The Design of Medical Devices
Conference
April 13 & 14, 2005
Radisson Hotel Metrodome - Minneapolis, Minnesota

The President's Second 21st Century Interdisciplinary Conference on Medical Devices
Lead the Change for Breakthroughs in Health through Medical Device Advancements
April 15, 2005
Radisson Hotel Metrodome
Minneapolis, Minnesota

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University of Minnesota
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WEDNESDAY APRIL 13

8:15 - 9:30  Guidant Plenary Session
Ballrooms A-D

Moderators: Arthur G. Erdman & William K. Durfee, University of Minnesota

"Modular Injectable Interfaces with the Body" Gerald E. Loeb, Alfred Mann Institute for Biomedical Engineering, University of Southern California
"Changing Axioms" Tad Simons, IDEO

9:30 - 10:30 Refreshment Break: Opening of Corporate Exhibits

10:30 - 12:00 Session A1: Drug Delivery Technologies 1
Ballroom A

Chair: Ron Siegel – Department of Pharmaceutics, University of Minnesota

"Drug Eluting Stents: Conception, Implementation and Current Challenges" Elazer R. Edelman, Harvard/MIT Division of Health Sciences and Technology, Brigham and Women's Hospital Harvard Medical School
"Drug Delivery Coatings to Enable Local Therapy" Aron Anderson, SurModics
"IONSYS (TM): A Transdermal System for Patient-Controlled Delivery of Fentanyl for Acute Post-Operative Pain Requiring Opioids" Brad Phipps, ALZA Corporation

10:30 - 12:00 Session A2: Orthopedic Devices
Ballroom B

Chair: Joan Bechold – Orthopaedic Biomechanics Laboratory

"Intervertebral Disc Nucleus Exraction from the Human Spine" Jon Moon, Devicix
"Biomechanical Evaluation of a Novel Lumbosacral Axial Fixation Device" Eric Ledet, Albany Medical College / Rensselaer Polytechnic Institute
"Introduction to a New Minimally Invasive Grafting Implant" Joe Gleason, Spineology
"Suture Fixation using a Locking "Morse Taper" Nut" Matthew Putnam, Department of Orthopaedics, University of Minnesota
"Doctor, will I be able to...? Current Trends in Orthotic and Prosthetic Applications" Kelly Clark, Otto Bock Health Care, Supportive Innovations

10:30 - 12:00 Session A3: Endourology
Ballroom C

Chair: Manoj Monga – Department of Urologic Surgery, University of Minnesota

"Biomaterials in the Urinary Tract: New Concepts" John Denstedt, Department of Surgery, The University of Western Ontario
"Field Driven Design" Mark Colella, Stryker
"Form and Function: What Goes Into the Design of a Medical Device" Frank Fischer, Cook

10:30 - 12:00 Session A4: Medical Device Product Design
Ballroom D

Chair: Richard Stein – Guidant Corporation

"The Opportunity" Rod Greder, New Productivity Group
"The Product" Chris Rozewski, Plexus Technology Group
12:00 - 1:30

St. Jude Luncheon

HHH Room

“The Idea” Craig Sampson, IDEO
“The Market” Ann Hickey, ev3 - The Endovascular Company

2:00 - 3:30

Session B1: Drug Delivery Technologies 2

Ballroom A

Chair: Ron Siegel – Department of Pharmaceutics, University of Minnesota

“Control of the Tissue / Implant Interface” Diane J. Burgess, Department of Pharmaceutical Sciences, University of Connecticut
“PROMAXX Microsphere Application and Device Harmonization” Larry Brown, Epic Therapeutics, Inc.
“Sub-50 Nanometer Capsules for Actively-Targeting Drug Delivery” Gretchen Unger, GeneSegues, Inc.

2:00 - 3:30

Session B2: Minnesota Bioscience Zones - Year 2

Ballroom B

Co-Chairs: Joan Bechtold, Peter Bianco, and David Durbenberger

“Will Government in Minnesota Encourage Bioscience Growth” Lynne Osterman, Gray Plant Mooty
“Minnesota Bioscience Zones - The State’s Perspective” Gene Goddard, Minnesota Department of Employment and Economic Development
“Saint Paul’s Efforts to Attract and Nurture Bioscience” Tom Triplett, Mayor’s Office, City of Saint Paul
“Marketing Bioscience Zones” Mike Christenson, City of Minneapolis, Community Planning and Economic Development
“Minnesota Bioscience Zones - The Rochester Perspective” Gary Smith, Rochester Area Economic Development
“Minnesota Bioscience Zones - The Company Perspective” Charles Halstenson, Prism Research
“Bioscience Business Development Incentives” Jim Stice, Twin Star Medical

2:00 - 3:30

Session B3: Laparoscopy and Robotic Surgery

Ballroom C

Chair: Manoj Monga – Department of Urologic Surgery, University of Minnesota

“Why Robotics in the OR?” Nancy A. Paviak, Intuitive Surgical
“Evolving Use of Robotics in Thoracic Surgery” Michael Maddaus, Department of Surgery, University of Minnesota
“Robotic Radical Prostatectomy” Kenneth S. Koeneman, Center for Prostate Cancer, University of Minnesota

2:00 - 3:30

Session B4: Contributed Papers 1

Ballroom D

Chair: Rajesh Rajamani – Department of Mechanical Engineering, University of Minnesota

“Design and Fabrication of a Multi-functional Complaint Instrument for Ophthalmic Surgery” Mary Frecker, Penn State University
“Multi-tiered Haemodynamics Tool for Design Synthesis of Minimally Invasive EndoCardiopulmonary Bypass (EndoCPB) Systems” Balakrishna Haridas, Department of Biomedical Engineering, University of Cincinnati
“A Novel Ex Vivo Heart Model for the Assessment of Cardiac Pacing Systems” Nick Skadsberg, Medtronic
“A Novel Passive Wireless Ultrasound Imaging System with Magnetic Actuation for In Vivo Mapping of Body Cavities” A. Serder Sezen, Department of Mechanical Engineering, University of Minnesota
“Passive Wireless MEMS Microphones for Biomedical Applications” Shyam Sivaramakrishnan, Department of Mechanical Engineering, University of Minnesota
THURSDAY APRIL 14

8:30 - 10:00  Session C1:  BioMEMS I
Ballroom A
Chair: Tianhong Cui – Department of Mechanical Engineering, University of Minnesota

"Introduction to BioMEMS" Steven S. Saliterman, Department of Biomedical Engineering, University of Minnesota
"Extreme Miniaturization Packaging Techniques" Jim Ohneck, Valtronic USA
"A Bio-fluidic Transdermal Microsystem" Cheng Luo, Louisiana Technical University
"A Micromachined Sparse Cell Isolation Device: Application to Cancer Detection and Prenatal Diagnostics" Hisham Mohamed, Wadsworth Center, New York State Department of Health, Nanobiotechnology Center

8:30 - 10:00  Session C2:  Cardiovascular Therapy
Ballroom B
Chair: Paul Iaizzo – Department of Surgery, University of Minnesota

"Cardiac Acceleration" Dan Kaiser, Medtronic
"Coronary Stents, 2005" Carmelo Panetta, Department of Medicine, University of Minnesota
"Ultrafiltration for Acute Decompensated Heart Failure: The Diuretic of Choice for the 21st Century" Andrew Boyle, Division of Cardiology, University of Minnesota
"Cardiac Resynchronization Therapy for Congestive Heart Failure, Minimally Invasive Surgical Approach" Kenneth Liao, Division of Cardiovascular and Thoracic Surgery, University of Minnesota

8:30 - 10:00  Session C3:  Innovative Technology in Ophthalmology
Ballroom C
Chair: Victor Barocas – Department of Biomedical Engineering, University of Minnesota

Jay McLaren, Mayo Clinic
Tingrui Pan, University of Minnesota
Allison Hubel, Department of Mechanical Engineering, University of Minnesota

8:30 - 10:00  Session C4:  Entrepreneurship
Ballroom D
Chair: Doug Johnson – Carlson School of Management, University of Minnesota

"FDA Regulatory Costs for Medical Device ‘Startups’" Morris Waxler, Godfrey & Kahn, S.C.
Mark B. Knudson, Enteromedics Inc.
"Angel Investing in Medical Devices: Praying for Good Management and Luck, One Investor’s Perspective" Tom von Kuster, Amex Inc.
"Top 10 List (and Bottom 10 List) of Starting a Medical Device Company" Michael Berman
"Creating Value in the Medical Device Industry: from Concept to Realization" Gerald W. Timm, NovaTek Medical, LLC and the Department of Urological Surgery, University of Minnesota

10:30 -12:00  Session D1:  Nanotechnology
Ballroom A
Chair: Steve Campbell – Electrical and Computer Engineering, University of Minnesota

"In Vivo Imaging with Flourescent Quantum Dots" David J. Norris, Department of Chemical Engineering and Materials Science
"Nanomachines that Drive Cell Division" David Odde, Department of Biomedical Engineering, University of Minnesota
"Drug Release from Nanolayered Particles" Timothy Wiedmann, Department of Pharmaceutics, University of Minnesota
10:30 - 12:00 **Session D2: Advances in Catheter Technologies**  
**Ballroom B**  
Chair: *Perry Li* – Department of Mechanical Engineering, University of Minnesota  
  
"Endovascular Catheter Based Devices for Treatment of Aortic Aneurysms: Biomechanics and Biomaterials Design Challenges" *Balakrishna Haridas*, Department of Biomedical Engineering, University of Cincinnati  
"Design and Application of Compliant Mechanisms for Surgical Tools" *Sridhar Kota*, Department of Mechanical Engineering and Applied Mechanics  
Panel: *Kenneth Liao*, Department of Surgery, University of Minnesota; *Manoj Monga*, Department of Urology, University of Minnesota; *Martin Freeman*, Hennepin County Medical Center, Gastroenterology Department

10:30 - 12:00 **Session D3: Neurologic Devices 1**  
**Ballroom C**  
Chair: *Paul Tuite* – Department of Neurology, University of Minnesota  
  
"EEG-based Brain-Computer Interface" *Bin He*, Department of Biomedical Engineering, University of Minnesota  
"Targeted Toxin Therapy for Brain Tumors" *Walter A. Hall*, Department of Neurosurgery, Radiation Oncology, and Radiology, School of Medicine, University of Minnesota  
"Brain Stimulation for Epilepsy: Past and Current" *Nina Graves*, Medtronic and College of Pharmacy, University of Minnesota

10:30 - 12:00 **Session D4: University of Minnesota Medical Startups**  
**Ballroom D**  
Chair: *Doug Johnson* – Carlson School of Management, University of Minnesota  
  
"Moving Islet Transplantation from Research to Clinical Practice" *Frank Solomon*, Islet Technology, Inc.  
*Charlie Minter*, MRI Instruments  
*Al Emota*, Stentech

12:00 - 1:15 **Box Lunch and Corporate Exhibits**

1:30 - 3:00 **Session E1: Microfluidics**  
**Ballroom A**  
Chair: *Victor Barocas* – Department of Biomedical Engineering, University of Minnesota  
  
*Brad Fox*, MicroTec  
*Bryan Fosnlow*, University of Minnesota  
*Victor Barocas* – Department of Biomedical Engineering, University of Minnesota

1:30 - 3:00 **Session E2: Cardiovascular Imaging Technology**  
**Ballroom B**  
Chair: *Bruce Hammer* – Department of Radiology, University of Minnesota  
  
"Cardiac MR: Evaluation of Heart Disease" *Cory Swingen*, Department of Radiology, University of Minnesota  
"Technical Aspects of Cardiac CT: 64 Slice Scanners" *Tom Payne*, Abbott Northwestern Hospital  
"Magnetocardiography: Principles and Application" *Steve Karr*, CardioMag Imaging

1:30 - 3:00 **Session E3: Neurologic Devices 2**  
**Ballroom C**  
Chair: *Paul Tuite* – Department of Neurology, University of Minnesota  
  
"New Therapies for Obesity and GI Disorders" *Mark B. Knudson*, EnteroMedics Inc.  
"Introducing New Neurologic Devices: Where Do We Go from Here and How Do We Get There?" *Steve Haines*, Department of Neurosurgery, University of Minnesota  
"The Use of Vagal Nerve Stimulation in the Treatment of Bulimia Nervosa" *Patricia L. Faris*, Department of Psychiatry, University of Minnesota
**Session F4: Contributed Papers 2**

*Chair: Balakrishna Haridas – Department of Biomedical Engineering, University of Cincinnati*

"A Light Weight Compliant Hand Mechanism with High Degrees of Freedom" **Jason Potratz**, Department of Mechanical Engineering, University of Iowa

"A Remotely Controlled Manipulator for Magnetic Resonance Imaging Guided Interventions on the Abdomen and Thoracic Cavities Inside High Field Cylindrical MR Scanners" **Nikolaos V. Tsekos**, Mallinckrodt Institute of Radiology, Washington University

"A Non-Invasive Device for In Vivo Assessment of Pelvic Floor Mechanics: Applications in Urinary Incontinence and Pelvic Floor Surgery" **Balakrishna Haridas**, Department of Biomedical Engineering, University of Cincinnati

"Tissue Characterization for Improved Penile Occlusive Device Design" **David Wulfman**, Department of Mechanical Engineering, University of Minnesota

"Detection of Heart Murmurs Using Wavelet Packet Analysis and Artificial Networks" **Nicholas Andrisievic**, University of Minnesota - Duluth

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**Session F1: Intellectual Property and Regulatory Affairs**

*Chair: Susan Bartlett Foote – School of Public Health, University of Minnesota*

"Paths to Market and FDA Product Lifecycle Regulation" **Patricia Kaeding**, Godfrey & Kahn, S.C.

"Successful Patent Strategies for Medical Device Companies" **Brad Pedersen**, Patterson, Thuente, Skaar & Christensen, P.A.

"Current Issues in Medicare Reimbursement of New Technologies" **Susan Bartlett Foote**, School of Public Health, University of Minnesota

"Obtaining Coverage for New Medical Device Technology in an Evolving Market" **Gary Goetzke**, ArthroCare Corp.

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**Session F2: Auscultation**

*Chair: Hatim Carim - 3M*

"The Power of Repetition in Mastering Cardiac Auscultation: A Psychoacoustic Model" **Michael Barrett**, Department of Medicine (Cardiology), Drexel University

"Stethoscope and Technology - Is Marriage Inevitable?" **Andrey Vyshesky**, Stethographics


"Diagnosis of Heart Sounds using Voice Recognition Technology" **Marie Guion**, Department of Mechanical Engineering, University of Minnesota

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**Session F3: Contributed Papers 3**

*Chair: Bruce Hammer – Department of Radiology, University of Minnesota*

"Design of a Robotic Gait Trainer using Spring Over Muscle Actuators for Ankle Stroke Rehabilitation" **Kartik Bharadwaj**, Department of Mechanical Engineering, Arizona State University

"MRI Compatibility Testing of Medical Devices for the R&D Engineer" **Bruce E. Hammer**, Department of Radiology and Center for Interdisciplinary Applications in Magnetic Resonance, University of Minnesota

"Design of the Robotic Tendon" **Kevin Hollander**, Department of Mechanical and Aerospace Engineering, Arizona State University

"Novel Stent for Dacryocystorhinostomy (DCR) and other Surgical Applications" **David Wulfman**, Department of Mechanical Engineering, University of Minnesota

"Optimization of Compositions in Hydroxyapatite-Gelatin Nanocomposites" **Ching-Chang Ko**, Minnesota Dental Research Center for Biomaterials and Biomechanics, University of Minnesota
3:30 - 5:00  **Session F4: Contributed Papers 4**

**Ballroom D**

Chair: *Rungun Nathan* – Department of Mechanical Engineering, Villanova University

"Kinematic Requirements for an Upper-Arm Orthosis Based on Activities of Daily Living (ADL)"  *Rungun Nathan*, Department of Mechanical Engineering, Villanova University

"Ureteral Stents: Coil Strength and Durometer"  *Kari Hendlin*, Department of Urology, University of Minnesota

"Robotic Surgery: Results of an Ethnographic and Design Research Program"  *Mary Beth Privitera*, University of Cincinnati

"A Novel Tool for Strength Assessment of the Hand and Wrist"  *Mark Carl Miller*, Allegheny General Hospital

"A Motorized Microdrive for Recording of Neural Ensembles in Awake Behaving Rats"  *David Redish*, Department of Neuroscience, University of Minnesota

5:30 - 7:00  **President's Conference Kick-Off Dinner (Sponsored by Medtronic)**

**Ballrooms A-D**

Chair: *Paul A. Iaizzo* – Department of Surgery, University of Minnesota

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

*Deborah E. Powell*, Dean, Medical School, Assistant Vice President for Clinical Sciences, University of Minnesota

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**A Special Thanks to:**

**Our Organizing Committee:**

*Arthur G. Erdman*, Conference Chair  
Department of Mechanical Engineering, University of Minnesota

*William K. Durfee*, Program Chair  
Department of Mechanical Engineering, University of Minnesota

*Paul A. Iaizzo*, President's Conference Program Chair  
Department of Surgery, University of Minnesota

*Alyssa A. Burger, Jennifer A. André, Lindsey M. Reiff*, Conference Administration  
Department of Mechanical Engineering, University of Minnesota

*Kristine Miller, Danielle M. Kasprzak*, Conference Administration  
The Biomedical Engineering Institute, University of Minnesota

*Gary Williams*, AV Coordinator  
Department of Surgery, University of Minnesota

*Mary Koppel*, Assistant Vice President for Public Affairs  
Academic Health Center, University of Minnesota

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**University of Minnesota:**

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Academic Health Center  
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Radisson Hotel Metrodome
8:00 - 8:10  Conference Objective and Vision
            Paul A. Iaizzo, Program Chair
            Arthur G. Erdman, Conference Chair

8:10 - 8:30  Welcome and Introduction
            Robert Bruininks, President, University of Minnesota

8:30 - 10:20  Session 1
            Leading change through creative partnerships with the State of Minnesota motivated by medical device breakthroughs
            Frank B. Cerra, CHAIR, Senior Vice President, Academic Health Center, University of MN
            Norm Coleman, Senator, State of Minnesota
            Timothy Mulcahy, Vice President for Research, University of Minnesota
            Kenneth H. Keller, Hubert H. Humphrey Institute, University of Minnesota

10:20 - 10:40  Break

10:40 - 12:30  Session 2
            Leading the change with industry to enhance research and development and engage the next generation of health professionals in the development and use of new medical devices
            Richard W. Bianco, CHAIR, Assistant Vice President for Regulatory Affairs, Office of the Vice President for Research, University of Minnesota
            Jeffrey McCullough, Director of Biomedical Engineering Institute, University of Minnesota
            Jagjit Gill, Vice President of Marketing and Business Development, Advanced Bionics/Boston Scientific
            Scott Augustine, CEO, Augustine Biomedical and Design

12:30  Luncheon

1:30 - 3:30  Session 3
            Leading change with the BioBusiness Alliance of Minnesota to ensure the state remains a leader in the medical device industry
            Dale Wahlstrom, CHAIR, Vice President, Medtronic
            Jeremy Lenz, Project Executive, BioBusiness Alliance of Minnesota
            Tim Laske, Sr. Director of Platform Technologies, CRM, Medtronic
            Timothy Mulcahy, Vice President for Research University of Minnesota

3:30  Social Hour
Tianhong Cui, PhD, is serving as the Regents Professor at the University of Minnesota starting from 2005. Prior to that, he was an Associate Professor at Tech University from 1999 till 2003. In 2000, he also served as the STA fellow in Japan from 1998 to 1999. He published more than 10 papers in peer-reviewed journals and conferences. His research interests include MNSBEM, micro/nanomanufacturing, and nanoparticle- and polymer-based micro-devices.

John Denstedt, M.F.R.C.S.C., is Professor of Urology and Chairman of Surgery at the University of Western Ontario in Canada. He is one of the top urologists in Canada and has been involved in developing new treatments for prostate disease, endourology and minimally invasive surgical techniques in Urology. Dr. Denstedt has had a major research interest in urologic endourology in biotransformations related to cancer therapy. He has published over 150 scientific articles and book chapters and has received a number of awards including the American Urological Association Gold Cystoscopic Award.

Daniel Eberly, is a former student and graduate from the University of Minnesota Law School. Since 1993 he is currently the Chair of the National Institute of Health Policy and President of Public Policy Partners LLC, a health policy consulting firm.

William K. Durfee, PhD, is a Professor and Director of Design Engineering at the Department of Mechanical Engineering at the University of Minnesota. His professional interests include optimization engineering, machinery design, and product design.

Elwood Eidelberg, MD, PhD, is a graduate of Harvard and is a pioneer in vascular biology and biotechnology development and assessment. He directs the Harvard-MIT Biomedical Engineering Center which applies the rigorous of physical sciences to elucidate biological processes and disease mechanisms.

AI Elmore is currently the CEO of Stantec and the former President and Chief Executive Officer of Vital Images, Inc.

Arthur E. Edelman, PhD, specializes in kinematics, biomechanics and medical device design. His research and development activities include dentistry, orthopedics, neurology, urology, MR-guided instruments, cardiology and sports biomechanics.

Patrick A. Faris, PhD, received his Ph.D. in psychological science from the Institute of Animal Behavior, Rutgers and a post-doctoral fellowship at Department of Psychiatry, Washington University School of Medicine. She is an Associate Professor at the University of Minnesota Department of Psychiatry and a licensed psychologist.

Frank Fischer is a mechanical engineer who has been developing medical devices for 16 years with the COOK Group of companies. Working in Radiology, Critical Care, Surgical and Urology departments, Dr. Fischer has consulted for the world's 15 largest US and international medical device companies.

Bryan Fonslow, works as a research assistant in the Chemistry Department at the University of Minnesota.

Brad could currently work with microTEC. Drawing from his long-term industrial experience and technical skills, Brad works with partners specialized in chemistry and robotics to make customer's products a reality.

Michael Fisher, MD, is an Associate Professor of Radiological Engineering at Penn State University. She holds a PhD in Mechanical Engineering from University of Michigan. Dr. Fisher's research involves developing instrumentation for minimally invasive surgical navigation of smart structural materials.

Jagi Gill is the President of Marketing and Business Development for Advanced Bionics/Boston Scientific. In this role, he is focused on identifying and cultivating new technologies and technologies to improve the state of the art for our neurostimulation business group. He was trained in the medical sciences at the Mayo Clinic, Georgetown Medical Center and McGill University.

Joe Gibson, B.S.M.E., is currently a student, with credits in life sciences, health policy and medical design, including 7 years in spine implant instrumentation and training.

Gene Goodfellow is the Bioscience Industry Specialist for the Minnesota Department of Employment and Economic Development (DEED). He serves as the lead staff for Governor Pawlenty's Bioscience Initiative. Gene also sits on the Board of Directors for the Biobusiness Alliance of MN and is a past board MNBIO.

Gary Geetko, JD, is an attorney with over 20 years experience in health care, including 15 with Medtronic. He speaks regularly to hospitals across the system on current compliance and executive vice president.

Nina Gomes, PharmD, Nina Graves, Pharmacology Program Manager at Medtronic, where she is working to develop new device-based therapies for epilepsy. Prior to joining Medtronic in 1996, she was Associate Professor in the College of Pharmacy at the University of Minnesota.

Rod Greder, PhD, President of New Productivity Group, works with technical leaders to develop breakthrough products. The company's seminars, workshops, and conferences focus on improving the seven criteria of the high product developer and technical leaders. Dr. Greder has spoken at and consulted with Medtronic, Pessia Medical, Medical Alley, Minnesota Technology Inc. Medical Device Resource Group, Center for the Development of Technological Leadership and the US Embassy in Belgium, and the University of Illinois. He is an expert in engineering and management at the University of St Thomas and Hamline University. He also serves on the board of the Product Development and Management Association (PDM).
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