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**NEWS RELEASE**

June/July 2009



**From the Desk of Ivan Vesely, Ph.D.**

Greetings from Berlin

This newsletter comes by way of Berlin, Germany, where ValveXchange attended the 5th biennial meeting of the Society for Heart Valve Disease. SHVD is the largest international society focused on the many issues of valve disease and its treatment by way of surgical techniques, therapeutic devices and basic science. This year's meeting was superbly organized by Dr. Frederick Mohr of Leipzig and billed itself as the first joint meeting between the SHVD, run primarily by surgeons and scientists, and the Heart Valve Society of America, which has a strong cardiology focus. VXi was proud to act as co-sponsor of the meeting and to show its latest data and valve exchange tools at the exhibits.

June witnessed continued progress in the development of the valve exchange procedure and evolution of our tool set. We worked with more advanced fibrotic overgrowth in the hyperfibrotic sheep model, which was far more severe than I have ever seen in human explants. Still we experienced no problems with leaflet set removal or replacement, and no complications resulting from fibrotic overgrowth.

In early June, we submitted an NIH grant application for funding a pediatric valve product. The exchangeable valve is particularly useful for young patients who face repeated open heart surgery to replace failed tissue valves. For this application, we have partnered with Dr. David Campbell, a noted pediatric surgeon in Denver.

Our Medical Advisory Board continues to expand with noted cardiac surgeons. We are most excited to announce that Dr. W. Randolph (Randy) Chitwood has agreed to join our MAB. Dr. Chitwood is a world leader in robotic valve procedures and will contribute tremendously to the evolution of our minimally invasive valve implantation and exchange program.

For those new to this Newsletter, ValveXchange is a start-up company based in Colorado. We call ourselves "The Lifetime Tissue Valve Company" and are developing the first-of-its-kind "serviceable" bioprosthetic valve. By offering periodic, minimally invasive exchange of the worn-out leaflet set, young and physically active patients can avoid the use of a mechanical valve and the associated Coumadin® anticoagulation therapy. By adhering to the time-proven design tenets of conventional bovine pericardial valves, the ValveXchange system offers the best combination of least-invasive reoperation and greatest longevity and durability.

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## **Press Release**

### **Randy Chitwood joins VXi Medical Advisory Board**

**June, 2009. Denver** - ValveXchange Inc. is pleased to announce that Walter Randolph (Randy) Chitwood, Jr., M.D., FACS, FRCS has joined the VXi Medical Advisory Board. Dr. Chitwood is a leading international pioneer in minimally invasive and robotic heart surgery. Dr. Chitwood is the Eddie and Jo Allison Smith Distinguished Professor of Surgery at East Carolina University, Founder and Director of the East Carolina Heart Institute and Senior Associate Vice Chancellor of Health Sciences. He was born in Virginia and educated at Hampden-Sydney College, the University of Virginia and Duke University. Immediately after finishing his residency at Duke, he joined the faculty as a full professor and Chief of the newly formed Cardiac Surgery Program at East Carolina University. The Robotic Surgical Center at East Carolina University has trained over 350 surgeons worldwide and Dr. Chitwood has personally performed the first robotic heart operations in ten countries. Currently, Dr. Chitwood's research activities relate to myocardial preservation, surgical simulation, and endoscopic and robotic cardiac surgery. He was the principal investigator of the FDA robotic mitral valve trials that led to approval for this use in the United States.



Dr. Chitwood is a member of 25 professional societies and has been on many of the most important committees in each of these societies. He is the immediate Past President of the Society of Thoracic Surgeons, the largest cardiothoracic surgery professional organization in the world. He is Past-President and a founding member of the International Society of Minimally Invasive Cardiac Surgery as well as past-president of the Society for Heart Valve Disease, the North Carolina Chapter of the American Heart Association, and past Vice President of the Southern Thoracic Surgical Association.

He has served on the editorial boards of the Annals of Thoracic Surgery, the Journal of Cardiac Surgery, the Journal of Heart Valve Disease, the Asian Annals of Cardiovascular and Thoracic Surgery, CTS Net, the Heart Surgery Forum, Chest, the American Heart Journal, and the Journal of Robotic Surgery. Currently, he is on the editorial board of the Journal of

Cardiothoracic and Vascular Surgery. He reviews manuscripts for Circulation, the New England Journal of Medicine, and the Journal of the American College of Cardiology. In the past, he has authored over 175 peer reviewed scientific and clinical articles, as well as many book chapters and several monographs. He is in the process of writing a book titled the Atlas of Robotic Cardiothoracic Surgery.

In 2003, he was elected to Fellowship in the prestigious Royal College of Surgeons of England, an honor to which few Americans are selected. In 2004, he received the O. Max Gardner Award from the University of North Carolina Board of Governors that recognizes a faculty member of the 16 system institutions, who during the scholastic year, made the greatest contribution to the "welfare of the human race." It is the only statewide honor given to faculty members by the UNC Board of Governors. In 2005 he received the national Mended Hearts - Harken Award, which recognizes excellence in the field of cardiovascular medicine. In the same year he received the National Phi Kappa Phi Scholar Award for outstanding teaching, research, practice, and service. In May 2009, he received the Ellis Island Medal of Honor.

Dr. Chitwood is a busy, active cardiac surgeon and has special expertise in complex valvular surgery, including mitral repair, as well as aortic valve and cardiac rhythm surgery. He continually writes and lectures internationally on innovative techniques in minimally invasive and robotic cardiac surgery. He has given over 60 visiting professor and invited lectures. Today, he is the world's leader in robotic mitral valve surgery.

### **ValveXchange exhibits at the Society of Heart Valve Disease Conference in Berlin**

**July 1, 2009. Denver** - ValveXchange Inc. was a co-sponsor and exhibitor at the 5th biennial meeting of the Society of Heart Valve Disease in Berlin, Germany. Our presence at this meeting was especially notable because of the participation of our Special Advisor, Dr. Gerard Guiraudon. Dr. Guiraudon is the inventor of the [Guiraudon Universal Cardiac Introducer \(GUCI\)](#), a technology that VXi has recently licensed from Dr. Guiraudon. Dr. Guiraudon's presence at the booth was an immediate magnet for countless physicians that know him for his many decades of work in beating heart cardiac surgery. In speaking to the conference delegates, Dr. Guiraudon explained the unique advantages of the GUCI for the transapical insertion and exchange of the VXi valve, in comparison to conventional rigid introducers and transcatheter valves.



## Other News

### Technology Update

In mid June, we continued our valve exchange experiments in the hyperfibrotic juvenile sheep model. In previous studies we exchanged our valve leaflet sets after two months. We confirmed that in two months fibrotic tissue overgrowth (pannus tissue) in the sheep model is approximately the same as in human explants after more than 10 years. In June we began looking at 3-month explants. Not surprisingly, the amount of fibrotic overgrowth observed was considerable, much more than would typically be present in the human condition. As in all previous studies, we were able to separate the leaflet set from the docking station. This is an important and exciting development that continues to build confidence in our approach.



Our 2nd generation tool set continues to show improved functionality. We are now using a single handle for all functions of the exchange tool set. This enables us to have more than adequate space inside the relatively narrow chest cavity of the sheep model. Improvements for the next iteration will involve better retraction of the aortotomy so that the new leaflet set slides in with minimal manipulation. What was also very gratifying was that after 3 months in the sheep model, the leaflets were completely pliable and apparently free from calcification. There was also no sign of leaflet prolapse or any other geometrical abnormality. We are very happy to see that so far our valve appears to work well, as designed, "right out of the box." We began our valve development program in July of last year, finished the valve by December and started to implant the valves in January of this year. No revisions to the valve design have been necessary. We have been very pleased with the valve's performance to date.

## Reality Check

### Clinical Trials vs. CLINICAL TRIALS!

When most people hear that a prosthetic heart valve requires a Clinical Trial, visions of arduous and costly clinical studies come to mind, along with concerns about unpredictable FDA approval timing. Some companies with Class III medical devices are faced with long, expensive and difficult clinical trials, and have been known run out of money and go out of business before approval is achieved. [Myocor](#) is one example. In most cases such

events can be avoided by careful planning of technology development and regulatory approval pathway. Clinical trials do not need to be solely the domain of the established valve companies like Medtronic and Edwards. A great recent example of a successful clinical study has been that of CoreValve and its approval to market the valve in Europe. Admittedly, CE Mark approval and a US FDA PMA can diverge greatly when new technologies with previously untested characteristics are introduced. However, for conventional heart valves, European clinical requirements have been substantially harmonized with those of the U.S. FDA. Let me review the three principal approaches to a Clinical Trial pertaining to heart valves - (i) CE Mark approval, (ii) PMA study with control arm, and (iii) PMA study without control arm using established Objective Performance Criteria (OPCs).

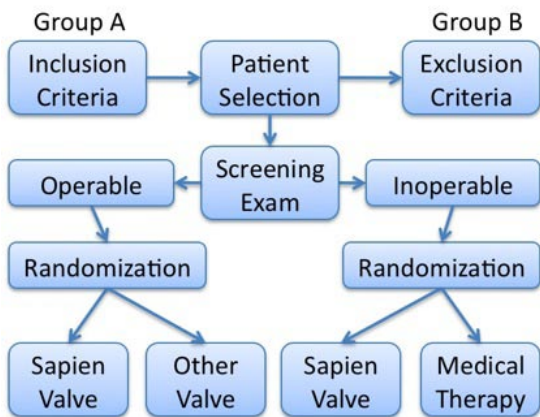
### **CE Mark**

Historically, CE Mark approval has been based on a quality manufacturing process with additional requirements for having acceptable outcomes in a clinical study. In recent years, CE Mark approval for conventional heart valve technologies has been substantially harmonized with the FDA guidelines into the standard ISO 5840. For conventional prosthetic heart valves, an American clinical trial is thus very similar to that of a European clinical trial regarding the type of tests that need to be done. Further, if properly coordinated, data gained from the European clinical trials can be applied to the US PMA application. When a new heart valve design moves significantly away from "conventional" approaches, however, PMA may require a clinical study with a control arm.

### **PMA with Control Arm**

This type of clinical trial is the most difficult one for a heart valve company. Typically, it requires that the candidate valve meets or exceeds the performance of a "control" valve or some alternative therapy that is the current gold standard. It is not only expensive, but the outcomes are typically unclear until the study is over. Depending on the control therapy, the number of patients required for approval may be small or very large, depending on the statistical power needed to support the manufacturer's claims. If the difference between the candidate valve and the control therapy is expected to be small, then a large patient population may be needed to achieve sufficient statistical power. If the difference is expected to be large, then a smaller patient population may be used. Lets use the Edwards [PARTNER](#) trial as an example of how complex such trials can get. This is a trial to test the clinical performance of the Edwards Sapien(R) transcatheter valve, a Percutaneously Implantable Valve (PIV).

Data obtained from [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) reports that the trial will last from April 2007 to September of 2014 - that is 7 years, 5 months, and will involve 1040 patients. Assuming a cost of \$50K per patient for the clinical trial, the costs will exceed \$50 million. This is more than double the size and cost of clinical trials for more conventional prosthetic valves. Besides the number



of patients enrolled, the PARTNER trial is also more complex than conventional valve trials in terms of outcomes. First of all, it is a multi-armed trial with randomization and with primary and secondary end-points.

As can be seen from the diagram above, the process begins by selecting the patients based on inclusion and exclusion criteria. Example inclusion criteria are co-morbidities that will give a predicted operative mortality greater than 15%, mean valve gradient greater than 40 mmHg, NYHA class II or greater, etc. AND a surgeon and two cardiologists agreeing that operating on the patient would lead to a probability of death or serious, irreversible morbidity greater than 50%. Exclusion criteria include bicuspid aortic valve, bleeding or coagulation disorders, MI less than a month prior to procedure, a drug eluting stent inserted less than 6 months prior to procedure, tortuous femoral arteries, and several other factors. The published specifications list 6 inclusion criteria and 22 exclusion criteria, most of which involve various co-morbidities. Indeed, it is probably because the patients need to be inoperable, yet not have too many co-morbidities, that patient enrollment will take almost 7 years to complete. Interestingly, the majority of the primary and secondary end-points are to be obtained only at the 30-day, 6-month and 1-year time points. Only freedom from death will be measured over the duration of the entire trial, and that is only in the inoperable (B) group. In the operable (A) group, freedom from death will be measured only over the first year of the study. Freedom from death is the only primary end-point to be measured - if the primary endpoint is not met the study would presumably be considered a failure by the FDA, and Premarket Approval would not be granted. What is to be determined, therefore, is whether more or less patients die over the first year after having a transcatheter or a surgical valve implanted, and whether more or less patients die over the 7-year duration of the study while being treated with medical therapy or a transcatheter valve. Secondary end-points involve measures such as improvements in NYHA class, length of hospital stay, evidence of valve dysfunction (A group only), improvement in quality of life, and more. These are used primarily to broaden the labeling claims (indications for use) of the device, once it is approved for sale.

Many of the end-points will be easy to meet, while others will not. Since the prognosis for patients with aortic valve stenosis is not good in the absence of a prosthetic valve, it should be relatively easy to demonstrate that the

implantation of a transcatheter valve is better than not using any prosthetic valve and managing the patient with drugs. Patients who do not receive a prosthetic valve have a [one year mortality of 50%](#) (see actuarial plot below). On the other hand, demonstrating that a transcatheter valve is better than open-heart surgery, in terms of patient death over 1 year, will be more difficult. The reason for this is that the long list of exclusion criteria required for group A (operable patient) makes this group actually "quite operable."

Surgeons routinely operate on octogenarians with double valve disease and other co-morbidities with very good outcomes. For example, recent reports on outcomes after valvular surgery in octogenarians indicate an [operative mortality in the 8% range](#), although it can be [as low as 4.6%](#) and a [30-day mortality of 9%](#). Once the patient survives the procedure, the prognosis for the short term is very good. For example, the one-year survival following aortic valve replacement for patients [older than 80 is 82%](#). Even in cases of severe aortic

stenosis and concomitant ventricular dysfunction, operative mortality can be as [low as 8%](#). Conversely, inclusion into the PARTNER trial, requires no significant mitral valve disease, coronary disease, blood coagulation problems, renal insufficiency or severe ventricular dysfunction. Even with such strict selection criteria, the one-year survival for patients that have enrolled in the early feasibility study for the PARTNER trial was about 85% for the transfemoral delivery of the Sapien valve (see figure above) and [less than 60% for transapical delivery](#). The same manuscript, however, reports that those patients who underwent conventional open surgery had [zero-operative mortality and near 100% one-year survival](#) (see figure above).

One can argue, of course, that the patient populations were different and that that lead to the diminished survival of the transcatheter valve patients, or that early deaths are part of the learning curve. Certainly, procedural mortality during transcatheter aortic valve implant (TAVI) had dropped to near zero in [the hands of some experts. For example, Dr. Webb's group reports 1.2% procedural mortality](#) in the most recent studies with a 30-day mortality of 8%. However, late mortality continues to accumulate. At one year, Dr. Webb's group still had a mortality of 26%. By comparison, Dr. Grossi's data from an apparently similar, high-risk group suggests that [a similar 27% mortality can be observed at 5 years following open-heart surgery](#), not the one-year time frame of transcatheter valves. The operative mortality in this surgical group, however, was 7.8%, greater than the 1.2% procedural mortality of Dr. Webb.

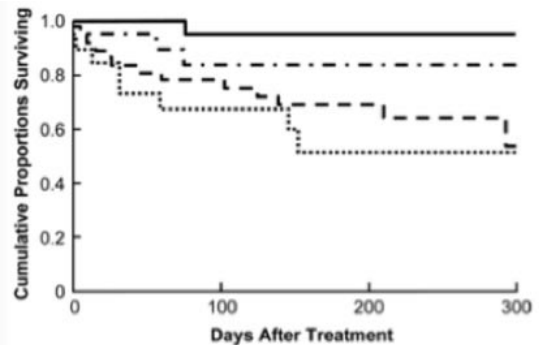
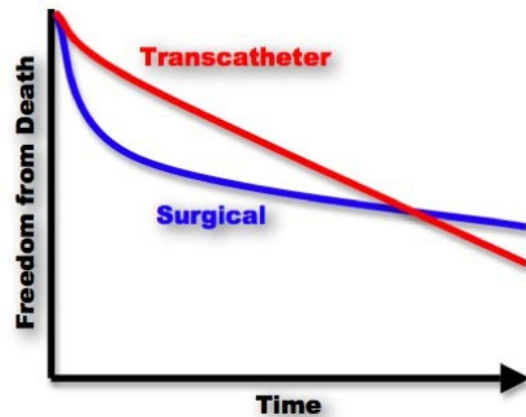


Fig 2. Kaplan-Meier survival for patients referred to Cleveland Clinic for possible percutaneous trans-left ventricular apex aortic valve insertion or transfemoral aortic valve insertion. (AVR = conventional open aortic valve replacement; — = surgical AVR; - - - = percutaneous AVR; · · · = no intervention; - · - = aortic valvuloplasty.)

The PARTNER trial will thus need to demonstrate the one-year mortality tradeoff between a surgical valve and a transcatheter valve. The expectation is that the procedural mortality will be near zero for the transcatheter valve and greater for the surgical valve. This is because the patients randomized between open-heart surgery and TAVI will be those in the high surgical risk category. This likelihood is supported by the reported procedural mortality of Dr. [Webb](#) (1.2%) and Dr. [Grossi](#) (7.8%). Over the ensuing one-year period, however, I expect that the surgical patients will have much lower cumulative mortality whereas the transcatheter valve patients will continue to die, as suggested by the actuarial curves of [Svensson](#) (see Kaplan Meier curve from Svensson - labelled as Fig. 2 above) and other more recent publications. The mechanism by which patients treated with transcatheter valves continue to die months after the procedure is unknown. The real test of the PARTNER trial therefore will be whether the actuarial curves cross before or after the one-year period (see hypothetical curve right). That date of that crossing point will thus determine the success or failure of the PARTNER trial. Although preliminary data may come sooner, we will all know for sure some time after September 2014, the expected completion date of the PARTNER trial.



#### **PMA without Control Arm**

In contrast to the Sapien valve and its PARTNER trial, the majority of conventional prosthetic valves have undergone a far simpler clinical trial protocol - one without a control arm. Because bioprosthetic valves have been around for over 4 decades, they have a remarkably long clinical history. As far back as 1994, the FDA has required that Premarket Approval will be granted only if candidate prosthetic valves demonstrate that their clinical performance is no worse than that of other devices that have already been approved.

### Objective Performance Criteria

	<b>Rigid</b>	<b>Flexible</b>
Thromboembolism	3.0	2.5
Valve thrombosis	0.8	0.2
All hemorrhage	3.5	1.4
Major hemorrhage	1.5	0.9
All paravalvular leak	1.2	1.2
Major paravalvular leak	0.6	0.6
Endocarditis	1.2	1.2

NOTE—Values are in % per valve-year.

More specifically, the FDA and ISO 5840 have established baseline "Objective Performance Criteria" (OPCs - see table above) and require that a candidate valve must have event rates (probability of a given complication, such as thromboembolism, hemorrhage, etc.) that are no worse than twice the prescribed OPC. Whether a candidate valve meets this requirement is determined by statistical tests that have sufficient power. If the expected event rates from the candidate valve are close to the minimum requirement, a greater sample size must be provided for the test to have sufficient statistical power. Because of the considerable statistical experience in the heart valve field, guidance is available on how to formulate an appropriate clinical trial. In the ISO 5840 document, it is stated that:

*"For events with an OPC of 1.2%, if the rate equals the OPC, a sample size of 800 valve years will furnish approximately 80% power for satisfying the formal statistical test ([see Grunkemeier, et al.](#)). If in the same circumstance the rate is 2/3 of the OPC, a sample size of 400 valve years will also furnish approximately 80 % power."*

The typical clinical trial for prosthetic valves is thus very well defined, and thus very predictable. A typical valve trial enrolls 300 or more patients and follows them for 2 or more years. Many new valves have travelled this path over the past 2 decades and most have succeeded in obtaining PMA. Recent examples of straight-forward clinical trials are (i) the CarboMedics/Mitroflow valve that completed [two years of data collection on 756 patients](#) in December of 2005 , and (ii) the St.Jude Biocor valve that has initiated a [2-year data collection process in 360 patients](#). This type of a trial is more typical of conventional bioprostheses, and the likely path that VXi will follow to get its initial valves to market.

#### **Sample Size and Time to Market**

As noted above, the sample size is tightly linked to the expected event rate by way of statistical power - the better the clinical outcomes, the smaller the required sample size to demonstrate that the event rates meet the requirements. The problem, however, is that with any truly new valve

design, one never knows how good the data will be. However, if one is developing a valve that is a revision to an already approved product, one can make use of historical data to better project performance during the clinical study. For example, clinical data for the Edwards PERIMOUNT<sup>(R)</sup> Model 6900 Mitral prosthesis available on the FDA web site shows that this valve exceeded the prescribed OPCs by a wide margin.

<b>Adverse Event</b>	<b>Reported by Edwards</b>	<b>Prescribed OPC</b>	<b>Edwards relative to OPC</b>
anticoagulation relate hemmorage	0.8	1.4	57%
Endocarditis	0.3	1.2	25%
Hemolysis	0.1		
Nonstructural dysfunction	0.3		
Perivalvular leak	0.5	1.2	42%
Structural valve deterioration	0.5		
Thromboembolism	0.7	2.5	28%
Thrombosis	0.0	0.2	0%

The table above shows that the Edwards valve was at least 57% better than the OPC, and in some cases had zero complication rates. This type of clinical performance would support approval through a clinical trial of only 400 valve-years per ISO 5840. Looking at the sample size of typical clinical trials from the [ClinicalTrials.gov](http://ClinicalTrials.gov) web site, however, we see that most have involved a far greater number of patients. This has happened for primarily two reasons: (i) uncertainty of what the final even rates will be, and (ii) the financial risk of not having a sufficient number of valve-years to obtain the required statistical power at the end of the clinical trial. Time to market with a new product can mean a difference of tens of millions of dollars of revenue. For a \$5000 valve with 2% market penetration of a 100,000 unit world market, the failure of a clinical trial and potential market launch delay of 3 years amounts to a loss of \$30 million in revenues. In many cases, that is more than the cost of the clinical trial itself. The most efficient, fastest clinical trial would be as short as 1.5 years, providing that one could enroll 300-400 patients over 6 months. Such a trial would yield the required 400 patient years over the enrollment and 1-year follow up period.

With this in mind, let's explore the options available for ValveXchange. Given that the VXi valve is based on the off-patent Edwards PERIMOUNT valve, it is likely that similar event rates could be achieved. Assume that the typical FDA review time for the PMA submission is 6 months. A well-planned, well-executed, clinical trial could bring the exchangeable valve to market in the US two years after the trial is initiated. It would be sold as a conventional surgical valve with surgical exchangeability. MIS off-pump exchangeability will be approved subsequently via PMA supplements with appropriate supporting data. ValveXchange expects to initiate its clinical trials during the first quarter of 2011. Accordingly, it expects to obtain PMA approval in 2013. That places ValveXchange market entry before the Edwards PARTNER trial is projected to end in September of 2014. Approval after completion of the PARTNER trial is expected to take until 2015, thus the VXi valve is expected to get to market 2 years ahead of the Sapien valve.

Through the above exercise, it is clear that following the time-proven design principles of cardiac valves is not only good for patient safety, but also the most timely, efficient and cost-effective regulatory approach.

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Sincerely,

Ivan Vesely, Ph.D.  
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ValveXchange Inc.  
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## Recent News Releases

**May 15, 2009. Denver** - ValveXchange Inc. is pleased to announce that it has signed an option agreement with Dr. Gerard Guiraudon to license his Universal Cardiac Introducer technology. Unlike rigid trocars, the Guiraudon Universal Cardiac Introducer (GUCI) is a flexible, collapsible system that facilitates intracardiac surgery and off-pump exchange of the VXi valve. [Read More.](#)

**March 18, 2009. San Francisco, CA** - Frost and Sullivan held their annual "Excellence in Medical Technologies & Life Sciences Awards" banquet on this date, honoring companies in the bioscience and medical device fields. ValveXchange Chairman and CEO, Larry Blankenship, was there to accept the award. [Read More.](#)

**March, 2009. Denver** - ValveXchange Inc. announced that Dr. Tirone E. David has joined the VXi Medical Advisory Board. Dr. David is recognized world-wide for his pioneering work in valve sparing surgery, his remarkable surgical skills and his commitment to teaching. [Read More.](#)

**March 30, 2009. Denver** - ValveXchange licensed its exchangeable valve technology patents from the Cleveland Clinic. The Clinic and ValveXchange have now entered into an arrangement whereby the Cleveland Clinic will in the future receive an equity position in ValveXchange, Inc. [Read More.](#)

**February, 2009. Denver** - ValveXchange Inc. announced that it is the recipient of the 2009 North American Frost & Sullivan Technology Innovation of the Year Award. According to Frost & Sullivan Research Analyst S.R. Priya, "The ValveXchange Heart Valve System represents a safe and less invasive alternative to conventional therapies.... Overall, the ValveXchange system provides the innate hemodynamic and non-thrombogenic benefits of tissue valves to patients of all ages, thus obviating the need for expensive and potentially problematic anti-coagulation therapies and major lifestyle modifications." concludes Priya.

**February, 2009. Denver** - ValveXchange Inc. announced that of Dr. Joseph Sabik, Chair of Cardiothoracic Surgery, The Cleveland Clinic Foundation, will serve as the Chair of the VXi Medical Advisory Board. [Read More.](#)

**January 30, 2009. Denver** - ValveXchange Inc. announced that it has begun animal testing of its proprietary exchangeable valve technology, working with the College of Veterinary Medicine at the Colorado State University, Fort Collins, CO, and with Experimental Surgical Services, University of Minnesota, Minneapolis, MN. Both Institutions are well-recognized for their expertise in animal surgery. [Read More.](#)



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