



## IOM offers clinical standards, effectiveness review guidance

By **JIM STOMMEN**  
*Medical Device Daily Contributing Writer*

Tackling two topics on which there has been much discussion in recent years, the **Institute of Medicine** (IOM; Washington) has issued recommendations for standards in developing clinical practice guidelines and for systematic review of the comparative effectiveness in medical or surgical procedures.

The IOM said Congress requested both studies through the Medicare Improvements for Patients and Providers Act of 2008.

Noting that healthcare providers “often are faced with difficult decisions and considerable uncertainty when treating patients,” IOM said those providers “rely on the scientific literature, in addition to their knowledge, skills, experience, and patient preferences, to inform their decisions.”

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## NeoTract enrolls first patients in its BPH treatment study

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

**NeoTract's** (Pleasanton, California) UroLift System, a device aimed at treating benign prostatic hyperplasia (BPH) is being evaluated in a multinational trial. The small med-tech company reported earlier this week, that the first patients have been enrolled in the L.I.F.T. study at the **Western Urological Clinic** (Salt Lake City). The trial will enroll patients at nearly 20 sites spread across the U.S. Canada and Australia. It specifically targets men 50 years or older who have urinary problems related to BPH.

To treat patients the device lifts prostate tissue out of the way so that it no longer blocks the urethra. Small customized sutures are placed on either side of the prostate to lift the excess prostate tissue out of the way and restore the urethral opening.

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### ISICME 2011

## New modality for monitoring lung set to challenge CT, TEE

By **JOHN BROSKY**  
*Medical Device Daily European Editor*

BRUSSELS, Belgium – To look into the lungs of a patient already in critical care the current choice is between forcing an ultrasound transducer down the throat or serial radiation exposure with computed tomography.

For a more functional assessment there is a tube to be inserted down the esophageous, or a rough guess of residual capacity, the amount of air left in the lung at the end of a breath according to the mechanical respirator

**Draeger Medical** (Lübeck, Germany) this week launched an alternative modality for functional lung imaging, the first-ever commercial application of electro-impedance tomography (EIT) (*Medical Device Daily*, Nov. 23, 2010).

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### FDA/AAMI annual conference

## Goldman; still too many stray e-parts in typical hospital suite

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

RESTON, Virginia – Julian Goldman, MD, of **Massachusetts General Hospital** (Boston) has offered a lot of perspectives on the issue of how to tie hospital instruments together in a seamless, glitch-proof continuum – a system of systems – but his presentation yesterday at the joint conference by FDA and the **Association for the Advancement of Medical Instrumentation** (AAMI; Arlington, Virginia) made clear that he does not think the truly e-integrated hospital suite is within immediate reach.

Goldman, whose titles include founding director and principal investigator of the device interoperability program at the **Center for Integration of Medicine & Innovative**

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**Don't miss today's MDD Extra: Orthopedics**



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*Deals roundup***Teleflex sells its Marine business to HIG for \$121M****A Medical Device Daily Staff Report**

**Teleflex** (Limerick, Pennsylvania), a provider of medical technology products, reported that it has sold its Marine business to an affiliate of **H.I.G. Capital** (Boston) for \$121.6 million, consisting of \$101.6 million in cash proceeds, the buyer's assumption of nearly \$15.5 million in liabilities related to the business and a \$4.5 million subordinated note from the buyer.

"Today we took another step towards achieving our strategic objective of becoming a pure-play medical technology company and continuing to focus on the development of our portfolio of quality medical technology products. As a result of this transaction, our medical technology products are expected to represent nearly 90% of our total revenues for 2011," said Benson Smith, president/chairman/CEO. "Proceeds from this transaction will be used to continue to reduce outstanding debt and further invest in our medical platform."

Marine, which generated net revenues of about \$195 million during 2010, is a provider of steering and throttle controls and engine and drive assemblies for the recreational marine market.

This transaction is expected to reduce 2011 annual revenue, adjusted cash earnings per share, and cash flow from operations by \$185 million, 45 cents per diluted share, and \$20 million, respectively. As a result, the company is adjusting its financial estimates with respect to forecasted 2011 revenue from a range of \$1.81 billion to \$1.84 billion to a range of \$1.625 billion to \$1.655 billion; adjusted cash earnings per share from a range of \$4.95 to \$5.15 to a range of \$4.50 to \$4.70; and cash flow from continuing operations from \$250 million to \$230 million.

The Marine business will be reflected as a discontinued operation in Teleflex's future consolidated financial statements.

In other dealmaking activity; **IPC The Hospitalist Company** (North Hollywood, California), a national hospitalist physician group practice company, reported that it has acquired **Mid-Michigan Hospitalist Group** (Grand Blanc, Michigan).

The acquisition of this acute care practice represents a further expansion for IPC in the Michigan market, where the company already has an established presence. Mid-Michigan Hospitalist Group has an annualized volume of nearly 20,000 patient encounters. ■

*People in the News*

• Edward Murphy reported that he will step down as president/CEO of the **Carilion Clinic** (Roanoke, Virginia) seven-hospital system on June 30 to go to work for an investment management firm and also to become chairman of a hospitalist organization. He will be replaced by Nancy Howell Agee, the COO for Carilion, effective July 1. Murphy joined Carilion as COO in 1998, and was promoted to president/CEO in 2001. Agee has been with Carilion for 20 years, starting as a nurse and then being named VP of medical education in 1996. She was promoted to senior VP in 2000 and became executive VP and COO in 2001.

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*Agreements/contracts***Tethys, Air Force to study effects of PreDx risk score****A Medical Device Daily Staff Report**

**Tethys Bioscience** (Emeryville, California), a privately held cardiometabolic diagnostics company, and the **United States Air Force** have established a collaboration to study the effect of the PreDx Diabetes Risk Score on behavioral change, the key component in reducing the incidence of Type 2 diabetes, among the Air Force's retirees and dependents. Type 2 diabetes is a serious, costly and growing healthcare risk within the military's large retiree population. Diabetes can be prevented, however, with improvements in lifestyle, including diet, nutrition and exercise. A common obstacle to lifestyle changes is lack of compliance among at-risk individuals.

To evaluate the effect of a more accurate assessment of type 2 diabetes risk on compliance with a lifestyle modification program, the Air Force is conducting a clinical study using Tethys' PreDx Diabetes Risk Score (DRS), a simple-to-use, multimarker blood test designed to determine an individual's personalized risk of diabetes conversion within five years. The study will assess the correlation between receiving comprehensive and individualized information about disease risk and the motivation to adopt a healthier lifestyle.

The DRS provides enhanced risk stratification through the measurement of multiple biomarkers linked to pathways of diabetes progression. PreDx DRS was developed using a unique approach to quantifying biomarkers suspected of playing roles in diabetes development. Tethys methodology enabled evaluation of many biomarkers utilizing very small amounts of blood from select and well-characterized large study cohorts with known diabetes outcomes. The company then determined the combination of these biomarkers with an algorithm that best identified an individual's risk of developing type 2 diabetes within five years. PreDx DRS has been validated by the Tethys Clinical Laboratory (TCL) in several large populations. The test uses standard immunoassay and clinical chemistry formats, sample collection and shipment methods.

Mark True, MD, Lieutenant Colonel, US Air Force, Medical Corps, of the Endocrinology Service at **Wilford Hall Medical Center** (San Antonio), is the principal investigator for the study. "We hope to determine whether improved knowledge of an individual's risk for diabetes impacts that patient's motivation to comply with lifestyle recommendations," said True. "We also believe this study could contribute to the medical community's efforts to target patients at the highest risk of disease. We need to be smart about how to best use limited resources in our attempts to reverse the Type 2 diabetes epidemic in the U.S."

The two-arm, randomized trial will enroll 600 pre-

diabetic subjects at six Air Force bases in the U.S. All subjects will participate in a 12-week "Group Lifestyle Balance Program." This program is based on the Diabetes Prevention Program (DPP), a major clinical trial which found that participants who lost a modest amount of weight through dietary changes and increased physical activity significantly reduced their chances of developing diabetes. All subjects will be administered the PreDx DRS test at the beginning and end of the study period. Half the study population (the intervention group) will be given the results of their PreDx DRS test before they start the Group Lifestyle Balance Program and will know their specific risk profile; the other half (the control group) will not see their results.

"Our collaboration with the U.S. Air Force provides an optimal setting in which to prospectively demonstrate the value of PreDx DRS in enabling physicians and patients to determine what behavioral and dietary changes can be most effective in preempting disease in high risk individuals," said Mickey S. Urdea, PhD, chairman/CEO of Tethys. "With the CDC estimating as many as 79 million prediabetic people in the U.S., our medical system urgently needs better tools to stratify and identify the small percentage of those at most imminent risk who will benefit from intervention. PreDx DRS is that tool, and we look forward to the results of this important study."

In other agreements/contracts news:

- The **Premier** (Charlotte, North Carolina) healthcare alliance reported several new agreements to its network members.

New agreements for positron emission tomography (PET) isotopes have been awarded to **Cardinal Health** (Dublin, Ohio); **IBA Molecular North America** (Sterling, Virginia); and **UPPI** (Suwanee, Georgia).

New agreements for television systems and services have been awarded to **Healthcare Information** (Loveland, Ohio); **LodgeNet Entertainment** (Sioux Falls, South Dakota); **MDM Commercial Enterprises** (Ponte Vedra Beach, Florida); **TB&A Hospital Television** (Amherst, New York), a small business enterprise; and **TeleHealth Services** (Raleigh, North Carolina).

A new agreement for MSDS management services has been awarded to **MSDSonline** (Chicago).

Premier maintains the nation's most comprehensive repository of clinical, financial and outcomes information and operates a leading healthcare purchasing network.

- **Virtual Incubation** (VIC; Fayetteville, Arkansas) has been awarded a \$100,000 contract to assist **NASA** (Houston) in evaluating commercial opportunities for promising, cutting-edge medical technologies. NASA's Human Research Program develops a significant amount of technology each year that advances the frontiers of medical science and can offer tremendous benefit to society. Virtual Incubation will use its expertise in technology venture development to assist NASA in identifying technologies from this program

*See Agreements, Page 5*

*Financings roundup***Degenerative eye disease firm ScyFIX seeks \$4M in offering****A Medical Device Daily Staff Report**

**ScyFIX** (Chanhassen, Minnesota), which is seeking FDA approval for its device that uses slight electric shocks to treat degenerative eye disease, is seeking to raise \$4 million in a just-under-way offering that expires in June 2012, according to a recent Securities and Exchange Commission filing.

The company's ScyFIX 700 device is aimed at treatment of macular degeneration, retinitis pigmentosa, Stargardt's disease and other degenerative eye diseases. With the device, pads are placed over a patient's eyes to deliver slight electrical charges that the company said have a "stimulative" effect on cells in the retina at the back of the eye, helping to slow or perhaps even restore sight loss.

The device already has the CE mark and is commercialized in Europe and other international locations. ScyFIX's European offices are located near Stockholm, Sweden.

In other financing news, subsidiaries of **Aviv REIT** (Chicago), an owner of skilled nursing and other healthcare facilities in the U.S., reported the pricing of \$100 million aggregate principal amount of 7 3/4% senior notes due 2019. The notes are being issued at a price equal to 102.75% of their face value, which the company said is equivalent to a 7.16% yield per annum.

The notes will be unsecured senior obligations of the issuers and of the same series as their existing \$200 million aggregate principal amount of 7 3/4% senior notes due 2019. The offering is expected to close on April 5, subject to customary closing conditions.

Aviv said it intends to use about \$36 million of the net proceeds of the offering to repay a portion of its secured debt, with the balance of roughly \$64 million to be used to fund the debt component of \$110 million of pending investments.

Aviv REIT said it has been among the largest owners of skilled nursing and other healthcare facilities in the U.S. for more than 30 years. As of year-end 2010, its portfolio consisted of 185 properties with 17,997 licensed beds leased to 32 operators in 24 states. ■

**Product Briefs**

• **Covidien** (Dublin, Ireland) reported interim results of its multicenter, international, prospective study comparing use of its Parietex ProGrip self-fixating mesh to the traditional Lichtenstein repair, the gold-standard technique for inguinal hernia repair. The interim data demonstrate that patients who received Parietex ProGrip self-fixating mesh during inguinal hernia repair experienced significantly less early pain compared to those whose hernias were repaired using the standard Lichtenstein method. Investigators measured pain at discharge and at day seven. To perform the Lichtenstein method, surgeons suture a mesh patch over the hernial opening to reduce weakness in the abdominal wall. This technique is associated with a 4% hernia recurrence rate after five years, and 6% of patients continue to experience severe chronic pain three years after the procedure. Parietex ProGrip self-fixating mesh has small, absorbable, polylactic acid grips on one side to secure immediate fixation to the abdominal wall, eliminating the need to suture the mesh into place. An inguinal hernia is a condition in which intra-abdominal fat or part of the small intestine, also called the small bowel, bulges through a weak area in the lower abdominal muscles. This type of hernia is designated inguinal because fat tissue or part of the intestine protrudes through a weak area at the inguinal ring at the opening to the inguinal canal, a passage in the front abdominal wall.

• **TransEnterix** (Research Triangle Park, North Carolina) has unveiled a new set of minimally invasive instruments for surgeons. Called the SPIDER MicroLap instruments, the new

line includes all of the familiar tools surgeons use during laparoscopic procedures – only in TransEnterix's case, each instrument is 2.7 millimeters or less in diameter. Typically, laparoscopic surgical instruments range in diameter size from 5 to 10 millimeters. The small size of the instruments means that instead of needing a scalpel to make necessary incisions, the surgeon need use only a special skin incision pick; and the patient comes away from the procedure with just a freckle-like mark. The company says that because their use requires no open incision, the MicroLap instruments advance the field of laparoscopic surgery into an entirely new category – micro-laparoscopic surgery. Although competitors sell some instruments that are less than 5 millimeters in diameter, TransEnterix's SPIDER MicroLap instrument line is the only complete and re-useable set of sub-3-millimeter instruments available in the market. TransEnterix's SPIDER MicroLap instruments are crafted from a ceramic-titanium alloy that ensures strength despite their small diameter. They can be used independently or in conjunction with TransEnterix's SPIDER Surgical System, the only single-incision and multi-port surgical system that delivers intra-abdominal triangulation, 360-degree flexible instrumentation and a stable operative platform. Using both systems together, surgeons can perform advanced procedures through less invasive means.

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## IOM

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It said clinical practice guidelines “include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. Clinical practice guidelines offer an evaluation of the quality of the relevant scientific literature and an assessment of the likely benefits and harms of a particular treatment.”

IOM said the Guidelines International Network database currently contains more than 3,700 clinical practice guidelines from 39 countries, as well as another nearly 2,700 guidelines in the National Guidelines Clearinghouse, part of the **Agency for Healthcare Research and Quality** (Washington).

“Because of the large number of clinical practice guidelines available, guideline users, including practitioners, find it challenging to determine which guidelines are of high quality,” the IOM report said. “If guideline users had a mechanism to immediately identify high-quality, trustworthy clinical practice guidelines, their health-related decisionmaking would be improved, potentially resulting in enhanced healthcare quality and outcomes.”

It added that existence of a set of standards for trustworthy clinical guidelines “would help developers create such guidelines, which, in turn, has the potential to improve healthcare decisionmaking and healthcare quality and outcomes.”

In a report titled “Clinical Practice Guidelines We Can Trust,” an IOM committee outlines eight standards covering such issues as establishing transparency, managing conflict of interest, and external review. The committee that formulated the standards and authored the report said the standards “reflect the latest literature, expert consensus, and public input.” It said the standards “reflect best practices across the entire guideline development process.”

In addition to the three items cited above, the other standards include:

- Guideline development group composition.
- Clinical practice guideline/systematic review intersection.
- Establishing evidence foundations for and rating strength of recommendations.
- Articulation of recommendations.
- Updating.

The committee recommended that all guidelines comply with these standards. According to the IOM, the proposed standards “have yet to be tested by clinical practice guideline developers and users to determine whether the standards produce unbiased, scientifically valid, and trustworthy clinical practice guidelines, and whether implementation of the clinical practice guidelines based on the committee’s standards improve health outcomes.”

The second IOM report, “Finding What Works in

Health Care: Standards for Systematic Reviews,” is focused on the reviews that are used in formulating evidence-based comparisons. The report said that while such reviews “identify, select, assess and synthesize the findings of similar but separate studies,” the quality of systematic reviews varies. “Often the scientific rigor of the collected literature is not scrutinized or there are errors in data extraction and meta-analysis,” the IOM said.

Dr. Alfred Berg, professor of family medicine at the **University of Washington School of Medicine** (Seattle), who chaired the committee that wrote the report, said in an IOM news release that it will take “an investment of resources and time to achieve such high standards,” but added the emphasis that “they should be adopted to minimize the chances that important health decisions are based on information that may be biased or erroneous.”

Those 21 guidelines include recommendations to first make sure that the team established to conduct the review has “appropriate expertise and experience to conduct the review; manage bias and conflict of interest; [and] ensure user and stakeholder input as the review is designed and conducted.”

It further calls for use of a third party to manage the peer-review process, and adds the important guideline that the final report be published in a way that ensures free public access.

Berg said the report “presents the ‘gold standard’ to which those who conduct systematic reviews should aspire to achieve the most reliable and useful products.” ■

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## Agreements

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that have the strongest commercial potential. VIC will conduct thorough market and competitive intelligence analyses and develop commercialization strategies.

VIC says it brings together the essential elements needed to establish new technology ventures and maximize the opportunity for product development and commercialization success. VIC has a history of building successful companies by developing early-stage technologies, typically licensed from universities and federal laboratories, into market-focused products. The company has a team of 17 business development professionals and provides complete management teams to its portfolio companies during their early stages of growth.

Kimberley Fuller, VIC’s Director of Market Research and Business Development, will oversee the project. Fuller has over 20 years of experience in conducting both quantitative and qualitative market research, completing in-depth competitive landscape analyses, identifying high-value market niches for new products, and developing actionable commercialization strategies. ■

## NeoTract

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"It opens the urethra without the removal of any tissue or ablation," Chris Rowland president/CEO of NeoTract told *Medical Device Daily*. "So it directly opens the urethra without injury."

BPH represents a tremendous opportunity for the small start-up which has a staff of 40.

There are more than 528 million men worldwide who suffer from BPH, a condition in which the prostate grows and eventually squeezes or blocks the urethra. While the symptoms of BPH vary, the most common are urination problems, such as frequent urination or a weak urine stream. In eight out of 10 cases, these symptoms suggest BPH. Left untreated, BPH can cause more serious problems, such as bladder or kidney damage, bladder stones, and incontinence.

BPH can cause loss of productivity, loss of sleep, depression and decreased quality of life. For patients with moderate-severe symptoms, medication is often the first-line therapy. However, with side-effects such as sexual dysfunction, dizziness and headaches along with inadequate relief, over one-quarter of patients discontinues medical therapy, often after only three months.

"Currently there are different treatment modalities, but few of them are [desirable for the patient]," Rowland told *MDD*. "Pharmaceuticals are a great option and they work, but BPH is a progressive disease and at some point the pharmaceuticals will stop working. That might be in a month, a year, two years or five years, but at some point as the prostate grows the therapy becomes ineffective."

For these patients, the next alternative is surgery. Most surgical approaches aim to resect or ablate prostate tissue in order to open up the blocked urethra. While effective in opening up the urethra and relieving symptoms, resecting or ablating prostate tissue also induces a healing response and tissue inflammation. As a result, patients have to 'earn' their symptom relief after a difficult period of irritative voiding symptoms and catheterization.

"While millions of men suffer from BPH, many remain frustrated because pharmaceutical options are not serving them well and they are concerned with the potential undesirable side-effects, including urinary incontinence and sexual dysfunction, that are associated with currently approved surgical treatments," said Steven Gange, MD, principal investigator for this first U.S. site in the L.I.F.T. Study. "The therapeutic goals of treating with the UroLift System, a minimally invasive device under investigation here at Salt Lake Research and Western Urological Clinic, are to give men rapid symptom relief by opening up the urethra while preserving normal sexual function. We see enormous promise for this novel approach as a potential treatment option for men diagnosed with BPH."

Grange added that, "Effective treatment of BPH can greatly improve the quality of life for men who suffer with

the condition. There is no reason any man should have to live with these difficulties."

UroLift has CE mark approval and is available in Australia. Plans call for the company to complete enrollment by the end of this year.

Rowland said that the device has the ability to give patients more options when it comes to treating BPH.

"I don't see UroLift being a competitive therapy to surgery," Rowland said. "I see it as being a complementary therapy. You can still have surgery past UroLift. You're just offering the patient another option."

The company recently reported closing a funding round that netted it close to \$27 million. According to Rowland the funding will be used to complete the IDE study and push commercialization of the product in the U.S. if it is able to garner FDA approval.

NeoTract was founded in 2004 through the **ExploraMed Development** (Mount View, California), a medical device incubator funded by New Enterprise Associates. ■

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## ISICME

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Developed over 10 years, this new monitor for intensive care units (ICU) begins what promises to be an equally long journey for the company on the road to altering clinical practice.

The PulmoVista 500 received a CE mark earlier this month, just in time to be rolled out at the annual International Symposium for Intensive Care and Emergency Medicine being held here this week.

The company said it submitted a 510(k) application for the PulmoVista 500 to the FDA with CT as the predicate technology.

If all goes well with the agency, Draeger said the American introduction for the new monitor will be in Tampa, Florida in November at the International Respiratory Congress of the **American Association for Respiratory Care** (AARC; Irving, Texas).

The first-to-market EIT device, PulmoVista 500 gives Draeger what company executives estimate to be a six-year lead to challenge incumbent imaging modalities of CT and ultrasound and to establish clinical evidence for its monitor.

The company is hardly ready to launch a multi-center clinical trial with five beta versions of the EIT monitor placed for temporary evaluation in reference centers and just one pre-launch sale, to the **University Hospital Leipzig**.

Key to Draeger's challenge is an ability to quantify practices for ventilator settings to control positive end-expiratory pressure (PEEP) that today are guided by guesswork and physician preference.

Despite the impressive critical mass of beeping technology surrounding a patient in ICU, mechanical respiration is operator-dependent, only as good as the clinician's experience and theories.

The risk of over- or under-ventilating the patient is pressure damage to the lung tissue or the collapse of the lung.

The PulmoVista 500 provides continuous information about the regional distribution of ventilation within the lung, represented by a dynamic image on the monitor that resemble a map on the Weather Channel or perfusion images from PET.

The clinical benefit is the functional information of EIT that complements morphological images from CT and may replace highly invasive transesophageal echocardiography (TEE).

Where a physician may see an area of concern in the lung with CT, MRI or TEE, the EIT display shows vividly the regional ventilation distribution.

The PulmoVista 500 is expected to have a high clinical value in quantifying effects from changes to mechanical ventilator settings to control positive end-expiratory pressure (PEEP) that currently are operator-dependent based on functional residual capacity (FRC) estimates of the ventilator unit.

Draeger's application of EIT technology, first introduced in 1978, features several unique, and in some cases, innovative features.

Key to the non-invasive monitoring of often frail or fragile patients in ICU is a holter placed around a patient's thorax positioning 16 paired emitter-receivers that are linked in series by a single cable.

The electrodes are placed in direct contact with the skin without the use of gels and can be rapidly deployed for a monitoring session.

In sequence each emitter sends a signal, using the same low voltage as an EEG, that is captured by 14 detectors. Up to 50 sequences of 208 data sets are acquired each second, though only 20 sequences are used for display on the PulmoVista 500.

In addition to the graphic depiction of air distribution in the lung, the monitor displays a quantification of lung capacity in both the dorsal and ventral regions of each lung.

Waveform displays track trends and clinicians can scroll along the waveform to read changes to lung capacity resulting from a recruitment maneuver or therapeutic intervention.

The monitor also calculates the change to lung capacity between two recording sessions displaying regions affected by an intervention.

The PulmoVista 500 is priced against high-end TEE ultrasound, according to Anne-Catherine Grüntges, who heads the marketing efforts for Draeger Respiratory Care in Europe.

### German patent court rules in favor of Given

**Given Imaging** (Yokneam, Israel), a developer of specialty GI products including capsule endoscopy systems, reported that the Regional Court (Patent Chamber) in Düsseldorf, Germany has ruled that the MiroCam capsule endoscopy system manufactured by **IntroMedic** (Seoul, South Korea) infringes two patents asserted by Given. The court's rulings allow Given to prevent IntroMedic's German distributor, **Medwork Medicinal Products and Services** (Höchststadt, Germany) from selling the current model of the MiroCam capsule and MiroView software in Germany.

"We are very pleased that the German court has ruled in favor of Given Imaging in this patent infringement case, which strengthens our competitive position in Germany," said Homi Shamir, president/CEO, Given Imaging. "We will continue to vigorously defend our intellectual property rights worldwide related to our innovative product portfolio." ■

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## FDA/AAMI

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**Technology** (Boston), presented at the 2009 of the World Healthcare Congress (WCC) on this very topic. At the time, he remarked that standards were needed for a number of functions and items, including hardware connectors and device drivers (*Medical Device Daily*, April 16, 2009), and the current crop of issues he described run fairly parallel to those he enumerated at WCC.

Showing a collage of instrument- and device-filled hospital suites, Goldman said the pictures were intended to help the audience “realize the complexity of the challenge” presented by the need to tie systems together. “They are becoming more complex” thanks to advances in technology, he said, adding that “smart-everything” devices roll out ever more routinely. The trick, he said, “is to make sure these devices are not working at odds with each other.”

Goldman asked attendees to picture the number of scenarios affected by device/operating system compatibility issues. “Imagine the complexity of using those platforms to write orders” he said of the various operating systems and applications in use for hand-held IT devices now available.

The complexity is in some cases making things more error prone, Goldman asserted, offering the case of a patient “having gall bladder surgery laparoscopically,” which sometimes requires shutting off the ventilator while the surgeon takes an X-ray to check on the procedure. “We stop the ventilator because we don’t want the diaphragm” to push the gall bladder, which fouls the image, and “usually it goes without a hitch,” he said. Still, “there have been quite a few cases where there were problems,” Goldman observed, noting that one issue that can arise is that the ventilator might not be reactivated, but “most of the cases of not starting the ventilator are not reported in the literature.” He also claimed that 70% of anesthesiologists turn off their alarms in the operating room (OR) because of too-frequent false alarms.

“In order to address a problem of this type,” one organization suggested synchronizing OR instruments, Goldman noted, adding, “if you could synchronize imaging with ventilation . . . you wouldn’t have to stop the ventilator.” In this scenario, a surgeon would presumably just take the image between breaths. “That may or may not work,” Goldman remarked, but he said “this is not a new idea. The notion of synchronizing . . . is old news,” referring to a 1999 article in the *American Journal of Respiratory and Critical Care Medicine*.

“Why don’t we synchronize these systems?” Goldman asked rhetorically, foreshadowing a fly in the ointment. Such a system would have to read ventilation parameters and trigger the X-ray at precisely the right moment, “but it’s also possible that the respiratory rate is relatively high,” leaving the X-ray machine little time

to acquire a clean image. Another possible confounder is a need for longer exposure, such as would be required for someone with a lot of adipose tissue. “It may be that the X-ray exposure will have to be too long” to capture the image without fouling by motion induced by the diaphragm.

Noting that network printers carry a lot of features that are idle unless the network invokes those features, Goldman tackled the “system of systems” concept from the top. “We have to start to look at the ecosystem and realize that we have to plan ahead if we want some features to be available,” he said. He mentioned the availability of ISO 80601-2-12, which deals with the operation of a ventilator and its interaction with accessories, “but there also has to be some glue for that system,” namely an ICE (integrated clinical environment) network controller.

Goldman reminded the audience ASTM F2761-09, which surfaced toward the end of 2009, provides for standardized interfaces as part of an ICE framework, although not all those standards are out as yet. In any case, an ICE supervisor software module allows a network controller operating on a plug-and-play basis to “keep track of all these things.” He said “the standard is intended to facilitate a medical system that has greater error resistance.”

Goldman said there are a number of use cases found in annex B of ASTM F2761-09, including “the notion of supporting apps,” or applications, which “have to allow clinical input.” However, he argued that such software has to be controlled even without human intervention in such a way as to deal with conflicting imperatives. “We don’t want an app that’s designed to maintain blood pressure at a high value and an app that’s designed” to keep BP down running at the same time without some system of governance in place.

Goldman laid out a similar argument in the context of patient-activated anesthesia systems. He noted that “if the system isn’t working adequately and [the patient] is in too much pain,” the patient can punch the call-nurse button. However, “if the patient is overdosed, the patient can’t push the nurse button and call for help” because the patient is probably delirious, assuming he or she is even conscious. The solution is a system that tracks vital signs and previous doses, and checks those whenever the patient hits the “stop pain” button. Goldman said the **Anesthesia Patient Safety Foundation** (Indianapolis) proposed the idea in a recent edition of the association’s newsletter. “One manufacturer has integrated this into a pump in a limited way,” Goldman said, but he said such a feature is tough to make use of in a non-integrated environment “because you can’t tie these systems together in an ad-hoc way.” ■

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# MDD'S ORTHO EXTRA

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

THURSDAY, MARCH 24, 2011

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*Keeping you up to date on recent developments in orthopedics*

## **Leg implants sealed against infection using nanomodified surfaces . . .**

In recent years, researchers have worked to develop more flexible, functional prosthetics for soldiers returning home from battlefields in Afghanistan or Iraq with missing arms or legs. But even new prosthetics have trouble keeping bacteria from entering the body through the space where the device has been implanted. "You need to close (the area) where the bacteria would enter the body, and that's where the skin is," said Thomas Webster, associate professor of engineering and orthopedics at **Brown University** (Providence, Rhode Island). Webster and a team of researchers at Brown may have come across the right formula to deter bacterial migrants. The group reports two ways in which it modified the surface of titanium leg implants to promote skin cell growth, thereby creating a natural skin layer and sealing the gap where the device has been implanted into the body. The researchers also created a molecular chain to sprinkle skin-growing proteins on the implant to hasten skin growth. The findings are published in the *Journal of Biomedical Materials Research*. The researchers created two different surfaces at the nanoscale, dimensions less than a billionth of a meter. In the first approach, the scientists fired an electron beam of titanium coating at the abutment (the piece of the implant that is inserted into the bone), creating a landscape of 20-nanometer mounds. Those mounds imitate the contours of natural skin and trick skin cells into colonizing the surface and growing additional keratinocytes, or skin cells. Webster knew such a surface, roughened at the nanoscale, worked for regrowing bone cells and cartilage cells, but he was unsure whether it would be successful at growing skin cells. This may be the first time that a nanosurface created this way on titanium has been shown to attract skin cells. The second approach, called anodization, involved dipping the abutment into hydrofluoric acid and giving it a jolt of electric current. This causes the titanium atoms on the abutment's surface to scurry about and regather as hollow, tubular structures rising perpendicularly from the abutment's surface. As with the nanomounds, skin cells quickly colonize the nanotubular surface. In laboratory tests, the researchers report nearly a doubling of skin cell density on the implant surface; within five days, the keratinocyte density reached the point at which an impermeable skin layer bridging the abutment and the body had been created. "You definitely have a complete layer of skin," Webster said. "There's no more gap for the bacteria to go through." Researchers came up with a synthetic molecular chain to bind FGF-2 to the titanium surface, while maintaining the protein's skin-cell growing ability. Not surprisingly, *in vitro* tests showed the greatest density of skin cells on abutment surfaces using the nanomodified surfaces and laced with FGF-2. Moreover, the nanomodified surfaces create more surface area for FGF-2 proteins than would be available on traditional implants. The U.S. Department of Veterans Affairs and the U.S. National Science Foundation funded the research.

## **Clinical trial seeks to determine whether platelet-rich plasma can ease osteoarthritis pain . . .**

For years, doctors have used platelet-rich plasma (PRP) to promote healing after surgery. Now, **Rush University Medical Center** (Chicago) is studying whether PRP can help relieve knee pain in patients with mild to moderate osteoarthritis. PRP contains growth factors that promote cell proliferation and is prepared from the patient's own blood tissue. It has received popular attention recently because of its use in treating sports injuries in professional athletes, but the jury is still out on whether it is effective. "There have been few controlled clinical trials, and results are inconsistent, but data so far suggests that it could be a promising treatment for healing in a variety of tissues," said Brian Cole, MD, orthopedic surgeon and head of the cartilage restoration center at Rush. "The therapy will not be a cure for osteoarthritis, but it could help put off the day when a patient will need to get a knee implant." Cole is professor of orthopedic surgery at Rush University and head team physician for the Chicago Bulls. At present, the standard of care is either corticosteroid injections, which may provide relief for about three months, or synthetic lubricants containing hyaluronic acid, which can last for up to a year. In the double-blind, randomized, controlled study, 100 patients will receive either hyaluronic acid or PRP. The PRP is prepared from 10 millimeters of the patient's own blood. The blood is spun in a centrifuge to separate the

platelets from the red and white blood cells. The platelets are then injected into the knee joint using ultrasound imaging to guide placement. Patients will receive three injections over three weeks and will be monitored for two years. In periodic clinical exams, the physician will assess pain and knee function. In addition, a teaspoon-size sample will be taken of the synovial fluid around the knee joint to test for molecular changes that may indicate a shift in the balance of anabolic factors that increase the buildup of tissue and catabolic factors that break it down. An imbalance in these factors has been implicated in the deterioration of cartilage that leads to osteoarthritis.

### **U.S. healthcare system can't keep up with number of Baby Boomers' bone fractures . . .**

Many Baby Boomers will experience a bone fracture as they age, and the current U.S. healthcare system is not prepared to provide the necessary care required, according to a special monograph released in the January 2011 issue of *Geriatric Orthopaedic Surgery and Rehabilitation* (GOS), published by SAGE. The first members of the post World War II Baby Boom generation will reach 65 years old this year. The Baby Boomers encompass an estimated 78 million Americans and are expected to live longer and healthier than preceding generations, however, due to their advancing age, will likely experience fragility fractures (a fracture from a weak or osteoporotic bone). The GOS Editors have addressed the challenge of caring for this specialized population, with the release of "A Guide to Improving the Care of Patients with Fragility Fractures." Written as a guide for physicians, nurses, therapists, hospital administrators, and students, this monograph offers an evidence-based approach to better quality - but still cost-effective - care of patients dealing with fragility fractures. The guide provides direction to improve both the system of care and on-site specific fracture management. "The scope of fragility fractures in the United States is large and will grow over the next 20 years as the population ages," write editors Stephen Kates, MD and Simon Mears, MD, PhD. "There is much that can be done to idealize the outcomes of these patients. Additional research is needed to further improve the quality of care. We plan to update this blue book as new information concerning the care of seniors with fragility fractures develops."

### **Forensics study reveals that overweight people really are big-boned . . .**

One of the blind spots in forensic science, particularly in identifying unknown remains, is the inability of experts to determine how much an individual weighed based on his or her skeleton. New research from **North Carolina State University** (Raleigh, North Carolina) moves us closer to solving this problem by giving forensic experts valuable insight into what the shape of the femur can tell us about the weight of an individual. "This research allows us to determine whether an individual was overweight based solely on the characteristics of a skeleton's femur, or thigh bone," says Dr. Ann Ross, an associate professor of anthropology at NC State and co-author of a paper describing the research. However, Ross notes, this research does not give us the ability to provide an individual's exact weight based on skeletal remains. Researchers found that the heavier an individual was, the wider the shaft of that person's femur. The researchers hypothesize that the femur of an overweight person is more robust because it bears more weight, but also because overweight individuals move and walk differently to compensate for their greater mass. The researchers evaluated the femur bones of 121 white men for the study. They used the bones of white men exclusively in order to eliminate any variation that could be attributed to race or gender.

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