



# 2013 IEEE Medical Device Symposium

*"Medical Device Innovation in 21<sup>st</sup> Century"*

November 7, 2013

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Richardson, TX

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## Welcome Message

Riding on the success of first Medical Device Symposium in 2012, IEEE Engineering in Medicine and Biology Society Dallas Chapter (Dallas-EMBS) and The University of Texas at Dallas (UTD) are pleased to present the Second Annual IEEE Medical Device Symposium, in collaboration with The University of Texas at Arlington (UTA) and The University of Texas Southwestern Medical Center (UTSW). This symposium includes invited talks, a student poster session, sponsor exhibit showcase and dinner reception. Our distinguished speakers come from diverse background, including the medical device industry, academia, clinical practice, and public sectors. The event is open to public.

## Goals

- \* Transform North Texas to be a new biomedical technology hub in the nation
- \* Bring together experts and decision makers from R&D, manufacturing, clinical, regulatory agencies, and public policy to share perspectives, innovations, and cutting-edge technologies
- \* Showcase the regional research institutes and manufacturers in the medical device community
- \* Foster the next generation leaders, innovators, and engineers in biomedical field

## Organizing Committee

Zhanjun “James” Li, PhD, St Jude Medical, Symposium Chair  
Dinesh Bhatia, PhD, University of Texas at Dallas, Symposium Co-Chair  
Harry F. Tibbals, PhD, University of Texas at Arlington  
Allison Case, PhD, University of Texas at Dallas  
James Ooi, PhD candidate, University of Texas at Dallas  
Danieli Rodrigues, PhD, University of Texas at Dallas  
Greg Breiland, The Boeing Company  
Diane Rutherford, Ken Block Consulting  
John N Gaffke, PhD, Abbott Laboratories  
Daniel Plymire, PhD candidate, University of Texas Southwestern Medical Center

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## Program Agenda

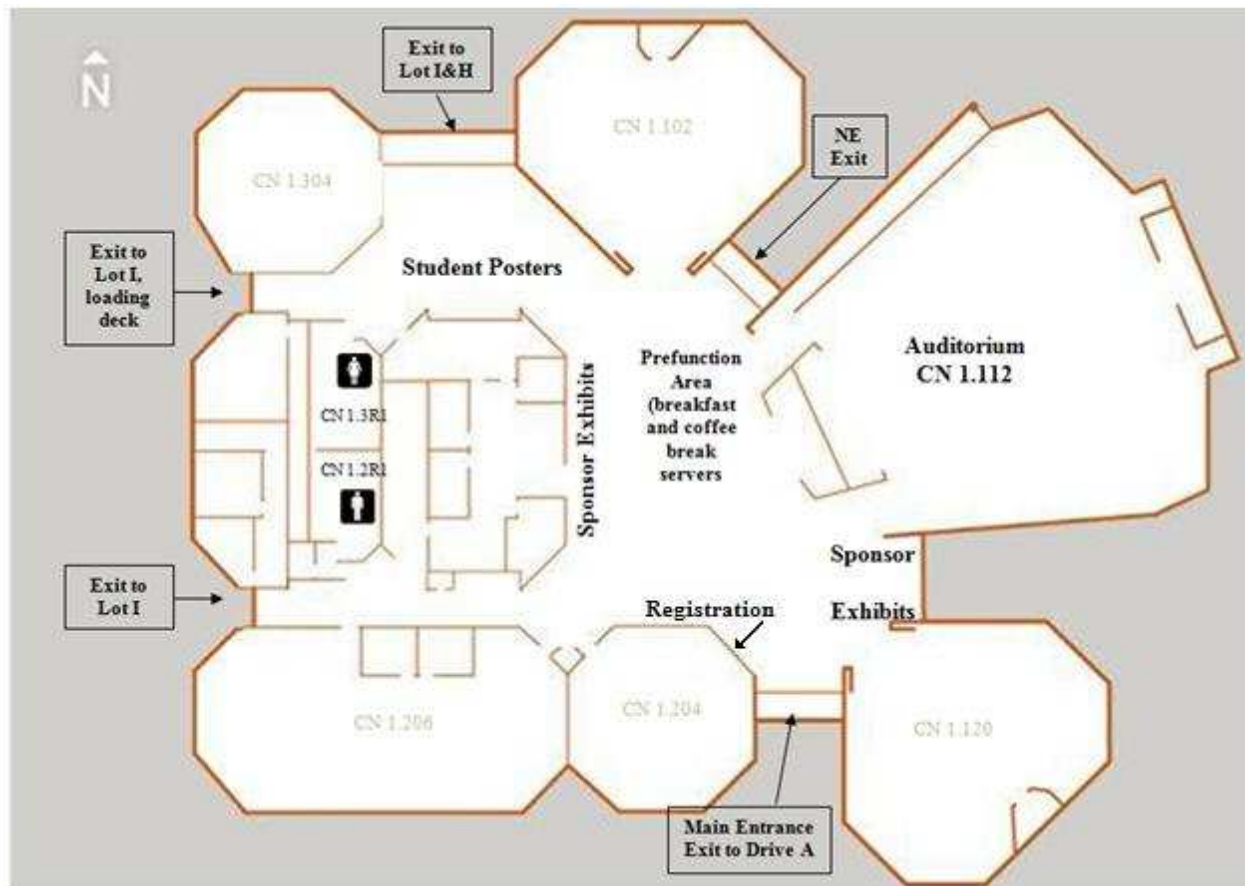
<b>7:45 - 8:45</b>	<b>Symposium Registration and Breakfast</b> <i>Prefunction area, Clark Conference Center (CN)</i>
<b>8:45 - 9:45</b>  	<b>Welcome and Introduction</b> <i>Auditorium CN1.112</i> <i>Moderator James Li, Symposium Chair</i> <b>Opening Remark</b> Mark W. Spong, PhD, Dean of Erik Jonsson School of Engineering & Computer Science, UTD <b>Keynote Address</b> <b>Medical Device Technology: A Case for Optimism</b> Dale Wahlstrom, President & CEO, LifeScience Alley and The BioBusiness Alliance of Minnesota
<b>9:45 - 10:45</b>	<b>Neuroengineering &amp; Neuromodulation</b> <i>Session Chair: Allison Case</i> <i>Auditorium CN1.112</i> <i>Spinal Cord Stimulation for Chronic Pain</i> Suzanne Elliott, Sr. Manager, Product surveillance, St Jude Medical <i>Directing Neural Plasticity to Treat Neurological Disorders</i> Michael Kilgard, PhD, Professor, School of Behavioral and Brain Sciences, UTD
<b>10:45 – 11:15</b>	<b>Sponsor Exhibit Showcase, Student Poster</b> <i>Session Chair: James Ooi</i> <i>Prefunction area, CN</i>
<b>11:15 – 12:15</b>	<b>Medical Imaging</b> <i>Session Chair: Harry Tibbals</i> <i>Auditorium CN1.112</i> <i>Imaging Physiology and Metabolism by MRI</i> Dean Sherry, PhD, Director of Advanced Imaging Research Center, Professor of Radiology, UTSW <i>Brain-Atlas-guided Volumetric Diffuse Optical Tomography to Study Human Cognitive Functions</i> Hanli Liu PhD, Professor, Bioengineering Department, UT Arlington
<b>12:30 - 1:20</b> 	<b>Keynote Luncheon</b> <i>Moderator: Dinesh Bhatia, Symposium Co-Chair</i> <i>Faculty Dining Hall</i> <b>Med-Tech Innovation: The TriVascular Case Study</b> Chris Chavez, President and CEO, Trivascular Inc.
<b>1:30 - 2:30</b>	<b>Regulatory, Investment &amp; Entrepreneurship</b> <i>Session Chair: Greg Breiland</i> <i>Auditorium CN1.112</i> <i>Lean and Efficient Medical Device Development</i> Will Rosellini, JD, MBA, Rosellini Scientific LLC, founding CEO, Microtransponder Inc. <i>FDA Regulations &amp; Entrepreneurship</i> Diane Rutherford, Submissions Manager, Ken Block Consulting
<b>2:30 – 3:00</b>	<b>Sponsor Exhibit Showcase, Student Poster</b> <i>Prefunction area, CN</i>
<b>3:00 – 5:00</b>	<b>Biomaterials and Biomechanics</b> <i>Session Chair: Danieli Rodrigues</i> <i>Auditorium CN1.112</i> <i>Progress in Machine Perfusion to Preserve Donor Hearts for Transplantation</i> Michael Jessen, MD, Professor and Chairman, Cardio Thoracic Surgery, UTSW <i>New Developments in Medical Fiber Technology</i> Robert C. Eberhart, PhD, Professor Emeritus, Department of Surgery, UTSW <i>Benefits of Engineering Simulation Tools for Medical Product Design and Regulatory Review</i> Marc Horner, PhD, ANSYS, Inc. <i>Modeling Different Locking Plate Construct Configurations for Large Segment Mid-shaft Humeral Fracture Fixation</i> Victor Kosmopoulos, PhD, Professor, University of North Texas, Health Science Center
<b>5:00 – 5:30</b>	<b>Student Poster (Judging Committee Review)</b> <i>Prefunction area, CN</i>
<b>6:00 – 8:00</b> 	<b>Symposium Reception and Award Banquet</b> <i>Moderator: James Li</i> <i>Faculty Dining Hall</i> <b>Keynote Address</b> <i>Investment Trends in Technology &amp; the Medical Device Industry in Texas</i> Bill Sproull, President and CEO, Metroplex Technology Business Council





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## Presentation Abstracts and Speaker Biographies

### Keynote Speakers



#### ***Medical Device Technology: A Case for Optimism***

Dale Wahlstrom

President & CEO, LifeScience Alley and The BioBusiness Alliance of Minnesota™  
Founding Executive Director, Medical Device Innovation Consortium (MDIC)

#### **Abstract**

The attendees to this presentation will learn how the globally recognized center for medical device technology in Minnesota came to be and how it is reinventing itself to address the rapidly changing market... and is achieving results that have implications for the global industry.

Dale will introduce the newly created Medical Device Innovation Consortium (MDIC). The MDIC is a formal partnership between the Medical Device companies and the FDA. The MDIC is a national organization intended to advance the state of the industry across the country. Attendees will also be introduced to the initiatives by FDA and MDIC to advance the application of Regulatory Science as a strategy to reduce the cost and time to market while improving the safety of medical devices: such as clinical trial innovation and reform, computational modeling and simulation, and patient preference in the medical device total-product-lifecycle (TPLC). The attendees will also learn how they can engage in that process with the FDA through involvement in the MDIC.

#### **Biography**

Dale retired from Medtronic in 2006 after 24 years. Most recently he served as V.P. of CRDM Venture Programs. Prior to this he served as V.P./G.M. of the CRDM Therapy Delivery business. Before Medtronic, he held different positions at Litton Microwave and Burroughs Corporation. Today he serves as the President and CEO for LifeScience Alley and The BioBusiness Alliance of Minnesota. LifeScience Alley is the largest state-based life sciences trade association in the United States and provides industry players with a powerful forum for engagement. The BioBusiness Alliance of Minnesota is an industry led nonprofit organization dedicated to the advancement of bioscience-based businesses. In 2011, in a partnership between LSA and the FDA, Dale led efforts to found the Medical Device Innovation Consortium. He currently serves as a Director on the Consortium's Board of Directors. Dale is currently a member of several board of directors, industrial advisory boards, and academic governance boards for different universities and companies. In 1988 he was a recipient of the Medtronic Star of Excellence Award, and in 1997 received the Wallin Leadership Award. In 2002 Dale was recognized as the outstanding graduate of the year by the engineering department of St. Cloud State University. In 2007 he was honored by Twin Cities Business Magazine and was the recipient of the Bioscience Success Story Award. In 2010 and 2011, Twin Cities Business Magazine selected Dale as one of 200 "Minnesotans You Should Know." In 2013 he was awarded the Engineering Manager of the Year Award by the American Society Of Engineering Managers. He currently has eleven patents in medical device technology.

## Keynote Speakers



### **Med-Tech Innovation: The TriVascular Case Study**

Christopher G. Chavez, *Chairman, CEO and President, TriVascular, Inc.*

#### **Abstract**

The presentation will summarize the fourteen year journey of TriVascular, Inc., a journey that began with the identification of an unmet clinical need and conception of a medical device technology. Today TriVascular offers to surgeons and patients an innovative and proprietary solution to a large and compelling clinical challenge - the minimally invasive treatment of complex abdominal aortic aneurysms. The presentation will provide a sober summary of challenges facing Med-Tech companies and what leaders must do to build a successful company in a very difficult economy and business environment. To succeed, leaders must think big and pursue a cause worthy of the significant time, effort and resources it will take to achieve success. Leaders must: compose a plan that will guide an organization through a decade of effort; pick a team that has the capability and tenacity to persevere and navigate beyond countless challenges; build an organizational culture where excellence can live, grow and achieve; and, above all, lead and inspire with leadership excellence. If you pick the right purpose and passionately pursue it with the right plan and people, your business will attract the needed funding. The successful completion of a challenging journey will be the reward.

#### **Biography**

Christopher G. Chavez was appointed Chairman, CEO, and President of TriVascular effective April 12, 2012. Chris joins TriVascular with over 30 years of leadership experience in the medical device industry. For the past six years, Chris served as President of the Neuromodulation Division (NMD) of St. Jude Medical. Chris joined St. Jude Medical through its acquisition of Advanced Neuromodulation Systems (ANS) in 2005. At ANS, Chris served as CEO, President and Director leading ANS/NMD through 14 years of profitable growth and innovation. Prior to ANS, Chris spent 17 years at Johnson & Johnson most recently as Vice President and General Manager of the Worldwide Infection Prevention Business. Chris has previously served as Chairman of the Medical Device Manufacturers Association, Chairman of the Dallas/Fort Worth Health Industry Council, and as a Board Member of Advanced Medical Optics, which was acquired by Abbott Laboratories in 2009. Chris received his MBA from the Harvard Business School and holds a bachelor's degree in accounting from New Mexico State University.

## Keynote Speakers



### Investment Trends in Technology & the Medical Device Industry in Texas

William C. Sproull, *President & CEO, Metroplex Technology Business Council, & the Richardson Chamber of Commerce. Past Chairman, Texas Emerging Technology Fund. Fellow Member and Vice-Chair of the Board of the International Economic Development Council. Member of the UT-Dallas Development Board and the Board of the Alliance for Higher Education.*

#### Abstract

Texas has seen a significant amount of investment, both in higher education and in private sector companies, in technology and the medical device fields. Opportunities exist for collaboration on many levels that will lead to further technology investment. Sproull will discuss investment recent trends and the opportunities to make Texas a global center for medical device development and investment.

#### Biography

Sproull is President and CEO of the Richardson Chamber of Commerce, Metroplex Technology Business Council and the Richardson Economic Development Partnership. This unique and complex set of organizations he runs has two separate Board of Directors and a City Council he supports. He has led the revitalization of Richardson's tech based economy through focus on diversification and technology start-ups. Sproull helped bring significant investment to UT-Dallas through "Project Emmitt", a \$3 billion Texas Instruments semiconductor factory project in 2003 that leveraged funding from the state to support the Jonsson School of Engineering & Computer Science. He also helped lead a statewide coalition that got legislation passed in 2005 to create the Texas Emerging Technology Fund, a half-billion investment fund, for which he served on the fund's board for 6 years, and as Chair in 2010-2011. Previously he held the senior economic development positions in Dallas, McKinney and in Kansas City, Missouri. Sproull is a graduate of Baylor University, where he received a BA degree with a double major in Economics and Political Science. Sproull is on the Boards of Directors of the International Economic Development Council and is currently Vice Chair, the University of Texas at Dallas Development Board and the Alliance for Higher Education. He is an inductee in the Tech Titans Hall of Fame.



## Technical Session Speakers

### Neuroengineering and Neuromodulation

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#### Spinal Cord Stimulation for Chronic Pain

Suzanne Elliott, BSN, RN, CNOR, *St. Jude Medical, President, North Texas Chapter of the Association of periOperative Registered Nurses*

**Abstract:** Chronic pain is a major health issue today; it is widely believed to represent a disease itself. It can not only be disabling, but also devastating to the people it affects. Effective management of chronic pain continues to challenge health care professionals. Spinal cord stimulation (SCS) is a valuable treatment strategy for this patient population. This presentation will provide an overview of pain as a major health issue in the United States. Pain management as a specialty will be discussed. The clinical applications, as well as the patient selection criteria for SCS will be discussed. The technical considerations of SCS therapy will also be presented.

**Biography:** Sue Elliott is the senior manager of product surveillance at St. Jude Medical. Prior to this role, she was the director of worldwide clinical education, a role that allowed her to collaborate with nurses and implant coordinators to set new standards for excellence in clinical support and patient education. She has been working with neurostimulators since the 1980s, when she was the director of clinical services for the Texas Back Institute in Plano, Texas. Later, she became a patient education consultant for Medtronic and the director of perioperative services at Doctors Hospital in Dallas before joining St. Jude Medical in 1998. A certified OR nurse, Sue has served multiple terms as president of the North Texas chapter of the Association of periOperative Registered Nurses and received its award for outstanding achievement in patient education. She is a graduate of Chamberlain College of Nursing in St. Louis, Missouri, where she earned her BSN degree.



#### Directing Neural Plasticity to Treat Neurological Disorders

Michael P. Kilgard, Ph.D., *Margaret Fonde Jonnson Professor, University of Texas at Dallas*

**Abstract:** All levels of the nervous system can change in response to new experiences or injury. Neural plasticity in response to new experiences provides the biological basis for all of our skills and memories. Pathological neural plasticity plays a major role in the genesis and maintenance of many neurological diseases. For example, the cascade of changes in neural activity after hearing loss can lead to debilitating chronic tinnitus. Reversal of aberrant plasticity is a promising approach to the treatment of tinnitus. We have developed a novel method to direct highly specific and long lasting neural plasticity. Brief bursts of vagus nerve stimulation (VNS) trigger release of neuromodulators that direct brain changes specific to associated neural activity patterns. Pairing VNS with tones is sufficient to powerfully shape responses in the central auditory system. We have demonstrated that this therapy can be therapeutic in an animal model of tinnitus and in human patients. We are now optimizing the clinical parameters and exploring the neural mechanisms through parallel studies in humans and preclinical studies in animals. I will briefly discuss our related research using VNS to direct targeted neural plasticity to treat other common conditions, including chronic pain, anxiety, and stroke.

**Biography:** Dr. Kilgard is the Margaret Fonde Jonnson Professor in the School of Behavioral and Brain Sciences at the University of Texas at Dallas. Dr. Kilgard holds a bachelor's degree in biochemistry and genetics from the University of California at Berkeley and a PhD in neuroscience from the University of California at San Francisco. His research is focused on understanding the mechanisms that regulate neural plasticity in order to develop clinical tools to treat neurological and psychiatric conditions using precisely targeted neural plasticity. Dr. Kilgard's laboratory uses behavioral training, environmental enrichment, drug therapy, deep

brain stimulation and peripheral nerve stimulation methods to enhance neural plasticity. The lab has recently developed treatments for tinnitus and stroke that employ brief bursts of vagus nerve stimulation paired with sound or movements to direct therapeutic plasticity. These treatments are highly effective in animal models and are now being tested in tinnitus and stroke patients.

## Medical Imaging



### Imaging Physiology and Metabolism by MRI

A. Dean Sherry, Ph.D., *Professor of Radiology, Director, Advanced Imaging Research Center, UT Southwestern Medical Center, Professor of Chemistry, UT Dallas*

**Abstract:** It is often stated that magnetic resonance is too insensitive for molecular imaging because sensitivity comparisons with other imaging modalities, especially optical and nuclear, leave MR far short. Nevertheless, MR has many advantages over other imaging modalities including superb anatomical resolution, lack of ionizing radiation, and deep tissue penetration so the quest to develop methods to make MR more competitive in the world of molecular imaging continues. Given that water is the major component of most MR images, efficient transfer of tagged spins from specific pools of molecules to water is key to using the water proton signal as an efficient readout of metabolism and physiology. Although Gd<sup>3+</sup>-based contrast agents have been widely used as non-specific extracellular agents for over 25 years, the rate of water exchange in all clinically approved agents is too slow for many molecular imaging applications. This is an especially important parameter to consider in the design of new Gd<sup>3+</sup> agents as responsive MR reporters. Paramagnetic lanthanide complexes that act as chemical exchange saturation transfer agents (PARACEST) have the opposite requirement. Here, the goal is to slow water exchange rates so that saturated spins can be efficiently transferred to water for MR readout. The chemistry of these novel reporters and their limitations for use in vivo to image tissue pH, redox, ROS and hypoxic tissues will be discussed. Other MR techniques, including imaging of diamagnetic CEST probes and hyperpolarized molecules also offer considerable potential for providing new insights into tissue metabolism and energetics. These newer technologies all contribute toward making MR more valuable as an effective tool for molecular imaging.

**Biography:** A. Dean Sherry, PhD, is Director of the Advanced Imaging Research Center at the University of Texas Southwestern Medical Center, Professor of Chemistry at UT Dallas, and Professor of Radiology at UT Southwestern Medical Center. He also holds the Cecil & Ida Green Distinguished Chair in Systems Biology at UT Dallas. Dr. Sherry has been recognized for his research in two major areas: the development of <sup>13</sup>C NMR tracers of metabolism in cells, animals and humans and in developing novel MRI agents that respond to physiology or metabolism including Gd<sup>3+</sup>-based agents, PARACEST agents and hyperpolarized agents. He has a long-standing interest in diabetes and other metabolic diseases. He currently serves on the Scientific Advisory Boards of the Molecular Imaging Program at the National Cancer Institute, the Ontario Institute for Cancer Research Institute and serves as Associate Editor of Contrast Media & Molecular Imaging and Deputy Editor for Magnetic Resonance in Medicine. He has won numerous awards including the 2013 Gold Medal Award from the World Molecular Imaging Society. He has published 390 scientific articles and 32 patents, and has mentored more than 100 graduate students & postdoctoral trainees. Dr. Sherry has founded two companies in Dallas, Macrocyclics, Inc. and Visual Metabolism, LLC.



### **Brain Atlas-guided Volumetric Diffuse Optical Tomography to Study Human Cognitive Functions**

Hanli Liu, Ph.D, *Professor of Bio-engineering, Department of Bio-engineering, Member of the UTA Academy of Distinguished Scholars, University of Texas at Arlington*

**Abstract:** Functional near-infrared spectroscopy (fNIRS) is a non-invasive imaging technique which can measure cerebral oxygenation changes induced by brain activations. Diffuse optical tomography (DOT), a variant of fNIRS with multi-channel measurements, has demonstrated the ability to image human brain activities on to a 3D standard human brain atlas. The spatial resolution and image accuracy of volumetric DOT are significantly enhanced by combining brain atlas-guided DOT with voxel-based general linear model. Consequently, this emerging neuroimage tool provides researchers with unique opportunities to study human cognitive functions that may reveal particular cognitive deficits associated with specific neurological disorders. In this talk, we will report our recent development on implementing brain-atlas-based 3D DOT, followed by volume-rendered brain activation images of the prefrontal cortex (PFC) in response to neuropsychological tests and an established risk-decision making paradigm. The study with the latter paradigm allows us to conclude that the dorsal lateral prefrontal cortex acts differently between genders when they make risk decisions. While the results show a great promise of using 3D DOT to shed light on human cognitive functions, further image processing techniques are needed for improved image quality since PFC is very complex and involves many cognitive and affective functions.

**Biography:** Dr. Liu received her Ph.D. in Physics from Wake Forest University in 1994 and had her post-doctoral training in the area of tissue optics and near infrared spectroscopy in the University of Pennsylvania from 1992-1996. Since then, she has been a Professor of Bioengineering at the University of Texas at Arlington. Her research expertise includes minimally invasive and non-invasive optical spectroscopy and imaging of tissues. Such optical techniques can be utilized for cancer diagnosis and prognosis, for treatment guidance and monitoring, as well as for functional brain imaging. Dr. Liu has served a principal and co-principal investigator for research projects with total external funding of more than \$7 million. She has published more than 90 peer-reviewed journal papers and 120 conference abstracts or proceedings. Over years, Dr. Liu has been a recipient of numerous awards for her excellent research: for example, the Outstanding Young Scientist Award from the Houston Biomedical Engineering Society in 1998, the Outstanding Research Award from the University of Texas at Arlington in 2004, as well as College of Engineering Excellence in Research Award in 2008. She was inducted to the UT Arlington Academy of Distinguished Scholars in April 2013.

## Regulatory, Investment, and Entrepreneurship



### Lean and Efficient Medical Device Development

Will Rosellini, JD, MBA, *Rosellini Scientific, LLC*, founding CEO of Microtransponder Inc.

**Abstract:** At Rosellini Scientific, LLC we operate under the mantra that if we are going to fail, it is best to fail fast. We strive to document our Plan A, and then quickly identify and test risks to find out where that plan fails. Through an iterative process of project planning/revising, risk identification and experimentation, we are able to efficiently de-risk medical device development using limited resources. Our goal is to efficiently iterate the Build-Measure-Learn cycle to enhance our learning, thereby expediting and improving odds of successful device development. This process was originally made popular in the high technology industry by the Lean Startup movement. Our enthusiasm stems from the opportunity to apply these principles to medical device development. From a resource perspective, we also strive to be “lean” by securing non-dilutive grant funding and outsourcing all development. This talk will focus on implementing these strategies in the context of a medical device startup, but are applicable to larger organizations.

**Biography:** Will Rosellini serves as the Director of Commercialization at the Texas Biomedical Device Center. The Center is tasked with helping to translate new medical device ideas into clinical technologies by supporting early state technologies with regulatory, clinical, financial and intellectual property support. Will also serves on the Board of Marathon Patent Group, Rosellini Scientific and Microtransponder. Previously, he was the founding CEO of Lexington Technology Group and raised nearly \$16 million in private equity in 2012, exit upon entering a definitive merger agreement with Document Security Systems (“DSS”). As the founding CEO of Microtransponder, Will led a team that raised \$23M to develop neurostimulators. Will is an inventor on three patent applications and has testified to Congress on the importance of non-dilutive funding for inventors and researchers. Will holds a BA in Economics from the UD, an MS of Accounting and an MBA (UTD) an MS of Neuroscience (UTD), a Juris Doctorate from Hofstra Law, an MS of Computational Biology from Rutgers, and an MS of Regulatory Science from USC.



### FDA Regulations & Entrepreneurship

Diane Rutherford, BSME, MSMSE  
*Submissions Manager: Ken Block Consulting*

**Abstract:** Within FDA, the group in charge of enforcing medical device regulations has a mission statement that includes assuring patient and provider access to safe and effective medical devices. That same FDA mission also includes facilitating medical device innovation. However, many entrepreneurs have experiences with FDA that seem to stifle innovation. Many times, the difficulty in understanding and meeting FDA expectations will slow or stop progress toward bringing new inventions to market. This presentation will discuss how entrepreneurs can successfully navigate the regulatory pathway of the new product through FDA, how to properly prepare for FDA enforcement of the new company, and how these activities can build company value and investor interest.

**Biography:** Ms. Rutherford is a regulatory consultant with extensive experience in assisting companies in meeting FDA requirements for bringing new products to market, including those with unique imaging, neural stimulation, advanced biomaterials, and wireless technologies. Ms. Rutherford regularly works with both large multinational and small startup companies to develop the appropriate FDA strategy, satisfy all regulations, submit 510(k) applications, and achieve FDA market clearance for innovative technologies. Prior to joining Ken Block Consulting (KBC), Ms. Rutherford spent ten years in product development with a Dallas/Fort Worth medical device manufacturer where she was involved in the design and release to market of new products, as well as improvements to existing products.



She was heavily involved in activities including biocompatibility, sterilization, and labeling for these products. She was also involved in the quality system and regulatory aspects related to her projects for both US and EU markets. Ms. Rutherford has a BS in Mechanical Engineering (UTA) and a MS in Materials Science Engineering (UNT). Ken Block Consulting was established in 2007 and has grown to include fully staffed offices in Richardson, Texas and Tokyo, Japan, providing clients with a complete range of FDA consulting services, including quality system implementation and FDA inspection preparation.

## Biomaterials and Biomechanics Session



**Progress in Machine Perfusion to Preserve Donor Hearts for Transplantation**  
Michael E. Jessen, M.D., *Professor and Chairman, Department of Cardiovascular and Thoracic Surgery, UT Southwestern Medical Center*

**Abstract:** Heart transplantation remains the most effective treatment for the growing number of patients with end-stage heart failure, but the number of patients waiting for transplants far exceeds the number of available donor hearts. Part of the problem stems from our limited ability to protect the heart through the procurement and transport process. Currently, hearts procured for transplantation are arrested with a solution, removed and stored in an ice chest. A new technology (machine perfusion) is under development that provides a continuous flow of oxygenated solution to the myocardium throughout the storage and transport interval. Our laboratory, working with industry partners, has conducted a number of animal experiments that have assessed the ability of this technology to improve the metabolic status of the heart during storage, and alter functional recovery of the organ after re-implantation in the recipient animal. These studies have paved the way for additional research on utilizing hearts from high-risk donors that are currently not being considered. If successful, this could allow greater numbers of heart transplants to occur and may improve outcomes for patients receiving this lifesaving therapy. Clinical trials evaluating this technique are now in progress.

**Biography:** The son of a veterinarian, Michael Jessen, M.D., was born, raised, and educated in Canada, graduating from the University of Manitoba Medical School in 1981. Dr. Jessen left Canada in 1986 for fellowship training at Duke University Medical Center, where his research focused on myocardial metabolism and the biochemistry of myocardial protection. While there, he joined the Residency Program in Thoracic Surgery, training under the direction of Dr. David C. Sabiston, Jr., an early innovator in cardiac surgery. Dr. Jessen joined the faculty of UT Southwestern in 1990, after completing his thoracic surgery residency. He serves today as Professor and Chair of the Department of Cardiovascular and Thoracic Surgery and holds The Frank M. Ryburn, Jr. Distinguished Chair in Cardiothoracic Surgery and Transplantation. He combines his continued interest in research and cardiothoracic surgery with teaching, faculty recruitment, and the management of a growing clinical team that has performed more than 400 heart transplants. Dr. Jessen directs an active basic research laboratory that has received funding from the National Institutes of Health, the American Heart Association, and the Texas Advanced Technology Program. His work has yielded a broad array of publications in the literature.



### **New Developments in Medical Fiber Technology**

Robert C. Eberhart, Ph.D., *Professor Emeritus, Department of Surgery, UT Southwestern Medical Center*

**Abstract:** Medical polymeric fiber technology is undergoing significant development as applications emerge in targeted drug delivery, wound care, scaffolds for regenerative medicine and tissue engineering, surgical mesh and stent design, etc. Fabrication methods have advanced, particularly in the areas of electrospinning and phase inversion, making it possible to generate fibers over the nano- and micro range with useful features, including drug-inclusion in cores and cladding, and convenient agent incorporation via porous structures. This presentation will take a brief look at this technology and its potential.

**Biography:** Dr. Eberhart began his professional career at Pacific Presbyterian Hospital in the areas of patient monitoring and artificial organ development. A focus on clinical results and technology evaluation led to a career-long interest in biomaterials. Dr. Eberhart served for many years as chairman of the Joint UT Southwestern-UT Arlington Biomedical Engineering Program. He is delighted to see the strong emergence of bioengineering activity at universities, health care institutions and industrial firms in North Texas. Dr. Eberhart received an AB in applied physics from Harvard University and PhD in mechanical engineering from the University of California at Berkeley. He is a Fellow of Biomedical Engineering Society (BMES), American Institute for Medical and Biological Engineering (AIMBE), and American Society for Mechanical Engineering (ASME).



### **Benefits of Engineering Simulation Software Tools for Medical Product Development and Regulatory Review**

Marc Horner, PhD, ANSYS, Inc.

**Abstract:** Engineering simulation software refers to physics-based modeling software tools such as finite-element analysis, computational fluid dynamics, and high- and low-frequency finite element modelers. These tools simulate product and process performance in a virtual environment, permitting an organization to evaluate the risks and benefits of proposed product designs before a single prototype is produced. The FDA now recognizes the benefits of engineering simulation tools for product development and review, and is therefore supporting utilization through a number of initiatives. The presentation will begin with an overview of engineering simulation tools and how they are currently utilized in the healthcare industry. This will be followed by a summary of FDA's current position on computational modeling for the medical device development and review processes. The talk will close with a brief summary of a collaboration between FDA, ANSYS, and medical device industry, the goal of which is to develop an open repository of human body models in CAD format for implanted device safety evaluation.

**Biography:** Dr. Marc Horner is currently working as lead healthcare specialist at ANSYS Inc. Marc joined ANSYS after earning his Ph.D. in Chemical Engineering from Northwestern University in 2001. Marc began by providing support for biomedical clients, primarily in the areas of cardiovascular devices, drug delivery, packaging, microfluidics and orthopedics. During this time, Marc developed numerous modeling approaches that can be used to establish the efficacy and safety of medical devices. Marc now helps coordinate business and technology development for the health care sector in North America.



### **Modeling different locking plate construct configurations for large segment mid-diaphyseal humeral fracture fixation**

Victor Kosmopoulos, PhD, *Associate Professor, Department of Orthopaedic Surgery, University of North Texas Health Science Center*

**Abstract:** Single large fragment plate constructs are currently the norm for internal fixation of mid-diaphyseal humerus fractures. The smaller size of the humerus in some patients however, limiting the available length for fixation, makes using a large fragment plate difficult. In such cases, small fragment locking plate constructs may serve as an alternative. Using the finite element (FE) method, this study compares the mechanical performance of different locking plate construct configurations for the fixation of mid-diaphyseal humeral fractures. Idealized humeral shaft models were developed based on mean dimensions reported in the literature using magnetic resonance imaging. A large segment mid-diaphyseal fracture was simulated using a 1-cm fracture gap. Different fracture fixation constructs were tested in torsion and compression. Outcome measures include construct stiffness, and screw, plate, and bone stresses. The results support using two small fragment locking plates as an alternative in cases where crutch weight-bearing (compression) tolerance may be important and where anatomy limits the humerus bone segment available for large fragment plate fixation. The mechanical construct comparisons presented in this study provide worthwhile information for the orthopaedic surgeon considering different treatment options.

**Biography:** Victor Kosmopoulos is an Associate Professor in the Department of Orthopaedic Surgery at the University of North Texas (UNT) Health Science Center, Fort Worth, TX. Dr. Kosmopoulos received his BS (1998) and MS (2001) degrees in Mechanical Engineering from the University at Buffalo (Buffalo, NY) with a focus in experimental orthopaedic biomechanics. He then went on to receive his PhD (2003) degree, also in Mechanical Engineering, from the University of Vermont (Burlington, VT) focusing on computational tissue mechanics. He served as an Assistant Professor in Mechanical and Biomedical Engineering at the College of New Jersey (2003-2006), Ewing NJ, after which he joined the research staff at the Hôpital Orthopédique de la Suisse Romande, in Lausanne, Switzerland. He left Lausanne and joined the UNT faculty in 2008, at which time he established the Bone and Joint Research Center. Dr. Kosmopoulos has authored 29 research articles, 3 book chapters, over 80 abstracts, and has received numerous research and teaching awards. His research interests include computational mechanics, multi-scale bone and spine mechanics, mechanobiology, and fracture fixation.

## Poster Presentations

### **Poly(ethylene glycol)-block-poly(L-lactide) (PEG/PLA) Encapsulation of Oral Antibiotics for Drug Delivery into Dentin Tubules**

*Michael Lau<sup>1</sup>, Ridwan Haseeb<sup>1</sup>, Lucas Rodriguez<sup>1</sup>, Francisco Montagner<sup>2</sup>, Kelli Palmer<sup>3</sup>, Mihaela C. Stefan<sup>1</sup>, Danieli Rodrigues<sup>1</sup>*

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<sup>2</sup>Department of Conservative Dentistry, Federal University of Rio Grande do Sul, Brazil;

<sup>3</sup>Department of Molecular and Cell Biology, University of Texas at Dallas, Richardson, TX

### **Top-down MS for Clinical Proteomics, Functional Biology, and Biomarker Discovery: Prototyping CNS Dysfunction**

*John R. Corbett<sup>1,2</sup>, Junmei Zhang<sup>2</sup>, Daniel A. Plymire<sup>2</sup>, Steven M. Patrie<sup>2</sup>*

<sup>1</sup> Department of Bioengineering, University of Texas at Dallas

<sup>2</sup> Department of Pathology, University of Texas Southwestern Medical Center

### **Development of methodologies to evaluate the effect of bacterial biofilm and micromotion on corrosion of dental implants**

*\*Anie Thomas<sup>1</sup>, Sathyanarayanan Sridhar<sup>1</sup>, Arvind Adapalli<sup>1</sup>, Maria Burbano-Salazar<sup>1</sup>, Sutton Wheelis<sup>1</sup>, Kelli Palmer<sup>2</sup>, Pilar Valderrama<sup>3</sup>, Thomas G. Wilson<sup>3</sup>, Danieli Rodrigues<sup>1</sup>.*

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### **Nanomics: Proteomic platform based solution for point of care quantification of cancer stem cell activity**

*Anjan Panneer Selvam, Lakshmimeghana Pamidighantam, Shalini Prasad*

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### **Preventing Operating Room Fires: Development of an Operating Room Fire Prevention Device**

*Aris J. Maguaddayao<sup>1\*</sup>, Bradley A. Kimbrough<sup>2</sup>, Sarah Luna<sup>1</sup>, William C. Culp, Jr. M.D.<sup>3,4</sup>*

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### **Gecko Hands: Novel cardiothoracic forceps for prevention of mechanical damage during CABG surgery**

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### **Metal-on-Metal Total Hip Implants: A Study Their Failure Modes in Relation to Adverse Local Tissue Reaction**

*\*Maria Burbano<sup>1</sup>; Isabelle M. Gindri<sup>1</sup>; Robert D. Russell<sup>2</sup>; Michael H. Huo<sup>2</sup>; Danieli Rodrigues<sup>1</sup>*

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### **A Software for Analyzing Brain's Dynamic Functional Connectivity from Functional Magnetic Resonance Images**

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## **A Software for Multivoxel Pattern Analysis of Functional Magnetic Resonance Imaging Data**

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## **Stimuli-Responsive Polymer Substrates for Improved Neural Interfaces**

*Dustin Simon<sup>1,5</sup>, Taylor Ware<sup>1,5</sup>, David E. Arreaga-Salas<sup>1</sup>, Adrian Avendano-Bolivar<sup>1</sup>, Jonathan Reeder<sup>1,5</sup>, Tony Kang<sup>2</sup>, Drew Sloan<sup>3,5</sup>, Robert L. Rennaker II<sup>3,4,5</sup>, and Walter Voit<sup>1,2,5</sup>*

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<sup>4</sup>Department of Bioengineering,

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## **Mechanically Adaptive Organic Transistors Enabled by Physiologically Responsive Shape Memory Polymer Substrates**

*Jonathan Reeder<sup>1,2\*</sup>, Martin Kaltenbrunner<sup>1,3</sup>, Taylor Ware<sup>2</sup>, David E. Arreaga-Salas<sup>2</sup>, Adrian Avendano-Bolivar<sup>2</sup>, Tomoyuki Yokota<sup>1,3</sup>, Yusuke Inoue<sup>1,3</sup>, Masaki Sekino<sup>1,3</sup>, Walter Voit<sup>2</sup>, Tsuyoshi Sekitani<sup>1,3</sup> and Takao Someya<sup>1,3</sup>*

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## **Paired Vagus Nerve Stimulation Enhances Functional Recovery Following Traumatic Brain Injury**

*David Pruitt; ; Contributors: Anthony Nguyen, Connie Choua, Lily Kim, Kevin Tran, Jenny Trieu, Pranhuti Suri, Sufyan Shaikh, Phillip Phan; Supervising Investigator: Dr. Robert L. Rennaker II*

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## **Vagus nerve stimulation paired with rehabilitative training improves recovery of forelimb function in two clinically relevant models of stroke.**

*Andrea Ruiz<sup>1</sup>, Seth Hays<sup>1,2,\*</sup>, Navid Khodaparast<sup>1,2</sup>, Andrew Sloan<sup>1,2</sup>, Daniel Hulsey<sup>1</sup>, Priyanka Das<sup>3</sup>, Xavier Carrier<sup>3</sup>, Iqra Qureshi<sup>1</sup>, Igor Kushner<sup>1</sup>, Meera Iynegar<sup>1</sup>, Sabiha Sultana<sup>1</sup>, Nikhila Kanthety<sup>1</sup>, Veera Kondura<sup>1</sup>, Suna Burghul<sup>1</sup>, Robert Rennaker II<sup>1,2,3</sup>, Michael Kilgard<sup>1,2</sup>*

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## **Zinc Oxide-based Nanosensor for the Ultra-sensitive Detection of Troponin-T**

*Michael Jacobs<sup>a</sup>, Sriram Muthukumar<sup>b</sup>, Shalini Prasad<sup>a</sup>*

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## **Movement-paired vagus nerve stimulation improves motor recovery following ischemic brain damage**

*Daniel Hulsey<sup>1</sup>, Navid Khodaparast<sup>1,2</sup>, Seth Hays<sup>1,2,\*</sup>, Andrew Sloan<sup>1,2</sup>, Andrea Ruiz<sup>1</sup>, Priyanka Das<sup>3</sup>, Xavier Carrier<sup>3</sup>, Iqra Qureshi<sup>1</sup>, Igor Kushner<sup>1</sup>, Meera Iynegar<sup>1</sup>, Sabiha Sultana<sup>1</sup>, Nikhila Kanthety<sup>1</sup>, Veera Kondura<sup>1</sup>, Suna Burghul<sup>1</sup>, Robert Rennaker II<sup>1,2,3</sup>, Michael Kilgard<sup>1,2</sup>*

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## **SWITCHING BASED HYBRID DEVICES FOR CLINICAL DIAGNOSTICS**

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## **Electrokinetically assisted drug targeting using lab on a chip technology**

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## **In-situ Observation of Deformation Behavior of NiTiCu Foams for Implant Applications**

*Hao Yu and Marcus L. Young*

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## **Local Brain Sonication Simulation with Gel Phantom by Stereotaxic Apparatus Guided HIFU**

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## **An automated supination assessment task**

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## **Unilateral Neglect: A Novel Model and Testing Method in Animals**

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## **Measuring Forelimb Speed on a Skilled Reaching Task in 6-OHDA lesioned rats**

*Anthony Nguyen, Seth Hays Ph.D., David Pruitt, Michael Kilgard Ph.D., Robert Rennaker Ph.D.*

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## **Characterization of Two-Solution Bone Cements (TSBC) with Calcium Phosphate (CaP)**

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## **A Wireless Transponder for Smart Shoe**

*Shahrazad Sheibani<sup>1</sup>, Bhaskar Banerjee<sup>1</sup>, Haiying Huang<sup>2</sup>, Rashaunda Henderson<sup>1</sup>*

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## **E-VEST: Athletic Heart Monitoring System**

*Rizan Shrestha, Jeff Smith, Miguel Ysuhuaylas, and Ryan Johnson*

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## **DESIGN AND FABRICATION OF NANOGAP FOR BIOSENSING APPLICATIONS**

*Meghana Pamidighantam and Dr Shalini Prasad*

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**Design and optimization of Electrical Cell-substrate Impedance Sensing (ECIS) biosensor for real time cellular monitoring**

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**Rare Cell Separation Using Dielectrophoresis**

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**Improved Cochlear Stimulation Based on Shape Memory Polymers**

*Abhishek Raj\*, Dustin Simon, David Arreaga and Walter Voit*

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**Raising the Core Body Temperature by Heating Glabrous Surfaces During Vasodilation**

*Andrew Stier;*

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**The *In Vitro* Effects of Embryonic Stem Cell Paracrine Signaling on Macrophage Phenotype**

*Melanie E. Maurer<sup>1,2</sup>, Lindsay E. Fitzpatrick<sup>2</sup>, Todd C. McDevitt<sup>2,3</sup>*

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**Application of Electrokinetics for Cell Separation**

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## **Special Thanks to**

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