



Design of Medical Devices
2009
Conference

April 14th-16th
Radisson University Hotel
Minneapolis, MN

DMD Corporate Sponsors:

Welcome! We are excited to present the 2009 University of Minnesota Design of Medical Devices Conference. This conference was created in 2001 to enhance collaboration between academia and industry, promote policy, research and educational initiatives as they relate to medical device design, and support the graduate fellowship program.

Over the years, this forum, uniquely positioned in the middle of one of the most significant medical device communities in the world, has provided invaluable insight and leadership in promoting the future of this evolving industry. Conference attendance has more than tripled in size since its inception, and we expect it to grow even larger.

The success of this conference is due, in large part, to the continued support from our University of Minnesota partners and industry sponsors. On behalf of the entire DMD planning committee, we thank you. We hope you enjoy this year's conference!

*Sincerely,
Arthur Erdman, Ph.D.
Conference Chair*

*William Durfee, Ph.D.
Technical Program Chair*

*Paul Iaizzo, MD
President's Conference Chair*

The Design of Medical Devices Conference is Presented by:

The University of Minnesota's Institute for Engineering in Medicine's Medical Devices Center, the Institute of Technology, the Academic Health Center, the Office of the President, and the Department of Mechanical Engineering

In Cooperation with:

American Society of Mechanical Engineers
Academic and Corporate Relations Center, UMN

3M

Automated Control Systems

Aspen Research Corporation

Boston Engineering Corporation

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Fredrikson & Byron, P.A.

Intuitive Surgical

LifeScience Alley

Medical Industry Leadership Institute at
the Carlson School of Management

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MN Nano

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THE DESIGN OF MEDICAL DEVICES
DMD
C O N F E R E N C E

UNIVERSITY OF MINNESOTA

SAVE THE DATE!

2010 DMD Conference:

April 13, 14 & 15

www.dmdconf.org

Tuesday, April 14th

7:00 am

Registration and Continental Breakfast

8:15 am

Conference Welcome and Plenary Session

Moderators: Arthur Erdman, Conference Chair;
William Durfee, Technical Program Chair

Sponsored by Boston Scientific Corporation

Keynote Addresses:

40 years of Implantable Medical-Electronics

Joseph H. Schulman, President Emeritus
of the Alfred Mann Foundation and
Chief Scientist of Incumed LLC

*Medical Device Development at the University of
Minnesota*

Arthur Erdman
Conference Chair
University of Minnesota

prefunction area

10:00-10:30am

SPONSOR EXHIBIT SHOWCASE

10:30 am - 12:00 pm
Concurrent Technical Sessions

NEURO ENGINEERING 1

Session Chairs: *Ballroom A*
Taner Akkin, University of Minnesota; Theoden
Netoff, University of Minnesota

*Polarizing Low-frequency Electrical Field (PLEF)
Brain Modulation for Seizure Control and Neural
Prosthetics*

Bruce Gluckman
The Pennsylvania State University

*High-Density Transcranial Electrical Stimulation
(HD-tES)*

Marom Bikson
The City College of New York of CUNY

*Novel Neural Tools and Prostheses using Infrared
Nerve Stimulation*

Mark Bendett
Lockheed Martin Aculight

MEMS/NANO 1

Session Chair: *Ballroom B*
Rajesh Rajamani, University of Minnesota

Microscale Neural Repair

David Sretavan
University of California at San Francisco

*Ultra-Small Sensors for Quantification of Muscle
Forces in Neuromuscular Diseases*

A. Serdar Sezen
St. Cloud State University

*Portable Low-Cost Measurement of Thin Film
Elasticity for Analyte Detection*

Shyam Sivaramakrishnan
University of Minnesota

*Nanomaterials and Stem Cells for Tissue
Engineering*

Song Li
University of California Berkeley

**ASSESSMENT AND VALUATION OF EARLY
STAGE MEDICAL DEVICE TECHNOLOGY**

Session Chairs: *Ballroom C-D*
Ruth Taylor, MILLI, University of Minnesota; Stephen
Parente, MILLI, University of Minnesota

*Producing Medical Technology Assessments for an
Investor Audience*

Stephen Parente
University of Minnesota

*Overview of the University of Minnesota Medical
Industry Valuation Laboratory*

Michael D. Finch
Finch & King

*Medical Industry Valuation Laboratory Best Live
Cases*

Randy Nelson
Evergreen Medical Technologies, LLC

THREE-IN-FIVE COMPETITION

Session Chair: *Regents*
Marie Johnson, University of Minnesota

Competition Presentations:

*Design of a Catheter-Based Device for Performing
Percutaneous Chordal-++Cutting Procedures*

Alexander H. Slocum, Jr., Massachusetts
Institute of Technology

*The Therapress 1600i: Accelerating Knee
Rehabilitation*

Andrew Geronimo, The College of New
Jersey

*Pre-Clinical Evaluation of Direct Current Ablation
for the Treatment of Benign Prostatic Hyperlasia*

Benjamin Fruland, OncoStim Inc.

*A Fibre Optic System for the Detection of Dental
Caries*

David A Hughes, DTC Medical Devices

*Mechanism Design for the Bending Section Motion
Control of a Colonoscope*

Debao Zhou, University of Minnesota

*A Muscle Energy Converter for Powering
Implantable Cardiac Assist Devices*

Dennis R. Trumble, Carnegie Mellon
University & The Gerald McGinnis
Cardiovascular Institute

*A Novel Combination Therapy for Post-Operative
Atrial Fibrillation*

Eric Richardson, University of Minnesota

*A Wireless Insufflation System for Capsular
Endoscopes*

Jenna L. Toennies, Vanderbilt University

*Recumbent Exercise Bicycle for Low-Impact
Rehabilitation of Obese Individuals*

Kimberly Newman, University of Denver

*A Soft-Polymer Piezoelectric Bimorph Cantilever-
actuated Peristaltic Micropump*

Neil J. Graf, University of Minnesota

Judges:

Sarah Audet - Medtronic, Inc.

Buzz Benson - Sightline Partners

Joe Biller - Sightline Partners

David Boudreault - Stanford Biodesign

Doug Johnson, University of Minnesota

Trevor McCaw - Aegis Medical

Tom Savard - St. Jude Medical

HUMAN FACTORS 1

Session Chair: *Johnson Great Room
(McNamara Alumni Center)*
Richard Stein, St. Jude Medical

Profiles in Outrage: the Audacity of Industry

Matthew B. Weinger
Vanderbilt University

Lessons Learned By FDA

Peter B. Carstensen
Wiklund Research and Design

*Using Work Process Analysis and Cognitive Science
to Guide the Design of Medical Technology*

Kathleen Harder
University of Minnesota

12:15 p.m.

*Memorial Hall
(McNamara Alumni Center)*

KEYNOTE LUNCHEON

Sponsored by St. Jude Medical

Moderator: William Durfee, Technical Program Chair

War Stories from a Medical Device Career

Mark Kroll
Mark Kroll & Associates

*(Keynote lunches are a separate billable event,
meal tickets are required.)*

2:00 pm - 3:30 pm

Concurrent Technical Sessions

NEUROENGINEERING 2

Session Chairs: *Ballroom A*
Taner Akkin, University of Minnesota; Theoden
Netoff, University of Minnesota

*Excitation and Secretion at Mammalian Nerve
Terminals: Optical and Mechanical Studies with
and without Voltage-Sensitive Dyes*

Brian M. Salzberg
University of Pennsylvania

*Optical Detection of Neural Activity: Action
Potential Related Transient Deformations and Dye
Signals*

Taner Akkin
University of Minnesota

Flavoprotein Imaging of Neural Circuits in Vivo

Timothy J. Ebner
University of Minnesota

MEMS/NANO 2

Session Chair: *Ballroom B*
Tian Cui, University of Minnesota

*Layer-by-Layer Self-Assembled Carbon Nanotube-
based Electrochemical pH and Biological Sensors*

Dongjin Lee
University of Minnesota

*Differentiation of Stem Cells on Carbon Nanotube
Substrates*

Xun Yu
University of Minnesota-Duluth

BioMEMS: Designing for Liquid Environments

Sue Mantell
University of Minnesota
Other contributors-S. Mubassar Ali and
Ellen Longmire

CARDIOVASCULAR 1 CARDIAC BIOENGINEERING

Session Chair: Ballroom C-D
Daniel Sigg, University of Minnesota/Novo Nordisk Inc.

Building Hearts with Molecules and Stem Cells
Daniel Gary
University of Minnesota

Dual Oxygen Sensing Genetic Vectors: New Bio-device for the Failing Heart
Joseph Metzger
University of Minnesota

Gene and Cell Therapies for Cardiac Arrhythmias: Biological Pacemaker and Conduction Repair
Yong-FU Xiao
Medtronic, Inc.

WEARABLE MEDICAL SENSORS

Session Chairs: Regents
Lucy Dunne, University of Minnesota; Ahmed Tewfik, University of Minnesota

Movement and Contact Artifacts in Garment-Integrated Body Sensing
Lucy Dunne
University of Minnesota.

IEEE Standards for Body Area Networks
Srinath Hosur
TI

Low Power IC Design for Wearable Sensors
Chris Kim
University of Minnesota

Low Power RF Design for Wearable and Implantable Sensors
Ramesh Harjani
University of Minnesota

Sleep Apnea Detection with Wearable Sensors
Co-presented by:
Abilash Patangay
Boston Scientific Corporation
Ahmed Tewfik
University of Minnesota

Wireless Body Area Networks Based Medical Devices: Issues and Applications
Emil Jovanov
University of Alabama in Huntsville

HOME TELEMEDICINE

Session Chairs: Johnson Great Room (McNamara Alumni Center)
Lars Oddson, Sister Kenny Research Center; Stan Finkelstein, University of Minnesota

Independent Living Through Remote Monitoring
Bryan Fuhr
Healthsense Inc.

Mobile Health Care Applications in the Developing World
Ron Poropatich, COL MIL USA
MEDCOM USAMRMC, Deputy
Director Telemedicine and Advanced
Technology Research Center

M-Rehabilitation: Wireless Systems to Support Patient Adherence

Co-Presented by:
Mary Vining Radomski
Sister Kenny Research Center

Holly Pavliscsak
Medical Research and Material
Command (MRMC) and Telemedicine
and Advanced Technology Center
(TATRC)-South

Personal Telehealth – A Vision for the Future of Medical Care
Stuart Speedie
University of Minnesota

prefunction area

3:30-4:00 pm

SPONSOR EXHIBIT SHOWCASE

4:00 pm - 5:30 pm
Concurrent Technical Sessions

NEUROENGINEERING 3

Session Chairs: Ballroom A
Taner Akkin, University of Minnesota; Theoden Netoff, University of Minnesota

Epilepsy Surgery: State-of-the-Art and Remaining Challenges
Aviva Abosch
University of Minnesota Medical School

Dynamic Neuronal Imaging in Animal Models of Epilepsy
Douglas A. Coulter
University of Pennsylvania School of
Medicine and Children's Hospital of
Philadelphia

Dynamical Approaches to Understanding and Predicting Seizures
Theoden Netoff
University of Minnesota

MEMS/NANO 3

Session Chair: Ballroom B
Sang-Hyun Oh, University of Minnesota

Overview Of Optical Oxygen/Perfusion Sensing Technologies For Implantable Use
Can Cinbis
Medtronic, Inc.

Nano Magnetic Sensing System with Zeptomol Sensitivity for Potential Personalized Medicine
Jian-Ping Wang
University of Minnesota

Applications and Opportunities for Nanohole Array Sensing
Dale Larson
Draper Laboratory

Size-Controlled Synthesis of Multifunctional Mesoporous Silica Nanoparticles
Christy L. Haynes
University of Minnesota

CARDIOVASCULAR 2 CARDIAC ANATOMY

Session Chair: Ballroom C-D
Alex Hill, Medtronic, Inc.

3-D Computed Tomography Imaging of the Aortic Root in the Context of Transcatheter Aortic Valve Implantation
Paul Schoenhagen
The Cleveland Clinic Foundation

Valve Anatomy
Jason Quill
University of Minnesota

Loading Conditions within RV-PA Conduits
Tim Kelley
Medtronic, Inc.

DESIGN OF SURGICAL SIMULATORS

Session Chair: Regents
Rob Sweet, University of Minnesota

Developing a Surgical Simulation Program for the Device Industry
David Hananel
Medical Education Technologies, Inc.
(METI)

Design of Surgical Simulators: an Engineer's Perspective
Yunhe Shen
University of Minnesota

Design of Surgical Simulators: a Surgeon's Perspective
Rob Sweet
University of Minnesota

ENTREPRENEURSHIP

Session Chairs: Johnson Great Room (McNamara Alumni Center)
Karen Kaehler, University of Minnesota; Doug Johnson, University of Minnesota

Raising Capital for Early-Stage Medical Device Companies in a Tough Funding Environment
Co Presented By:
Norm Cocke
Twin Cities Angels, LLC
Archie Smith
Sightline Partners
Katie Szyman
Medtronic, Inc.

5:30 pm

ADJOURN



LifeScience Alley™

High-Impact Networking Breakfast for Scientists & Engineers

This session is designed with scientists and engineers in mind, and hosted by LifeScience Alley, the region's leading trade association for the life sciences. Learn how to effectively expand your network of experts and collaborators, and how to make these new connections work for both parties.

This one-hour breakfast will feature a brief presentation by Janet Stacey, communications and networking expert, who will share some tried and true techniques for identifying potential collaborators and other helpful resources that can impact your work today and in the future.

Wednesday, April 15, 2009 (Day 2, Design of Medical Devices Conference)

- 7:15 a.m. Registration & continental breakfast
- 7:30 – 7:45 a.m. Networking techniques presentation**
- 7:45 – 8:15 a.m. Focused Networking – attendees put new skills to good use!**



Janet Stacey

Vice President, Health Care and Medical Device, Padilla Speer Beardsley

Wednesday, April 15th

7:00 am

Registration and Continental Breakfast

7:15 am

Special Event: High Impact Networking Breakfast for Scientists & Engineers
Sponsored By: LifeScience Alley

8:30 am - 10:00 am

Concurrent Technical Sessions

MILITARY MEDICAL DEVICE AIRWORTHINESS

Session Chairs: *Ballroom A*
Chip Laingen, Defense Alliance; Betsy Lulfs, MN DEED

AE Clinical Equipment Modernization

Captain Shaun Westphal
USAF, NC, OIC, Chief of AE Clinical Issues & Equipment Research, Air Mobility Command - Office of the Command Surgeon

The United States Army Aeromedical Research Laboratory, Airworthiness Certification and Evaluation Program

Bobby L. Bowers
Airworthiness Certification & Evaluation Branch, U.S. Army Aeromedical Research Laboratory

REGENERATIVE TECHNOLOGIES IN ORTHOPAEDIC SURGERY

Session Chairs: *Ballroom B*

Joan Bechtold, Hennepin County Medical Center; Peter Bianco, Halleland Health Consulting, Inc.

Strategies to Develop Biologically Active Orthopedic Devices

William Murphy
University of Wisconsin

Industry Perspective on Musculoskeletal Regenerative Technologies

Elliott A. Gruskin
SYNTHES (USA)

Regenerative Technologies: Orthopaedic Surgeon - Practical Considerations

Joel J. Smith
University of California San Diego

CARDIOVASCULAR 3 CARDIAC LEADS

Session Chair: *Ballrooms C-D*
John Helland, St. Jude Medical, CRMD

Five Decades of Cardiac Lead Technology: What Did We Learn?

John Helland
St. Jude Medical

What Are The Cardiac Lead Failure Modes & What Testing Is Done To Reduce The Risk Of Failure?

Chris Jenney
St. Jude Medical CRMD

What Are The Current Designs & Technologies Used In Cardiac Leads?

Shantanu Reddy
Boston Scientific CRM

What Are The Technologies & Requirements Needed For Future Cardiac Leads?

Rick McVenes
Medtronic CRDM

Panel Discussion & Audience Questions

HUMAN FACTORS 2

Session Chair: *Johnson Great Room (McNamara Alumni Center)*
Kathleen Harder, University of Minnesota

Visuomotor Coordination in Endoscopic Surgery

Caroline Cao
Tufts University

Involving Human Factors from the Start: Design of an Infusion Pump

Co-Presented by:
Robert A North
Human Centered Strategies, LLC
Anjum Chagpar
The University of Toronto Health Network

Human Factors, Design Lessons Learned, Case History

Richard E. Stein
St. Jude Medical

prefunction area

10:00-10:30am

SPONSOR EXHIBIT SHOWCASE

10:30 am - 12:00 pm
Concurrent Technical Sessions

**INDUSTRY MEDICAL DEVICE
AIRWORTHINESS**

Session Chairs: *Ballroom A*
Chip Laingen, Defense Alliance; Betsy Lulfs, MN
DEED

*Military Airworthiness Testing for Twin Star
Medical's Compartment Monitor*
Rick Odland
Twin Star Medical

*Military Airworthiness Testing for Nonin Medical's
Portable Pulse Oximeters – 1991 to Present*
Co-Presented by:
Terry deBruyn
Nonin Medical
Brodie Pedersen
Nonin Medical

**CARDIOVASCULAR 4
ARTIFICIAL HEARTS AND VADS**

Session Chair: *Ballrooms C-D*
James St. Louis, University of Minnesota

*Mechanical Circulatory Support in 2009 and
Beyond*
Ranjit John
University of Minnesota

*Anticoagulation Management of Pediatric
Ventricular Assist Devices*
Marie E. Steiner
University of Minnesota

Pediatric Cardiac Mechanical Support
Mark Plunkett
University of Kentucky

*The Evolution of Cardiac Assist Devices: Total
Artificial Hearts versus Left Ventricular Assist
Devices*
Lyle Joyce
Mayo Clinic

CARDIAC VALVES: REPAIR, REPLACE OR ?

Session Chair: *Ballroom B*
Richard W. Bianco, Director, Experimental Surgical
Services

*"Heart Valve Replacement in the Aortic, Mitral, and
Tricuspid Positions"*
Sarah Shumway
University of Minnesota

*"Aortic Valve Treatment in the Modern Era: Small
Puncture, Big Valve"*
Robert F. Wilson
University of Minnesota

*"The Development of Transcatheter Heart Valves:
Opportunities and Challenges"*
Timothy G. Laske, PhD, Cardiovascular,
Medtronic, Inc

"New Directions in Cardiac Valve Repair"
J. Scott Rankin
Vanderbilt University

MEDICAL DEVICE INNOVATION 1

*Johnson Great Room
(McNamara Alumni Center)*
Session Chair:
Marie Johnson, University of Minnesota

Post-It® Notes Were Not an Accident
Art Fry
3M, Inventor of Post-It® Notes

Innovation Processes and Tools
Larry Schmitt
Inovo Technologies

The Intersection of Innovation and IP
Thomas E. Bejin
Rader Fishman and Grauer

**UNIVERSITY OF MINNESOTA'S MEDICAL
DEVICES CENTER TECHNOLOGIES
SHOWCASE**

Regents
Organizers: Arthur Erdman, University of Minnesota;
Dillon Hodapp, University of Minnesota; Stefan
Hertel, University of Minnesota

This informal session will include an opportunity to view
in 3D the types of surgical procedures available on the
simPORTAL. You will be able to experience this state
of the art method of gaining device needs directly from
the medical professionals. Also, staff from the Medical
Devices Center will be present to show various medical
devices and inform you how the Medical Devices Center
can work with you to develop prototypes and perform
testing of device concepts.

12:15 p.m.

*Memorial Hall
(McNamara Alumni Center)*

AWARD LUNCHEON

Sponsored by Medtronic, Inc.

Moderator: Arthur Erdman, Conference Chair

*Recipient of 2009 Design of Medical Device
Conference Award*

*"Medical Devices and the Future World of
Healthcare Delivery"*

Rebecca M. Bergman
Vice President, New Therapies &
Diagnostics Research, Medtronic
CRDM

*(Keynote lunches are a separate billable event,
meal tickets are required.)*

2:00 pm - 3:30 pm
Concurrent Technical Sessions

LIVE SURGERY

*Memorial Hall
(McNamara Alumni Center)*

Laparoscopic Gastric Bypass

Moderator:
Dr. Robert D. Acton, M.D.
University of Minnesota

In this session, a University of Minnesota surgeon
will be performing a laparoscopic bariatric (weight
loss) operation at the University of Minnesota
Medical School-Fairview. The surgery will be
transmitted to the conference room via live video
feed. The objective of the session is to discuss the
limitations and design opportunities for the tools
and devices used in modern surgery. A second
surgeon will be in the conference room to explain
and show the use of each tool and to take questions
from the audience. There may be a collection
of surgical tools for the audience to manipulate.
The session will open with a brief tutorial by the
moderator on the surgical procedure.

**CONFLICT OF INTEREST IN HEALTH
CARE**

Regents
Session Chair:
Chuck Swanson, St Cloud State

Conflict of Interest- the FDA Perspective
Sonali P. Gunawardhana
U.S. Food and Drug Administration

*Physicians and the Medical Device Industry - The
Right Relationship*
Susan Alpert
Medtronic, Inc.

*Update from University of Minnesota Medical
School's Task Force on Conflict of Interest*
Denis Clohisy
University of Minnesota

MEDICAL DEVICE INNOVATION 2

*Johnson Great Room
(McNamara Alumni Center)*
Session Chair:
Marie Johnson, University of Minnesota

Framing the Problem
Benjamin Arcand
University of Minnesota

Framing a Solution: Ideation/Brainstorming Tools
David Boudreault
Stanford Biodesign

Opportunities and Challenges from the Real World
Daniel Titcomb
Pulse Innovation

Panel Discussion

prefunction area

3:30pm-4:00pm

SPONSOR EXHIBIT SHOWCASE

HHH ROOM

3:30pm-5:30pm

SCIENTIFIC POSTER SESSION I

See website www.dmdconf.org or the
conference folder insert for a complete
list of 50+ poster titles and authors

5:30 pm

ADJOURN

Thursday, April 16th

**President's 21st Century
Interdisciplinary Conference:
"Translational Research: from
Prototype to Product"**

7:00 a.m. *prefunction area*
Registration and Continental Breakfast

8:00 am - 10:10 am
President's Conference Keynote Addresses

PLENARY SESSION

Moderator:
Paul Iaizzo, Program Chair, President's Conference

Welcoming Remarks:

Frank Cerra
Senior Vice President for Health Sciences,
McKnight Presidential Leadership Chair,
Academic Health Center
University of Minnesota

Paul Iaizzo
Associate Director for Institute for
Engineering in Medicine
University of Minnesota

Keynote Addresses:

*The CTM and the NIH Clinical and Translational
Science Award (CTSA) Program at the U of MN*
Bruce Blazer
Chief of the Pediatric Blood and Marrow
Transplantation Program, Director-ACH-
Center for Translational Medicine
University of Minnesota

*The Changing Role of R&D in an Emerging
Medical Device Company*

Dave Stassen
Managing Director Split Rock Partners

8:00 am - 10:00 am
Concurrent Technical Sessions

NOTES

Session Chairs: *Regents*
Timothy Kinney, University of Minnesota; Perry Li,
University of Minnesota

NOTES: The Next Revolution in Surgery

Christopher Gostout
Developmental Endoscopy Unit at Mayo
Clinic, Rochester, MN

*Natural Orifice Surgery: Designing the Next
Generation of Surgical Devices*

Vihar Surti
Cook Endoscopy

TISSUE ENGINEERING

Session Chair: *Nolte*
Robert Tranquillo, University of Minnesota

Cardiac Tissue Engineering

Milica Radisic
University of Toronto

*The Development of ECM Based Prohealing
Coatings to Improve Device / Body Interfaces*

Jeff Ross
Surmodics

A Fully Biological Living Heart Valve Replacement
Robert Tranquillo
University of Minnesota

prefunction area

10:10 am-10:40 am

SPONSOR EXHIBIT SHOWCASE

10:40 am - 12:00 pm
President's Conference Keynote Addresses

KEYNOTE ADDRESS:

*Training Individuals to Perform Translational
Research*

Prof. Russell V. Luepker
Mayo Professor of Public Health
University of Minnesota

KEYNOTE ADDRESS:

*Commercialization of Medical Devices - Successes
and Lessons Learned*

Mir Imran
Managing General Partner
Incube Laboratories

10:40 am - 12:00 pm
Concurrent Technical Sessions

COMPUTER AIDED DESIGN

Session Chair: *Regents*
Victor Barocas, University of Minnesota

*Case Studies on the Use of Numerical Simulation for
Design and Optimization of Medical Devices*

Co-Presented by:
Eph Sparrow
University of Minnesota
J. Abraham
University of St. Thomas

*Free Convection in a Parallel-flow Protein
Crystallizer*

Co-Presented by:
Masano T. Sugiyama
University of Minnesota
Victor H. Barocas
University of Minnesota

*A Dissolution-diffusion Model for the TAXUS
Trade Mark Drug-eluting Stent with Surface Burst
Estimated from Continuum Percolation*

Ed Parsonage
Boston Scientific Corporation

Static Analyses of Spine Interbody Implants

Andreas Pfahnl
Devicix, LLC

**LEGAL ISSUES IN THE DESIGN OF
MEDICAL DEVICES: FROM PATENT
PORTFOLIOS TO PRODUCT LIABILITY**

Session Chair: *Nolte*
Ruth Okediji, University of Minnesota

*The Preemption Defense to Product Liability Claims
Brought Against Device Manufacturers*

Mark Herrmann
Jones Day

*Parallels between FDA Device Regulations and
Common-law Tort Claims after Riegel: Private
Enforcement of Alleged Regulatory Violations
Against Medical Device Manufacturers as an
Exception to Preemption*

Jim Beck
Dechert, LLP

*Increasing Investment Value through Smart Patent
Procurement*

Co-Presented by:
Leslie I. Bookoff
Dinesh N. Melwani

Innovation Risks in a Global Market
Eliaz P. Babaev

12:15 pm-12:45 pm

SPONSOR EXHIBIT SHOWCASE

12:15 p.m.

KEYNOTE LUNCHEON

Moderator:
Paul Iaizzo, Program Chair, President's Conference

Three-in-Five Awards

Presented by:
Marie Johnson
University of Minnesota

"Project Destination 2025 Analyst"

Dale Wahlstrom
BioBusiness Alliance of Minnesota

prefunction area

Ballrooms A-D

Ballrooms A-D

HHH ROOM

2:00pm-3:30pm

SCIENTIFIC POSTER SESSION I

See website www.dmdconf.org or the
conference folder insert for a complete
list of 50+ poster titles and authors

prefunction area

2:00pm-3:30pm

SPONSOR EXHIBIT SHOWCASE

TOURS

2:00-3:30pm

Tour departures will take place near the
Registration Desk. You will be escorted to the
facility. See the tour ads on the next page of the
program for more information on each of these
facilities.

EXPERIMENTAL SURGICAL SERVICES
www.ess.umn.edu/

MEDICAL DEVICES CENTER
www.mdc.umn.edu/

SimPORTAL
www.simportal.umn.edu/index.html

THE VISIBLE HEART LABORATORY
www.vhlab.umn.edu/

3:30 pm

ADJOURN

The following tours will take place on Thursday, April 16th from 2:00 pm - 3:30pm.

If you wish to attend any one of these tours, please meet at the registration table on the second floor of the Radisson University Hotel.

EXPERIMENTAL SURGICAL SERVICES

www.ess.umn.edu/

At Experimental Surgical Services, we're experts in designing and conducting the appropriate research to determine the safety and efficacy of medical devices. We have 25 years experience in pre-clinical assessment for the medical industry. In fact, we're the industry leader in researching and testing cardiac devices and surgical techniques. We complete over 500 open heart procedures a year and over 1,500 procedures annually. and you will be escorted to the ESS Lab.

ESS is Directed by Richard W. Bianco who has 25 years of experience in the pre-clinical assessment of virtually every animal model. The ESS staff of in-house surgeons work with device companies to develop and/or validate research methods, provide consultation as necessary and offer interpretative and technical support.

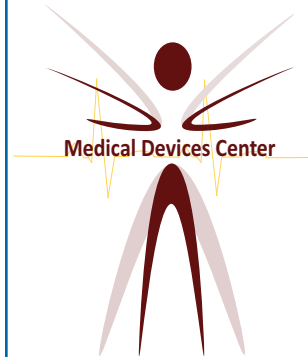


MEDICAL DEVICES CENTER

www.mdc.umn.edu/

The Medical Devices Center at the University of Minnesota is a unique interdisciplinary program that resides within the Institute for Engineering in Medicine. The Center has a combined mission of basic research,

applied and translational research education and training, and outreach and public engagement all related to medical devices.



The Medical Devices Center aims to strengthen interdisciplinary research among faculty in the health sciences and engineering specifically related to medical devices.

The center trains the next generation of medical device inventors and fosters new relationships with the medical device industry and government agencies to improve health care worldwide.

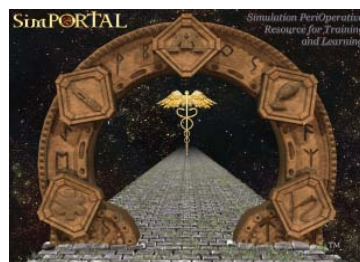
SimPORTAL

www.simportal.umn.edu/index.html

SimPORTAL (Simulation PeriOperative Resource for Training and Learning) is the primary simulation training "portal," or point of entry, for the procedurally oriented departments within the Medical School at the University of Minnesota. It arranges for, or directly provides space, equipment, technical and logistical support for educational activities involving technical skills and team training via simulation. Via the Center for Research in Education and Simulation Technologies (CREST), it also supplies research and evaluation capacity to support innovation in simulation equipment, tools, and processes as well as training curricula.

The mission of SimPORTAL is:

"To augment the procedural training needs of medical professionals through leadership in the use and development of simulation resources."



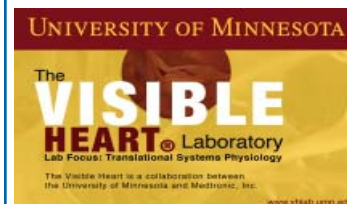
THE VISIBAL HEART LABORATORY

www.vhlab.umn.edu/

Dr. Paul Iaizzo has been at the University of Minnesota since 1990, performing research and teaching graduate and undergraduate courses. In 1997, Dr. Iaizzo and his coworkers began working on large mammalian isolated heart models, and thus the Visible Heart® laboratory was created

in collaboration with Medtronic, Inc. Today, this lab is a premiere place to perform translational systems physiology research which ranges from cellular

and tissue studies to organ and whole body investigations. The Visible Heart® lab embodies a creative atmosphere which is energized by some of the best and brightest students at the University. Our lab staff has over 100 years of collective research experience and functions as a highly efficient and productive team.



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Gary Glover, PhD, NAE

Professor and Director of Radiological Sciences Lab
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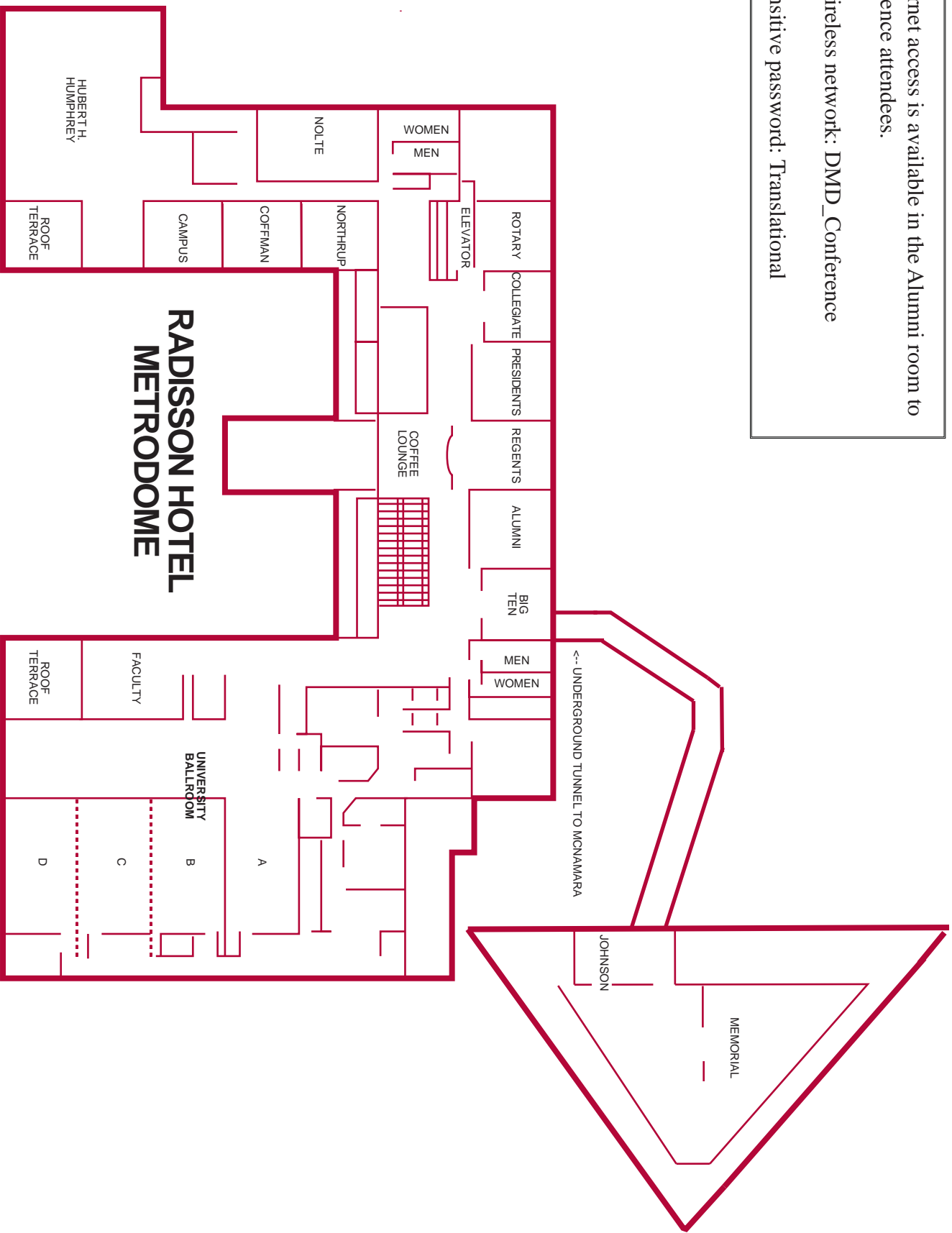
Douglas Lauffenburger, PhD, NAE

Whitaker Professor and Director
Department of Biological Engineering, MIT

Wireless internet access is available in the Alumni room to DMD Conference attendees.

Connect to wireless network: DMD_Conference

With case-sensitive password: Translational



Not to scale.

MEDICAL DEVICES CENTER

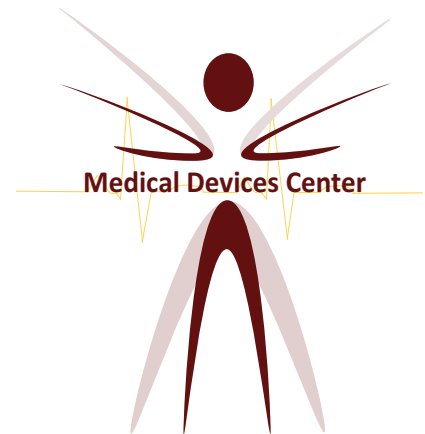
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The MDC has many roles within the U of M including:

- * Acceleration of interdisciplinary medical device R&D
- * Funding new medical device projects based on a rigorous peer review process
- * Maintaining a Core Lab with common use equipment for creative prototypes
- * Facilitating connections to other Centers and Labs
- * Supporting UMN functions related to medical devices
- * Supporting UMN the teaching/training programs of departments related to medical devices
- * Interfacing with the medical device industry
- * Focus on improvement of health care world-wide



INNOVATION FELLOWS PROGRAM

The Medical Devices Center Innovation Fellows Program is a full immersion educational and product development program. Each Fall, the MDC Fellows Program brings together a cross-disciplinary team comprised of postgraduate engineers, seasoned medical device professionals and physicians to develop medical devices across a broad range of clinical areas. The team, led by Dr. Marie Johnson, collaborates for one year to identify and solve unmet clinical needs through a disciplined decision making technique which includes consideration of FDA regulatory pathway, insurance reimbursement, intellectual Property and business strategies. This one-year product clinical literature development experience includes identification, development, prototype and test of medical devices.

The Fellows Program curriculum includes formal instruction in product development and innovation. Fellows observe surgery, attend medical rotations, and participate in medical device company visits. In addition, the Fellows teach, share and learn by mentoring undergraduate and graduate student design teams across the Institute of Technology, and support the Design of Medical Devices conference. MDC Fellows work with faculty collaborators from both engineering and medicine. The program generates a minimum of 20 patent disclosures for advanced novel medical technologies over the course of the year.

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- Special receptions at two events—Fall and Spring Open House
- Two seats at the annual DMD conference
- Early information about research findings and technology
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