funds, Point Judith Capital, and Village Ventures & Affiliates, participated in the financing.

GetWellNetwork, in partnership with leading hospitals and healthcare systems across the country, delivers technology and services to drive optimal patient outcomes. Empowering patients as active participants in the healthcare process, IPC solutions are patient-centric applications delivered at the point-of-care to ensure the completion of service and quality requirements, while driving new revenue opportunities and operational efficiencies for healthcare providers, according to the company. ■

*Grants roundup***ProteoTech awarded grant from the Michael J. Fox Foundation****A Medical Device Daily Staff Report**

ProteoTech (Kirkland, Washington) reported that it has been awarded a grant from the Michael J. Fox Foundation for Parkinson's Disease Research. In collaboration with **Avid Radiopharmaceuticals** (Philadelphia), ProteoTech scientists will utilize ProteoTech's small-molecule platform drug technology to develop new imaging agents that will allow doctors to use PET imaging to identify and determine the extent of alpha-synuclein accumulation in the living human brain.

Alpha-synuclein is a major protein identified in Lewy bodies in the Parkinson's disease brain, and its accumulation

in brain is believed to be important in the motor dysfunction observed in Parkinson's patients. The 1-1/2 year project, titled "18-F-labeled Alpha-Synuclein Ligands for PET Imaging of Lewy Bodies," will be led by Dr. Alan Snow, chairman/president/CSO of ProteoTech, and Dr. Franz Hefti, CSO of Avid.

ProteoTech is in its 4th year of a LEAPS award funded by the Michael J. Fox Foundation to develop a new small molecule targeting alpha-synuclein in Parkinson's brains. ProteoTech's Synuclere has been demonstrated to inhibit alpha-synuclein aggregation in the brains of genetically engineered mice that develop motor dysfunction, when alpha-synuclein deposits aggregate and accumulate in brain.

The LEAPS award consortium led by Snow includes research teams from **University of California-San Diego, Boston University, Boston College** and **MedChem Source** (Federal Way, Washington). ■

Patent*Continued from Page 5*

of heat to instantly penetrate the skin to neutralize the underlying bacteria that causes breakouts. ThermaClear-treated pimples clear four times faster than those not treated with the device, with results visible in as little as 24 hours.

"The patent confirms the uniqueness of ThermaClear's heat-enabled Thermal Pulse Technology for treating acne," said Sandra Lawrence, president/CEO of Therative. "Consumers benefit from the speed and effectiveness of the technology. It's no wonder tens of thousands of consumers

have incorporated ThermaClear into their acne skin care regimen."

ThermaClear is similar to laser technology used by professionals to treat mild to moderate inflammatory acne, but designed for use at home for a fraction of the cost. Using only heat, ThermaClear does not cause the drying, irritation or skin hyper pigmentation often associated with chemicals in many topical acne products. In addition, it is safe on all skin types and tones. ThermaClear's portable design allows convenient use anytime, anywhere and even over makeup. ThermaClear treats all mild to moderate inflammatory acne, even hormonal and stress-induced blemishes, both above and below the skin's surface. ■

Study

Continued from Page 1

keep up with the assisted left ventricle, explained Roger Ford, CEO of **SynCardia Systems** (Tucson, Arizona), the company that makes the CardioWest temporary Total Artificial Heart.

"The mystery is how in the heck can you determine whether you have a poor function right and left side before you assist the left side? Nobody knows, some people think they know but nobody really knows," Ford told *Medical Device Daily*.

One article published in *JHLT* is from the **German Heart Institute Berlin**. It suggests that RV dysfunction develops in 20% to 50% of patients after LVAD implantation, leading to prolonged ICU stays and elevated mortality, according to the study authors. The article concludes that pre-operative evaluation of tricuspid incompetence and RV geometry may help to select patients who would benefit from biventricular support.

A second article, from the **Hospital of the University of Pennsylvania** (HUP; Philadelphia), found that of 266 LVAD recipients, 99 required a RV assist device (37%).

RV failure after LVAD placement is a "serious complication and is difficult to predict," according to the authors of the HUP article. "In the era of destination therapy and the total artificial heart, predicting post-LVAD RV failure requiring mechanical support is extremely important."

According to the HUP article, researchers reviewed patient characteristics, laboratory values and hemodynamic data from those 266 patients who underwent LVAD placement at the University of Pennsylvania from April 1995 to June 2007.

The researchers compared 36 parameters between LVAD and BiVAD patients to determine pre-operative risk factors for RVAD need. The study authors concluded that the most significant predictors for RVAD need were cardiac index, RV stroke work index, severe pre-operative RV dysfunction, creatinine, previous cardiac surgery and systolic blood pressure. Using these data, the researchers constructed an algorithm that can predict which LVAD patients will require RVAD with more than 80% sensitivity and specificity.

Both articles were presented at the 28th annual meeting of the **International Society for Heart and Lung Transplantation** (ISHLT; Addison, Texas) in April.

"The obvious point is, my goodness, 37% of people that got LVADs needed RVADs," Don Isaacs, director of communications for SynCardia, told *MDD*. "If they could determine whether that patient would need an RVAD or not . . . [then they could get a] more appropriate device, which for tiny patients would be a biventricular assist device and patients of any size would be a CardioWest total artificial heart."

SynCardia is in the process of developing a 50 cc version (compared to the 70 cc version) of its total artificial heart for smaller adults and adolescents. Ford said the

development of the smaller device is on track to be completed by the third or fourth quarter of this year.

"Right ventricular failure in LVAD patients is tragic," said Jack Copeland, MD, chief of cardiothoracic surgery at **University Medical Center** (Tucson), who reports owning equity in SynCardia. "If it can be anticipated, the solution is bi-ventricular support from the start. If it becomes a crisis, in appropriate patients, the CardioWest temporary Total Artificial Heart (TAH-t) may be life-saving."

Originally designed as a permanent replacement heart, the CardioWest artificial heart is currently approved as a bridge to human heart transplant for patients dying from end stage biventricular failure. The device is the only FDA, Health Canada and CE mark approved total artificial heart in the world, the company notes.

"By replacing both sides of the dying heart, the CardioWest eliminates complications caused by failing ventricles, diseased valves, ventricle defects and electrical problems requiring a pacemaker and/or defibrillator," Copeland said.

Although the CardioWest device is approved as a bridge-to-transplant device, Ford said there are some patients in Germany with a CardioWest artificial heart implanted who have decided to "avoid the hospital and have been on our device for three years now."

Meanwhile, LVAD makers continue to release new and improved devices designed to support the left ventricle. Last year **Terumo Heart** (Ann Arbor, Michigan) received the go-ahead from FDA to start its U.S. trial of the DuraHeart Left Ventricular Assist System (LVAS) as a bridge-to-transplant device (*Medical Device Daily*, March 5, 2008).

Then, in August, the company reported that the first U.S. patient implanted with the DuraHeart had been discharged from the **University of Michigan Health System** (Ann Arbor) 15 days after receiving the device (*MDD*, Aug. 25, 2008).

Terumo says the hockey puck-sized DuraHeart LVAS uses a new type of magnetic levitation technology (Mag-Lev) designed to eliminate mechanical contact within the blood flow path thus minimizing the chance of mechanical failure. Mark White, marketing manager for Terumo Heart, told *MDD* at the time that the Mag-Lev technology is the core benefit of the DuraHeart, as it prevents a lot of the problems associated with other systems in which the impeller is suspended through pressure distribution.

That news came almost simultaneously with **HeartWare** (Farmingham, Massachusetts/Sydney, Australia) reporting that the first U.S. patient had received its LVAS at **Washington Hospital Center** (Washington), marking the start of its U.S. trial (*MDD*, Aug. 22, 2008). Similar to the DuraHeart, the impeller that spins inside the HeartWare LVAS pump is also suspended by magnetic forces. Although both pumps are much smaller than earlier generation devices, the HeartWare is actually small enough to fit

See Study, Page 11

MAKO

Continued from Page 1

“We’re kind of the talk of the town.”

Asked how surgeons were reacting to the new systems being exhibited by the company, Ferré said, “When they put their hands on the robot, they have an epiphany.”

He said the RIO system’s passive robotic arm means “you can truly introduce minimally invasive surgery” to the knee-replacement sector.

Ferré said that for unicompartmental and bicompartamental knee systems, “you need perfect placement,” and that’s what RIO and the Restoris implants provide. He described Restoris as “the first robotic-enabled implants, specifically designed to be put in with a robotic system.”

The RIO system provides patient-specific, 3-D modeling for pre-surgical planning. “As surgeons use the robotic arm to resurface the knee for placement of the implants,” the company said in a statement, “RIO provides real-time, inter-operative visual, tactile and auditory feedback, enabling a high level of precision and optimal positioning of the implants.”

MAKOplasty makes partial knee resurfacing available to a larger patient population. It previously was only possible to perform such resurfacing on the inner, or medial, portion of the knee. With the RIO system and Restoris MCK components, it now can be performed on both the medial and patellofemoral, or top, portion of the knee.

MAKO is well-positioned to gain serious traction in a space dominated by such big players as **DePuy** (Warsaw, Indiana), **Stryker** (Kalamazoo, Michigan), **Smith & Nephew Orthopaedics** (Memphis, Tennessee) and **Zimmer** (also Warsaw).

“We hold the key patents in orthopedic robotics,” said Ferré. The company’s IP portfolio includes more than 250 licensed or owned patents and patent applications relating to computer-assisted surgery, haptics, robotics and implants.

Declaring that robotics “has come of age,” he said MAKO thinks it can address fully 50% of the existing total knee replacement (TKR) market. That’s especially true, Ferré said, given today’s economic travails. “With the kind of resurfacing approach we offer, the recovery period is much shorter,” so patients undergoing a MAKOplasty procedure miss less work.

He noted that one of the difficulties in building clinician interest in minimally invasive approaches is that unicompartmental procedures are difficult to do, “but now, with robotics, they can do it.”

Ferré likened the process to a paint-by-numbers project. “Via CT [computed tomography], the clinician creates ‘virtual walls’ – you have borders, and this keeps you from drawing or painting outside the lines.”

He said that the orthopedic sector has seen “a lot of progress with materials and implant design, but not a lot of progress in terms of delivery systems.”

Enter the RIO System, which Ferré said targets a market of 15 million persons with osteoarthritis of the knee. Of that market, only 10% currently are done as unicompartmental procedures. “We feel we can address 350,000 procedures,” he said.

“We think in particular of those over 70,” who are reluctant to face knee replacement surgery, he said. “Now, here’s an implant that won’t be as difficult for them to endure the rehabilitation. That’s a great patient population for us.”

The company has come a long way in a relatively short period of time. It was founded in November 2004 and received clearance for the first version of its Tactile Guidance System (TGS) a year later. Two enhanced versions of TGS were released in 2008, then came the Restoris Unicompartmental Knee System, cleared by the FDA last June.

December 2008 brought approval of the second-generation robotic system, the RIO, along with the Restoris MCK.

As of year-end 2008, a total of 782 MAKOplasty procedures had been conducted, with 17 sites up and running.

See MAKO, Page 9



MAKO Surgical's recently introduced RIO Robotic Arm System

Imalux

Continued from Page 1

to be used worldwide and that it could be used as a one-day scenario: A patient would come in the morning and test for high risk human papillomavirus (HPV). If they were positive for HPV, they would go on to have the visualization of OCT testing and then between those two, we could determine if the patient has precancerous dysplasia. They could then be treated on the spot, the same day."

Tresser refers to HPV because cervical cancer, the second-greatest cause of cancer deaths in women, is directly linked to the high-risk types HPV. It's the link between cervical cancer and HPV that has made it possible to identify patients at high risk of cervical cancer by testing for the HPV virus.

Imalux recently reported early results on two studies to determine the diagnostic efficacy of real-time OCT. Both IRB-approved studies took place in China in partnership with the **Peking University** (Peking), **Shenzhen Hospital** (Shenzhen) and the **Renmin Hospital** (Buyi-Miao Autonomous District of Guizhou Province).

Some 2,000 women participated in the studies, which gathered 2,800 OCT images. Those images were compared to diagnostic impressions and pathologic findings to determine the accuracy of OCT. The studies both yielded the statistically significant abilities of OCT to differentiate grades of pre-invasive cervical dysplasia prior to biopsy.

"These studies showed that we could use Imalux's Niris Imaging System in both high- and low-resource settings with the intent to improve women's healthcare globally," Tresser said. "OCT allows for very small details in tissue to be appreciated. Our current system provides a resolution that is approximately 10 microns to 15 microns in depth resolution, which is up to 100 times the resolution available in standard ultrasound."

While ultrasound uses sound, OCT uses light. "OCT doesn't penetrate tissue as well as ultrasound," she said. "It's used at the surface to examine tissue changes."

Imalux's Niris received FDA clearance in 2005 (*MDD*, Jan. 7, 2005). Since then, Tresser said that in working with researchers at the **Cleveland Clinic**, it was discovered that OCT could more precisely identify different types of disease. That's when the current studies were launched in China.

"We found that, after reviewing the first set of 300 patients, we were able to look at data afterward and saw the epithelium became brighter as the stage of cancer advanced," Tresser said. "We were able to see there was a change in brightness along the stages of cancer."

More specific details of those studies will be presented at the 25th International Papillomavirus Conference in Malmo, Sweden in May.

"Now we're at the point that we're trying to create a computer algorithm to help clinicians, in real time, see those changes in brightness to differentiate the early

stages of cancer," she said.

Tresser said the company has been working with a prototype version of Niris and will likely have a commercially viable system by 2010 and a complete computer-aided diagnostic system by 2014.

"Over the next three years, we plan to study approximately 3,000 patients," she said. "We may decide to go back to the FDA if we build a system specifically for cervical cancer." ■

MAKO

Continued from Page 8

"We have two years worth of data on some cases," Ferré said, and seven journal articles have just been accepted for publication.

Seven of those studies were reported in the February issue of *The American Journal of Orthopedics*.

Among the authors was Martin Roche, MD, chief of orthopedic surgery at **Holy Cross Hospital** (Fort Lauderdale), who performed the first MAKOplasty procedure back in June 2006 and has been a big fan of the approach since he first learned of the company from "one of the financial guys" who had left the hospital to join the fledgling firm.

"We were their first site to do MAKOplasty," he said, adding that the procedure "gives results" for both clinicians and patients. He noted that patients "go home much quicker" than with conventional knee replacement approaches.

"I look on it as a very smart software system that lets me put in a knee that I can micro-adjust in order to put it in perfectly," Roche said. "What I plan is what I consistently get."

He has now done about 180 MAKOplasty procedures, including doing his first bi-compartmental knee procedure with the RIO system in January, and says the new system and new knees from MAKO likely will mean he'll increase his percentage of knee replacement procedures done via MAKOplasty from 10% to 20% of the total.

Roche said patients are "very excited" about the concept of doing their procedures robotically, seeing it as an advancement of technique that can improve their respective outcomes.

Poised for gains in a crowded knee-replacement market, the company has had success in the financial markets, raising \$91 million last year from an IPO in February and a private placement in October.

"We've seen this coming," Ferré declared. "The future is all about precision surgery and the use of robotics." ■

Sign up for our free, weekly e-mail blog, **Perspectives**, commenting on today's med-tech.

Go to **www.MedicalDeviceDaily.com** and sign up.

International

Continued from Page 1

Angiotech said Quill SRS “represents a revolutionary technology in wound closure made possible by bidirectional fixation within the wound.”

The company said the products’ design allows the surgeon to begin closure at the midpoint of the wound and suture in two directions from the midpoint. “Barbs within the Quill SRS distribute tension across the wound and eliminate the need for knots,” according to Angiotech.

The product lines have previously been approved for sale in both the U.S. and Europe.

GE unveils products in Malaysia

GE Healthcare Information Technologies (Milwaukee, Wisconsin) used the HIMSS Asia Pac conference in Kuala Lumpur, Malaysia, as a launching point for a new suite of Centricity solutions targeted for hospitals and outpatient imaging centers.

The company also released Centricity PACS Web Diagnostic (WebDX), a new web-based diagnostic viewer application that is tightly integrated to Centricity RIS/ PACS, which bring comprehensive detailed patient history to a single patient folder.

Building on Centricity’s business process and advanced clinical capabilities, the new Centricity suite provides what GE Healthcare termed “the robust, web-based accessibility of IntegradWeb solutions through the acquisition from Dynamic Imaging.”

“For optimal patient care, images and their related clinical information need to be available anywhere, at anytime,” said Don Woodlock, vice president/general manager of GE Healthcare IT. “These web-based solutions will provide hospitals and outpatient imaging centers with streamlined workflow inside and outside of their walls. Better yet, referring physicians throughout the community will be serviced with simple, yet powerful access to imaging results.”

The Centricity PACS-IW Solutions for hospitals will offer web-based portability, instantaneous image reporting and scalable business processes, GE said. “This single-desktop solution will drive practice efficiency, productivity for the radiologist and immediate results access for the referring physician by fostering a more collaborative approach to patient care and provider partnerships, thus driving better patient care and business practices in an increasingly competitive market,” the company said in its announcement

Centricity PACS IW allows a radiologist to view images on any PC with regular monitors, but for diagnosis purposes, GE said it recommends **Barco’s** (Kurne, Belgium/Sacramento, California) Coronis 6MP monitors, “due to their impressive image quality, [and] accuracy . . . offering two screens together with equal luminance, automatic calibration and broad usability.”

Building on existing enterprise connectivity and comprehensive infrastructure of Centricity PACS, Centricity

PACS WebDX provides an enterprise-wide archive, using EMC storage technology, for access to any type of image in one complete platform, GE said. Centricity PACS seamlessly integrates with RIS and EMR solutions to reduce paper.

Woodlock said Centricity PACS WebDX “enables the migration to a virtual environment, where information is delivered to the center of care through one desktop, one patient and one community.”

Leksell Perfexion in first Japanese use

Elekta (Stockholm, Sweden) said Leksell Gamma Knife Perfexion, its new system for stereotactic radiosurgery, has been used for the first time in Japan to treat patients at the Jiro Suzuki Memorial Gamma House of **Furukawa Seiryō Hospital** (Miyagi).

The company said the 100-bed hospital has a strong neurosurgery program, and is the first in Japan to offer treatment with Leksell Gamma Knife Perfexion, an advanced radiosurgery treatment system for intracranial stereotactic radiosurgery or Gamma Knife surgery.

Hidefumi Jokura, MD, VP of Furukawa Seiryō and director of the hospital’s Gamma Knife Center, said, “The sophistication of the technology is allowing us to treat more patients in less time. And importantly, both staff and patients appreciate the greater efficiency of the design, which results in reduced hospital visitation for the patient.”

Jokura and his colleagues have treated 107 cases, 60% of them brain metastases, during the two first months of using the Perfexion system. “We now have the capability to treat three or four patients in just half a day – a process that normally would have taken a full working day,” Jokura said.

Leksell Gamma Knife is in daily use in more than 50 centers in Japan and Furukawa Seiryō Hospital currently utilizes Gamma Knife surgery to treat about 500 patients each year.

“With Leksell Gamma Knife Perfexion, we are further realizing our ambition of offering effective treatments for a wide range of neurological challenges; and are achieving this with a greater degree of positive outcomes and shorter patient treatment times than before,” says Hideo Watanabe, managing director of **Elekta Japan**.

Leksell Gamma Knife Perfexion, the latest version of the Leksell Gamma Knife systems, is a complete system for intracranial stereotactic radiosurgery or Gamma Knife surgery. It is designed to treat multiple targets, such as brain metastases. ■

Access Medical Device Daily Archives Online!

You have FREE access to articles dating back to 1997 — perfect for company research or for finding supporting data for presentations and reports.

Go to **www.MedicalDeviceDaily.com** for access.

Study

Continued from Page 7

directly adjacent to the heart in the pericardial space. Most other systems, including the DuraHeart, are implanted into a surgically-created pump pocket in the abdomen.

Other companies developing similar devices include **Ventricor** (Chatswood, Australia), **Abiomed** (Danvers, Massachusetts) and **Thoratec** (Pleasanton, California).

Last month Thoratec agreed to acquire HeartWare in a cash-stock deal valued at about \$282 million. The company

said it would pay about 50% in cash and the rest would be paid in shares of its common stock (*MDD*, Feb. 17, 2009). Ford speculated that Thoratec was motivated to buy HeartWare because its device is small enough to fit directly in adjacent to the heart in the pericardial space, without the surgeon having to create a pump pocket in the abdomen.

"Thoratec had to get above the diaphragm to reserve their spot in the space because being above the diaphragm is where the surgeons want to go, it is a less invasive surgery . . . put the pump right in the pericardial space," Ford said. ■

Deals

Continued from Page 4

for the development of certain intraocular lens (IOL) materials.

Under the terms of the agreement, B&L has obtained the rights to Santen's hydrophobic acrylic polymers, from which it may commercialize new IOLs for sale worldwide. Santen reserves the right for the use of these materials in the Japanese market. Financial terms will not be disclosed.

- **Baxa** (Englewood, Colorado), a developer of technology for the safe handling, packaging and administration of fluid medications, reported that it has acquired **ForHealth Technologies** (Daytona Beach, Florida), a healthcare

robotics and software company, in a strategic expansion of its focus on health-system pharmacy automation and IV room productivity. Terms were not disclosed.

The ForHealth acquisition adds IntelliFill i.v. and IntelliFlowRx to the existing Baxa products for pharmacy operations management. IntelliFill i.v., a high-speed robotic system for preparing intravenous doses, is an industry standard for performance, cost savings and patient safety. IntelliFlowRx IV Room Workflow Manager promotes reductions in drug costs and waste, while ensuring patient safety and improving accuracy and efficiencies in manual IV compounding.

ForHealth operations will continue from its U.S. headquarters in Daytona Beach. ■

Washington

Continued from Page 2

Now that Hall has hit the age of 65, CMS wants him to enroll in Medicare or lose his Social Security benefits and repay the benefits he's received over the past three years. Hall is one of five who are suing the Department of Health and Human Services over the matter in the U.S. District Court for the District of Columbia.

In another delicious irony, the suit names Tom Daschle as the defendant as the Secretary of Health and Human Services despite that the former South Dakota Democrat never actually held the position for even a day. CMS does give Hall the option of avoiding Medicare's notorious Part B program, but the requirement that he enroll in Part A would override his FEHBP coverage for hospitalization, a prospect he and his co-litigants evidently are not pleased with.

Court documents indicate that Hall sought a temporary restraining order on HHS, but the judge supervising the case, Rosemary Collyer, denied that motion. However, while she also acknowledged the procedural bind the agency is in, Collyer nonetheless comments: "It is passing strange that SSA insists that all persons receiving Social Security retirement benefits, a federal program that is running out of money, also must be part of Medicare Part A, another federal program that overruns budgets."

(AdvaMed; Washington) is looking for panel submissions for its AdvaMed 2009 conference, scheduled for Oct. 12-14 in Washington. In a March 3 statement, the association said that it seeks ideas for educational panels that will run about 75 minutes and will deal with any one of a number of topics, including reimbursement, legal and intellectual property, regulatory developments, and emerging company issues.

AdvaMed's President/CEO Stephen Ubl said in the statement that input on these sessions from industry "ensures world-class educational panels that truly meet the interests of conference attendees."

Submissions will be evaluated based on relevance and timeliness as well as the educational value and, of course, panel expertise. Anyone wishing to file a submission should do so by April 1 at the advamed2009.com web site. According to the statement, submissions from AdvaMed members will be reviewed first. ■

REPRINTS REPRINTS REPRINTS
REPRINTS REPRINTS REPRINTS

For reprints of articles appearing in
Medical Device Daily, please contact
Stephen Vance at (404) 262-5511 or
stephen.vance@ahcmedia.com

AdvaMed seeks proposals

The **Advanced Medical Technology Association**

PRODUCT BRIEFS

- **Alcon** (Huenenberg, Switzerland) reported FDA approval of its aspheric AcrySof IQ Toric intraocular lens (IOL). The new lens offers an enhanced aspheric optic that improves image quality and increases contrast sensitivity in cataract surgery patients with astigmatism. Alcon says that the AcrySof Intraocular lenses are the most frequently implanted lenses in the world, with more than 40 million implants since their introduction in the early 1990s. Alcon's AcrySof IOL platform offers cataract patients a variety of benefits and is available with a variety of optics designed to help patients achieve the best possible vision. The AcrySof family of IOLs includes the AcrySof IQ, AcrySof IQ Toric and AcrySof IQ ReSTOR IOLs.

- **Ansys** (Southpointe, Pennsylvania) reported the introduction of the @neurIST project, saying it has completed a milestone toward its goal of helping clinicians understand and manage cerebral aneurysms. The project teamed with Ansys to use high-end engineering simulation, which is being increasingly used in the fields of biomedicine and healthcare. The @neurIST project successfully demonstrated its underlying series of linked tools – called a “toolchain” – using software from Ansys, which automates complex tasks such as aneurysm modeling and simulation. The project is now moving toward developing patient-specific treatment for this devastating condition.

- **Cantel Medical** (Little Falls, New Jersey) said the FDA has cleared its Medivators Advantage Plus Endoscope Reprocessing System and new Rapicide PA High Level Disinfectant for sale in the U.S. The Advantage Plus System, with its accompanying new chemistry, represents the latest in a long line of “state of the art”, innovative reprocessing technologies that Medivators has been delivering to hospitals and stand-alone GI centers for over 20 years.

- **Serica Technologies** (Medford, Massachusetts) received FDA clearance for its SeriScaffold silk-based, long-term bioresorbable scaffold technology. The company says that the SeriScaffold platform technology provides a natural protein-based alternative to synthetic materials and

graft products harvested from human or animal cadaver tissue. “We believe our . . . SeriScaffold technology has applications for a wide range of necessary procedures for patients requiring reconstructive plastic surgery, as well as for patients undergoing elective and other forms of soft tissue repair surgery,” said President/CEO Gregory Altman.

- **Smith & Nephew's** Advanced Wound Management division (St. Petersburg, Florida) reported the U.S. launch of its Renasys EZ Negative Pressure Wound Therapy (NPWT) system, which the company says is designed to address the needs of wound care professionals and patients. Smith & Nephew said it designed the Renasys EZ based on customer insights to improve the NPWT experience, focusing on greater ease of use and patient comfort across the full range of wound types. Renasys EZ allows clinicians to use variable pressure control, enables clinicians to treat surgical, traumatic or chronic wounds according to the individual needs of the patient and the characteristics of the patient's wound.

- **Southwest Medical Associates** (SMA; Las Vegas) has introduced a portable medical record (PMR) designed to give healthcare providers immediate access to their patients' health care information. The PMR is a compact disc that instead of containing the data on the disc has a link to a portal containing a patient's current, vital medical records, which can be accessed in real time by any healthcare provider, including emergency room physicians and staff. The records contain healthcare information including medications and health issues, recent hospital stays, EKG test results, allergies; emergency contact information.

- **Teleflex Medical** (Research Triangle Park, North Carolina), has introduced the Arrow Pressure Injectable Triple Lumen PICC (Peripherally Inserted Central Catheter). The catheter has a non-tapered body, contoured tip and strong polyurethane construction that softens *in situ*. The catheter's Blue FlexTip is designed to reduce patients' vessel trauma. The catheter's firmness also maintains patency throughout treatment, as it withstands high-pressure injection procedures. This unique tip design, with its staggered ports, is designed to reduce the risk of medications mixing and forming a precipitate that could obstruct other trimmed catheters. The Arrow Pressure Injectable Triple Lumen PICC is also indicated for central venous pressure monitoring.

PEOPLE IN PLACES

- Doug Sweet was named VP of sales and marketing for **Biolmage** (Cupertino, California). Sweet previously was VP of marketing and sales for Celerus Diagnostics. Biolmage makes digital pathology solutions.

- Andrew Jay, DMD, was named to the board of **CorNova** (Burlington, Massachusetts). Jay is managing partner of the Medical Solutions Fund of Siemens Venture

Capital, the venture organization for Siemens AG. CorNova makes endovascular products.

- **Foley Hoag** (Washington) reported that Thomas Barker has joined the firm as a partner in its Healthcare and Life Sciences practices. Barker served in a succession of federal healthcare policy positions throughout the Bush Administration and most recently served as acting general counsel and policy advisor under HHS Secretary Mike Leavitt. Foley Hoag is a law firm in the areas of dispute resolution, intellectual property, and corporate transactions for emerging, middle-market, and large-cap companies.