Infection concerns spur B&L’s halt of U.S. ReNu shipments

By HOLLAND JOHNSON
Medical Device Daily Associate Managing Editor

Bausch & Lomb (B&L; Rochester, New York) reported that it is temporarily suspending U.S. shipments of ReNu with MoistureLoc contact lens care products made at its Greenville, South Carolina, facility in order, it said, “to facilitate the further investigation of reports of fungal keratitis infections among contact lens wearers in the United States.”

The suspension follows the release of a report by the U.S. Centers for Disease Control & Prevention (CDC; Atlanta) that it is reviewing reports of 109 cases in 17 states since June 2005 of suspected fungal keratitis, which is caused by the fusarium fungus.

The CDC said that the majority of cases have yet to be reviewed, but of the 30 cases reviewed so far, 28 involved contact lens wearers. Twenty-one reported using ReNu contact lens care products and five reported

Hand-held fluorescence device enlisted to detect oral cancer

By KAREN YOUNG
Medical Device Daily Staff Writer

Researchers in Vancouver, British Columbia, have reported “initial success” in detecting oral cancer using a customized optical device designed for dentists to visualize cancer lesions or precancerous lesions “in a completely new way.”

The development was reported by the National Institute of Dental and Craniofacial Research (NIDCR; Bethesda, Maryland), part of the National Institutes of Health, which funded the research.

Called a Visually Enhanced Lesion Scope (VELScope), the hand-held device emits a cone of blue light into the mouth that excites various molecules within the patient’s cells, causing them to absorb the light energy and re-emit it as visible fluorescence.

“The natural fluorescence of the mouth is invisible to

Report from Europe

NHS Confederation backs lean operation as hospitals cut jobs

A Medical Device Daily Staff Report

A variety of measures for leaner operation by Britain’s hospitals are being supported by the NHS Confederation, a group representing more than 90% of National Health Service organizations, in the face of current and potential personnel layoffs.

Gill Morgan, MD, chief executive of the NHS Confederation, said that in order to “balance the books, some hospitals have been looking at how they can work more productively by changing the way they organize and run services.”

Among the changes he mentioned include more out-of-hospital care to reduce the number of beds needed “or using new and better technologies to treat patients more effectively” to reduce staffing needs.

He added: “For patients that are treated in hospitals, reducing the amount of days that they spend on the ward is both good for them because they recuperate quicker at home but also means that bed, ward and staff numbers can be reduced.”

Deals roundup

Moog completes $75 million buy of infusion pump maker Curlin

A Medical Device Daily Staff Report

Greatly expanding its presence in the medical market, industrial conglomerate Moog (E. Aurora, New York) reported completing the acquisition of the assets of Curlin Medical (Huntington Beach, California), a manufacturer of infusion pumps, plus the assets of two affiliated companies.

Moog paid $75 million for the acquisition, $63 million in cash and $12 million in the form of a 53-week note. The deal was first unveiled in February (Medical Device Daily, Feb. 15, 2006).

In recent years, Moog has supplied a variety of components to manufacturers of medical equipment. It says that sales of these products have grown significantly, and in FY06 will approach $40 million before considering the purchase of Curlin that will expand the company’s participation in the medical market.

Curlin’s sales in calendar 2005 were $16 million, and operating profits were $5.4 million. It said that sales in calendar

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Despite Northfield’s widening 3Q loss, PolyHeme trial progresses

A Medical Device Daily Staff Report

Blood substitute manufacturer Northfield Laboratories (Evanston, Illinois) reported a wider third-quarter loss as its research and development costs surged, but the company noted progress in the controversial trial of its PolyHeme hemoglobin-based oxygen therapeutic in the treatment of trauma patients.

For the three months ended Feb. 28, losses totaled $6.4 million, or 24 cents per share, vs. $4.8 million, or 21 cents per share, in the year-earlier quarter. Analysts expected the company to post a loss of 25 cents per share, according to a Thomson Financial poll.

The company generated no revenue this quarter or in the year-ago period. Costs, meanwhile, surged to $7.2 million from $5.1 million, due to a 52% jump in research and development expenses to $5.8 million.

At the close of the quarter, the company reported shareholders’ equity of $77.4 million, with $80.3 million in cash and marketable securities.

Last month, the company reported that regulators are investigating its development-stage PolyHeme product, which is being used as an alternative to transfusion for extreme blood loss. PolyHeme is undergoing a late-stage clinical trial.

Public concerns about the safety of the blood substitute arose after a Feb. 22 report in The Wall Street Journal (Medical Device Daily, Feb. 28, 2006). The newspaper reported that Northfield pushed to continue testing the blood substitute without disclosing earlier results, which included the deaths of two patients among 10 who had suffered heart attacks that trial focused on use of PolymHEME in elective surgery.

Northfield reiterated that it is cooperating with the staff of the SEC and the Senate Finance Committee with respect to their requests to provide certain information regarding the prior elective surgery trial. The company will also be defending a number of purported class action lawsuits recently filed against it.

The company did offer some positive news in its report, noting that 665 patients out of a planned total of 720 total patients have been enrolled thus far in its pivotal Phase III study designed to evaluate the safety and efficacy of PolyHeme when administered to patients in hemorrhagic shock following traumatic injury. The reported enrollment figure the company noted has enabled the study to pass the 90% mark of the planned enrollment.

In a conference call, Steven Gould, MD, CEO and chairman of Northfield, said the company plans to complete trial enrollment in “the second quarter of calendar year 2006.”

Northfield also said it will receive $3.5 million in designated funding for the continued development of PolyHeme as part of the Fiscal 2006 Defense Appropriations Bill, bringing the total defense appropriations for the product to $4.9 million.

The company additionally noted that it has completed its review of multiple proposals for the planned expansion of its manufacturing capacity in Mt. Prospect, Illinois, and is finalizing negotiations on a contract with the Jacobs Engineering Group.

Biomarker shows risk for recurrent heart event

Results from a major new cardiovascular study showed that when measured about 30 days after an acute coronary event such as chest pain or heart attack, elevated levels of Lp-PLA2 (lipoprotein-associated phospholipase A2) activity are an independent risk marker for death or recurrent cardiovascular (CV) events.

Lp-PLA2 activity has been associated with the development and progression of atherosclerosis, a process that may lead to heart attack, stroke or other serious CV events but until now, little information has been available on the prognostic role of Lp-PLA2 in patients following acute coronary syndromes.

Results from this sub-study of the PROVE IT-TIMI 22 (PRavastatin Or atorVastatin Evaluation and Infection Therapy) trial were published this week in Circulation.
Financings roundup

Theranox gathers in more than $14 million in Series A round

A Medical Device Daily Staff Report

Theranox (Philadelphia), a company exploring medical applications of topically applied gaseous nitric oxide (gNO), reported that it has raised more than $14 million in Series A financing.

Theranox said it plans to use the financing to fund clinical trials and commercialize the use of gaseous nitric oxide for the treatment of chronic wounds such as diabetic ulcers and venous stasis ulcers, as well as for other topical applications such as the treatment of post-surgical infections. The financing was led by Quaker BioVentures and NewSpring Capital.

The key patent portfolio for the topical use of gaseous nitric oxide was licensed from Viasys Healthcare (Conshohocken, Pennsylvania). Viasys said it determined that the optimal path for exploring the full potential of the patent estate was a new, focused externally funded enterprise.

"Published studies have demonstrated that nitric oxide has anti-infective and anti-inflammatory properties, as well as effects on cell populations that are important in the wound healing process," said Randy Thurman, chairman, president and CEO of Viasys. He added that his company is pleased "to be licensing its patents in this area to a company dedicated to the commercialization of this technology and to improving the quality of the lives of those suffering from chronic wounds, serious post-surgical infections, and other topical wounds or infections."

Former Viasys officer Frank McCaney was named as the president and CEO of Theranox.

Theranox said that Pulmonox Medical (Tofield, Alberta), a company that has completed scientific and clinical work on the effects of gNO, will perform preclinical work, design the gas delivery devices, and assist in clinical trials.

Both Viasys and Virtucon, a company owned by investors in Pulmonox, participated in the financing.

In other financing news:

CytoCore (Chicago) reported that it has secured more than $1 million in new financing from institutional sources through the issuance of common stock "at current market prices." The company said the funding will be used to implement its product development plans.

"This new funding . . . will be putting a number of key programs into motion," said CEO David Weissberg. "They include hiring key personal for our research laboratory with Dr. [George] Gorodeski and our product development laboratory with the AIPS project in Chicago, putting the e2 Collector into manufacturing development, and bringing together resources and people to develop the strategic distribution strategy for the collector. We expect to have a string of positive developments to announce over the coming months."

CytoCore develops cancer screening systems used in a laboratory or at the point-of-care to assist in the early detection of cervical, endometrial and other cancers.

Immucor (Norcross, Georgia), a maker of automated instrument-reagent systems for the blood transfusion industry, reported that its board of directors has approved a 3-for-2 stock split, which will be effected in the form of a 50% stock dividend to shareholders of record as of the close of business on April 24.

As of March 31, the company said it had about 45.21 million shares of common stock outstanding. The split will increase the number of shares of common stock outstanding to roughly 67.82 million shares, with the expected date of distribution May 15.

The stock split is the eighth for Immucor since its initial public offering in December 1985. Most recently, the company implemented 3-for-2 splits in June and November 2004.

Invivo gets $500,000 DoD award for brain injury MRI assessment

A Medical Device Daily Staff Report

Intermagnetics General (Latham, New York) reported that its subsidiary, Invivo (Gainesville, Florida) has been awarded a $500,000 Department of Defense grant to develop an integrated hardware and software system that will enable high-resolution MRI of traumatic brain injuries and promote more effective diagnosis and treatment in many difficult cases. Invivo is partnering with the Office of Naval Research on the project.

Rep. Cliff Stearns (R-Florida) formally unveiled the award at Invivo’s headquarters yesterday.

"Brain injury is the second leading cause of battlefield deaths, and this grant is intended to provide a means of diagnosis and treatment that, in many cases, is not totally reliable under current procedures," Stearns said. "We owe it to our wounded military personnel returning from combat duty to have the best possible care available."

Tom Schubert, chief technology officer of Invivo, said: "We believe Invivo’s advanced MRI radio frequency coils, which enable highly detailed organ-specific imaging, combined with modifications to our innovative DynaCad computer-aided diagnostic system, will provide the solution the military is seeking."

Schubert added that CT is the main radiological tool for diagnosing traumatic brain injury patients but limited "to visualizing fractures and significant hematomas but is ineffective in diagnosing more subtle injuries." He said it does not provide fine soft-tissue discrimination to investigate small white matter lesions common in traumatic or concussive brain injury and cannot be used in the investigation of subarachnoidal hemorrhage.

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Agreements roundup

Misys in accord for Homecare use by Lifetime Management

A Medical Device Daily Staff Report

Misys Healthcare Systems (Raleigh, North Carolina), focused on healthcare IT, reported that it has entered into an agreement with LifeTime Management Solutions (LMS; Rochester, New York) to make Misys Homecare available to small and mid-size home care and hospice agencies in the northeastern U.S.

LifeTime Care is using Misys Homecare to automate all of its business processes, from patient registration and scheduling to billing.

Misys Homecare enables homecare facilities to capture, integrate and act on patient data in real-time. Misys Homecare is part of the Misys Optimum family of clinical products and web-based technologies that connect community-based physicians and caregivers to the acute care enterprise.

LifeTime Care, the result of a merger between Genesis Region Home Care and ViaHealth Home Care, has 1,300 employees including 300 professional field staff.

In other agreements news:
- GE Healthcare (Waukesha, Wisconsin) reported the company will offer wCareAssist, a wireless application developed by Care Fusion (McLean, Virginia), on the Dinamap ProCare and Pro Series monitors to commercial hospitals nationwide.

Dinamap monitors are designed for a patient population that includes neonatal, pediatric and adults. By combining the Dinamap monitor with Care Fusion’s wCareAssist, GE expects to better provide workflow benefits by helping to eliminate transcription errors and reduce chart time.

wCareAssist, which runs on a hand-held PDA device, is designed to allow clinicians to interface patient vital signs from Dinamap ProCare and Pro Series monitors into an electronic medical record (EMR) without manual transcription and without moving an entire workstation to a patient’s bedside. The application software uses barcode technology to verify patient identification information and can be programmed to perform continuous patient monitoring automatically, recording the history of the patient’s vital signs and then sending that information wirelessly to an EMR.

- Amicas (Boston), which focuses on radiology and medical image and information management solutions, reported that San Diego Imaging (SDI) has chosen Amicas as its information technology partner for its new imaging center. Amicas’ Vision Series RIS and Vision Series Document Management will complement Vision Series PACS, which is deployed at Children’s Hospital of San Diego where the SDI radiologists practice.

SDI staffs five hospitals and four outpatient imaging centers, and is part of Children’s Hospital and Health Center. SDI’s new imaging center, located near Children’s Hospital, will be completely digital and feature the latest in diagnostic imaging technology.

Amicas Vision Series Document Management will provide paperless operations at every step in the imaging process, from patient check-in, to technologist imaging, to radiologist interpretation, and ultimately to medical billing.

Grants

Continued from Page 3

Schubert noted that the Invivo solution would be used in the highest-field MRI systems available, such as those powered by the 3.0 Tesla magnets from Intermagnetics.

Invivo said that, working with the Office of Naval Research, it expects to deliver evaluation models of both the advanced imaging hardware and the analysis software this year.

In other grants/contracts news:
- Acacia Research (Newport Beach, California) reported that its CombiMatrix group (Mukilteo, Washington), in collaboration with Texas A&M University (College Station), has been awarded a National Academies Keck Futures Initiative grant to fund a method to increase the speed of hybridization in DNA microarray applications. The amount of funding was not disclosed.

Co-principal investigators Dr. Robin Liu of CombiMatrix and Professor Victor Ugaz of Texas A&M will launch studies to obtain data serving as the cornerstone for additional funding.

Dr. Robin Liu, manager of microfluidic technology at CombiMatrix, said, “A rapid, field compatible and low-cost hybridization enhancement technique would result in a revolutionary step forward in DNA microarray capabilities. This proposal will address this need by combining our expertise in microarrays and fluid dynamics to develop a versatile technique for DNA microarray enhancement. This work will be the first time these approaches have been applied toward biomolecule hybridization.”

The National Academies Keck Futures Initiative is a 15-year effort to push interdisciplinary inquiry and enhance communication among researchers, funding organizations, universities and the general public.

- Zonare Medical Systems (Mountain View, California), a developer of ultrasound technology, reported a two-year contract with Kaiser Permanente, for Zonare’s z.one ultrasound system. The contract value was not disclosed.

Zonare, based on Zone Sonography technology, enables clinicians to instantly convert the z.one system from a full-featured, cart-based unit into a compact, portable ultrasound system with the performance of larger, more expensive units, the company said.

“Kaiser Permanente thoroughly evaluated Zone Sonography technology throughout its development cycle,” said John Rego, MD, chief of radiology, San Francisco, and chair of Northern California chiefs for Kaiser Permanente.
**Gambro meets with FDA about Prisma System, quality issues**

*Medical Device Daily Staff Report*

Senior executives at Gambro (Stockholm, Sweden) said they recently met with the FDA officials to address the agency’s concerns about the safety of the company’s Prisma System and the adequacy and effectiveness of Gambro Renal Products (Lakewood, Colorado) quality program addressed earlier this year in a warning letter.

Gambro Dasco (Medolla, Italy), a production unit within Gambro Renal Products, reported receiving an FDA warning letter concerning the agency’s inspection of its Medolla facility that manufactures monitors and indicating concerns about the safety of the Prisma System and the adequacy and effectiveness of Gambro Dasco’s quality systems (Medical Device Daily, Jan. 10, 2006).

It said that the FDA also issued an import alert calling for the detention of Gambro’s monitor products – Prisma, Prismaflex and Phoenix – shipped into the U.S.

The company said in a statement, however, that the devices can be used “when directions are followed.”

Gambro said that in mid-March it submitted a comprehensive corrective action plan (CAP) to the FDA detailing the steps it will take to resolve the agency’s issues “as quickly and thoroughly as possible.”

The company also said it has created an organization and management team to create and implement the CAP and that it has hired outside experts to support the development of the quality systems in order to meet the FDA’s requirements.

It said that in a separate meeting, senior Gambro officials and outside experts met with the FDA to discuss a new software version for Prisma under development to address the concerns raised by the FDA and further strengthen Prisma’s Fluid Balance management system. The company said that it anticipates that the new Prisma software and associated training module will be released for “a gradual rollout” this summer.

“The company continues to train and inform customers and intensive care nurses on the proper use of the Prisma System,” it said in a statement.

It emphasized that caregivers must pay particular attention to the “Incorrect Weight Change Detected” alarm on the system. This alarm should never be overridden without first identifying and removing the cause of the alarm, it said.

“Our goal is to ensure that Gambro products meet the highest standards for quality, safety and effectiveness,” says Sören Mellstig, president and CEO of Gambro.

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**Europe**

*Continued from Page 1*

Additionally, “Introducing digital X-ray facilities, robotic pharmacists or applying lean manufacturing techniques to pathology services all save money and provide a more efficient service to patients.”

Morgan defended the NHS, suggesting that such measures, while productive, are likely to draw unfounded criticism. “The NHS is castigated for not being productive and then castigated again when it takes action to improve productivity,” he said.

Steve Barnett, director of NHS Employers, which is part of the NHS Confederation, said: “Spending on work force makes up the largest part of trust budgets, and employers will be looking critically at staffing as a way of managing deficits and improving productivity.”

The NHS Confederation represents more than 90% of the organizations that make up the NHS. Its members include the majority of NHS acute trusts, ambulance trusts, foundation trusts, mental health trusts, primary care trusts, special health authorities and strategic health authorities in England; trusts and local health boards in Wales; and health and social service trusts and boards in Northern Ireland.

**ONI supporting MRI access in Denmark**

ONI Medical Systems (Wilmington, Massachusetts), developer of MSK Extreme and OrthOne high-field, 1.0T extremity MRI systems, reported that it is working with health authorities in Denmark to reduce the time patients need to wait for an MRI. With the increase in the number of patients needing MRI, the waiting time for a scan in Denmark can be as long as six months.

“The decision by the radiology community in Denmark to support the ONI solution validates the need for dedicated extremity MRI units in health systems with strong MRI utilization,” said Bob Kwolyk, founder of ONI. “MSK Extreme and OrthOne dedicated high-field extremity MRI systems will play an ever-increasing role in helping provide timely imaging services while containing soaring medical costs worldwide.”

At the end of 2004, Danish health authorities made a strong recommendation that no one should have to wait more than six weeks for an MRI exam. If the hospitals in the county where the patient lives cannot guarantee an examination within that time, the county will have to pay for the examination and transport, even to another country.

Aarhus County, which consists of 26 municipalities, has seven whole body MRI systems which range in strength from 0.7 Tesla to 3.0 Tesla. In an effort to cut waiting time and contain costs, Aarhus County ordered two OrthOne 1.0 Tesla systems. By installing a specialized extremity system, the throughput on the whole body systems was maximized without the need for the extra cost of another whole body system.

It is anticipated that a third hospital in Aarhus County will get approval for another OrthOne to be installed in early 2007, ONI said.
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using a combination of ReNu and products manufactured by Advanced Medical Optics (Santa Ana, California) and Alcon (Fort Worth, Texas).

An estimated 30 million Americans wear soft contact lenses, the CDC noted.

“The CDC data released today are both troubling and perplexing, as there is an apparent disproportionate representation of U.S.-manufactured ReNu with MoistureLoc in the underlying data,” said Ronald Zarella, B&L CEO and chairman, in a statement. He said the source of the infections has not been determined and that the available scientific evidence “does not establish any type of ReNu solution as a cause.”

The fungus rarely affects contact lens users, and the surge in reported cases has raised alarm at centers across the country, including cornea specialists at Bascom Palmer Eye Institute of the University of Miami’s Miller School of Medicine (Miami, Florida) who reported their concerns last week (Medical Device Daily, Apr. 5, 2006).

Soft contact lens use has been the only identified risk factor in the majority of the cases seen between January and March 2006 at the institute’s facility, where it said 21 cases have been identified, 12 among contact lens users.

Between 2000 and 2005, the average number of Fusarium keratitis cases was 21 per year. Usually, less than 2% of these cases have been in contact lens users, the institute said.

The fungus is commonly found in plant material and soil in tropical and subtropical areas. Singapore health officials noticed an increase in reports of infection in January and discovered 39 cases involving contact lens users from 2005 to February of this year. Cases have also been reported in Malaysia and Hong Kong.

In February, B&L halted sales of its ReNu contact lens solution in Singapore and Hong Kong.

Without treatment, which can last two to three months, the infection can scar the cornea and blind its victims. Eight U.S. patients have required cornea transplants, the CDC reported.

B&L said it has been collaborating with the FDA, the CDC, major eye centers and health authorities to determine if the reports represent an increase in the historical incidence of these infections and determine the root cause.

The company had previously noted that many of the reported cases in Asia involved examples of poor patient compliance with lens care and contact lens wear, including wearing expired lenses and re-using daily disposable contact lenses. It urged contact lens wearers to follow good hygiene and proper lens care practices to prevent infection and warned against the use of unregulated “knock-offs.”

The company stressed that this suspension does not affect any other B&L products.

Daniel Schultz, MD, director of the FDA’s Center for Devices and Radiological Health, said it was too early to determine if B&L’s solution was the cause of the infections. Both the FDA and CDC are investigating the growing number of reports of infection by the fungus.

“We are relatively early in this investigation. It may be we will find this particular product does not have an association. We may find a strong association,” Schultz told reporters, adding that the company’s decision to stop shipments was “a very appropriate and responsible action.”

While the company is halting shipments, stores can continue to sell ReNu until supplies run out, Schultz said.

The concerns began on March 8 when a New Jersey ophthalmologist called the CDC to say that he had seen three patients in the previous three months who were suffering from Fusarium keratitis.

The infections are rare but are more likely to occur in the South. That so many cases have been found in New York and New Jersey caused particular concern, Schultz said.

Some analysts said that the suspension could hurt the company at least in the short-term.

Med-tech analyst Joanne Wuensch of investment banking firm Harris Nesbitt (New York) in a research report wrote that the product could be absent from the U.S. market until the end of the year.

“We estimate each $10 million in lost lens care sales reduces EPS by roughly 2 cents,” she said, adding that still uncertain “is the collateral damage to other Bausch & Lomb brands.”

The company said that the product generated sales of about $45 million in the U.S. in 2005, and that it already had reported that the situation is expected to reduce its 1Q vision care revenues in Asia by as much as $10 million vs. internal expectations.

FDA to meet on dental amalgam devices

The FDA said a joint meeting of the Dental Products Panel of the Medical Devices Advisory Committee of the Center for Devices and Radiological Health and the Peripheral and Central Nervous System Drugs Advisory Committee of the Center for Drug Evaluation and Research will be held Sept. 6 and 7 from 8 a.m. to 5 p.m. at the Holiday Inn in Gaithersburg, Maryland.

The joint committee will review and discuss peer-reviewed scientific literature on dental amalgam devices and their potential mercury toxicity, specifically as it relates to neurotoxic effects. Dental amalgam, also called “encapsulated amalgam,” consists of dental mercury and amalgam alloys.

The FDA said certain consumer groups have raised concerns about the effects of using mercury as a component of dental restorative materials.
Fluorescence
Continued from Page 1

the naked eye,” said Miriam Rosin, MD, a senior author on the paper and a cancer biologist at the British Columbia Cancer Research Center, in a statement. “The VELScope literally brings this natural fluorescence to light, helping dentists to answer in a more informed way a common question in daily practices: To biopsy or not to biopsy.”

Because changes in the natural fluorescence of healthy tissue generally reflect light-scattering biochemical or structural changes indicating developing tumor cells, the VELScope is designed to allow dentists to shine a light on a suspicious sore in the mouth, look through an attached eyepiece and watch directly for changes in color.

Normal oral tissue emits a pale green fluorescence, while potentially early tumor, or dysplastic, cells appear dark green to black.

The VELScope device – similar to devices currently being used to detect both lung cancer and cervical cancer, according to the NIDCR – was tested in 44 people, with the results published online in the Journal of Biomedical Optics.

In the testing, the researchers evaluated 50 tissue sites from the 44 people. All sites were biopsied, and pathologists classified seven as normal, 11 as severe dysplasia and 33 biopsies were oral squamous cells carcinoma.

Reading the fluorescence patterns of the 50 sites, the group correctly identified all of the normal biopsies, 10 of the severe dysplasias and all of the cancers. Those numbers translated to 100% specificity, or the ability to correctly identify people with a disease, and 98% sensitivity, the ability of a test to correctly identify those who are well.

The correct distinction between normal and abnormal tissue was possible in all but one instance. The NIDCR said that the diagnoses were confirmed to be correct by biopsy and standard pathology.

In an online interview with the NIDCR web site, Rosin told the institute: “The earlier that you catch a suspicious sore, or lesion, in the mouth, the better the outcome will be for the patient.”

Unfortunately, she noted also that “the problem is the morbidity and mortality rates for oral cancer have remained fairly static for several decades,” although they can be seen by the human eye.

She said “the lack of progress tells us three things: One, we need better screening tools that more sensitively and specifically determine whether a suspicious lesion is precancerous and should be removed.”

Included in that list was outreach to the dental and medical communities to develop a more “seamless system to manage patients.”

“We can’t allow anyone to get lost in the system,” she said in the interview with NIDCR.

The NIDCR said that because developing tumors in the mouth are “often easily visible,” public health officials have long advocated early detection of oral cancer. But determining whether a suspicious sore is benign or potentially cancerous has remained scientifically problematic, because “looks alone can be deceiving” when trying to diagnose cancer, based on the general appearance and staining patterns of tissue biopsy. In the web site interview, Rosin said that they can also be deceiving in the pathology lab.

“You can’t just look at these lesions under a microscope and know definitively how they will behave in the future,” she said. “To better characterize a mild or moderate dysplasia, you need access to molecular information. You need to know whether abnormal molecules are present in the cells that drive the abnormal growth.”

Rosin said the VELScope goes a long way toward answering this unmet need.

“Historically, the problem in developing a fluorescence-reading instrument has been largely organizational,” said Rosin, a leader of the British Columbia Oral Cancer Prevention Program. “No one scientific discipline possesses sufficient expertise to build such a sophisticated imaging device, and the needed interdisciplinary groups weren’t forming to tackle the problem.”

Ultimately, after Rosin’s suggestion, Calum MacAulay, MD, the head of the British Columbia Cancer Research Center’s cancer imaging program, agreed to begin the process of designing a hand-held device that would be user-friendly in a dentist’s office, along with post-doctoral fellow Pierre Lane, the NIDCR said.

“We essentially refined and integrated [a] box-and-goggles concept into one device,” said MacAulay, who also works with a corporate partner looking to commercialize the device. “The box was molded into the lightweight, hand-held structure, a flexible cord attaches the examination light, and the goggles became the view finder that allows dentists to directly evaluate lesions in real time.”

Rosin’s group is conducting a larger follow-up study to evaluate further the VELScope device.

“Laboratories are developing similar devices to detect lung and cervical cancer,” said Rosin. “That means that the same basic technology is now being used to evaluate three tumor sites, and we can begin hopefully to pool our data and fine tune the characteristics and meaning of the changes in fluorescence.”

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Advances in Cardiovascular Technology Vol. 3: State of the Industry and Emerging Markets

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Deals
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2006 have been running at almost twice that rate.

Infusion pumps provide controlled delivery of therapeutic drugs to the patient, either in a hospital or in an outpatient setting. The technology employed in infusion pumps has been advancing such that they now employ microprocessor controls and sophisticated software.

Moog said it believes that its background in the electronic control of fluid-flow metering devices combined with Curlin’s reputation in the medical market will facilitate the continued growth of Moog’s medical equipment sales. Curlin’s products are distributed in North America by B. Braun Medical (Bethlehem, Pennsylvania). Moog said it expects to continue this relationship and will expand it.

In the remaining six months of its fiscal year ending Sept. 30, Moog said it expects that Curlin’s profit contribution will offset financing costs and the amortization of purchase accounting intangibles.

“We’re very excited about the addition of Curlin Medical to our company,” said R. T. Brady, CEO and chairman of Moog. “We made an extensive search to find the right product to expand our participation in medical equipment. We believe that Curlin provides an outstanding platform to extend Moog’s technology into the medical market through the B. Braun Medical distribution network, enabling us to continue growing this business.”

Moog manufactures precision control components and systems, its high-performance systems controlling military and commercial aircraft, satellites and space vehicles, launch vehicles, missiles, automated industry machinery and medical equipment.

In other dealmaking:

• Zoll Medical (Chelmsford, Massachusetts), a manufacturer of resuscitation devices and related software solutions, reported completing the purchase of the assets of Lifecor (Pittsburgh), a manufacturer of wearable external defibrillator system.

Zoll acquired Lifecor’s assets and business, assumed Lifecor’s outstanding debt of about $5.8 million (plus an additional $3 million owed to Zoll), and also assumed certain stated liabilities of around $1.5 million. Additional consideration will be in the form of earn-out payments to Lifecor based upon future revenue growth of the acquired business over a five-year period.

Zoll on March 22 reported the exercise of a previously granted option to acquire the assets.

Zoll will operate the Lifecor business through its Zoll Lifecor subsidiary (Pittsburgh).

Besides manufacturing resuscitation products, Zoll develops software that automates the documentation and management of both clinical and non-clinical information. It sells its products in more than 140 countries.

• NanoInk (Skokie, Illinois), focused on the emerging field of nanometer-scale manufacturing and applications development, has appointed three senior executives. Jim Whittle has been named vice president, business development and joins NanoInk from AT Kearney, where he was a member of the Global Healthcare/Lifesciences sector team. Bruce Dudzik has been named senior director, business development for NanoInk. Previously Dudzik was at Affymetrix and has more than 25 years of experience in the microarray and bioscience industries. Tom Levesque has been named senior director, DPN global sales.

Levesque joins NanoInk from Synova, with more than 25 years of experience in sales and marketing capital equipment.

• David White, MD, has been named chief medical officer of Respironics (Murrysville, Pennsylvania), effective May 1. White currently is director of the Clinical Sleep Disorders Program at Brigham and Women’s Hospital and a professor of sleep medicine at Harvard Medical School. Respironics develops products and programs that serve the sleep and respiratory markets.

• John Howe has joined Sanarus Medical (Pleasanton, California), a developer of minimally invasive medical devices for diagnosing and treating breast disease, as chief operating officer and CFO. Howe most recently was CFO for Eunoe.
Angiotech posts strong data results for Adhibit

Angiotech Pharmaceuticals (Vancouver, British Columbia), at the 19th Annual European Congress of Obstetrics and Gynecology in Torino, Italy, reported positive results from its Adhibit adhesion prevention gel myomectomy study.

The data showed that Adhibit was able to reduce post-operative adhesion formation as measured by the modified American Fertility Society (mAFS) score, a system that factors both the extent and tenacity of adhesions. Patients in the group that were treated with Adhibit experienced a statistically significant reduction in their mAFS score when compared with those in the control group. The controlled, single-blind, clinical study — designed to evaluate the safety and efficacy of Adhibit in reducing the incidence and severity of post-operative adhesions when applied immediately after the removal of uterine fibroids — was conducted at six sites in Europe, Canada, and the Netherlands Antilles.

The trial randomized 71 patients, with 48 patients receiving the Adhibit treatment and 23 patients receiving no post-operative adhesion treatment. Patients were surgically re-examined eight to 10 weeks, post-procedure, to determine the incidence and severity of adhesions.

Adhibit, a synthetic sprayable hydrogel that is resorbed by the body over 30 days, is approved in Europe to prevent or reduce post-surgical adhesion formation in pediatric patients undergoing cardiac surgery. It is marketed by Baxter Healthcare (Deerfield, Illinois) worldwide, excluding the U.S. Baxter has an option to license Adhibit in the U.S., but it is not approved for sale in the U.S.

Radi reports on FemoStop efficacy

Radi Medical Systems (Uppsala, Sweden) reported the results of an independent study of 1000 patients that confirmed the efficacy of using the FemoStop Plus Femoral Compression System to manage hemostasis as part of an early ambulation protocol for patients undergoing elective coronary angiography with 6 Fr sheaths.

Physicians taking part in the study at the Freeman Hospital (Newcastle, UK) managed patient hemostasis using the FemoStop Plus compression device. Patients were mobilized after only 90 minutes of bed rest. In the absence of complications, they were allowed to leave the hospital after two hours of mobilization.

“The low complication rate reported in this study is remarkable, as the majority of patients were obese,” according to the physicians who authored the study, “Rapid Ambulation After Coronary Angiography via Femoral Artery Access: A Prospective Study of 1000 Patients.” “Our study’s results show early ambulation after 90 minutes to be safe for patients undergoing elective 6 Fr coronary angiography.”

The results also appeared in the March issue of the Journal of Invasive Cardiology. Radi manufactures devices used in interventional cardiology, specializing in intravascular sensors and hemostasis management.

Product Briefs

- Biotronik (Portland, Oregon), focused on cardiac rhythm management, reported FDA approval and the first implant of the newest member of its Biotronik implantable cardioverter defibrillator lead family, the Linox SD active fixation, steroid-eluting lead. The Linox SD incorporates a slim 7.8 Fr isodiametric lead body, an advanced helix mechanism, and two color-coded DF-1 connectors. Linox SD also features Biotronik’s fractal technology for improved sensing performance and a steroid-eluting collar to control acute threshold increases. The first U.S. implantation of Linox SD was performed at Riverview Regional Medical Center (Gadsden, Alabama) on April 10. The company said it also recently received FDA approval for the Setrox S active fixation, steroid-eluting bradycardia lead. It features a slim isodiametric profile at 6.7 Fr with the same advanced helix mechanism and flexible distal tip that provides greater maneuverability for implantation and improved post-implantation results. Both Linox SD and Setrox S offer great mapping capability that allows physicians to identify the optimal implant location prior to extension of the helix, the company said.

- MobileMD (Newtown, Pennsylvania), a division of IntraPrise Solutions that provides health information technology, reported a release of MobileMD, the Practical EMR. MobileMD, the Practical EMR Version 3.0 is an intuitive electronic medical record system that allows medical clinicians and staff to record, capture and process patient medical information resulting in accessible electronic patient charts. Using standard, readily supportable technologies, MobileMD provides a fully secure, web-based solution that automates the capture, management, integration and access of diverse and complex patient information whether received electronically or on paper. E-mail alerts automate notification processes and follow-up, while MobileMD’s security architecture ensures only authorized personnel are able to view specific records or documents in a secure, protected environment.

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