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PAGE 1 OF 9

Sunshine Heart's C-Pulse passes 5-year durability test

By OMAR FORD

Medical Device Daily Staff Writer

Sunshine Heart (Sydney, Australia) is seeking to initiate an Investigational Device Exemption feasibility trial for its C-Pulse device, a non-blood-contacting heart therapy for patients with moderate to severe heart failure. The company reported passing a five-year milestone on the durability testing of the device last Wednesday.

"Right now we're into the normal question-and-answer phase of the [IDE] process with the FDA," Sunshine Heart CEO Don Rohrbaugh told *Medical Device Daily*. "But we hope to be able to enroll our first U.S. patient in clinical trials sometime this year."

The company, has six clinical trial sites planned that include **Ohio State University Heart Center** (Columbus), **Northwestern University Fineberg School of Medicine** (Chicago), **Penn State Milton S. Hershey**
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International report

Medtronic opens implantation center of excellence in India

A *Medical Device Daily Staff Report*

Medtronic (Minneapolis) has opened the first center of excellence for device implantation in India in collaboration with **Care Hospital** (Hyderabad, India). Care Hospital will be the first center in the South Asia region to offer hands-on training to cardiologists, according to a news service report.

IANS said physicians will be trained on dual-chamber pacemaker therapy and cardiac resynchronization therapy (CRT) implants through hands-on experience under the guidance of noted electrophysiologist Calambur Narasimhan.

Narasimhan, head of the electrophysiology department at Care Hospital and president of the **Indian Society of Electrocardiographers**, said a series of didactic and practical training modules has been designed to ensure that physicians receive a quality of care unmatched in the industry.

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Proteus' in-body computer directed toward HF patients

By AMANDA PEDERSEN

Medical Device Daily Staff Writer

Proteus Biomedical (Redwood City, California) certainly is not the only company looking at how to improve the measurement of cardiac performance in heart failure patients. But according to Andrew Thompson, CEO and co-founder, "everybody else" has come up with a new lead and/or a new procedure.

"We don't want to invent a new therapy," Thompson told *Medical Device Daily*. Proteus is more interested in using its cardiac electronic tomography (CET) and multi-sensor lead system to make existing therapies safer, more effective and higher-value, he said.

CET is an operator-independent modality developed by Proteus. The first product application, in the field of heart failure, is intended to improve outcomes by "objectively assessing the relative hemodynamic effect of lead"
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Washington roundup

Senate in unanimous vote on genetic anti-discrimination

A *Medical Device Daily Staff Report*

After more than a decade of attempts, it looks like Congress might finally pass a bill that would block health insurers from denying coverage to otherwise healthy persons based on that person's predisposition to come down with a particular disease.

The bill, the Genetic Information Nondiscrimination Act (GINA), would also bar employers from using genetic information as part of hiring, firing, job placement or promotions.

The 95-0 Senate vote sends GINA back to the House, which could approve it this week. President George Bush supports the legislation.

The House approved the bill last year on a 420-3 vote, but now must reconcile its version with that of the Senate, which inserted changes that attempt to make the bill easier on insurers. The changes are a concession to Sen. Tom Coburn (R-Oklahoma), who had blocked the bill, arguing
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INSIDE: HARVARD PILGRIM HEALTH CARE IN \$1B PEROT SYSTEMS ACCORD2
DRAXIS OBTAINS INTERIM ORDER FOR ACQUISITION BY JUBILANT3

 **AHC Media LLC**

*Contracts***Harvard Pilgrim Health Care in \$1B Perot Systems accord****A Medical Device Daily Staff Report**

Harvard Pilgrim Health Care (Wellesley, Massachusetts) has negotiated a \$1 billion contract extension with **Perot Systems** (Texas) for IT and business process services.

Harvard Pilgrim will realize an estimated \$150 million in administrative cost savings throughout the life of the agreement through the consolidation and leveraging of its technology, administrative functions and redesign of administrative operations.

Perot Systems will operate and support Harvard Pilgrim's information technology infrastructure, business applications and administrative business operations.

In other contract news:

- **AmeriChoice** (Vienna, Virginia) has been notified by **TennCare** (Nashville) that it was awarded contracts to expand services in East and West Tennessee.

When the new contracts are fully operational in January 2009, AmeriChoice will serve nearly 574,000 members in the state and be the only company operating a full-risk health plan in all three TennCare regions. This award is expected to add an estimated \$1 billion in 2009 revenue to AmeriChoice.

- **SourceMedical** (Birmingham, Alabama) a provider of outpatient information management solutions, said it is providing its TherapySource solution to **Atlanta Falcons Physical Therapy Centers** (Suwanee, Georgia), a new physical therapy and sports rehabilitation business operated by Falcons owner Arthur Blank's management company.

TherapySource is a clinical and administrative practice management system designed for the specialized needs of outpatient rehabilitation clinics. Built to handle multiple sites across the enterprise, TherapySource streamlines and automates clinical and financial processes, including

Today's MDD food for med-tech thought

"For the first time, we act to prevent discrimination before it has taken firm hold and that's why this legislation is unique and groundbreaking."

Sen. Olympia Snowe (R-Maine) who co-sponsored the Senate's version of the Genetic Information Nondiscrimination Act which passed 95-0 last week, "Senate in unanimous vote on genetic anti-discrimination," pp. 1, 8.

scheduling, registration, clinical documentation, billing and revenue cycle management.

SourceMedical provides outpatient information solutions and services for ambulatory surgery centers, surgical hospitals and rehabilitation clinics nationwide. ■

Beware of increased FDA scrutiny in performance of contractors, suppliers

You are responsible for the quality of your product, regardless of what areas of your operation you outsource. The company of record for Heparin could be facing trouble after subcontracting work to a Chinese manufacturer, which subsequently lead to four deaths and hundreds of illnesses. Avoid warning letters, recalls, seizures, and potential lawsuits.

In a new *Medical Device Daily* and *BioWorld Today* audio conference, speaker Dennis Moore, president and CEO of AUK Technical Services, will provide insight on topics such as supplier's practices, what they do about non-conforming product, what to look for in CAPA, product release, training, customer complaint handling and more.

"Auditing Suppliers and Contractors: Be Ready for Increased FDA Scrutiny" is just \$349 per listening site. Scheduled for May 1st, from 1-2:30 p.m., it includes presentation handouts and a half-hour Q&A session with the speaker. A conference CD (MP3 format) is also available. For more information or to register, call 800-688-2421 or 404-262-5474. Please mention conference code T08491.

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*Deals roundup***Draxis obtains interim order for acquisition by Jubilant****A Medical Device Daily Staff Report**

Draxis Health (Mississauga, Ontario), a supplier of radiopharmaceuticals, reported that it has obtained an Interim Order from the Quebec Superior Court in connection with the proposed statutory arrangement under which all of its common shares will be acquired by **Jubilant Organosys** (Noida, India) for \$6 per share, or a total of about \$255 million (*Medical Device Daily*, April 7, 2008).

The arrangement will be considered at the annual and special meeting of Draxis shareholders scheduled to be held on May 23.

The Draxis board recommends that its shareholders vote in favor of the transaction on the basis that it creates immediate value for shareholders. The board said it also expects the transaction to provide operational and technical resources to accelerate the growth of Draxis's business and its customer base.

Jubilant said that Draxis offers it entry into the radiopharmaceutical market. It also enables the Indian firm to consolidate its position in the sterile and non-sterile contract manufacturing business.

Jubilant said it plans to fund the acquisition through a combination of cash on hand and debt. The transaction is not contingent on any financing condition.

The transaction is expected to close in 2Q08, shortly after receipt of shareholder and court approvals.

In other dealmaking news:

• **The Tri-Isthmus Group** (TIGroup; Beverly Hills, California), a provider of financial solutions to the healthcare industry, has agreed to acquire **Southern Plains Medical Group** (Southern Plains, Oklahoma).

The center includes 21 physicians and offers a range of services including cardiology, pediatrics, oncology, orthopedics, radiology and urgent care.

The physician group from Southern Plains will continue to manage the new operation, supported by the **Physician's Hospital of Anadarko**, TIGroup's locally owned hospital and medical clinic. TIGroup also will provide financial and operating support to Southern Plains and will introduce expanded diagnostic and dialysis services to the community in addition to making new local investments in the region's healthcare infrastructure.

• **Oaks Development Group** (Cary, North Carolina) said it has acquired **Cypress Professional Center**, a 29,927-square-foot Class A medical office building located near **Charlotte Regional Medical Center** (both Punta Gorda, Florida).

The property currently includes an established cardiology practice.

The building is being converted to Oaks' tenant-ownership model. Oaks' hybrid structure is set up as a single pur-

pose limited liability company. Tenant partners split 50% ownership interest based on how much space they occupy. While there is no capital outlay required for pro rata ownerships, tenant partners have first right of refusal on an additional 25% ownership through equity investment. Oaks retains only 25% ownership and is responsible for professionally managing the asset over the long term. Tenant partners receive distributions of operations profits as well as refinancing profits. ■

*Financings roundup***Nastech hopes to gross over \$10M in private share sale****A Medical Device Daily Staff Report**

Nastech Pharmaceutical (Bothell, Washington) reported that it has entered into definitive agreements with new and existing investors to raise gross proceeds of \$7,932,500 through a registered direct offering.

The company will sell 4,585,260 shares of its common stock at \$1.73 per share. As part of the transaction, the investors also will receive warrants, with a seven-year term, to purchase 4,585,260 shares of common stock at an exercise price of \$2.38 per share. The warrants will be exercisable beginning Oct. 25.

In addition, the investors have the right to purchase up to 1,375,578 shares of common stock at a price of \$2.17 per share during the 90-day period beginning Oct. 25. If fully exercised, total gross proceeds would be \$2,985,005.

The company said it plans to use the proceeds of this transaction for working capital.

Nastech is a clinical-stage biopharmaceutical company focusing on the development of therapeutic products based on its molecular biology-based drug-delivery technologies and ribonucleic acid interference technology.

The company and its collaboration partners are developing products for multiple therapeutic areas including diabetes, obesity, osteoporosis, autism, respiratory diseases and inflammatory conditions.

Maxim Group is serving as placement agent for the offering. ■

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MED - TECH NEWS AND NOTES

FDA sponsoring DES workshop

The FDA is co-sponsoring a public workshop, "Coronary Drug-Eluting Stent (DES) Guidance Document Workshop," with the **Advanced Medical Technology Association** (AdvaMed; Washington) on Tuesday.

The purpose of the workshop is to discuss the draft guidance titled "Coronary Drug-Eluting Stents: Nonclinical and Clinical Studies" announced in the March 27 issue of the *Federal Register* and its companion document, "Coronary Drug-Eluting Stents-Nonclinical and Clinical Studies."

The workshop is intended to solicit additional com-

ments on the issues and questions presented in the draft guidance during the open comment period.

The workshop will be held from 8 a.m. to 6 p.m. Security screening will begin at 7 a.m., and registration will begin at 7:30 a.m.

The conference will be held at the FDA's White Oak Campus, Building 2, located at 10903 New Hampshire Ave., Silver Spring, MD.

For more information, contact Ashley Boam, Center for Devices and Radiological Health, 9200 Corporate Blvd. (HFZ-400), Rockville, MD 20850, call 240-276-3983 or e-mail ahsley.boam@fda.hhs.gov.

CardioDynamics gets Nasdaq deficiency letter

CardioDynamics International (San Diego), a maker of impedance cardiography (ICG) technology, said that it received a Nasdaq staff deficiency letter from the listing qualifications department indicating that the company's common stock continues not to meet the \$1 minimum bid requirement set forth in Marketplace Rule 4310(c)(4).

The latest Nasdaq letter follows the previously reported receipt of a letter from Nasdaq, on April 18, 2007, noting non-compliance with the minimum bid price requirement set forth in Marketplace Rule 4450(a)(5) and transfer of the company's common stock from the Nasdaq Global Market on Oct. 25, 2007. Upon transfer to the Nasdaq Capital Market, the company was provided a second

180 calendar days, until April 15, 2008, to regain compliance with the \$1 minimum bid requirement while listed on the Nasdaq Capital Market.

CardioDynamics CEO Michael Perry said, "We look forward to completing the reverse split process and maintaining our Nasdaq listing. We are in the midst of a positive turnaround in the business with five consecutive quarters of revenue growth and most recently achieved 22% growth in our first quarter 2008. We believe that the capital structure, post-reverse split, will be more attractive to potential investors considering the revenue growth we are experiencing, international sales momentum, new partnership development and intense focus on achieving positive operating cash flow by the fourth quarter 2008."

Report: CHF drug treatments to increase

The market for congestive heart failure (CHF) drug treatments was estimated at \$18 billion in 2007, and is expected to reach \$30 billion by 2017, according to a new report by **Kalorama Information** (New York). The report is titled, "Congestive Heart Failure: Major World Markets, Volume I: Pharmaceutical Management."

Growth is being driven by three factors: an increased incidence of CHF, the application of innovative technolo-

gies in search of targeted therapies which is creating opportunity for new entrants into this market, and physicians prescribing multi-drug regimens in response to the failure of traditional drugs to treat CHF.

"The future of CHF drug treatments lies in newer technologies such as biotechnology and genomics," said Kenneth Krul, the report's author. "The identification of fetal genes associated with CHF, new treatments that address the endothelium and cell therapy to regenerate damaged heart muscle tissue present some promising areas."

SCA gains medical association interest

In an effort to boost public awareness of sudden cardiac arrest (SCA), the **National Medical Association** (NMA; Washington) convened medical professionals, government officials and patient advocacy organizations in Washington.

At the SCA Leadership Conference, held on April 15, health leaders addressed SCA risk factors, prevention measures, health disparities associated with the disease, and diagnosis and treatment options.

"More than 300,000 lives are lost every year due to the rising epidemic of sudden cardiac arrest. This public health crisis kills more people than lung cancer, breast cancer and HIV/AIDS combined," said Dr. Nelson Adams III, president of NMA. "Particularly alarming is that SCA disproportionately affects African-Americans and women, the majority of whom die before ever reaching emergency care and that adequate data is not available for Hispanics."

Sunshine

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Medical Center (Hershey, Pennsylvania), **University of Louisville Jewish Hospital** (Louisville, Kentucky), **University of Alabama at Birmingham** and the **University of Florida** (Gainesville).

Previously Sunshine reported that William Abraham, MD, of Ohio State Heart Center, and Patrick McCarthy, MD, of Northwestern University Feinberg School of Medicine, would be the co-principal investigators for the C-Pulse feasibility trial (*MDD*, March 12, 2007).

"These are very talented people — we have an outstanding team," Rohrbaugh said. "Dr. Abraham was once the lead principal investigator for **Medtronic** (Minneapolis). So we've got a tremendous amount of talent."

He added that C-Pulse "is exceptional. Through this device, we're helping the heart pump blood without ever coming in contact with the blood."

C-Pulse uses a standard pacemaker lead, a single soft percutaneous line and an external pneumatic battery-operated driver. The driver unit, which resembles a Walkman or portable CD player, is worn outside of the body along the hip and linked by an air tube to the cuff. The cuff is secured around the ascending aorta.

Implantation is performed through a simple surgery on a beating heart, without the need for heart-lung bypass or any incisions to the heart or great vessels.

This is how the device works. A balloon found in the cuff is inflated and deflated in time with the heart rhythm to improve blood supply to the body and to the heart muscle itself, as well as serving to reduce the workload of the heart. A sensing lead conveys the heart's electrical signals to the driver unit. As a result, the balloon in the cuff inflates and deflates with the heart's rhythm creating a counterpulsation action.

This counterpulsation action forces the blood out of the ascending aorta and assists the heart in pumping blood more efficiently.

Sunshine Heart partnered with **Polymer Technology Group** (PTG; Berkeley California), a biomaterials company, to come up with durable biomaterials for components of the device.

"Our relationship with PTG started back in 2004, when we needed a high-quality material for the balloon," Rohrbaugh said.

PTG supplied the company with BioSpan for the balloon, a segmented polyether urethane (SPU) that is used in the majority of clinical ventricular assist devices and artificial heart cases worldwide. It also used Bionate, a thermoplastic polycarbonate urethane (TPU) for the tubing of the device.

BioSpan is characterized by high strength, flexibility and fatigue resistance. PTG developed BioSpan in response to the crisis created by the withdrawal of Biomer by **Ethicon** (Somerville, New Jersey) a **Johnson & Johnson**

(New Brunswick, New Jersey) company.

Bionate is a thermoplastic elastomer formed as the reaction product of a hydroxyl terminated polycarbonate, an aromatic diisocyanate, and a low-molecular-weight glycol used as a chain extender. It is used in devices such as pacemaker leads, ventricular assist devices, catheters and stents. They also are extensively used in orthopedic applications for their tough, load bearing qualities. Bionate TPUs are stable to dry heat, as well as Gamma sterilization.

C-Pulse doesn't yet have the CE mark.

"A lot of people go after [the CE mark] like it's the Holy Grail, but we are not running a separate clinical study for Europe," Rohrbaugh said. "We'll just use the clinical study from the U.S. once it's completed."

To date, both companies are enjoying a measure of success.

PTG reported launching its spin-off of a life sciences incubator, **Emergence** (also Berkeley) (*MDD*, Sept. 26, 2007).

Emergence will have access to PTG's staff and facilities for synthesis, characterization, processing, regulatory approval and manufacturing resources in the development of new devices, PTG said.

"We're excited about it, we've also just expanded our center here in Berkeley," Robert Ward, president/CEO of PTG, told *MDD*.

Sunshine Heart, which was founded by William Peters, MD, in 2000 and has emerged from a small virtual company, said that it was still riding high from key funding it received a few years ago.

"The company is funded by Australia & New Zealand Venture Capital. Our market capitalization is \$25 million and we raised \$15 million of that from an IPO in Australia [in 2005]," Rohrbaugh said.

C-Pulse was developed by Peters, working on a theory that those with heart failure needed support rather than replacement.

To date Sunshine Heart's primary offering is the C-Pulse. ■

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Proteus

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placement sites during and after CRT device implantation, and by quantitatively tracking a range of standard cardiac synchrony and performance measures over time," the company said.

The technology is designed to be fully integrated into any existing cardiac rhythm management system, and used without requiring additional complex pressure sensors or invasive procedures, Proteus said. The technique works by tracking the three-dimensional displacement of cardiac regions using standard CRT systems that have been modified to incorporate Proteus sensing technology and software. The procedure takes a few minutes and can be performed on patients at rest or on a treadmill, the company said.

A CRT device implantation procedure runs upwards of \$60,000 – about \$30,000 for the device and roughly another \$30,000 for the procedure – "and it doesn't work about half the time," Thompson said. "That's a problem."

On Thursday Proteus reported the start of its Resynchronization using Electric Tomography to Improve Myocardial Efficiency (RETIME) 2.0 study, designed to assess the performance of its CET technology in heart failure patients undergoing implantation of a CRT device.

The point of the study, Thompson said, is "to show that the technology that we've now tested very extensively in animals and a previous feasibility study in humans does what we say it does."

According to Proteus, data from pre-clinical studies and from its RETIME 1.0 study demonstrated that CET quantifies important aspects of cardiac performance using an automated, operator-independent technique that yields results comparable to Tissue Doppler Imaging. The company said the RETIME 2.0 study will evaluate the system's ability to provide "immediate, actionable physiologic feedback" to determine optimal pacing sites in individual patients by correlating CET data with left ventricular pressure catheter readings, the current gold standard for measuring hemodynamic performance.

The three-site study will enroll from 30 to 50 patients and should be finished by the end of the year, Thompson said. Participating sites include **Ohio State University** (Columbus), with William Abraham, MD, and Ayesha Hasan, MD, serving as co-investigators; the **University of Southern California** (Los Angeles), with Ray Matthews, MD, and Michael Cao, MD, as co-investigators; and **Cardiocentro Ticino** (Lugano, Switzerland), with Angelo Auricchio, MD, as investigator.

"Advances in technology are expanding the clinical utility of implanted networked devices to a much broader range of heart failure patients," said Abraham, a professor of internal medicine and director of the division of cardiovascular medicine at Ohio State. "Cardiac electric tomogra-

phy offers potential value in improving the efficacy of CRT as well as polypharmacy by providing objective, longitudinal measures of cardiac performance such as contractility, synchrony, and output."

By integrating in-body computer, sensor and communications technologies into existing device and drug therapies Thompson said Proteus is "pioneering" a space the company terms intelligent medicine.

He compared the technology to the computer in a car that runs every aspect of the vehicle yet is completely invisible to the driver to describe how the company can build sensors and computers into existing devices and connect to a mobile computing platform for patients and their physicians can monitor how well their heart is working.

According to Proteus, heart failure afflicts 5 million Americans and more than 30 million people worldwide, and is the single largest expense for hospitalizations in the U.S., costing \$30 billion a year. ■

Patent watch

Tissue oximetry measurement method receives U.S. patent

A Medical Device Daily Staff Report

GlucoLight (Bethlehem, Pennsylvania) a development-stage company focused on the non-invasive, continuous measurement of blood glucose levels, reported that it has been awarded U.S. patent No. 7,356,365 for the non-invasive method and apparatus of measuring tissue oximetry. The patent was assigned to the company effective April 8.

The patent, granted to Matthew Schurman, PhD, the company's chief technology officer and co-founder, uses infrared light to measure oxygenation of blood in human tissue. This method uses optical coherence tomography (OCT), which GlucoLight also has used to develop non-invasive, continuous glucose measurement technology, and its first product, Sentris-100.

The oxygenation of blood-perfused tissue is measured by shining light into the perfused tissue and analyzing the light reflected within the tissue.

The light is reflected by cell walls in the tissue and is partially absorbed by hemoglobin in the blood. Since the extent of absorption is sensitive to the extent of hemoglobin oxygenation, measurement and processing of the reflected light provides a measure of the oxygenation of the blood.

GlucoLight is conducting additional clinical trials of its Sentris-100 monitor in the second and third quarters of 2008.

GlucoLight is focused on continuous, non-invasive blood glucose monitoring in the acute-care environment. ■

International

Continued from Page 1

B. Soma Raju, chairman and managing director of the Care Group of Hospitals, said India, with a population of more than a billion, has very few implantable cardioverter-defibrillator and CRT implant centers compared to the U.S. or Europe.

He said the number of patients who are indicated for these devices is far greater than the actual number of patients implanted as very few cardiologists have expertise in device implantation, and the awareness among physicians and patients about the latest medical device therapies and their benefits is low.

"Medtronic is committed to providing leading-edge education to medical professionals, since training and education are key to ensuring safe, appropriate and efficient use of the company's . . . devices and therapies," said Milind Shah, managing director of **India Medtronic**.

Indian firm releases new version of software

In other news from India, **Ocimum Biosolutions** (also Hyderabad), a provider of integrated genomics solutions, reported the release of Genowiz 4.0, which it terms "a comprehensive solution for gene expression analysis."

The company said the latest version of the software "makes the process of microarray data analysis simpler with a host of features such as AutoGuide to execute automated work flows for analyzing data, addition of organisms/genomes, automatic update of annotations, PLIER algorithm, data export in different formats, box plots and enhanced scatter plots."

CEO Anuradha Acharya said, "Ocimum aims to be the No. 1 genomics outsourcing partner in the world. Genowiz is . . . central to our vision of providing integrated end-to-end genomic solutions for our customers by combining biology and IT in an easy-to-use interface to handle different kinds of expression and genotyping formats such as [those from] Affymetrix, Agilent and Ocimum."

Chinese distribution deal for MacuChek

MacuChek (West Bloomfield, Michigan) has signed a distribution deal to bring its macular degeneration diagnosis device, the MacuScope, to China. The company reached a distribution agreement with **Beijing ABS Science & Technology** to license and distribute the MacuScope within three months.

Beijing ABS will have the exclusive rights to distribute the MacuScope in China, and will provide sales and support staff for all of the products sold under the agreement.

David Segel, president/CEO of MacuChek, said two other Chinese companies had backed out of earlier distribution deals.

The company said the MacuScope is the first commercially available screening device to assess a patient's risk of

developing macular degeneration, sometimes years before symptoms begin.

MacuScope is available in the U.S. and Canada, as well as Europe, South Africa and soon, South Korea.

Distribution accord for Care Clean product

Regional Medical Supplies (RMS; Ypsilanti, Michigan), a medical supply company, has entered into a new, exclusive agreement with **Hanmedics**, a South Korea-based device company recognized for what the U.S. firm characterized as "their creative medical twists."

The agreement will allow U.S. distribution of the Care Clean 3000, which RMS said is the only automatic urine collector with a bidet. The company said Hanmedics' product "[Is] quickly becoming the only solution for patients suffering from incontinence."

RMS referred to the product as the "wonder machine," saying it "cuts down on caregiver and diaper costs, eliminates offensive odors, and allows the patient to maintain a semblance of dignity, all at an unbelievably low cost."

The machine collects urine, cleans the patient and dries the perineal area, RMS said.

"When I first met with the Hanmedics team and they showed me the Care Clean 3000, I could not believe that the product did not exist in the U.S.," said Ike Odum, president of RMS. "The appliance not only provides a positive experience for the patient, it also increases the productivity of the healthcare workers."

Odum said he has had the Care Clean 3000 reviewed by several healthcare facilities in southeastern Michigan. "The feedback has been phenomenal," he said. The product is ISO 9001:2000 certified as well as being FDA-approved.

RMS provides home medical equipment and services to the Midwest region of the U.S.

New facility in India for Solvay Polymers

Solvay Advanced Polymers (Alpharetta, Georgia) said it has commissioned its new commercial PEEK (polyetheretherketone) facility at its site in Panoli, India. The new facility is now in its start-up phase and is running initial commercial production.

The company said the plant is capable of producing 500 metric tons annually, and is scalable in design to double capacity to meet demand for Solvay's KetaSpire PEEK and AvaSpire modified PEEK products for a variety of uses, healthcare prominent among them.

Since launching its Spire line in late 2006, Solvay has been supplying KetaSpire PEEK and AvaSpire modified PEEK from its unit in Alpharetta. The new commercial facility in India will support and expand upon the company's market opportunities.

KetaSpire PEEK and AvaSpire modified PEEK are ultra-polymers that offer design engineers advanced chemical resistance and mechanical properties, including strength, stiffness and ease of processing. ■

Genetic

Continued from Page 1

that it could impose unintended liability risks.

The Senate compromise, worked out earlier this week tightens language to ensure that there is a “firewall” between the part dealing with health plans and the section regarding employment, so as to discourage inappropriate claims.

The Senate passed genetic nondiscrimination bills on unanimous votes in 2003 and 2005 but couldn’t get the House to act.

If this bill passes, it could have important implications for the future of personalized medicine. Currently, some researchers studying gene-specific effects of treatments are finding that some subjects won’t participate due to fears that their data will be used against them at some future date.

“For the first time, we act to prevent discrimination before it has taken firm hold and that’s why this legislation is unique and groundbreaking,” said Sen. Olympia Snowe (R-Maine), who sponsored the Senate bill with Sens. Ted Kennedy (D-Massachusetts) and Mike Enzi (R-Wyoming).

There are more than 1,100 genetic tests available today, she said, but these are “absolutely useless” if fear of discrimination discourages people from taking tests or participating in clinical trials, Snowe said.

It is believed that genetic testing could lead to early, lifesaving therapy for a wide range of diseases with hereditary links such as breast and prostate cancer, diabetes, heart disease and Parkinson’s disease.

Several groups and companies echoed Snowe’s enthusiasm for passage of the bill.

“We are very pleased that GINA is close to enactment,” said Edward Abrahams, executive director of the **Personalized Medicine Coalition** (Washington). “The guarantees provided by this legislation will encourage millions of Americans to use their genetic information to improve their healthcare, and to help prevent and treat cancer and other diseases. We urge President Bush to sign GINA into law.”

“Passage of GINA comes at a critical time, when the potential for discrimination is growing as more genetic tests are becoming available,” said Stephen Fodor, CEO of **Affymetrix** (Santa Clara, California), which makes the GeneChip microarray technology used for analyzing complex genetic information to enable scientists to develop diagnostics and tailor treatments for individual patients “We will look back at this time as a historic turning point in the evolution of medicine.”

GINA closes important gaps in the current patchwork of federal and state protections against the misuse of genetic information. Current federal statutes for protecting medical information, including the Health Insurance Portability and Accountability Act, do not prohibit insurers from requiring genetic testing or from denying coverage based on genetic information. And while the Americans with Dis-

abilities Act protects individuals with symptomatic genetic disabilities, it is not clear if it explicitly covers discrimination based on unexpressed genetic susceptibility to disease.

Only a few states have strong protections against genetic discrimination, leaving some individuals more vulnerable depending on where they live.

Data backs routine Medicare coverage of PET

Proponents of increased Medicare coverage of scanning services may work in the mode of attrition, and a recently reopened national coverage analysis (NCA) seems to work in precisely that way.

Thanks to a decision to apply the coverage with evidence development (CED) reimbursement rubric to the use of positron-emission tomography (PET), the Centers for Medicare & Medicaid Services has reopened an NCA for FDG (fluorodeoxyglucose) PET usage in detection of several cancers, including cervical, ovarian, testicular and pancreatic cancers.

This is the third review of the matter since the beginning of the decade, and on this occasion, the review came at the request of the **National Oncologic PET Registry** (NOPR; Philadelphia). In a March 25 letter to the agency, Bruce Hillner, MD, who chairs NOPR, and three co-chairs said that data “collected over the past 18 months” on almost 23,000 individual cases provides “strong empirical evidence to justify a decision to end the CED requirements . . . and to support a Medicare coverage policy for PET across all cancer types” for diagnosis and staging. The data indicate that more than “one-third of patients undergoing PET for one of the cancer types . . . had a major change in intended management, including type of treatment.”

The authors of the NOPR letter acknowledge a lack of evidence to support “coverage of PET for treatment monitoring,” but the registry will accumulate further data to address this use.

The most recent decision memo, dated Jan. 28, 2005, concluded that “there is sufficient evidence to conclude that an FDG PET scan for the detection of pre-treatment metastases (i.e., staging) in newly diagnosed cervical cancer subsequent to conventional imaging . . . is reasonable and necessary as an adjunct test.”

The agency said that for the other cancers, “an FDG PET scan is reasonable and necessary only when the provider is participating in and patients are enrolled” in an IDE trial or a trial “designed to collect additional information at the time of the scan to assist in patient management.”

Previous coverage decisions have indicated reimbursement for roughly 30 uses, including initial staging and diagnosis of lung and colorectal cancers. CMS will take public comments through May 10 and will offer a proposed decision memo by Oct. 10. ■

PRODUCT BRIEFS

• **Delcath Systems** (New York) said that the institutional review board of the **University of Maryland Medical Center** (UMMC; Baltimore) has approved UMMC's participation in the Phase III study of the company's percutaneous hepatic perfusion (PHP) system for the isolated, high-dose delivery of the anti-cancer agent melphalan to treat inoperable metastatic melanoma in the liver. The study is being led by the National Cancer Institute, which previously approved the study's expansion to a multi-center trial. The study is designed to test Delcath's PHP System for the regional delivery of melphalan to the liver to treat patients with metastatic ocular and cutaneous melanoma who have unresectable tumors in the liver. The Delcath system is designed to deliver significantly higher doses of anti-cancer drugs to a patient's liver while preventing entry of the drugs to the rest of the patient's circulatory system. Delcath Systems makes percutaneous perfusion technology for the isolated delivery of therapeutic and chemotherapeutic agents.

• **DePuy Spine** (Raynham, Massachusetts) has launched the Viper2 Pedicle Screw Fixation System, a minimally invasive spine system offering what the company termed "comprehensive instrumentation and implant options that can be used on a wide range of spinal pathologies including deformity, trauma, tumor and degenerative disc disease." DePuy Spine made the announcement at the 76th annual meeting of the American Association of Neurological Surgeons in Chicago, where it is showcasing the Viper2 System. DePuy Spine said Viper2 is the first minimally invasive rod-and-pedicle screw system that can be used to perform minimally invasive spinal fixation across the length of the entire thoracolumbar spine (T1 to pelvis), with rods of any curvature and lengths from 30 mm to 480 mm. The new rod insertion technique allows surgeons to utilize existing incisions to deliver any curvature rod up to 480 mm long, eliminating the need for remote rod insertion

and complicated alignment jigs. The 5.5 mm-diameter titanium rods come in straight, pre-lordosed and pre-kyphosed configurations or can be contoured on-site to match the patient's anatomy. DePuy Spine also reported the launch of the Vertigraft VGI cervical allograft, a bio-implant for anterior cervical fusion surgery designed to align with the spinal anatomy. The allograft is made of a single piece of cortical bone that is freeze-dried for room-temperature storage. Its trapezoidal design matches the anatomy of the cervical spine, stabilizing the implant by increasing the surface area. Its open central chamber allows surgeons to add graft material of their choice. The cervical bio-implant features a bulleted posterior edge to facilitate graft insertion and a textured surface for resistance to migration. Its seven-degree lordotic angle maintains proper alignment of the spine.

• **Dolbey** (Concord, Ohio) has introduced a new speech-recognition product. Voice2Text is designed for the medical transcription service industry and offers the productivity enhancements of back-end speech without requiring a change to the document management platform used by the service company. With Voice2Text, speech recognition has been integrated with Dolbey's fusion voice digital dictation system and provides simple, yet functional integration to a company's existing document platform. This approach to applying back-end speech is being offered in a pay-as-you-go model to minimize up-front investment. Dolbey specializes in healthcare dictation, transcription, speech and coding products.

• **Rubbermaid Medical Solutions** (RMS; Huntersville, North Carolina) reported the launch of a medication expansion pack for its M38 mobile computer cart line. This secure storage system, which is available for the recently released M38 powered and non-powered computer carts, creates a hybrid of traditional computer and medication carts. The cart line features multiple drawer sizes, keyless entry system with PIN code management and a bar-code scanner. Rubbermaid Medical Solutions makes mobile carts and mobile computing solutions for healthcare facilities.

PEOPLE IN PLACES

• **Cantel Medical** (Little Falls, New Jersey) reported the resignation of President/CEO R. Scott Jones. Concurrently, the board created the office of the chairman and promoted COO and executive VP Andrew Krakauer to president and a member of the office of the chairman. Krakauer has served in his current role at Cantel since November 2004. Cantel Medical makes infection prevention and control products.

• Marc Peterman was named VP of R&D for **Facet Solu-**

tions (Logan, Utah). Peterman most recently was director of R&D at Abbott Spine. Facet Solutions makes surgical devices for the treatment of facet-related spinal disorders.

• Clent Richardson was named president/CEO of **Immersion** (San Jose, California). The company also expects that Richardson will be named to its board. Most recently, Richardson was chief marketing officer of TiVo. Immersion makes touch feedback technology.

• Donald Stevens was promoted to president of **Pall** (East Hills, New York). Stevens joined Pall in 1968 and has held various management positions with the company, including that of COO and president of Pall Industrial. Pall specializes in the field of filtration, separation and purification.