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TCV valve-in-valve considerations, accelerated wear testing, and making the most of your pulse duplicator - all in this issue of ViVitro Labs' VNews



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A New Online Community for

In the News

ATLANTA, July 7, 2011 /PRNewswire/ --CryoLife, Inc. (NYSE: CRY), a leading tissue processing and medical device Company focused on cardiac and vascular surgery, announced today a \$3.5 million equity investment in ValveXchange® Inc. http://www.devicespace.com/news_story.aspx?StoryID=226258&full=1

28 Jun 2011 Four Clinical Trials Document The On-X Heart Valve's Exceptional Clinical Performance

On-X(r) Life Technologies, Inc. (On-X LTI) announced today that four clinical trial reports, documenting the On-X(r) Prosthetic Heart Valve's extraordinary performance, will be presented at the upcoming meeting of the Society for Heart Valve Disease in Barcelona, Spain being held June 25-28, 2011. The reports will include interim clinical results from the Prospective Randomized On-X Anticoagulation Clinical Trial (PROACT)...<http://www.medicalnewstoday.com/releases/229836.php>

Jun 28, 2011 Medtronic Inc. sued Edwards Lifesciences Corp. in

Community for Cardiovascular Device Professionals

Ask questions, offer answers, and discuss the latest trends in testing heart valves, LVADs, stents, and other cardiovascular devices. Guess less, do more at:

Cardiovascular
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Cardiovascular Device Testing Tips and Tricks

Tip: ViViTest pulse duplicator software offers you a wealth of information but if you are hassled by seeing all the waveforms during analysis, click off the

two U.S. lawsuits accusing the company of infringing patents on a heart valve system. <http://www.bloomberg.com/news/2011-06-28/medtronic-accuses-edwards-of-infringing-heart-valve-patents.html>

Tue, 7 Jun, 2011 The FDA committee of experts is "scheduled to review the company's Premarket Approval (PMA) application for its Edwards SAPIEN transcatheter heart valve on July 20, 2011," Edwards Life Sciences said in a statement. <http://ca.news.yahoo.com/fda-panel-consider-transcatheter-heart-valve-190125761.html>

ST. PAUL, Minn., Jun 07, 2011 -- St. Jude Medical, Inc., a global medical device company, today announced the first human implant of its Portico(TM) transcatheter aortic heart valve. The procedure was performed by Dr. John Webb, director of cardiac catheterization and interventional cardiology at St. Paul's Hospital in Vancouver, British Columbia.

<http://www.pconline.com/News/Press-releases/St.-Jude-Medical-Announces-First-Implant-of-Portico-Transcatheter-Heart-Valve>

Trifecta valve was designed to house a catheter-based valve, such that a replacement valve could be inserted using a less-invasive catheter as opposed to repeat open-heart surgery, according to Indiana U. Health

Cardiovascular http://www.heart.org/HEARTORG/Affiliate/Dr-Art-Coffey_UCM_428623_Article.jsp

SHANGHAI, CHINA, June 06, 2011 -- Edwards Lifesciences Corporation, the global leader in the science of heart valves and hemodynamic monitoring, today announced the successful first Chinese implants of the Edwards SAPIEN XT valve. <http://www.pconline.com/News/Press-releases/First-Edwards-Transcatheter-Valve-Replacement-Cases-Performed-in-China>

Hot Topic

ViVitro's General Manager, David Mester, discusses current topics in the cardiovascular device arena

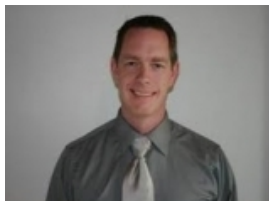
ones you don't want to see on the right side pane. These keys differ from the bottom on/off buttons by remembering your setting from collect to analysis.

Trick: Did you know that the ViVITro pulse duplicator can operate as a left or right heart model? Its configuration is optimized for left heart modeling but with a small change you can adapt it for right heart testing. Contact us if you would like to know how.

ISO/FDA FAQs

ISO5840

a. When measuring regurgitant volumes during pulsatile-flow testing per L.4.3.3, consider what is appropriate for a mitral valve. Does measuring regurgitant volumes at back pressures of 10,4 kPa, 15,6 kPa and 20,8 kPa (80 mm Hg, 120 mm Hg and 160 mm Hg) make sense?



Valve-in-Valve, "The Perfect Storm"

Possibly the most promising approach at the current state for transcatheter valves (TCV) is the valve-in-valve procedure. After decades of advancements in surgical tissue valves, patients are living longer. A perfect storm may be occurring as surgical tissue valves, typically implanted in a 60+ year-old patient are lasting up to and over 20 years. Now, these elderly patients in need of a second valve replacement could have the option of a TCV. In many cases, they will not be surgical candidates, but for those who are, should TCV be an option?

Now that TCV technology seems to be making significant progress, can its focus be on the best proving ground for this technology? We know it can be implanted successfully, but the most challenging aspects are determining device and procedural success in native sites deployments and through clinical results. It's an exhausting amount of effort to simulate in-vitro all the possibilities of native site deployments. The out-of-round conditions alone can create dozens of possible scenarios that need to be assessed. Clinical studies are equally difficult to filter for success, due to the frailty of eligible candidates and their multiple comorbidities.

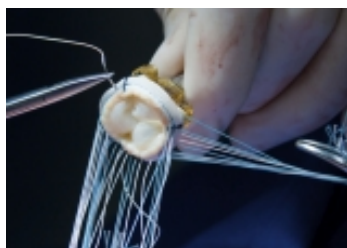
Recent studies have shown that a valve-in-valve procedure may be the best treatment for high-risk patients with failing bioprosthetics. In fact, the outcomes showed "trivial" valvular or intervalvular regurgitation, but is this really surprising? Those of us who have assessed TCVs know what a challenge the native environment is compared to the platform a previously implanted bioprosthetic provides. As TCVs become better known to the public, it's inevitable that demand will increase with healthier patients wanting a less torturous option.

Manufacturers may want to focus on demonstrating safety and efficacy of a valve-in-valve procedure since it can fill a growing need

b. Status Report - 5840
Part 3: Heart valve substitutes implanted by minimally invasive techniques. ISO reports that it is currently at stage 40.20 DIS; ballot initiated. The expected timeframe of this stage is 5 months.

FDA

The FDA recognizes the ISO 5840 standard but differs in some very specific ways. For example, the FDA recommends that for Valve Durability Testing the back pressure should be between 125 and 150 mmHg. Consider this when you are constructing your AWT protocol to meet the ISO 5840 standard.



Publications of Interest

Structural analysis of the natural aortic valve

efficacy of a valve-in-valve procedure since it can fill a growing need and be administered to healthier patients as a real option. The In-vitro testing is more straightforward; similar to proving a surgical tissue valve. Fewer unknowns would open the door to a larger patient population and clinical outcomes that give better indications of this new technology's long-term potential. A relatively healthy patient with a failing bioprosthesis, who understands the torturous nature of open heart surgery, will want a choice.

1. Webb J, Wood D, Y Jian, et al. Transcatheter valve-in-valve implantation for failed bioprosthesis heart valves. *Circulation* 2010; DOI:10.1161/CIRCULATIONAHA.109.924613. Available at: <http://circ.ahajournals.org>.

2. Edwards Valve Study May Spur Patient Demand Doctors Aren't Ready to Meet, By Michelle Fay Cortez - Apr 4, 2011 1:15 PM PT, <http://www.bloomberg.com/news/2011-04-04/edwards-valve-study-may-spur-patient-demand-doctors-aren-t-ready-to-meet.html>.

Satya's Corner

ViVITRO's Director of Laboratory Services, Satya Karri, offers his opinion on current issues in cardiovascular device testing



When is Accelerated Wear Testing Too Accelerated?

Achieving confidence in the accelerated wear testing (AWT) is often more complicated than expected. In this new age of transcatheter valve technology, materials and designs are making AWT more complicated than ever. The durability or fatigue of a heart valve is vital to demonstrating safety as well as demonstrating long-term viability. We must take into account several factors, justification for the accelerated rate, false-positive results, results skewed by testing artifacts and how to accommodate large and novel valve designs. All these factors should cause us to revisit the basics or think outside the box.

in dynamics: from unpressurized to physiologically loaded.

[J Biomech. 2010 Jul 20;43\(10\):1916-22. Epub 2010 Apr 7.](#)

[Labrosse MR, Lobo K, Beller CJ. ...](#)

Hydrodynamic Evaluation of a Minimally Invasive Heart Valve in an Isolated Aortic Root Using a Modified In Vitro Model: [Qiang](#)

[Wang, Fernando Jaramillo, Yasushi Kato, Leonard Pinchuk, and Richard T.](#)

[Schoepfoerster; J. Med. Devices 3, 011002 \(2009\) ...](#)



Your

source for information and emerging trends related to heart valve, stent, LVADs, and other cardiovascular device development and testing. We welcome your comments and invite you to contribute

For cycle rate justification, potential for false-positives and testing artifacts we must consider the materials that we are testing. The response of viscoelastic -materials is dependent upon the time history of the loading. While there is a desire to accelerate a test, simply increasing the test frequency without consideration of the intrinsic material time scale may induce behavior that is not representative of in-vivo conditions. Accelerated testing of viscoelastic materials will accentuate the elastic response and decrease the viscous behavior of certain materials.

Tissue used to make heart valves is especially prone to rate dependent viscoelastic behavior. Sufficient time is needed to allow tissue fibers to return to their natural state between cycles or a valve will be subjected to a higher baseline preload. Moreover if the tissue is not subjected to a proper duration of strain-rate stretching it may not be subjected to equivalent in-vivo loading or creep may not be detected.

An overestimation or underestimation of your device durability is almost certain without proper consideration of materials or designs. Uncertain early failures are a frustration to any product development team and false-positives could mean clinical failure. Take the time to evaluate your materials, understand your tissue properties, and choose the proper test conditions to ensure accurate results. If you are testing a transcatheter valve, you cannot rely solely on a control because that valve will not be a predicate device. We'll leave the implications of choosing a control valve for another time. Short of quasi real-time testing (RWT) you have to do your homework.

Satyaprakesh Karri, Ph D, Biomedical Engineer, Director of Laboratory Services, ViVITRO Labs

**items for inclusion in
future issues of VNews.**

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