

NewCo on the block

PixelOptics develops notable new alternative to bifocals

By OMAR FORD

Medical Device Daily Staff Writer

In just a few short months patients are going to be able to do something fairly unique with their eye glasses. They're going to be able to switch between vision settings, thanks in part to a technology created by start-up **PixelOptics** (Roanoke, Virginia).

The firm said that its emPower line of electronic eyeglasses lets wearers switch between two prescriptions, with settings for close-up and distance vision.

"We chose the name [emPower] because we felt it would capture the essence of what we're trying to do for the patient and the consumer," PixelOptics president/CEO Ron Blum, MD, told *Medical Device Daily*. "We wanted, for the very first time, to empower [patients] to be able to gain
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Analyst sees opportunity in 'new age' of orthopedics

A Medical Device Daily Staff Report

As William Plovanic, a research analyst at **Canaccord Genuity** (Toronto), alluded to in a recent research note, most people who follow the orthopedics industry already know that the best days of that sector - "the days of lavish spending on surgeons and consulting agreements - have passed. However, Plovanic says there will be winners and losers in what he calls the "new age" of orthopedics, and thus an opportunity for capital gains.

"While we believe the glory days of the orthopedic industry are unlikely to return, business should improve from current levels as the economy improves due to underlying demographics," Plovanic says in his note.

"Following our Musculoskeletal Conference and through our channel checks at the American Academy of Orthopedic Surgeons (AAOS) meeting in February, we
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International report

Misonix in new distribution agreement for Colombia

A Medical Device Daily Staff Report

Misonix (Farmingdale, New York), a device company that designs therapeutic, ultrasonic products for wound debridement, spinal surgery, cosmetic surgery, neurosurgery, laparoscopic surgery, and other surgical and medical applications, has entered into a new, three-year, exclusive distribution agreement with **Instrumentacion** (Bogota, Colombia). Instrumentacion will sell and distribute the SonaStar ultrasonic surgical aspirator and the BoneScalpel ultrasonic bone cutter throughout Colombia. The agreement includes annual minimum purchase requirements.

Instrumentacion supplies a wide range of specialty medical products to the Colombian market with a focus on
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Washington roundup

APEC drafts code of ethics for device, diagnostics firms

By MARK McCARTY

Medical Device Daily Washington Editor

The Asia-Pacific Economic Cooperative (APEC) has drafted a series of principals for ethical business practices that are specific to makers of devices and diagnostics, titled the Kuala Lumpur principals, but critics of industry may find an irritant in the fact that the **Advanced Medical Technology Association** (AdvaMed; Washington) had a hand in creating the principals.

In an April 19 statement, APEC states that its principals are designed to ensure that medical decisions are "made in the best interest of the patient," but the document hints that many APEC nations have little or no such requirements of their own. In one passage late in the document, the statement
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Don't miss today's MDD Extra: Neurology



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Agreements/contracts**Novation adds Biotronik cardiac rhythm products****A Medical Device Daily Staff Report**

Novation (Irving, Texas), a healthcare supply contracting company, reported the addition of **Biotronik** (Lake Oswego, Oregon) to its Cardiac Rhythm Management (CRM) Devices portfolio. This 30-month agreement represents the first collaboration between the respective organizations. The collaboration between Novation and Biotronik will open access to products with many new options for the members of **VHA**, **Provista** (both also Irving), and the **University HealthSystem Consortium** (UHC; Oak Brook, Illinois).

"Biotronik will invest in opportunities and we are enthusiastic about this newly forged relationship with Novation and the member hospitals it serves. This agreement acknowledges our commitment to continued growth in the U.S. as well as our excellent reputation for product quality and reliability." The two companies are looking forward to their new partnership as Dan Schlewitz, executive VP of sales for Biotronik, describes,

Biotronik makes technological advancements designed to provide maximum reliability for patients with cardiac arrhythmias. During the process, members of VHA, UHC and Provista fully supported the addition of Biotronik to Novation's robust CRM portfolio.

In other agreements/contracts:

• **The Department of Veterans Affairs** (VA; Washington) has awarded the first major contract to construct a new VA Medical Center in the Denver area.

"The new medical center for Denver demonstrates VA's commitment to the Veterans it serves," said Secretary of Veterans Affairs Eric Shinseki. "It will provide Veterans with the state-of-the-art medical care that they deserve while investing in the local economy."

The \$22.5 million contract was awarded to Kiewit-

MDD's Fun Facts

Editor's note: In an effort to enlighten your day, we now offer a weekly ponderance or two...

Made in China

How long before our devices and drugs are stamped with that still-foreboding ascription? And barring a major reputation makeover, how comfortable will we feel when we will potentially have to rely on those products to treat the diseases and conditions that may have been brought on by tainted foods and suspect goods that originated from the same Far East location?

– Michael J. Harris, Fact of the Week Editor

Turner a joint venture of Englewood, Colorado.

The new medical center will replace the Denver Medical Center for the Eastern Colorado Health Care System and will be constructed at the Fitzsimons campus in Aurora, Colorado. The new 184-bed replacement medical center will include a 30-bed Spinal Cord Injury/Disease Center, a 30-bed community living center, a research building, a central utility plant and parking structures.

The Clinic Building South is located at the corner of Colfax and Wheeling Street on the Fitzsimons campus.

• The **Premier** (Charlotte, North Carolina) healthcare alliance aid new agreements for vascular grafts have been awarded to **Atrium Medical** (Hudson, New Hampshire), **Maquet Cardiovascular** (Wayne, New Jersey), **Terumo Cardiovascular Systems** (Ann Arbor, Michigan) and **W. L. Gore** (Flagstaff, Arizona). Premier also reported that new agreements for quality control material have been awarded to **Bio-Rad Laboratories** (Hercules, California) and **Randox Laboratories** (Kearneysville, West Virginia).

Premier operates a healthcare purchasing network. ■

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*HIT roundup***Harrison Medical deploying GE Healthcare's HIE solution****A Medical Device Daily Staff Report**

Harrison Medical (Bremerton, Washington) says its healthcare community is now operational with **GE Healthcare's** (Waukesha, Wisconsin) bi-directional, industry standards based eHealth Information Exchange. The HIE allows physicians to search and view patient documents such as history and physicals, lab and pathology reports from within their electronic medical records (EMR) workflow.

"Working with GE to implement a health information exchange (HIE) supports our Vision 2015 strategic priorities around physician and provider alignment, operations redesign, and cultural transformation," said Adar Palis, executive VP and chief administrative officer of Harrison Medical Center. "GE's HIE platform will help us significantly improve the quality and efficiency of the care our clinician community provides to patients."

Harrison is a not-for-profit hospital offering medical, surgical, and emergency services at five locations in Washington state: Bremerton, Silverdale, Port Orchard, Belfair, and Poulsbo.

GE's HIE solution supports GE Healthcare's own Centricity EMR, used by Harrison's affiliated physicians, as well as non-GE clinical software products.

In other HIT activity:

- **Salar** (Baltimore) has earned EHR Modular certification for its TeamNotes and TAP Charge Capture software solutions. The designation officially deems Salar's solutions capable of enabling providers to qualify for funding under the American Recovery and Reinvestment Act (ARRA). Tested and certified under the Drummond Group's EHR Office of the National Coordinator Authorized Testing and Certification Body (ONC-ATCB) program, TeamNotes and TAP Charge Capture are 2011/2012 compliant in accordance with the criteria adopted by the Secretary of Health and Human Services.

The certification enables healthcare providers leveraging Salar's software to significantly improve their quality of care, achieve meaningful use and qualify for incentive funds under ARRA.

TeamNotes enhances clinical productivity by giving physicians powerful electronic documentation tools that eliminate paper-based notes. A fully customizable user interface empowers physicians to work the way they want, saving them time and achieving a more accurate and comprehensive clinical document. As an overlay to a hospital's existing information systems, every TeamNotes document is available in the EMR for access by physicians and clinical staff.

TAP Charge Capture increases efficiency and enhances

revenue by capturing and completing charges at the point of care. Electronically captured charges, along with compliant CPT and supporting ICD codes, are automatically routed to back-end billing systems, eliminating labor-intensive, error-prone manual billing processes. By integrating with TeamNotes, TAP seamlessly links physician documentation and billing to ensure physicians and billing staff that every charge is captured from every patient visit.

- **Stockell Healthcare Systems** (St. Louis) reported that **Emerus Hospital Partners** (Woodlands, Texas) has selected its InsightCS Patient Access, Patient Accounting and Revenue Cycle Information software solution.

The implementation is part of a major information systems initiative for the organization's five emergency service delivery facilities (three in the Houston area and two in the Dallas/Fort Worth Metroplex).

Emerus also selected the Ingenix/Picis ED PulseCheck clinical information system and will be integrating it with InsightCS to achieve true, end-to-end electronic patient care and patient information management, according to Stockell. ■



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Washington

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notes that APEC economies should consider developing “clear laws and regulations that are objectively applied” and that they should also consider working collaboratively to develop “joint policies” and “capacity-building activities.”

The rub for the industry’s critics is noted in AdvaMed’s April 21 statement which states that the association’s general counsel, Chris White, served as co-chair of the working group that developed the principals. White is quoted as saying the principals were “modeled after AdvaMed’s own code of ethics.” Those concerns, however, might be allayed by the fact that the Kuala Lumpur principals include the recommendation that firms “institute appropriate internal monitoring and auditing mechanisms” as well as “safe mechanism for . . . employees who raise concerns.”

According to the AdvaMed statement, senior APEC officials will take up the Kuala Lumpur principals in a May conference to be held in Big Sky, Montana, which will also be attended by the Small and Medium Enterprise Corporation, an agency of the government of Malaysia.

The issue of gifts is addressed in the principals, including that attendance at events or any other form of gratuity or gift “shall not be regarded as appropriate for nurturing appropriate business relationships,” although free products are not *verboten* so long as they are “for evaluation and demonstration purposes.”

On the other end of the transaction, the principals include the recommendation that healthcare providers, including academic institutions, “develop and implement codes of ethics consistent” with the framework of the principals, but also that those providers draft and implement “clear, distinctive, accountable and comprehensive policies on procurement processes and procedures.”

The impact of the principals could be widely felt if APEC’s membership is any indication. According to the AdvaMed statement, its members include mainland China, the U.S., the Russian Federation, and Indonesia, which collectively make up roughly 2 billion of the world’s population. India has applied for membership, but it lacks a Pacific coastline, and some member nations are reported to have expressed concern that the inclusion of India would tilt the group’s decisions toward the mainland of Asia and away from other regions, including the island nations of the Pacific Ocean.

FDA fares well in continuing resolution

Despite concerns that the FDA budget would collapse under the pressure of the current federal budget deficit, the agency’s tax dollars held ground in the continuing resolution for the fiscal 2011 budget, an outcome perhaps forecast by comments from the agency’s commissioner after a recent hearing in a subcommittee of the House Appropriations Committee.

FDA commissioner Margaret Hamburg, MD, testified at the hearing that FDA’s mission was sensitive to the agency’s

budget despite the growing use of user fees to help float the agency’s operations, a view that met with little resistance from the subcommittee members (*Medical Device Daily*, March 14, 2011). The view that FDA has been chronically underfunded for the past couple of decades excites little opposition on Capitol Hill, although effective support for increases in the agency’s appropriated funds has regularly proved tepid at best. Hamburg told *Medical Device Daily* at the end of the hearing that she found it “encouraging” that the Obama administration’s proposed budget for the agency was up for fiscal 2011 and that the subcommittee chairman, Rep. Jack Kingston (R-Georgia), had described FDA as a “unique agency” during the hearing.

The net effect of the continuing resolution on FDA’s appropriated monies is that the agency will receive \$107 million more than in fiscal 2010 for a total of slightly more than \$2.4 billion, the lion’s share of which will go toward food programs run by FDA.

According to an April 12 statement by the **Alliance for a Stronger FDA** (ASFDA; Washington), the agency’s Center for Food Safety and Applied Nutrition (CFSAN) will reap a sum of \$837 million for fiscal 2011, while the Center for Drug Evaluation and Research will end up with slightly more than half, \$478 million. The Center for Devices and Radiological Health logs in at third place at \$323 million, an \$8 million bump over the amount of \$315 in fiscal 2010. The ASFDA chart indicates that CDRH employed just less than 1,500 full-time equivalent employees in fiscal 2010, although no figures are offered for the current fiscal year.

Nancy Brandish Myers, president of ASFDA, said in the statement that Congress “heard our message that a robust, well-funded FDA is essential for patients, consumers and industry,” adding that the alliance “will continue to make our case as Congress considers” appropriations for the upcoming fiscal year.

AFSSAPS: PIP implants not genotoxic

France’s medical device regulatory authority has determined that unauthorized changes to breast implants made by **Poly Implant Prothèse** (La Seyne-sur-Mer) are not genotoxic, a development that was also announced by the UK’s Medicines and Healthcare Products Regulatory Agency (MHRA) on April 21.

In an April 14 statement, France’s Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS) states that it had suspended marketing for the implants after reports in 2009 of “an increase in precocious shell ruptures” and a March 2010 inspection of the firm’s plant, at which time French authorities discovered that PIP was filling the implant shells with a silicone gel using a formulation other than that described in the firm’s regulatory filing.

AFSSAPS states that the first series of tests on the implants demonstrated “a significant heterogeneity in the quality of these implants” in terms of the “level of fragility,”

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PixelOptics

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control of their eyeglasses.”

The company has been working on this project for 12 years and according to Blum it has been “quite a journey.”

He briefly described the concept of the technology, which has been touted by some as being disruptive to the way bifocals are designed.

“It’s important to understand that when our glasses are turned off they’re distinctively designed so a person can see far away and all the way up to what we call intermediate vision,” Blum said. “And when they’re turned on it allows you to see near.”

He added, the advantage of that is significant because now for the first time if a person has a bifocal if they stand up and look at their feet its like they’re looking through a blur, because the bifocals are focused at 14 inches and their feet are much further out.”

The device works a bit like this, after powering up for six to eight hours the glasses can run for roughly three days. The company said the emPower lenses have a thin layer of liquid crystal located between two layers of plastic.

Once the electrical charge hits the liquid crystal the molecules realign, changing the prescription.

According to Blum, the company will first launch the glasses in Virginia and then follow up in North Carolina. Since eyeglasses are a Class I device there was no need to seek 510(k) approval, he said.

“Our goal is to be across all the states before year’s end,” he told *MDD*. He added that there would be plans to take the device to Europe.

Investors seem to be sold on the company’s idea. Most recently **Safeguard Scientifics** (Wayne, Pennsylvania) a holding company that builds value in growth-stage life sciences and technology companies reported that it led a \$45 million financing for PixelOptics. The financing is comprised of \$35 million in equity, of which Safeguard provided \$25 million, and \$10 million in venture debt (*Medical Device Daily*, April 8, 2011).

“I have to tell you I’m not surprised by the dollars that we’ve raised,” Blum said. “I want to say honestly, and I don’t want to be cocky, but this is a billion dollar opportunity and it could be a multi-billion dollar opportunity. It’s so significant and the investors, I believe, see that.”

Investors said the reason PixelOptics was so attractive was because of emPower’s potential to become a disruptive technology.

But could it really replace bifocals?

“It’s not going to happen overnight,” Blum answered. “Before 1784 people had two pairs of glasses, then Benjamin Franklin came along and showed them that they didn’t have to have two pairs of glasses anymore and then bifocals came about. Now some 50 years ago progressive lens were developed and people started using them. EmPower is no different. It is a disruptive technology and we believe that

it’s the first of a breed of many different types of dynamic lenses.”

Although funding isn’t a surprise to Blum, the attention is.

“This is not my first company, I’ve done this several times,” he said. “[But] I’ve never been associated with a product where there is so much human interest and so much media interest.”

Blum pointed out that the device has been featured in media outlets across the world. He said that the product has been featured on CNN, NBC, and ABC just to name a few stations. He also added that the product has been discussed overseas, in Chile and Japan.

“When you have this kind of attention on a [global scale], which is at least in our industry unprecedented, it’s tremendous pressure on a company like PixelOptics to make sure its product lives up to the promise that we deliver what it is we say we’re going to deliver.” ■

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Washington

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but also observed “an irritant behavior of PIP’s gel” not seen in silicone gels of other breast implants or with the gel approved for PIPs implants. However, this first round of tests was negative for *in vitro* genotoxicity and inconclusive for a mouse *in vivo* test. Further *in vivo* mouse tests, including one using the comet assay, demonstrated no genotoxicity.

The remaining problem is that PIP’s implants had demonstrated a “highly variable rupture rate [of] up to 10%,” as well as an 11% rate of gel leakage, according to AFSSAPS. The agency recommends that users of the implants go in for a clinical exam, to include ultrasound, every six months and that any extraction of one implant be accompanied by extraction of the other. ■

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Orthopedics

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have become very upbeat about the space – and large joint reconstruction and sports medicine in particular. Our checks found an overwhelming consensus that a bottom has likely been reached as far as procedure volumes in semi-elective procedures,” he wrote. He noted, however, that spine remains under more pressure than large joint reconstruction and sports medicine as it is dealing with payer push backs.

In particular, Plovanic said, for hip and knee reconstruction, which experienced another dip in volumes in the 2Q10 and 3Q10, it seems as though the tier 2 and tier 3 surgeons’ surgical queues are filling back up again. “We see this as a very positive indicator, as during the recent difficult times, the lower volumes had relatively a smaller impact to the top-tier, high-volume surgeons, while the lower-volume surgeons experienced a larger drop-off in their case loads,” Plovanic wrote. “We believe that a robust surgical queue could mean pent-up demand is working its way through, as the economy gradually rebounds and consumer confidence builds. . . . Simply stated, we believe the bottom of the cycle has been reached and growth rates will improve going forward for the U.S. total joint market.”

According to Plovanic’s note, the procedure volume growth rates in spine were reduced significantly, with payer push backs being the main contributor. In addition, pre-approval criteria were increased to exclude degenerative disc disease and/or low back pain alone, and lastly, stand-alone anterior lumbar interbody fusion surgery was being declined as a procedure. This has driven a shift toward decompression combined with transforaminal lumbar interbody fusion and/or posterior lumbar interbody fusions, he noted.

“The intent is to eliminate expensive procedures performed for simple lower back pain,” Plovanic said. As a result, physicians noted that about 10% to 20% of the patients were being removed from the surgical queue starting early in 2010. “We believe reported results for spine should stabilize and/or show a hint of improvement starting in the 1Q11 with J&J’s results, as that is when difficult comparisons are annualized,” he added.

Pricing pressures in spine continue, according to the research note, but have lightened for now.

“Surgeons are becoming more aware of what they are paying for implants, and as their motivations become more aligned with the hospitals, pricing pressure should continue. We believe it is going to be more difficult for manufacturers to play the R&D cost card as innovation has slowed (thanks to a difficult FDA environment) and spine becomes a commoditized marketplace,” Plovanic said.

Still, he pointed out that gross margins remain in the 70% to 80% and above level for the spine implant market, which is “unsustainable in our opinion.”

Investors in the orthopedic industry might also want to consider the effects that the recent earthquake and tsunami in Japan could have on certain companies in this space. In particular, Plovanic points out that in a hospital environment of power and supply rationing, semi-elective procedures could likely be delayed in the short term, which would impact first and second quarter results.

Of the orthopedic companies Canaccord covers, the firm predicts **Wright Medical** (Arlington, Tennessee), **Zimmer** (Warsaw, Indiana), **Alphatec** (Carlsbad, California), and **Stryker** (Kalamazoo, Michigan) could experience this headwind in the second quarter and slightly in the first.

Plovanic says purchase of capital equipment could also be impacted in both the short and mid-term. The Health, Labor, and Welfare ministry could begin to limit the number and size of capital equipment purchases made by hospitals as the country is already dealing with a difficult macro-economic situation. Stryker’s MedSurg business could be particularly vulnerable in this environment, he added.

“However, as was the case with Katrina in the U.S., over the long term we continue to believe that the high aging patient population and the solid reimbursement environment that have made this the world’s second-largest medical device market continue to look attractive for implant manufacturers,” Plovanic said. ■

Med-Tech Notes

CSS converts machined jaw housing

Connecticut Spring & Stamping (CSS; Farmington), a manufacturer of precision parts for the medical, aerospace, firearms and defense industries, said it helped **Aragon Surgical** (Palo Alto, California), a startup medical device firm, to significantly reduce its costs by converting a fully machined jaw housing for a laparoscopic surgical device to a stamped part with machined features.

CSS uses its metal stamping expertise in the medical device arena, which includes prototyping and high speed progressive die stamping from 30-300 tons, in-die tapping, reel to reel processes, modular die options and short run stamping. The company has supplied stampings for hand held surgical devices, endoscopic clip applicators, suturing devices, and staple removers. Drive channels, jaws, surgical staples, and titanium clips are some of the components produced for these assemblies.

The Aragon Surgical part requires a unique rotary head used on milling the portion of the part that gets machined after it is stamped. After the part is formed, it goes into the milling operation to finish mill certain surfaces that need a particular surface finish and accuracy. The tooling costs were significant, but the high per part savings made the investment worth it, Aragon said.

International

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head, neck and spine surgery.

The SonaStar is used by neuro and general Surgeons for quick and efficient removal of both hard and soft tumors while sparing most vessels. In addition, OsteoSculpt bone sculpting technology can be used with the SonaStar to safely remove osseous structures, thus providing access to the surgical site.

The BoneScalpel is a tissue specific osteotomy device capable of making precise cuts through bone and hard tissue while largely preserving delicate soft tissue structures. It offers the convenience and speed of a power instrument while minimizing the peril associated with rotary sharps, according to Misonix.

SERI using AB Sciex system for clinical trials

AB Sciex (Framingham, Massachusetts), a provider of life science analytical technologies, reported that the **Singapore Eye Research Institute** (SERI), an internationally known eye research center, will advance biomarker candidates it identified for chronic inflammatory eye conditions into large-scale clinical trials for validation with the TripleTOF 5600 System. SERI plans to use the data from the TripleTOF system to accelerate the process to develop a clinical test to significantly improve understanding of inflammation of the eye. This information is expected to be invaluable in helping SERI develop methods with measurable end-points for improved diagnosis and pharmacological treatments of dry eye and other eye conditions that affect millions of people across the world.

Objective clinical tests to accurately measure the severity of dry eye syndrome and preclinical evaluation of new pharmacological therapies currently do not exist. As a leader in ocular proteomics studies, SERI is advancing eye research by identifying and verifying six biomarker candidates that are associated with dry eye syndrome. The institute is collaborating with **Allergan** (Irvine, California), an ocular pharmaceutical company, to conduct a clinical trial with hundreds of patient samples to validate early data that these biomarkers show an accuracy rate close to 100% whether a person has dry eye.

SERI said it selected the TripleTOF 5600 System for this important research because of the system's high throughput and high sensitivity coupled with high resolution and accurate mass. SERI is also using the Eksigent nanoLC-Ultra and cHiPLC-nanoflex chromatography technology to increase productivity and improve reproducibility. The researchers can utilize these technologies to generate better quality information from samples more easily than previously possible. With the TripleTOF system, SERI is expecting to complete the clinical trials in less than half the time it would take using other systems to collect research data. ■

Grants roundup

Eigen awarded two HHS QTDP grants worth a total of \$488,000

A Medical Device Daily Staff Report

Eigen (Grass Valley, California) said it has received two grant awards from the Qualifying Therapeutic Discovery Project (QTDP) funded by the Department of Health & Human Services. Eigen received the maximum \$244,000 award for each grant awarded in October 2010, and January 2011. These credits support biomedical research by small companies which may have major impact on the diagnosis and treatment of significant diseases.

With this grant, Eigen says it continues to "rapidly move forward, bringing breakthrough medical imaging products to market." Additionally, the QTDP grants have enabled the company to hire additional local talent to support growing company needs. Artemis, Eigen's flagship product, uses next-generation imaging technology and provides solutions not previously available which enhance urologists' existing 2-D ultrasound imagery with full color 3-D modeling used for "smart" prostate biopsies.

"Artemis has provided a great leap forward in the diagnosis of prostate cancer," said Eigen CEO Brian Burr. "It has added precision along with the ability to guide, track, and record exact biopsy locations. Artemis lets doctors re-biopsy the same location accurately in a subsequent biopsy. This has previously not been an option. Artemis technology provides high quality, real-time information that enhances how prostate cancer is managed. Better patient information equals better patient decisions."

The company says it also is breaking into the prostate cancer therapy market. Eigen said it hopes to receive future support from such programs as the QTDP, allowing it to continue providing quality imaging devices to medical professionals worldwide. ■

People in the News

- **PLC Systems** (Franklin, Massachusetts) said its chief financial officer, James Thomasch, will leave the company effective May 2, to become CEO at Clinquest. PLC's controller, Karen Raus, will fulfill the financial reporting duties previously handled by Thomasch upon his departure. Raus has served as PLC's corporate controller since August 1996 and is a certified public accountant. PLC Systems is a medical technology company specializing in innovative technologies for the cardiac and vascular markets.

Product Briefs

• **Avita Medical** (Northridge, California) said a clinical study of 18 patients suffering from partial-thickness burns, some of which had failed to heal after treatment with other wound-healing methods, demonstrated successful wound-healing after being treated with ReCell Spray-On Skin from Avita Medical. ReCell allows in-theatre preparation of a spray on suspension consisting of cells derived from a small (2 by 2 cm), thin (0.150.20 mm) biopsy of the patient's own skin that is sufficient to cover an area up to 80 times the size of the biopsy. The ReCell suspension contains basal keratinocytes, melanocytes, fibroblasts and Langerhans cells. The metabolically responsive epithelial cells migrate across the wound surface, leading to regeneration of skin of normal color and texture. ReCell requires only a minimal donor site and is immediately available as a cell-based spray at the patient's bedside.

• **DJO Global** (San Diego) reported the implantation of the first blended vitamin E total knee replacement in the U.S. The e-plus total knee replacement insert component was developed by the company's surgical division, DJO Surgical, formerly Encore Medical. E-plus is the first total knee replacement material to be offered to patients in the U.S. with vitamin E blended into the insert component. Polyethylene wear continues to be a weak point in the long-term success of total knee replacements. E-plus is a formulation of high-density polymer blended with vitamin E, a natural anti-oxidant. Vitamin E improves the material's strength while preventing polyethylene degenerating oxidation, leading to a reduction in wear. This helps the material hold up to the higher expectations of today's active patient. E-plus is the first blended vitamin E polyethylene, with the vitamin E homogeneously blended directly into the resin. The e-plus insert was created for the 3DKnee, a knee replacement system designed to improve strength, stability, and flexion in patients.

• **Kelyniam Global** (New Britain, Connecticut) has received FDA clearance to begin marketing its patient specific custom cranial implants. The Kelyniam Custom Skull Implants (CSI) are designed and manufactured for each individual patient to correct or replace bony voids in the cranial skeleton caused by trauma or birth defects. Streamlined CAD/CAM design and manufacturing techniques will enable Kelyniam to deliver patient specific implants to surgeons in as little as 24 hours from the receipt of an order. The ability to provide custom implants quickly and accurately will reduce the time between trauma and implantation and provide surgeons additional treatment options, the company said. Kelyniam Global specializes in the use of CAD/CAM technology to provide patient specific custom implants to assist medical professionals by allowing them to operate more effectively, improve patient care, and reduce health care costs by providing the highest quality

products available with today's technology.

• **Masimo** (Irvine, California) said a new study demonstrates that noninvasive Masimo carboxyhemoglobin (SpCO) measurements provide an "effective means for screening at-risk populations for CO poisoning" with "acceptable bias and precision" compared to invasive blood gas analysis. The prospective diagnostic accuracy study is more than ten times larger than any other published SpCO accuracy study to date and provides a strong rationale for clinical use of SpCO in the evaluation of emergency department (ED) patients. Study authors concluded that SpCO measurement via multiwave pulse oximetry has "an acceptable bias and precision" and "keeping influencing factors in mind, it can therefore be used to screen large numbers of patients for latent CO poisoning." They also noted the "potential for different measurement results from correct and incorrect (sensor) placement," an encouragement for users to closely follow the directions for use.

• **Novo Nordisk** (Princeton, New Jersey) reported the launch of the NovoTwist needle in the U.S. Novo Nordisk says the NovoTwist needle has a unique fitting that allows users to 'just twist' when attaching the needle with compatible Novo Nordisk pens. An audible and tactile 'click' confirms attachment of the needle and this can be less time consuming for patients. NovoTwist comes in 32G Tip (5 mm) and 30G (8 mm) versions.

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

• **Systagenix** (West Sussex, UK) said a recent product evaluation published in the journal *Wounds UK* demonstrates the clinical effectiveness of Adaptic Touch as a primary wound contact layer that addresses the needs of both patients and healthcare professionals. The study reviewed a cross section of sources including *in vitro* and *in vivo* studies, focus groups and case reports on the use of Adaptic Touch in treating acute or chronic wounds. The evidence base shows clearly to clinicians that Adaptic Touch offers a non-adherent silicone-based primary contact layer that provides ease of application, free flow of exudate to the secondary dressing, and minimal or no trauma on removal. As demonstrated in the study, the dressing stays in place in articulating surfaces, allowing mobilization and rehabilitation to take place.

MDD'S NEUROLOGY EXTRA

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

MONDAY, APRIL 25, 2011

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Keeping you up to date on recent developments in neurology

Improved recovery of motor function after stroke . . . After the acute treatment window closes, the only effective treatment for stroke is physical/occupational therapy. Now scientists from **Children's Hospital Boston** report a two-pronged molecular therapy that leads to significant recovery of skilled motor function in a rat model of stroke. Their findings are reported in the April 20 issue of the *Journal of Neuroscience*. By combining two molecular therapies—each known to promote some recovery on its own—the researchers achieved more nerve growth and a greater recovery of motor function than with either treatment alone. One therapy, inosine, is a naturally-present molecule that promotes nerve growth; the other is NEPI-40, an agent that counteracts natural inhibitors of nerve growth. “When you put these two together, you get much stronger growth of new circuits than either one alone, and very striking functional improvements,” said senior author Larry Benowitz, PhD, of the Children's Department of Neurosurgery. Benowitz has three issued U.S. patents and several U.S. and foreign patent applications pending for the use of inosine to treat stroke, spinal cord injury and traumatic brain injury, and a pending patent application for the inosine/NEPI-40 combined treatment of CNS injury. Inosine works by activating a key regulator of nerve growth (an enzyme known as Mst3b). It has a history of safe usage in humans—it is widely available as a nutritional supplement, and is currently being investigated in clinical trials for the treatment of multiple sclerosis and Parkinson's disease. NEPI-40 complements inosine's effects by counteracting molecules outside of nerve cells that inhibit nerve growth. Specifically, it blocks signaling through the Nogo receptor, shown by a number of studies to promote the rewiring of neural circuits and to improve functional recovery after stroke.

The senior brain may benefit from musical activity . . . A study conducted by Brenda Hanna-Pladdy, PhD, a clinical neuropsychologist in **Emory's Department of Neurology** (Atlanta), and cognitive psychologist Alicia MacKay, PhD, found that older individuals who spent a significant amount of time throughout life playing a musical instrument perform better on some cognitive tests than individuals who did not play an instrument. The findings were published in the April journal *Neuropsychology*. While much research has been done to determine the cognitive benefits of musical activity by children, this is the first study to examine whether those benefits can extend across a lifetime. “Musical activity throughout life may serve as a challenging cognitive exercise, making your brain fitter and more capable of accommodating the challenges of aging,” said lead researcher Hanna-Pladdy. “Since studying an instrument requires years of practice and learning, it may create alternate connections in the brain that could compensate for cognitive declines as we get older.” The study enrolled 70 individuals age 60-83 who were divided into three groups. The participants either had no musical training, one to nine years of musical study or at least ten years of musical training. All of the participants had similar levels of education and fitness, and didn't show any evidence of Alzheimer's disease. Cognitive performance was measured by testing brain functions that typically decline as the body ages, and more dramatically deteriorate in neurodegenerative conditions such as Alzheimer's disease. The high-level musicians who had studied the longest performed the best on the cognitive tests, followed by the low-level musicians and non-musicians, revealing a trend relating to years of musical practice. The high-level musicians had statistically significant higher scores than the non-musicians on cognitive tests relating to visuospatial memory, naming objects and cognitive flexibility, or the brain's ability to adapt to new information. “Based on previous research and our study results, we believe that both the years of musical participation and the age of acquisition are critical,” Hanna-Pladdy says. “There are crucial periods in brain plasticity that enhance learning, which may make it easier to learn a musical instrument before a certain age and thus may have a larger impact on brain development.”

USC research shows critical role of placenta in brain development . . . Research at the Keck School of Medicine of the **University of Southern California's** Zilkha Neurogenetic Institute shows for the first time that the human placenta plays an active role in synthesizing serotonin, paving the way to new treatment strategies that could mitigate health impacts such as cardiovascular disease and mental illness. The groundbreaking findings, conducted with researchers from **Vanderbilt University** (Knoxville, Ten-

nessee) as part of a Silvio Conte Center of Excellence grant from the National Institute of Mental Health, offer conclusive evidence that the placenta provides serotonin to the fetal forebrain, not through the mother's blood supply, as theorized for the past 60 years. The research, "A transient placental source of serotonin for the fetal forebrain," was published in the April 21 issue of the journal *Nature*. "Our research indicates that the placenta actually synthesizes serotonin, and the serotonin is released from the placenta into the fetal bloodstream where it can reach the fetal brain," said lead author Alexandre Bonnin, PhD. "The placenta was seen as a passive organ, but we now know that it has significant synthetic capabilities and has a much more critical role in developmental programming of the fetus than previously thought." Serotonin, a neurotransmitter known to affect well being in humans, also has been implicated in brain, cardiac and pancreas development. In the early stages of development, neurons that synthesize serotonin develop in the fetal hindbrain, where heart, respiration and other critical functions reside, eventually building their way up to the forebrain, the home of higher cognition and emotional regulation. The study shows that during this gap between hindbrain and forebrain serotonin development, the placenta is an important source of serotonin to the forebrain – a process that could be affected by the mother's nutrition, since her diet is the only source for the essential amino acid tryptophan.

Neuroscientists discover new 'chemical pathway' in brain for stress . . .

A team of neuroscientists at the **University of Leicester**, (Leicester, UK), in collaboration with researchers from Poland and Japan, reported a breakthrough in the understanding of the 'brain chemistry' that triggers our response to highly stressful and traumatic events. The discovery of a critical and previously unknown pathway in the brain that is linked to our response to stress is published in the journal *Nature*. The advance offers new hope for targeted treatment, or even prevention, of stress-related psychiatric disorders. About 20% of the population experience some form of anxiety disorder at least once in their lives. The cumulative lifetime prevalence of all stress-related disorders is difficult to estimate but is probably higher than 30%. Robert Pawlak, PhD, from the University of Leicester who led the UK team, said: "Stress-related disorders affect a large percentage of the population and generate an enormous personal, social and economic impact. It was previously known that certain individuals are more susceptible to detrimental effects of stress than others. Although the majority of us experience traumatic events, only some develop stress-associated psychiatric disorders such as depression, anxiety or post-traumatic stress disorder. The reasons for this were not clear." Pawlak added that a lack of correspondence between the commonness of exposure to psychological trauma and the development of pathological anxiety prompted the researchers to look for factors that may make some individuals more vulnerable to stress than others. The study found that the emotional center of the brain – the amygdala – reacts to stress by increasing production of a protein called neuropeptide Y. This triggers a series of chemical events which in turn cause the amygdala to increase its activity. As a consequence, a gene is turned on that determines the stress response at a cellular level.

Functioning synapse created using carbon nanotubes . . .

Engineering researchers at the **University of Southern California** have made a significant breakthrough in the use of nanotechnologies for the construction of a synthetic brain. They have built a carbon nanotube synapse circuit whose behavior in tests reproduces the function of a neuron, the building block of the brain. The team, which was led by Alice Parker, PhD, and Chongwu Zhou, PhD, in the USC Viterbi School of Engineering Ming Hsieh Department of Electrical Engineering, used an interdisciplinary approach combining circuit design with nanotechnology to address the complex problem of capturing brain function. In a paper published in the proceedings of the IEEE/NIH 2011 Life Science Systems and Applications Workshop in April 2011, the Viterbi team detailed how they were able to use carbon nanotubes to create a synapse. Carbon nanotubes are molecular carbon structures that are extremely small, with a diameter a million times smaller than a pencil point. These nanotubes can be used in electronic circuits, acting as metallic conductors or semiconductors. "This is a necessary first step in the process," said Parker, who began the looking at the possibility of developing a synthetic brain in 2006. "We wanted to answer the question: Can you build a circuit that would act like a neuron? The next step is even more complex. How can we build structures out of these circuits that mimic the function of the brain, which has 100 billion neurons and 10,000 synapses per neuron?" Parker emphasized that the actual development of a synthetic brain, or even a functional brain area is decades away, and she said the next hurdle for the research centers on reproducing brain plasticity in the circuits. The human brain continually produces new neurons, makes new connections and adapts throughout life, and creating this process through analog circuits will be a monumental task, according to Parker.

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