
MEDICAL DEVICE DAILY™

THE DAILY MEDICAL TECHNOLOGY NEWSPAPER

MONDAY, DECEMBER 4, 2006

VOL. 10, No. 231

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Piper Jaffray Healthcare Conference

SilverHawk to NightHawk is next big step for FoxHollow

By DON LONG

Medical Device Daily Managing Editor

NEW YORK — John Simpson, MD, PhD, said his staff wouldn't let him talk about the NightHawk first in his presentation at last week's Piper Jaffray Healthcare conference because he was so excited about it that it would take up the whole half hour allotted to him.

So we'll explain the NightHawk last too.

Besides, just as interesting was the Power Point slide used by Simpson, CEO and founder of **FoxHollow Technologies** (Redwood City, California), early in his presentation.

The slide featured multiple images of very queasy-making stuff, and Simpson wryly offered to provide any of these images "in screen saver mode." Nobody seemed very interested.

Pictured in detail were various icky, yarn-like, wormy-
See SilverHawk, Page 5

Radiological Society of North America

Guardian studying bomb-threat technology in healthcare arena

By KAREN YOUNG

Medical Device Daily Staff Report

CHICAGO — What do bomb detection technology and healthcare imaging technology have in common?

Guardian Technologies (Herndon, Virginia) execs attended the 2006 annual meeting of the **Radiological Society of North America** (RSNA; Oak Brook, Illinois) to explain just that.

The company is taking its core digital imaging detection technology, 3i (Intelligent Imaging Informatics), which is now being evaluated in the labs of the U.S. **Transportation Security Administration**, and applying it to medical uses. Guardian was on hand to describe how its technology that can detect the material inside a bomb or other container can also detect lesions in the brain, for example, that could indicate the progression of multiple sclerosis.

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Report from Europe

Interventional Spine receives CE mark for its PDS System

A Medical Device Daily Staff Report

Interventional Spine (formerly Triage Medical; Irvine, California) reported that its European notified body has granted CE mark approval for the company's Percutaneous Dynamic Stabilization (PDS) system for the early-stage treatment of spinal disorders.

CEO Walter Cuevas said, "This approval enables us to launch the PDS system in European markets during 2007. Dynamic stabilization has become a rapidly growing procedure in Europe and we believe that the PDS system has significant clinical and patient advantages over the dynamic stabilization devices currently available."

He added, "This approval also gives us the impetus to both initiate a series of clinical studies in Europe to broaden the application of the PDS System to an even wider group of patients and move forward to begin our first pivotal clinical study in the U.S."

The company said it believes the PDS system is the
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Study finds DES patients more at risk for blood clot formation

By AMANDA PEDERSEN

Medical Device Daily Staff Writer

In just a few days a panel of federal health officials and outside experts will meet in Washington to scrutinize the safety of drug-eluting stents (DES), a growing controversy in the cardiovascular sector. Adding to the debate is a recent study led by the **Cleveland Clinic** (Cleveland) that found as much as a four- to five-fold increased relative risk for late thrombosis, or blood clot formation, in patients with DES compared to those with bare-metal stents.

The meta-analysis, published in the December issue of the *American Journal of Medicine*, is the first published analysis of its kind, according to the Cleveland Clinic.

Drug-eluting and bare-metal stents are commonly used to treat patients with coronary artery disease. There has been a growing body of evidence that drug-eluting stents, when compared to bare-metal stents (BMS), may increase the risk of blood clot formation long after they are implanted, potentially triggering a heart attack.

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 **AHC Media LLC**

*Financings roundup***Dade Behring in stock buyback;
Angiotech prices note offering****A Medical Device Daily Staff Report**

Clinical diagnostics company **Dade Behring Holdings** (Deerfield, Illinois) reported that its board of directors has approved an expansion of the company's stock repurchase plan by authorizing the company to purchase an incremental five million shares of common stock.

This authorization follows two prior authorizations of five million shares each, the first in April 2005 and the second in February 2006.

During the last 17 months, the company has repurchased 9.7 million shares, or about 11% of the diluted number of shares outstanding, of which 2.7 million shares were purchased in October and November of this year.

As of Nov. 30, there were 5.3 million shares available for repurchase under the plan, including the newly authorized shares. The company said it anticipates both a year-end and ongoing net debt level of about \$500 million.

"With our second expansion of the company's stock repurchase plan this year, and with our aggressive level of share repurchases in the last two months, the board of directors has underscored its confidence in the company's future capabilities and attractive growth opportunities," said Jim Reid-Anderson, Dade Behring's chairman, president/CEO. "Our capital allocation ensures that the company can continue to fund investments in new products and initiatives key to its business strategy, and further enhance returns for our shareholders through stock repurchases."

Angiotech Pharmaceuticals (Vancouver, British Columbia) reported that it has priced its previously disclosed offering of \$325 million in aggregate principal amount of senior floating rate notes due 2013.

The offering is being made in a private placement and is expected to close on Dec. 11, subject to the satisfaction of closing conditions.

The notes will bear interest at an annual rate of LIBOR

plus 3.75% and will rank equally in right of payment to all of the company's existing and future senior indebtedness.

The company said the net proceeds of the offering, plus cash on hand, will be used to repay the outstanding principal amount under the company's senior secured term loan facility. The company intends to terminate its existing revolving credit facility when it repays its senior secured term loan facility.

In other financing news:

- **Neoprobe** (Dublin, Ohio), a developer of oncology and cardiovascular surgical and diagnostic products, reported that it had completed negotiations for the elimination of certain note covenants and the modification of the maturity of the notes with Great Point Partners, the holder of \$8 million in secured notes that were originally due on Dec. 13, 2008.

Great Point has agreed to eliminate the revenue and cash covenants that were in the original notes through the remaining term of the notes. In exchange for the elimination of the note covenants, Great Point will receive an increased annual interest rate of 12%. Under the terms of the amended agreement, Neoprobe gains the option of repaying the notes early without penalty but will be required to pay a portion of proceeds from certain transactions, such as equity raises, to the note holders.

Great Point will retain the option to convert its notes into Neoprobe common shares at a fixed conversion price of 40 cents per share but has waived anti-dilution rights under the notes. Additionally, the parties agreed to modify the repayment schedule to include periodic repayments over the course of 2007 and 2008, and to extend the final maturity of the notes to Jan. 7, 2009.

David Bupp, Neoprobe's President and CEO, said, "The elimination of the key note covenants, the relief from anti-dilution protection and the ability of the company to retire the notes without any prepayment penalty provides Neoprobe with considerable flexibility to manage its capital structure going forward, all without any incremental dilution to the shareholders of Neoprobe."

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AHC Media LLC

Deals roundup

AMS sells Laserscope aesthetic assets to Iridex for \$37 million

A Medical Device Daily Staff Report

American Medical Systems Holdings (AMS; Minnetonka, Minnesota) reported that it signed a definitive agreement to sell the assets of its aesthetics division acquired via the **Laserscope** (San Jose, California) acquisition to **Iridex** (Mountain View, California) for total consideration estimated at up to \$37 million. The transaction is anticipated to close no later than Jan. 31.

The transaction calls for \$28 million in total consideration to be paid to AMS at closing, with up to an additional \$9 million in cash to be paid for any remaining inventory at the end of a six- to nine-month manufacturing transition period.

The net after-tax cash proceeds resulting from this transaction will be used to pay down the company's long-term debt.

Martin Emerson, president /CEO of AMS, commented, "We are very pleased with the results of our aesthetics division divestiture process which we believe has produced attractive terms in a relatively short timeframe."

AMS bought **Laserscope** (San Jose, California) back in July for \$715 million (*Medical Device Daily*, July 21, 2006). Laserscope manufactures minimally invasive medical products, including medical laser systems and related energy delivery devices.

"We believe this acquisition will provide significant growth opportunities for our dermatology business and allow us to become one of the key players in the estimated \$750 million global aesthetics laser market, as well as provide a platform for continued growth in ophthalmology," said Barry Caldwell, president and CEO of Iridex.

Caldwell said he expects the transaction to be accretive to the company's earnings within the first year excluding one-time expenses related to the transaction.

"In addition, we will acquire a direct sales, clinical and service presence in the international aesthetics markets, which will expand our current international dermatology business beyond its current limited focus. We believe this acquisition will also help expand the support we provide to our present international distribution channels in the ophthalmic segment," added Caldwell.

Since its founding in 1982, Laserscope's aesthetics business has sold about 2,100 laser systems in the U.S. and 500 internationally. Combining this with the more than 1,000 Iridex dermatology lasers in the field, Iridex's installed base will exceed 3,600 laser systems, it said.

Iridex is a worldwide provider of therapeutic-based laser systems, disposable laser probes and delivery devices to treat eye diseases in ophthalmology and skin diseases in dermatology markets.

Micrus Endovascular (San Jose, California) reported that it has acquired certain assets of privately held **VasCon** (Doral, Florida), a maker of vascular access and delivery devices.

Micrus Design Technology, the subsidiary of Micrus formed to acquire the assets, will develop and manufacture neurovascular catheter products for Micrus, including Micrus' steerable catheter the Enzo. VasCon's existing cardiovascular products will continue to be sold through non-Micrus distribution channels.

Micrus, through its subsidiary, acquired assets of VasCon for an up-front payment of about \$5 million, paid in cash and Micrus stock, and performance based earn-out payments over three years.

Certain VasCon personnel have become employees of Micrus Design Technology. Mitch Auran, formerly VasCon's president and CFO, has been appointed vice president of the newly formed Micrus subsidiary.

Founded in 2000, VasCon has made diagnostic catheters, guiding catheters, PTCA catheters, catheter sheath introducers, neurological stimulators, hydrophilic coating and stent deployment systems under private label, as well as for a list of blue chip medical device customers.

In other dealmaking news:

- **PerkinElmer** (Wellesley, Massachusetts) has signed a definitive agreement to acquire **Evotec Technologies** (Hamburg, Germany) in a cash transaction valued at about EUR 23 million (\$30.64 million).

Evotec Technologies is a majority owned subsidiary of **Evotec AG**, which provides systems for confocal imaging, cell handling, ultra-high throughput screening as well as image capture and cellular analysis software. The transaction is expected to occur late December 2006 or early 2007.

"Together with the sale of certain technology assets of Evotec Technologies to **Olympus** (Tokyo) earlier in the year, the combined divestments value Evotec Technologies at approximately EUR 30 million. The cash proceeds will provide us with additional flexibility to progress and expand our Central Nervous System pipeline," said Joern Aldag, CEO of Evotec AG.

Evotec Technologies' high-performance HCS instruments and image analysis software help pharmaceutical, biotechnology and academic researchers automate cell screening and analysis for drug discovery. Included in the company's portfolio is the Opera HCS platform, a premier tool for high content analysis that combines the precision of confocal microscopy with the throughput required for primary and secondary screening. ■

Agreements

Emageon in Allscripts pact for TouchWorks software

A Medical Device Daily Staff Report

Emageon (Birmingham, Alabama) reported that it will resell TouchWorks Electronic Health Record (EHR) and Practice Management (PM) solutions from **Allscripts** (Chicago) to its 585 healthcare system and hospital customers. Additionally, Emageon said it would provide implementation and first-level support for the combined Allscripts EHR and PM solution to its hospital customers.

The companies said they plan to provide integration between their solutions, enabling physicians who use TouchWorks in ambulatory offices to view images taken in the hospital using Emageon's Enterprise Visual Medical System platform, including the RadSuite and HeartSuite product lines.

Financial terms of the agreement were not disclosed.

The agreement will help address recent changes to anti-kick-back and self-referral regulations, which govern the scope of hospital-physician relationships. On Oct. 10, final rules from the **Centers for Medicare and Medicaid Services** and the **Office of the Inspector General** took effect, creating a new safe harbor to the federal Anti-Kickback Statute and a corresponding exception to the federal Stark Act. The new safe harbor and exception permit hospitals to provide their affiliated physicians with electronic health record (EHR) and electronic prescribing technology. As a result, hospitals need EHR and ePrescribing solutions that meet the needs of ambulatory physicians, Emageon said.

Allscripts is a provider of clinical software, connectivity and information solutions for physicians. Emageon provides enterprise information technology systems for hospitals and healthcare networks.

In other agreements news:

- **Dmetrix** (Tucson, Arizona) has teamed with **Definiens** (Munich, Germany) to combine platforms and provide a high-throughput, ultra-rapid quantitative and objective tool for preclinical research to speed the development process for new therapeutics.

The partnership is intended to develop a complete solution to enable automated digital pathology. The partners will jointly develop connectors for the new solution, which will enable customers to benefit from the image capture-to-analysis process in drug discovery, delivering faster results, the companies said. The solution includes the DMetrix DX-40 array-microscope whole slide scanner designed to capture images of slides in less than one minute as well as the Definiens Enterprise Image Intelligence suite of products.

DMetrix is a privately held company and the exclusive developer of array-microscope technology. Definiens bills itself as the No. 1 enterprise image intelligence company for interpreting images from microscopic cell structures to satellite images.

- **Acuo Technologies** (St. Paul, Minnesota) and **NU**

Design Medical Technologies (Minnetonka, Minnesota) reported that NU Design would incorporate DICOM Services Grid technology from Acuo Technologies into its Mammography Manager. The technology will allow NU Design's Mammography Manager to automatically route, based on content, to a reading physician without manual intervention, the company said. The system will enable content-aware DICOM routing, storage virtualization, JPEG, encryption and storage virtualization.

Acuo was founded in 2000 to develop the first enterprise-wide collaborative asset management solution for medical DICOM images residing in a Picture Archiving and Communications System. NU Design is a privately held software and tel-radiology company specializing in women's healthcare.

- **Smiths Medical** (Carlsbad, California), part of the global technology business Smiths Group and provider of temperature management products worldwide, recently signed an exclusive agreement with **Inditherm** (Rotherham, UK), a provider of heating solutions to the medical industry.

The three-year distribution agreement stipulates U.S. market sales of Inditherm heated mattresses and blankets under Smiths Medical's Level 1 brand, adding to Smiths Medical's range of temperature management brands such as Snuggle Warm Convective Warming Blankets and Hotline Fluid Warming. ■

Court report

Lifestream files petition for protection under bankruptcy

A Medical Device Daily Staff Report

Lifestream Technologies (Post Falls, Idaho), a supplier of cholesterol monitors, said yesterday it has filed a petition for protection under Chapter 11 of the U.S. Bankruptcy Code in the U.S. Bankruptcy Court for the District of Nevada. As a "debtor in possession," the company remains in possession of its assets and properties, and continues to operate its business pursuant to Sections 1107(a) and 1108 of the Bankruptcy Code.

In connection with the bankruptcy filing, on Nov. 27 the company entered into an asset purchase agreement with **Polymer Technology Systems** (PTS; Indianapolis) to sell substantially all of its assets for \$750,000, subject to higher and better offers.

To consummate the sale, the company filed a motion pursuant to Section 363(f) of the Bankruptcy Code to seek court approval for sale of the assets referred to above. As its bankruptcy pleadings detail, based on preliminary indications, the company expects that after the sale it is unlikely that any assets will remain for distribution to the common shareholders.

Certain additional information concerning the matters announced in this release are contained in a current report on Form 8-K to be filed with the Securities and Exchange Commission. ■

SilverHawk

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looking messes, with incredibly unpalatable hues and looking scarily alive — all samples of plaque taken from the peripheral vasculature of patients via the FoxHollow SilverHawk device.

The SilverHawk is the flagship system developed by FoxHollow for this procedure and so far winning the largest headlines for the company — via its recent deal with **Merck** (Whitehouse Station, New Jersey) in which the big pharma company acquired an 11% stake in the company and committed to a research agreement that could bring the device company up to \$100 million over the next four years (*Medical Device Daily*, Sept. 28, 2006).

The agreement calls for FoxHollow to supply samples of plaque materials excised by the SilverHawk, which will be supplied to Merck and examined to better understand the biology of plaque — especially “vulnerable” plaque — and develop drugs to treat peripheral artery disease (PAD), a vasculature problem increasingly being brought to the front burner of the “unmet needs” category.

The device “cleans” the peripheral arteries by “shaving out plaque so that blood flow can be reestablished and normalized,” Simpson said.

And he showed the beneficial results with before and after images of a 92-year-old woman’s leg that was healed after SilverHawk treatment, and standard treatment could not (not bothering to offer the ugly “before” in screen saver mode).

Simpson also detailed the unhappy numbers for PAD: 150,000 in the U.S. receiving bypass surgery, 400,000 treated via balloon/stent, and 50,000 amputations, which Simpson termed “a usual therapy, but I don’t even call it a therapy — it’s an event, tragic and leading to a large number of bad outcomes.” For most of these patients, he noted, it is a story of repeat hospitalizations and huge costs.

He said that using its technology to prevent these results is the “commitment” of FoxHollow, and he reported that about 60,000 cases will be treated with the SilverHawk in 2006.

He estimated that a patient pool of 700,000 of the 2.5 million PAD sufferers is appropriate for SilverHawk treatment, but there may be “closer to 10 million with the disease undiagnosed.”

Using an animation, Simpson showed how the device is moved into the vasculature, and a “cutting element” is then elevated to remove the yellowish plaque from the arterial wall. This “spinning device is advanced through the artery, shaves off material, and the process is repeated as many times as you need to [the vessel].”

This can be done “maybe 20 times in a profusely diseased vessel,” he noted, with a key benefit that the interventionalist can manipulate the device with “standard technique.”

He added: “Our device doesn’t discriminate, it doesn’t care, whatever is obstructing the artery, it’s coming out.”

Turning to the future, Simpson said the company will

be developing trials that compare the SilverHawk against bypass surgery, and eventually compare it against the use of peripheral stents when these are “approved for PAD.”

Further out, he indicated other possibilities: use of the technologies to treat the coronary arteries; development of a device/paclitaxel drug combination, with the advantage of “not leaving a foreign body behind,” he said — referring to the problem of thrombosis with drug-eluting stents; use of the company’s technologies for treatment of the coronary arteries; and the development of a “RockHawk,” a device for cutting through calcium and combined with “embolic protection.”

Then came the excitement.

Simpson described the NightHawk, so named because it provides a sort of arterial night vision by adding to the SilverHawk an optical fiber, “so we can see what we’re cutting to supplement the information we would ordinarily get.”

Providing a detailed view of the artery being cleaned and the irregularities of the target plaque will provide more precise cutting, “with certainty,” he said, and reduce procedure time — that certainty he again demonstrated with slide images of a treated vessel.

The optical fiber in its first use will be behind the cutter, he said, and then moved forward in the next-generation device.

Compared to the need to take after-procedure “single-plane” angiogram images of the vessel, the NightHawk offers “quite a breakthrough for us,” Simpson said.

While acknowledging that the word “revolutionary” is too often used, he said that the “detail for the structure of the arterial wall is literally revolutionary — I promise you this is not what you’ve ever seen before in interventional treatment. The revolutionary part is a 10-fold improvement in resolution.”

A FoxHollow executive told *MDD* that the company has begun a small trial of NightHawk in Poland, and it will soon launch a larger trial there, and the company also has its sights set on a trial in the U.S. in 2007.

Simpson said that the broad opportunities for FoxHollow’s technologies are to gain a greater understanding of vulnerable plaque and using this information to stratify patients “to make better, more accurate determination of what the patient should have” by characterizing “the biological opportunities.”

And referring to the various unwholesomely colored samples that the company is sending to Merck, Simpson asserted: “plaque does not belong in an artery, it belongs in a jar.” ■

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Guardian

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"The uniqueness about this is that we've learned that every material has a very unique substance signature or fingerprint," Vice President of Business Development Richard Borrelli said in an interview with the ABC network program "Ahead of the Curve," which the company was showing at its RSNA booth.

With other technologies that exist currently, "thousands and thousands of these algorithms can be analyzed simultaneously," he told the program. And it can be used for the human body as well, he said.

"As you might imagine, these organic materials [in bombs] have a unique signature — so does all the material in your body," he said. "Lesions, fluid, liquid in your body all have a unique signature as well. Now, we're training these algorithms, with some minor modifications [to detect] things like multiple sclerosis in the brain or for blood in the brain where it's not supposed to be."

The company's technology uses mathematic equations and algorithms "to really extract information that's unseen by the naked eye in these pixels of information."

These algorithms are expected to give radiologists "the ability to see something that was not quite as clear before — and seeing it more sharply and clearly." For example, the healthcare applications are designed to determine whether a material in the body is a solid lesion or a fluid-filled lesion.

"Hopefully, as we progress the technology we'll be able to tell the radiologists whether this corresponds to a material that looks like a lesion — like a cancer," Borrelli said on the program.

Ideally, if the technology works the way the company hopes, it would be able to look at tissue very early in a disease state to detect a disease earlier than is now possible.

The company said that Signature Mapping clinical results were derived from five pilot studies that have been conducted through an agreement with the Image Processing and Informatics Laboratory of the **University of Southern California** (USC; Los Angeles).

The research has covered detection and quantification of multiple sclerosis lesions; normal pressure hydrocephalus; acute intracranial hemorrhage; tuberculosis; and the quantification, tracking, clarification and detection in dense breast tissue.

As an example, Borrelli told *Medical Device Daily* that Guardian was able to train its algorithms to detect multiple sclerosis in the brain and "do it accurately and with more specificity than the radiologists that were helping us train the algorithms."

"So, we were able to dependably say, 'Yes, this algorithm is capable of detecting multiple sclerosis and then quantifying it and determining the size of the lesions, which is actually more important in multiple sclerosis,'" Borrelli said, "because it's not such a difficult area to detect, but it's a very difficult area to measure and quantify."

For example, more lesions — or lesions that are larger in size — equate to a patient whose disease is progressing.

With acute intracranial hemorrhage, it's possible, particularly in trauma cases, Borrelli said, for there to be blood seepage in this area that is sometimes missed by the radiologists or emergency room physicians. Still, it may be present, which would indicate a serious problem and require the patient to be kept at a treatment center.

"As we begin to understand the capabilities of the technology, we can apply it to many areas of the body and help diagnosticians get more information out of the image they create," he said.

The next step for the company and the technology is to meet with the FDA to discuss what the company expects its claims to be and "what is going to be required in order to demonstrate safety and efficacy," Borrelli said, acknowledging that there is "still a fair amount to do on the clinical side."

Guardian said this technology essentially will be used as an adjunctive technology to the imaging devices already used by radiologists to help supplement their optical diagnosis.

"We don't necessarily think of ourselves as a competitive technology," Borrelli told *MDD*. "We would be happy to work with **R2 Technologies** (Sunnyvale, California) or **i-CAD** (Nashua, New Hampshire) to help them build a better product."

Guardian reported on Nov. 8 that, in accordance with a purchase agreement with a group of institutional accredited investors, it successfully completed the first of two closings of a private placement of its securities.

The company said investors have agreed to purchase in the aggregate, and before deduction of certain fees and expenses of the offering, \$5,150,000 of securities, \$2,575,000 of which were purchased at the first closing and \$2,575,000 of which will be purchased upon effectiveness of a registration statement to be filed by the company with regard to shares underlying the securities. ■

Dade

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• **Advanced Magnetics** (Cambridge, Massachusetts) reported its intention to publicly offer 1.95 million shares of its common stock pursuant to an effective shelf registration statement in an underwritten public offering.

The company said it intends to grant the underwriters a 30-day option to purchase up to an additional 292,500 shares of common stock. All of the shares are being offered by Advanced Magnetics.

Morgan Stanley & Co. is acting as the sole book-running manager for the offering. UBS Securities is acting as joint lead manager for the offering. Jefferies & Co. and ThinkEquity Partners are acting as co-managers for the offering.

Advanced Magnetics is a developer of superparamagnetic iron oxide nanoparticles used in pharmaceutical products. Its nanoparticle technology is used in therapeutic iron compounds to treat anemia, as well as imaging agents to aid in the diagnosis of cancer and cardiovascular disease. ■

Europe

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only procedure available that can provide dynamic stabilization of the spine via a percutaneous access puncture. It said that all other dynamic stabilization systems and procedures require a major or minimally invasive surgical incision to provide pain relief to patients with degenerative spinal disc disease.

Dynamic stabilization is an alternative to medical management, corticosteroid injections and, when indicated, invasive surgical fusion therapies, to the approximately 500,000 patients on a worldwide basis who suffer from degenerative disc disease of the spine.

The procedure provides relief from the pain of degenerative disc disease while maintaining far greater motion compared to patients of spinal fusion surgery, the company said.

Third-party experts have estimated that the market for dynamic stabilization products will grow to more than \$500 million within the next five years.

In addition to providing the least-invasive approach to dynamic stabilization, the results from the company's initial pilot clinical study indicate that the PDS system provides greater relief from pain for individuals suffering from spinal disc disease than any other dynamic stabilization product or procedure.

Interventional Spine said it intends to conduct a series of extensive clinical trials and continue to prove the clinical value.

The company said it changed its name from Triage Medical this month to "more effectively communicate the clinical and business strategic emphasis of the company."

In addition to the PDS system, Interventional Spine also has both FDA market clearance and CE mark approval for its PLS system, which allows the least-invasive method of providing fixation of the vertebral structures following conventional spinal fusion procedures.

Rather than needing a surgical incision to implant the required vertebral fixation devices, the PLS system can accomplish such fixation with one small percutaneous-access puncture. This improves patient compliance, recuperation time and lowers the cost of such procedures, according to the company.

Interventional Spine's products for the treatment of degenerative spinal disc disease as well as a broad range of orthopedic applications are based upon its Clasp and Teleport Access technologies.

Biotherapeutics firm opens European offices

Talecris Biotherapeutics (Research Triangle Park, North Carolina) has established **Talecris Biotherapeutics GmbH** (Frankfurt, Germany) to serve as its European headquarters.

The new European subsidiary represents the second expansion in 2006 for the biotherapeutics manufacturer, completing the next regional phase in the company's ongoing global expansion plan.

"Our expansion into Europe signifies another key milestone demonstrating the strategic growth we have planned

for our company," said CEO and President Alberto Martinez, MD. "We established Talecris Europe to deliver tailored sales and support services to our European customers, and our European leadership team brings the knowledge, experience and dedication to do exactly that."

Commenting on Talecris' establishment of a European presence, Claus Vogelmeier, MD, of the Division of Pulmonary Diseases at University Hospital Marburg (Marburg, Germany), said, "We are pleased to continue working with Talecris, now in Europe, to help physicians identify and treat patients with alpha-1 antitrypsin deficiency, also known as genetic emphysema. Their commitment to invest in research projects and patient and professional support programs will continue to strengthen our ability to improve patient outcomes."

With the new German offices, Talecris said it is now positioned to work closely with physicians and their patients to improve clinical care of primary immune deficiency patients.

In business for just 20 months, Talecris already has achieved annual sales of more than \$1 billion and has grown to employ more than 3,000. The company supplemented its business with the acquisition of Precision Pharma Services, which provides additional fractionation capacity, and by acquiring 58 plasma collection centers from International BioResources to complete the vertical integration of the business.

England is going smoke-free

All enclosed public places and workplaces in England will become smoke-free beginning July 1, 2007, according to Health Secretary Patricia Hewitt, who said, "This is a triumph for public health and a huge step forward for health protection. Thousands of people's lives will be saved and the health of thousands more protected"

She added, "Smoke-free legislation will protect everyone from the harm of secondhand smoke when working, socializing and relaxing and will provide a more supportive environment for smokers who wish to give up."

In making the announcement, Hewitt said the scientific and medical evidence "is clear — second-hand smoke kills, causing a range of serious medical conditions including lung cancer, heart disease and sudden infant death syndrome in children. This legislation will help to prevent the unnecessary deaths caused every year from second-hand smoke, and recognizes that there is absolutely no safe level of exposure."

She said that never has a health issue created such debate in Parliament, across government, through the business and the voluntary sectors, and among the general public. "And the more it has been debated, the more people have responded and pushed the limits to ensure that enclosed public places and workplaces in England will become wholly smoke-free."

The Health Secretary also launched a new Smokefree England campaign that will help the country's 3.7 million businesses — including nearly 200,000 pubs, bars, restaurants and other leisure outlets — prepare for the implementation of the legislation. ■

DES

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Deepak Bhatt, MD, associate director of the Cleveland Clinic Cardiovascular Coordinating Center and the senior author of the study, told *Medical Device Daily* that for an individual patient the risk of clotting after the drug-eluting stents are implanted is “very small.” But the analysis provides valuable information, he said, for the physicians implanting the stents as well as other physicians caring for the patients after the stents have been implanted.

“Our analysis found there is a small, but real, hazard of late stent thrombosis with drug-eluting stents more so than with bare-metal stents, likely in the setting of discontinuation of anti-clotting drugs,” Bhatt said. “This does not, however, mean that drug-eluting stents should not be used, as other studies have shown that they do significantly reduce the need for repeat procedures compared with bare-metal stents.”

Fourteen studies with 6,675 total patients were included in the analysis comprising nine sirolimus stent trials and five paclitaxel stent trials. Eight of the trials reported more than a year of clinical follow-up. The sirolimus trials mandated anti-clotting medication for at least two to three months and the paclitaxel trials required six months.

Bhatt said he believes the analysis provides useful information for the physician implanting the stent to consider and might encourage them to “just be a bit more cautious” when using drug-eluting stents. For example, if a patient has a higher-than-average risk of bleeding or a history of non-compliance with medication, the physician may want to consider using a BMS instead of a DES, he said. Similarly, if a patient is likely to face surgery in the coming year BMS may be a better choice because the patient’s surgeon will most likely stop their anti-clotting medication prior to surgery.

The analysis might also encourage the patient’s other doctors — such as their primary care physician or surgeon — to put some extra thought into their care or perhaps even consult the implanting physician before discontinuing their anti-clotting medication, Bhatt said.

“I think drug-eluting stents are really quite advanced in the treatment of cardiovascular disease,” Bhatt said.

But like any medical treatment, he said, there is a risk of side effects.

“The key is just proper patient selection and some care with the use of anti-clotting medication,” Bhatt said.

The analysis precedes an FDA Advisory Panel set to meet Thursday and Friday in Washington to discuss and make recommendations regarding issues related to stent thrombosis in coronary drug-eluting stents. The panel charged with evaluating the cardiovascular devices is likely to pay the most attention to products by the two makers with FDA-approved devices — **Cordis** (Miami Lakes, Florida), a unit of **Johnson & Johnson** (New Brunswick, New Jersey) and **Boston Scientific** (Natick, Massachusetts).

The debate concerning DES technology was a panel

discussion at the annual scientific sessions of the **American Heart Association** (AHA; Dallas) in Chicago last month (*Medical Device Daily*, Nov. 15, 2006). During the AHA panel, David Williams, MD, of **Rhode Island Hospital** (Providence) reported on a comparison of 3,000 patients in the National Heart, Lung, and Blood Institute Dynamic Registry who received either DES or BMS. Though DES patients tended to have more complex disease, they had lower rates of mortality in-hospital and at one year. Heart attack was slightly higher in the DES group, but DES patients required less repeat revascularization. And the researchers supported use of DES “in standard clinical practice.”

Presenting the anti-DES position at AHA, Joseph Muhlestein, MD, professor of medicine at the **University of Utah** and director of research at **LDS Hospital** (Salt Lake City), reviewed a three-year comparison of the Cypher and Taxus stents, the two that are FDA-approved and the focus of the debate. That comparison showed an “all-cause” rate of death higher in DES patients than BMS and a greater rate of adverse events, such as heart attacks, and repeat revascularization procedures out to three years.

Earlier this year Cordis, maker of the Cypher stent, issued a study at the Transcatheter Cardiovascular Therapeutics (TCT) conference in Washington on what it called the multiple factors of stent-related thrombosis (*MDD*, Oct. 25, 2006). Its study showed that the Cypher stent is not associated with an increased overall risk of thrombosis when compared to BMS out to four years.

Bhatt said Cleveland Clinic’s analysis is based on a randomized clinical trial and he emphasized that more research on drug-eluting stents is needed.

Cleveland Clinic Heart & Vascular Institute is a world leader in diagnosis and treatment of cardiovascular disease and has been ranked No. 1 in the nation for cardiac care by *U.S. News & World Report* every year since 1995. Cleveland Clinic is a not-for-profit multispecialty academic medical center that integrates clinical and hospital care with research and education. ■

BRIEFLY NOTED

ATSF gets AATB accreditation

American Tissue Services Foundation (ATSF; Oklahoma City) has been awarded accreditation of the **American Association of Tissue Banks** (AATB, McLean, Virginia).

Accreditation follows an intensive process, including an on-site inspection by the AATB, establishing that the medical, technical and administrative performance of the tissue banking facility meets or exceeds AATB standards. By successfully meeting those requirements, ATSF joins 100 other AATB-accredited tissue banking facilities in the U.S. and abroad.

ATSF is a not for profit foundation recovering donated human tissue for an extensive variety of clinical needs.

PRODUCT BRIEFS

• **ATS Medical** (Minneapolis) said it received a notice of allowance from the U.S. Patent and Trademark Office for a key patent application on its anti-coagulation and demineralization of conductive medical devices technology. It expects this patent to issue in early 2007. The ATS technology is used to treat implantable medical devices to minimize blood/platelet interaction with the device. ATS Medical provides products and services for cardiac surgery.

• **CardioDynamics** (San Diego) reported that the Centers for Medicare and Medicaid Services released the final version of its national coverage decision (NCD) maintaining coverage for high blood pressure, also known as hypertension. The decision will maintain the carrier discretion policy for coverage of ICG for patients' with resistant hypertension, defined as those whose blood pressure is not controlled on three or more medications. This coverage decision for hypertension, along with prior NCD indications for shortness of breath and heart failure will enable both clinicians and patients to benefit from ICG utilization. **CardioDynamics** makes noninvasive BioZ ICG products and medical device electrodes.

• **CoreValve** (Irvine, California) said its ReValving system was used to percutaneously implant its porcine pericardial tissue bioprotheses over the severely diseased aortic heart valves of four consecutive high-risk patients: two at the **HELIOS Heart Center** (HHC; Siegburg, Germany) and two at the **University of Leipzig Heart Center** (Germany). CoreValve said each of the ReValving procedures were performed without the necessity of a surgical cut-down for catheter access, without the use of extracorporeal bypass, and without any other cardiac assistance or

even rapid pacing. CoreValve has developed a delivery system for percutaneous heart valve replacement, based on a novel catheter-and-self-expanding-frame approach on a beating heart, thus avoiding open-heart surgery.

• **CytoCore** (Chicago) reported the start of clinical trials in support of its EndoScan, a non-invasive uterine cancer screening method expected to become a standard gynecological wellness test available worldwide, according to the company. Phase I trials should be complete in six months; Phase II trials will begin immediately, with a product market release anticipated during 2008, the company said. CytoCore develops cancer screening systems.

• **MedicalCV** (Minneapolis) said Allen Raczkowski, MD, a cardiothoracic surgeon at **Banner Baywood Heart Hospital** (Mesa, Arizona) completed the first closed-chest, robotic procedure using the AtriLaze surgical ablation system to treat atrial fibrillation in conjunction with a minimally invasive mitral valve repair. MedicalCV is a cardiovascular surgery device maker.

• **Micrus Endovascular** (San Jose, California) reported positive initial results from a single-center study of neurovascular aneurysms treated with Micrus Endovascular's Cerecyte microcoils indicating an excellent safety profile and a recanalization rate below historical published rates for bare platinum coils. Cerecyte microcoils incorporate a bioactive filament with Micrus Endovascular's three-dimensional microcoils that deploy within a cerebral aneurysm, forming a scaffold that conforms to a wide diversity of aneurysm shapes and sizes. Micrus believes Cerecyte will stimulate a healing response, thus improving outcomes by reducing the rate of recanalization (continued or new aneurysm growth) and the need for retreatment. Micrus makes both implantable and disposable medical devices used in the treatment of cerebral vascular diseases.

PEOPLE IN PLACES

• **Accuitive Medical Ventures** (AMV) and **The Innovation Factory** (TIF; both Duluth, Georgia) have added Rudy Mazzocchi to both management teams. He will serve as a venture partner with AMV and as vice president, business development with TIF. Mazzocchi most recently served as chairman and Interim-CEO of Triton BioSystems. Previously, he was co-founder and CEO of Image-Guided Neurologics. The Innovation Factory, a medical device-focused venture, was created in 1999 and has spun out several device companies, including Acufocus, LipoSonix, Neuronetics, and NeoVista. Accuitive Medical Ventures.

• **Dade Behring Holdings** (Deerfield, Illinois) said Donal Quinn has been appointed to the newly created position of chief operating officer, and Mark Wolsey-Paige

has been appointed to the newly created position of chief strategy and technology officer. Hiroshi Uchida, president, global operations and supply chain has resigned from the company to join another firm. Quinn joined Dade Behring in 1998 and has served as the company's president, global customer management since 2002. For the last four years, Wolsey-Paige has managed the company's research and development and strategic planning functions. He joined Baxter Diagnostics, the company's predecessor, in 1991. Quinn and Wolsey-Paige's newly appointed roles will become effective Jan 1. Dade Behring offers products and services for laboratories.

• Anthony Kesman has been appointed an operating partner at **Linden** (Chicago), a private investment firm that focuses on middle market leveraged buyout investments in the healthcare and life sciences sector. Previously Kesman was with Allegiance Healthcare, a subsidiary of Cardinal Health.