

Surfaces in Biomaterials Foundation

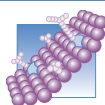


## BiolInterface Workshop & Symposium

October 3-5, 2016

The Commons Hotel | Minneapolis, Minnesota USA

# 2016 Program Book



Surfaces in Biomaterials Foundation

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# Welcome from the President



Welcome  
Surface Science  
Professionals,  
Colleagues and  
Friends,

On behalf of  
the Surfaces  
in Biomaterials  
Foundation  
(SIBF), I  
welcome you  
to BioInterface  
2016. The  
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Symposium has been presented annually by the Foundation since 1991. The Foundation was founded based on the premise that the interface between the body and a medical device is critical to the device's performance. From another perspective, the Foundation also facilitated the interface between various industries and with academia to address challenges with bringing medical devices through to the clinic. As was the case in previous Symposia, this year's technical program provides a forum where a diverse group of scientists can openly discuss and debate recent innovations and research topics. The BioInterface Symposium has a strong applied

focus and brings together engineers, scientists, clinicians, and regulatory experts from all aspects of the biomedical community. Throughout the years, this conference has been characterized by many in our industry and academia alike as a preeminent technical symposium that allows easy connection between attendees; I am confident that this year's technical program will more than live up to this description.

I encourage you to take this opportunity to engage and interact with your fellow attendees who represent the leading corporations, startups and educational institutions that research and produce the innovative medical devices and products that help people to live longer, healthier and more productive lives.

Thank you for attending this year's meeting. We hope your experience at the 2016 BioInterface Symposium stimulates your thinking and provides you with information and solutions that will be beneficial in your ensuing scientific endeavors.

Sincerely,

Chander Chawla  
President, Surfaces in Biomaterials Foundation

## 2016 Program Committee

**Roy Biran**, W.L. Gore & Associates

**Dave Carr**, Physical Electronics

**Siobhan Carroll**, Boston Scientific

**Joe Chinn**, J Chinn LLC

**Elizabeth Cosgriff-Hernandez**, Texas A&M

**Aylvin Dias**, DSM Ahead

**Greg Fisher**, Physical Electronics

**Rob Kellar**, Development Engineering Sciences, LLC

**Chelsea Magin**, Sharklet Technologies, Inc.

**Joe McGonigle**

**Bill Theilacker**, Medtronic plc

**Chris Wattengel**, DSM Biomedical

# Schedule (Monday & Tuesday)

## MONDAY, OCTOBER 3

7:45–8:45am	Pre-Registration and Continental Breakfast Room — Meridian Foyer
8:45am–3:00pm	<b>BIOINTERFACE WORKSHOP — MERIDIAN I-III</b> <b>Theme: Sensing at the BioInterface</b> <b>Chair: Joe McGonigle, Dymedex</b>
8:45–9:00am	Welcome and Introductions — Meridian I-III
9:00–9:45am	<i>Ron Siegel, University of Minnesota</i> “ <b>Sensors and Drug Delivery</b> ”
9:45–10:30am	<i>Raeann Gifford, Medtronic Diabetes</i> “ <b>Contrast of Foreign Body Response (FBR) on Different Functional Types of Implanted Medical Devices (e.g. Sensors Versus Pacemakers)</b> ”
10:30–10:45am	Break — Meridian Foyer
10:45–11:30am	<i>Natalie Wisniewski, Profusa</i> “ <b>Tissue Integrating Sensors</b> ”
11:30am–12:15pm	<i>Diana Eitzman &amp; Amy McNulty, 3M</i> “ <b>Adhesive and Material Considerations for Wearable Devices</b> ”
12:15–1:15pm	Luncheon — Pinnacle Ballroom
1:15–2:00pm	<i>Gerard L. Coté, PhD, Texas A&amp;M</i> “ <b>Sensors, Wearables and Mobile Technologies</b> ”
2:00–2:45pm	<i>Jian-Ping Wang, University of Minnesota</i> “ <b>Nanomagnetic Biosensing as a Platform Technology for Early Disease Detection and Prevention</b> ”
2:45–3:30pm	Break — Meridian Foyer

3:30–4:30pm	<b>KEYNOTE LECTURE — MERIDIAN I-III</b>
	<i>Stephen Badylak, McGowan Institute</i> “ <b>Mechanisms by Which Biologic Scaffolds Influence Cell Behavior</b> ”



Biomaterials can be generally classified as synthetic versus biologic, or degradable versus nondegradable. The utility of biomaterials for various clinical applications has historically focused upon mechanical and material variables such as composition, strength, and porosity, among others. However, the ultimate determinant of clinical success or failure is the host response to the material itself. The immediate host response to an implanted biomaterial involves the vroman effect (adsorption of plasma proteins), followed by an acute and chronic innate cellular immune response. The phenotype of cells which respond to the material in the early phase contributes to the microenvironmental conditions which orchestrate downstream events. The signals which are associated with favorable versus unfavorable outcomes are only partially known and will be the subject of the present discussion.

## TUESDAY, OCTOBER 4

7:30–8:30am	Registration and Continental Breakfast — Meridian Foyer
8:30am	President's Welcome — Meridian I-III



# Schedule (Tuesday)

## 8:30–10:00am SESSION 1

### Engineering Interfaces for Regenerative Medicine

#### — Meridian I-III

**Co-Chairs:** Roy Biran — W.L. Gore & Associates and Chelsea Magin  
— Sharklet Technologies, Inc.

8:30–9:00am *Invited Speaker: Bob Tranquillo, University of Minnesota* “Off the Shelf” Heart Valves and Vascular Grafts Grown In Vitro”

9:00–10:00am *Melissa Reynolds, Colorado State University* “Materials as Conduits for Directing Cell Behavior”

*Conrado Aparicio, University of Minnesota* “The Use of Oligopeptides and Recombinamers to Improve Performance of the Biomaterials Surface”

*John O'Donoghue, TheraDep* “BioDep - Tailored Interfaces Using Pure Biologic Coatings”

10:00–10:30am Exhibitor Break — Meridian Foyer

## 10:30am–12:00pm

## SESSION 2

### Structural Heart Valve/General Mechanics — Meridian I-III

**Chair:** Siobhan Carroll — Boston Scientific

10:30–11:00am *Invited Speaker: Alan Pelton, G. Rau Inc.* “Towards the Understanding of the Biocompatibility of Nitinol Biomedical Devices”

11:00am–12:00pm *Jonathan Stinson, Boston Scientific* “Tailoring Radiopacity of Thin-Wall Vascular Implant Alloy”

*Juergen Scherer, Evans Analytical Group* “Surface and Other Analytical Characterization Methods for Implantable Medical Devices”

*Christina Gross, American Preclinical Services* “Preclinical Models for Surgical or Trans-Catheter Heart Valves”

12:00–1:00pm Attendee Luncheon & Student Town Hall Meeting — Pinnacle Ballroom  
**Co-Chairs:** Norman Munroe, Florida International University and Melissa Reynolds, Colorado State University

1:00–1:30pm Surfaces in Biomaterials Foundation Annual Business Meeting — Pinnacle Ballroom

## 1:30–3:00pm SESSION 3

### Polyurethane Biodegradation and the New Generation of

### Biostable Polyurethanes — Meridian Foyer

**Chair:** Elizabeth Cosgriff-Hernandez — Texas A&M

1:30–2:00pm *Invited Speaker: James Anderson, MD PhD, Case Western Reserve University* “Historical Perspective of Polyurethane Biostability”

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# Schedule (Tuesday & Wednesday)

2:00–3:00pm

*Robert Ward, ExThera Medical Corporation* “**Development of Replacement Polyurethanes for Implantation and Their Use as Platforms for New Biomaterials Development**”

*Christopher Jenney, St. Jude Medical* “**The Evolving Science of Siloxane-Based Polyurethane Biostability**”

*Joseph Kennedy, The University of Akron* “**Biostable Polyisobutylene-based Polyurethanes**”

3:00–4:00pm

Reception Featuring the Academic Poster Competition — Meridian IV  
**Co-Chairs:** Norman Munroe, Florida International University and Melissa Reynolds, Colorado State University

4:00–5:00pm

## SESSION 4

**Point Counterpoint — Meridian I-III**

**Moderator:** Frank Bates, University of Minnesota

“**How to Introduce New Materials?**”

*Speakers: Kimberly Chaffin, Medtronic; Christopher Jenney, St. Jude; Patrick Willoughby, Boston Scientific; Elizabeth Cosgriff-Hernandez, Texas A&M; Tim Lodge, University of Minnesota*

**Thank You, Session Sponsor!**



5:00pm

Conclusion of Symposium Day One

## WEDNESDAY, OCTOBER 5

8:00–8:30am

Registration and Continental Breakfast — Meridian Foyer

8:30–10:00am

## SESSION 5

**Neurovascular — Meridian I-III**

**Chair:** Bill Theilacker — Medtronic plc

8:30–9:00am

*Invited Speaker: Duncan Maitland, Texas A&M* “**Cerebral Vascular Aneurysm Embolization Using Shape Memory Polymer Foam-Over-Coil Devices**”

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9:00–10:00am

*John Wainwright, Medtronic* “**Advances in Flow Diverters and Neurothrombectomy Devices**”

*Ramanathan Kadirvel, Mayo Clinic* “**Intra-saccular Flow Disruption in Brain Aneurysms: New Observations and Hypotheses at the Interfaces between Blood, Aneurysm Sac, and Device.**”

10:00–10:45am

Exhibitor Break & Poster Session — Meridian Foyer & Meridian IV

10:45am–  
12:15pm

## SESSION 6

**Characterization Methods & Molecular Imaging (Part 1)**

**— Meridian I-III**

**Co-Chairs:** Dave Carr — Physical Electronics and Greg Fisher — Physical Electronics



# Schedule (Wednesday)

10:45–11:15am	<i>Invited Speaker: Professor Ron M.A. Heeren – University of Maastricht (M4I) “Multimodal Molecular Imaging at the Interface of Health and Disease”</i>	<div><div><b>Thank You, Session Sponsor!</b></div><div></div></div>
11:15am–12:15pm	<i>Nathan Havercroft, ION-TOF USA, Inc. “Label-Free 3D Analysis of Biological Tissue with Micron Spatial and 240k Mass Resolution Using a New SIMS Hybrid MassAnalyser by Advancements in Mass Analyzers”</i> <i>Kevin Chen, Medtronic, plc “Design, Materials and Characterization of Primary Batteries for Implantable Devices” — Meridian I-III</i> <i>Christopher Anderton, Environmental Molecular Sciences Laboratory, Pacific Northwest National Laboratory “We’re not in Kansas anymore: exploring new SIMS applications spawned by advancements in mass analyzers”</i>	
12:15- 1:40pm	Awards Luncheon & Student Poster Winner Announced Presentation of the Excellence in Surface Science Award — Pinnacle Ballroom	
<b>1:40–3:00pm</b>	<b>SESSION 7</b> <b>Characterization Methods &amp; Molecular Imaging (Part 2)</b> <b>— Meridian I-III</b> <b>Chair:</b> Chris Wattengel — DSM Biomedical  <i>Greg Haugstad, Characterization Facility, University of Minnesota “Probing the Morphology, Nanomechanics and Tribology of Biomedical Gels with AFM”</i> <i>Stefan Kaemmer, JPK Instruments USA “From Molecular Imaging to MicroRheology: Nanomechanics and Imaging on the Nanometer Scale”</i> <i>Chuck Extrand, CPC “Measuring Contact Angles Inside of Capillary Tubes with a Tensiometer”</i> <i>Syed A. Asif, Hysitron “A New In-Operando Technique for Mechanical Property Characterization of Soft Matter”</i>	
3:00–3:10pm	Break — Meridian Foyer	
<b>3:10–5:00pm</b>	<b>SESSION 8</b> <b>3D Printing and Bioplotting for Medical Applications</b> <b>— Meridian I-III</b> <b>Co-Chairs:</b> Aylvin Dias — DSM Ahead and Janelle Schrot — Materialise	
3:10–3:40pm	<i>Invited Speaker: LT James Coburn, Center for Devices and Radiologic Health and Laura Ricles, PhD, Center Biologics Evaluation and Research “FDA Perspective: 3D Printing for Medical Devices and Combination Products”</i>	
3:40–4:40pm	<i>Michael C. McAlpine, University of Minnesota “3D Printing Functional Materials and Devices”</i> <i>Janelle Schrot, Materialise “Implants for Hard and Soft Tissue: 3D Printing Changing the Market”</i>	
4:40pm	Program Concludes	

# Point Counter Point “How to Introduce New Materials?”

Moderator: Frank Bates, University of Minnesota

## Part 1: Point of View from Three Major Medical Device Manufacturers

— *Medtronic (Kimberly Chaffin); Boston Scientific (Patrick Willoughby); and St. Jude (Christopher Jenney)*

## Part 2: Academic Point of View Around Biological Testing vs. Material Testing Conditions

— *Biological perspective (Elizabeth Cosgriff-Hernandez, Texas A&M) and Materials perspective (Tim Lodge, University of Minnesota)*

## Part 3: Open Discussion (by Frank BATES)

A material's useful life in the human body is defined by the length of time that the material is able to perform its function in a given application. Depending on the functional requirements of the material, one application may result in a drastically different useful life compared to a different application using the identical material. This is precisely the reason that the FDA and other regulatory bodies do not “approve” materials, but rather, they approve devices. Trends in healthcare, which include earlier diagnoses and more effective treatments, have led to an increasing and sharply rising change in the time a typical patient will live with a chronically implanted medical device. This expanded longevity combined with the push toward smaller devices has driven the materials traditionally used in many medical device applications to, or even beyond, their performance limits. Because of this, now more than ever, the industry needs new materials to fill the performance gap created by miniaturization coupled with increasing longevity expectations.

In this panel discussion, we will explore the topic of how one should think about introducing new materials for use in chronically implanted devices which are designed to have longevity expectations in the decade plus range.

**Position 1:** The biological environment of implanted devices is too complex to understand. New materials should follow the same testing methodology as traditional materials. This strategy has led to design rules and a material level understanding that has allowed for the highly reliable chronically implanted medical devices we have today. The approach primarily relies upon 0.5-2 year preclinical in vivo work. A secondary consideration is the performance of the material in extreme in vitro oxidative and hydrolysis challenges as compared to a control material which has previously shown acceptable human in vivo performance. Similar results in the tests between the control material and the new material give high confidence in a new material's bio stability and thus a “green” light for use in a product. Performance feedback from real time human in vivo exposure allows for product designs to evolve, leading to highly reliable medical devices.

**Position 2:** To meet the longevity expectations of tomorrow, predictive accelerated testing must be used to understand the future properties of the material (10+ years). This change in thinking demands three things. First, the reactions causing degradation must be identified. Second, testing protocols that isolate and accelerate these reactions must be developed. Third, the role of preclinical animal testing must be de-emphasized. By identifying, isolating, and quantitatively accelerating potential degradation reactions in vitro, the rate of chemical change and the associated mechanical consequences can be assessed for extents of reaction that are predicted to occur a decade or more down the road. The low number of replicates and the high variability of pre-clinical animal data mean the role of preclinical testing is drastically changed. Rather than being the primary tool for determining biocompatibility, the role of the pre-clinical animal work becomes to validate that the real time in vivo and the accelerated in vitro test conditions result in the same chemical susceptibilities.



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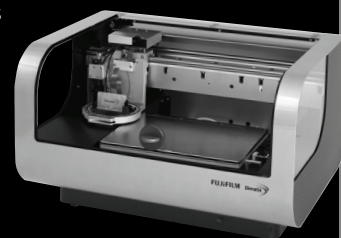
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# Student Posters

## Material Characterization of Natural and Synthetic Thrombus

— Sharna Beahm, Northern Arizona University

## Imaging ToF-SIMS of Human Breast Cancer Tissues: Results from a Clinical Trial

— Blake Bluestein, University of Washington

## In Vitro Neurovascular Model Development for Accurate Biomaterials Characterization and Testing

— Laura Bonsmann, Northern Arizona University

## Fabrication of Biomimetic Bone Grafts with Multimaterial 3D Printing

— Prachi Dhavalikar, Texas A&M University

## Synthesis and Characterization of Biostable Shape Memory Polymer Foam Scaffolds

— Grace Fletcher, Texas A&M University

## Characterization and Analysis of Human Blood Clot

— Connor Gonzalez, Northern Arizona University

## Characterizing the Material Properties of an in Vitro Neurovascular Model

— Kayla Goodrich, Northern Arizona University

## Investigation of the Cytocompatibility of Shape Memory Polymer Devices

— Scott Herting, Texas A&M University

## Development of Synthetic Thrombus

— Anne Marie Holter, Northern Arizona University

## Development of Synthetic Neurovascular Hydrogel

— William Merritt, Northern Arizona University

## Improving the Degradation Resistance of a Magnesium Alloy Using a Polymer Coating

— Elnaz Mirtaheri, Florida International University

## Effects of Sterilization on Shape Memory Polyurethane Embolic Foam Devices

— Rachael Muschalek, Texas A&M University

## Integration of a Chelation Agent into an Electrospun Scaffold

— Bronson Pinto, Northern Arizona University

## Criteria for Neurological Applications of Translucent Nanograin Hydroxyapatite Ceramics

— Jonathan Schnur, Alfred University

## Degradation of Shape Memory Polyurethanes

— Andrew Weems, Texas A&M University

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Opening day at Target Field. Photo by Wayne Kryduba, MLB Photographer; photo courtesy of Meet Minneapolis. North Star Bicycle Festival in Minneapolis, MN; photo courtesy of Meet Minneapolis. First Avenue the night Prince passed away. Photo by Faster Horses Workroom. "Minnehaha falls - night." Photo courtesy of Flickr: m01229.



# Excellence in Surface Science Award Winner



*Antonios G. Mikos*

**Antonios G. Mikos** is the Louis Calder Professor of Bioengineering and Chemical and Biomolecular Engineering at Rice University. His research focuses on the synthesis, processing, and evaluation of new biomaterials for use as scaffolds for tissue engineering, as carriers for controlled drug delivery, and

as non-viral vectors for gene therapy. His work has led to the development of novel orthopaedic, dental, cardiovascular, neurologic, and ophthalmologic biomaterials. Mikos is a Member of the National Academy of Engineering, the National Academy of Medicine, and the Academy of Medicine, Engineering

and Science of Texas. He is a Fellow of the American Association for the Advancement of Science, the American Institute of Chemical Engineers, the American Institute for Medical and Biological Engineering, the Biomedical Engineering Society, the Controlled Release Society, the International Union of Societies for Biomaterials Science and Engineering, the Tissue Engineering and Regenerative Medicine International Society, and the National Academy of Inventors. He has been recognized by various awards including the Lifetime Achievement Award of the Tissue Engineering and Regenerative Medicine International Society-Americas, the Founders Award of the Society For Biomaterials, and the Robert A. Pritzker Distinguished Lecturer Award of the Biomedical Engineering Society.

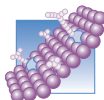
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