year, potentially due to the shifting demographics of our older population."

Currently, TYRX has approximately 2% annual penetration of the pacemaker/defibrillator market, representing over 40,000 patients who have received AIGISRx since 2008. "But we anticipate in five years to command over 30% of this market," White asserts. "Still, the overall market is growing at perhaps 1% annually, the same slow-growth rate we expect for many years to come."

Charles Kinder, MD, an electrophysiologist at MacNeal Hospital in Berwyn, IL, is more optimistic about the growth of the CRM market. "There are 10,000 baby boomers retiring every single day," he remarks, "and the need for cardiac implantable devices – both pacemakers and defibrillators – increases as people age. Therefore, I think we are in for a very busy time."

Kinder, who has no financial interest in TYRX, also notes that previously implanted devices require battery replacement: typically about every seven years for a pacemaker and five years for a defibrillator. And, "there is a high risk for infection during battery replacement," he says.

The new resorbable AIGISRx envelope "truly removes any barrier to implanting the envelope because you will no longer have to contend with that envelope when you reoperate years down the road to replace the battery," Kinder explains. "The envelope adds a minimal cost to the procedure and is a very small cost compared with the cost of a device infection."

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– Bob Kronemyer

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>
> - James Corbett, Vertos Medical

Vertos Medical's $23 Million Series E Highlights Minimally Invasive Trend In Spine Surgery

A Series E financing round in the amount of $23 million that closed June 17 will allow **Vertos Medical Inc.** to further expand commercialization of its minimally invasive *mild* procedure for patients with lumbar spinal stenosis. The outpatient mild procedure is performed under fluoroscopy and removes excessive ligament tissue (hypertrophic ligamentum flavum) between the vertebrae that causes pain and reduced mobility. Once the tissue is removed, space in the spinal canal is restored and thus reduces nerve compression.

The new capital adds to the previously raised $42 million by the Aliso Viejo, CA-based company, bringing the total raised to date to $65 million.

The mild device kit received 510(k) clearance in 2008. "We performed about 100 cases that first year, and to date have treated about 15,000 patients," says James Corbett, Vertos president and CEO. "During the ensuing years, we have been establishing extensive foundational clinical evidence."

The device was granted the CE mark in December 2012 and the first commercial sale in Europe occurred in Switzerland this past July. "Switzerland is one of many European countries that we believe offer ready commercial access; the others being Germany, Belgium, Holland, the United Kingdom, Italy, and the Scandinavian countries," Corbett notes.

The Series E financing will broaden sales efforts in the US and launch sales in 11 European countries. "We are very optimistic about the potential for adoption of the mild device," says Corbett. "We take a three-day hospital stay and turn it into an outpatient event. The procedure itself takes under one hour and the patient arrives and leaves the facility within a few hours." In addition, "we take general anesthesia and turn it into local, plus take a three-inch incision and turn it into a puncture the diameter of a baby aspirin that does not even require a suture."

Corbett also points out that 15% of patients undergoing similar surgery require a blood transfusion. "We have not had a single case of blood transfusion among all of the 15,000 cases performed to date," he explains. "Overall, the mild procedure is a tremendous advancement in minimizing patient trauma while trying to help them stand and walk longer."

In 2008, Corbett sat in on a one-week follow-up patient visit, in which the physician first asked the patient "Where is your walker?" The patient replied, "I've had that damn walker for five years. I left it in the lobby after you treated me last Monday." Corbett also stresses the functional outcomes study of the mild procedure conducted by the **Cleveland Clinic**, which showed an average improvement in standing from eight minutes to 56 minutes. "This is extraordinary," he says.

Corbett projects that an additional 15,000 patients will undergo the mild procedure by next year. The procedure is reimbursable in the US, but reimbursement challenges will

need to be solved in some European countries. "However, the 11 countries we have targeted all have insurance that is adaptable to a new technology, and we were reimbursed for the case we recently performed in Switzerland," says Corbett.

In the US, the Centers for Medicare and Medicaid Services (CMS) opened a National Coverage Analysis in April for percutaneous image-guided lumbar decompression for lumbar spinal stenosis, saying it wanted "to complete a thorough review of the evidence." There is currently no US national coverage policy in place for this procedure. CMS is expected to issue a proposed national coverage determination by October 5 and a final NCD by January 3, 2014. (*See "CMS Opens National Coverage Analysis For Percutaneous Image-Guided Lumbar Decompression"* — "The Gray Sheet," *April 15, 2013.*)

"My sense is that this is wonderful therapy for a select group of patients who otherwise would need to have a much more invasive procedure," comments Peter Staats, MD, who practices interventional pain management in Monmouth County, NJ, and has treated about 85 patients with the mild procedure over the past few years.

But Staats, who has no financial interest in Vertos, says some of his patients have not benefited from the mild procedure. "It does not cure everyone, but I believe the risks are quite low," he says. "There are a large number of studies that consistently demonstrate about a 70% to 80% success rate. These results are similar to my own outcomes." But in those patients for whom the therapy is unsuccessful, a more invasive procedure is still possible. "Still, the benefit-to-risk profile for the mild procedure is really quite favorable," says Staats.

The procedure is more effective in patients with central stenosis as opposed to lateral stenosis, according to Staats. "If the primary problem is lateral stenosis, the procedure does not work," he explains. "However, some patients have both central and lateral stenosis." In these cases, it can be difficult for a clinician to determine how much of the pain is originating from the central stenosis.

"I think the therapy has just scratched the surface," says Staats, who is also an adjunct associate professor of anesthesiology and critical care at **Johns Hopkins University School of Medicine**. "Much like the cardiovascular field has moved to much more minimally invasive therapies, spinal surgery is going to move in a similar direction. The mild procedure is the first of several new treatments that are likely to change the paradigm on how we address spinal disorders. Not only will these therapies be much less invasive, but they will preserve the muscle layers. In some settings, these new treatments will also avoid fusions with instrumentation. This is one of these situations where less is more."

Vertos Medical's new round of financing was led by Israeli-based Pitango Venture Capital, which has invested in the spine space for many years, but this was Pitango's first investment in Vertos. "For some time, we have been looking for minimally invasive solutions for spine and severe pain symptoms," remarks Ittai Harel, a general partner at Pitango. "Vertos presented a compelling opportunity because of the amount of data and experience that the mild procedure has amassed, both in terms of clinical efficacy and safety."

Pitango believes the mild procedure will change the medical landscape by extending treatment options for patients suffering from lumbar spinal stenosis. "These patients cannot be treated well with medication or other means," Harel explains. "The only real option is open decompression surgery, which is quite complex and carries real risks. In contrast, the mild procedure is a very simple procedure with very minimal risk of complications." Harel believes the outpatient procedure has the potential to be a game-changer by shifting treatment from the spine neurosurgeon to the pain specialist.

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– Bob Kronemyer

Wireless Revolution Raises Device Security Fears

The word "cybersecurity" has been part of the vernacular for several years now, but the term is applied most frequently to computer network security issues. Now, however, health care's wireless revolution is raising the same types of concerns in the medical device arena.

Anyone who has used the Internet is well aware of the potential threats from malicious attacks or software malfunctions that can compromise the functionality of a computer and/or the data residing on it. But experts say medical devices with the ability to com-