

SurFACTS in Biomaterials

1000 Westgate Drive Suite 252 • St. Paul, MN 55114 • (651) 290-6267 Phone • (651) 290-2266 Fax

www.surfaces.org

Fall 2006

Volume 11 Issue 3



This year's BioInterface promises to be the best yet!

This year's premier Symposium has finally arrived: BioInterface. The Foundation has worked hard to bring the best of what the industry has to offer for educational and networking opportunities. This year we travel to the San Francisco Bay Area to meet and learn from our colleagues involved in Neurovascular technology.

HIGHLIGHTS This year, there are many different opportunities for attendees to learn and network with the industry—for both student and current industry professionals alike. All attendees will find the symposium to be truly enlightening!

EXCELLENCE IN SURFACE SCIENCE AWARD The Excellence in Surface Science

award is given once a year to an individual who has demonstrated work that has significantly advanced the field of Surface Science. This year, the Surfaces in Biomaterials foundation is proud to bestow this honor upon Robert Ward.

Robert Ward's distinguished career in the biomaterials field began at Avco Corporation in the 1970s. There, he developed Cardiothane®-610, and was instrumental in advancing Cardiothane®-51, the silicone-modified polyurethane used in the first clinical intra-aortic balloon pump. While employed at Thoratec Laboratories, Ward developed the material now known as Thoralon®, a thromboresistant and biocompatible polymer blend used in the Pierce-Donachy VAD.

Biosurfaces and Bioinventions

By Steve Goodman

I trust you've made your reservations for BioInterface 2006 already, but if not, it's not too late. As always, BioInterface offers an opportunity to connect, reconnect, and learn about the latest developments in our various Bio-Surface disciplines. This issue of *SurFACTS* provides all the details on the meeting. Please note our esteemed keynote speakers, Dr. Allan Hoffman and Dr. Robert Ward, and note the full program with the usual broad range of exciting scientific presentations and posters, and the ever-popular and provocative debate format of the Rump Session. But that is not all.

I want to bring to your attention a new type of session, the Invention Symposium that will close the meeting. This session provides a unique forum for those with very-early-stage biomedical devices and device concepts to present their ideas. Submissions are currently streaming in, and range from cutting-edge tissue-engineering applications to novel birth control technologies. Each is in search of funding and partnerships.

While the Invention Symposium may be the closing session, this is really the beginning: Entrepreneurship is where our business really began and where it finds continual renewal. Most, if not all, of our medical device technologies at some time began as a simple germ of an idea that was then further

*Biosurfaces and Bio Inventions
Continued on Page 9*

What's Inside

Biomedical Surface Characterization with Time-of-flight Secondary Ion Mass Spectrometry Pg. 2

Regulatory Update Pg. 3

Stents in the News Pgs. 4-7

Committee Volunteers Wanted! Pg. 7

Board of Directors Nominations Open Pg. 9

Complete BioInterface 2006 Schedule Pgs. 12-13

Register for BioInterface Pg. 14

Member Profile: Plasma Technology Systems Pgs. 15-16

Member Profile: Hysitron, Inc. Pgs. 20

Hysitron Receives National Recognition at the Tibbetts Awards Pg. 21

Calendar Pg. 22

Volunteers Wanted! Pg. 22

BioInterface Continued on Page 12

Biomedical Surface Characterization with Time-of-Flight Secondary Ion Mass Spectrometry *By David Castner*

When a biomedical device is placed in the body, its surface region is the interface between the material and the biological environment. It is at the surface where the biological reaction (protein adsorption, cell attachment, inflammation, etc.) with the biomedical device occurs. Thus, it is essential to characterize the surface composition and structure of the materials used to fabricate biomedical devices and the biomolecule interactions with the surfaces of those materials. A wide range of surface analysis techniques can be used to characterize biomaterials. Some examples include electron spectroscopy for chemical analysis (ESCA, also known as x-ray photoelectron spectroscopy or XPS), secondary

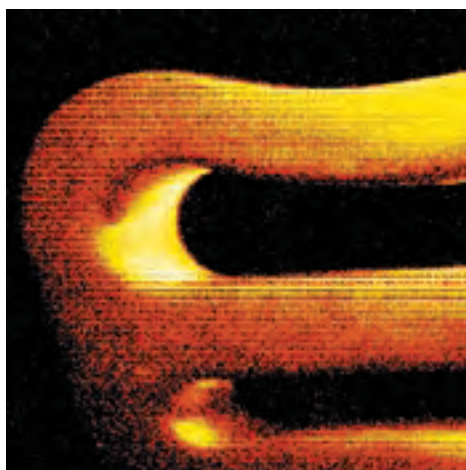


Figure 1. A total positive ion image of a metallic stent acquired with an ULVAC-PHI TRIFT instrument using a Au LMIG. The field of view is 400 μm x 400 μm .

ion mass spectrometry (SIMS), contact angle measurements, and atomic force microscopy (AFM). Each of the different surface analysis techniques has its own set of strengths and weaknesses. Thus, it is typically necessary to use a complementary, multi-technique analysis approach to obtain a detailed characterization of biomaterial surface composition and structure.

SIMS, being a mass spectrometry based technique, has the strength of providing information about the molecular structure of biomedical surfaces and biomolecules (proteins, lipids, etc.) immobilized onto those surfaces. It is also the surface analysis technique that has probably seen

the largest number of advances in the past 20 years. Originally this technique used a quadrupole mass analyzer and gas primary ion sources. Although some interesting results were obtained with that instrumentation, the low-level performance of those instruments (low mass resolution, poor spatial resolution, and lack of high molecular weight fragments, etc.) limited what could be achieved. Fortunately, significant advances have been made in mass analyzers, primary ion sources and data analysis methodologies over the past 20 years. Some of the most important developments include the implementation of time-of-flight (ToF) mass analyzers, liquid metal ion guns (LMIGs), cluster ion beam sources, and multivariate analysis (MVA) methods. These have resulted in significant (in some cases orders of magnitude) improvements in the mass resolution, spatial resolution, high mass fragment yields, sensitivity and information content of SIMS data. ToF analyzers are now so widely used the technique is typically referred to as ToF-SIMS. LMIGs have been the work-horse ion sources for over 10 years, and in the last five years MVA methods are finding increasing use for processing the complex and information-rich ToF-SIMS data. Although the first cluster ion beam sources appeared 15 years ago, it has only been in the past few years that they are starting to become widespread. Now commercial ToF-SIMS instruments can be purchased with a C60 electron impact ion source and a Au or Bi cluster LMIG. These new cluster ion beam sources hold the promise of revolutionizing the types of experiments that can be done with ToF-SIMS.

The key advantages of the cluster ion sources for biomedical ToF-SIMS applications are their increased yield of high molecular weight fragments and low sample damage rates, especially for the C60 source. Traditionally the SIMS analysis has been divided into two regimes, dynamic and static. The dynamic SIMS regime focused on sputter depth profiles of atomic compositions in inorganic materials. This has widespread application in

Characterization Continued on Page 10

SurFACTS in Biomaterials is the official publication of the foundation and is dedicated to serving industrial engineers, research scientists, and academicians working in the field of biomaterials, biomedical devices, or diagnostic research.

Foundation Officers

Dan Ammon, President

Bausch & Lomb
1400 North Goodman Street
PO Box 30450
Rochester, NY 14609-0450
Telephone 585-338-8387
Facsimile 585-338-5304

Jim Brauker, Past President

Dexcom, Inc.
6725 Mesa Ridge Road
San Diego, CA 92121
Telephone 858-812-9600 x204
Facsimile 858-812-9601

Victoria Carr-Brendel, President-Elect

Boston Scientific Corporation
47900 Bayside Parkway
Fremont, CA 94538-6515
Telephone 510-624-2348
Facsimile 510-440-7650

Joe Chinn, Vice President

SurModics, Inc.
9924 West 74th Street
Eden Prairie, MN 55344-3523
Telephone 952-947-8640
Facsimile 952-829-2743

Daniel J. Hook, Secretary

Bausch & Lomb
1400 North Goodman Street
PO Box 30450
Rochester, NY 14609-0450
Telephone 585-338-6580
Facsimile 585-338-5304

Lise Duran, Treasurer

SurModics, Inc.
9924 West 74th Street
Eden Prairie, MN 55344-3523
Telephone 952-829-2745
Facsimile 952-829-2743

Committee Chairs

Membership

Larry Salvati

BiolInterface 2006 Program

Carl Turnquist

BiolInterface 2006 Workshop

Joe Chinn

Awards

Joe Chinn

Foundation Office Staff

Bill Monn, Executive Director

1000 Westgate Drive, Suite 252
St. Paul, MN 55114
Telephone 651-290-6267
Fax 651-290-2266
Email: surfacesinbiomaterials@ewald.com

SurFACTS in Biomaterials Editors

Executive Editor

Steven Goodman
10H Technology
sgoodman@10htech.com

Biology Editor

Matthew Phaneuf
BioSurfaces
biosurfaces@verizon.net

Characterization & Analysis Editor

Klaus Wormuth
SurModics
kwormuth@surmodics.com

Modification Editor

Min-Shyan Sheu
Boston Scientific
sheu@bsci.com

Regulatory Editor

Phil Triolo
Phil Triolo & Associates LC
philt@philt.com

Advertising Manager

Ewald Consulting
surfacesinbiomaterials@ewald.com

© 2006 published by the
Surfaces in Biomaterials Foundation.
All rights reserved.

REGULATORY UPDATE

Following are some recent regulatory announcements of interest to the surfaces community. Please email me (philt@philt.com) with suggestions for other regulatory topics you'd like to see addressed in future issues of *SurFACTS*:

Drug Eluting Stents

The planned reductions in reimbursement for Drug Eluting Stents (DES) by the Centers for Medicare and Medicaid Services (See Summer Edition of *SurFACTS*) have been reduced from the originally proposed 24% to approximately 1%. In addition, the proposed changes to the diagnosis-related group (DRG) system from charge-based to cost-based calculations will be phased in over a 3-year period. The changes reflect recommendations from the Medicare Payment Advisory Commission (MedPAC) to reduce incentives for hospitals to invest in certain service areas because payment rates significantly exceed costs. Strong opposition to the originally much larger reductions was expressed by industry and professional groups who argued that the proposed reductions in reimbursements would have significantly reduced incentives to develop innovative medical products. As a result of the payment reforms implemented in 2006 and now for 2007, payments to cardiac specialty hospitals are expected to decline by a modest, but significant, 5 percent between 2005 and 2007. <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1921>.

Also of interest to manufacturers and suppliers of DES technologies is the FDA announcement that it will hold a meeting of the Circulatory System Devices Advisory panel by the end of the year to "increase [its] knowledge regarding the incidence and timing of

stent thrombosis as well as the appropriate duration of clopidogrel use in patients who receive DES." The panel will be asked to provide appropriate recommendations, specifically for possible changes to device labeling or the need for additional clinical studies. The FDA is concerned because a small but significant increase in the rate of death and myocardial infarction has been observed in patients 18 to 36 months after stent placement. The Agency reiterated its position that DES are safe and effective for their approved indications for use. <http://www.fda.gov/cdrh/news/091406.html>

FDA to Accept Electronic Copies for Pre-Market Submissions

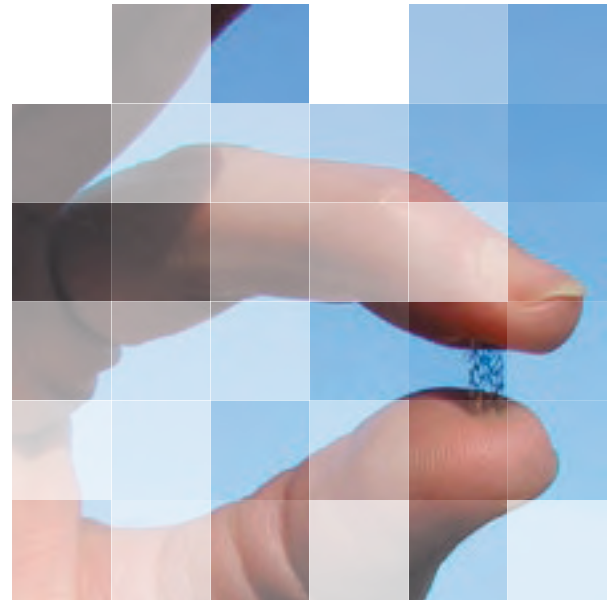
The FDA's Center for Devices and Radiologic Health (CDRH) recently published a guidance document indicating that this Center will now accept one electronic copy of premarket submissions in portable document format (.pdf). The guidance applies to, IDE, PMA, and 510(k) applications, among other documents. Hard copies of documents requiring signatures will have to accompany the .pdf copies. Formatting requirements and suggestions can be found at <http://www.fda.gov/cdrh/electsub.html>. Submission of an electronic copy is voluntary. The FDA has indicated its preference for electronic submissions, and it is predictable that eventually they will be required for all device submission. It is advised that manufacturers become familiar with the format requirements and begin to submit copies in the format to work out any problems before the format becomes mandatory. <http://www.fda.gov/cdrh/electsub.html>

Regulatory Continued on Page 18





Stents in the News



Novel Stent May Stimulate Natural Heart Bypasses

On September 3, Dutch doctors said they had developed a novel drug-coated stent to stimulate the growth of natural heart bypass arteries, potentially offering a new way to ensure blood supply to sick patients' hearts.

The device has yet to be tested on humans but tests in animals found it almost doubled the blood flow in small col-lateral arteries compared to treatment with a conventional stent.

Stents are tiny, wire-mesh tubes that are use to prop open the arteries.

Newer drug-coated stents, which are designed to prevent arterial scarring, have grown hugely in popularity in the last three years and now generate annual sales of more than \$5 billion.

Rather than simply focusing on the main coronary arteries, the experimental Dutch stent is designed to help smaller ones develop, enabling them to take over the function of narrowed or blocked ones.

It works by releasing the drug TGF-beta1, which makes ar-teries grow faster and increases their diameter, Dr. Sebas-tian Grundmann of Amsterdam's Academic Medical Center told the World Congress of Cardiology.

Further pre-clinical testing is needed before the first pa-tients can be treated with the new device. But Grundmann believes the system could eventually become an important treatment option for patients with complex heart disease for whom bypass surgery is difficult or impossible.

Boston Scientific, J&J Both Say Their Stents Are Better

*By Avram Goldstein
Bloomberg News*

Johnson & Johnson and Boston Scientific, the top makers of drug-coated heart stents, both released studies saying their \$2,200 devices are safer than bare-metal stents that cost half as much.

Johnson & Johnson's Cordis subsidiary, based in Miami Lakes, was the first to market drug-coated stents in the United States.

The new studies climaxed three days of emotional debate at Europe's biggest medical conference, the World Car-di-ology Congress in Barcelona, sparked by independent researchers who said the bare-metal stents were safer. The response in the medical community may be confusion, one analyst said.

"It's definitely muddying the water," said Robert Faulkner, an analyst with JMP Securities in New York in a telephone interview. "My instinct is that American doctors are going to find it difficult to draw an action-oriented conclusion from all this new data. It could be a statistical fluke."

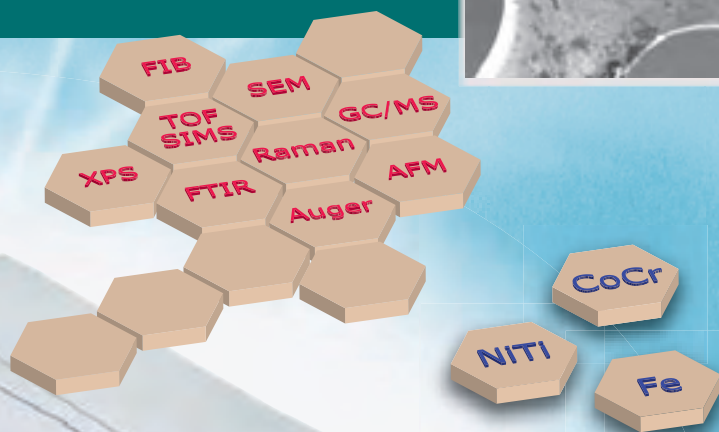
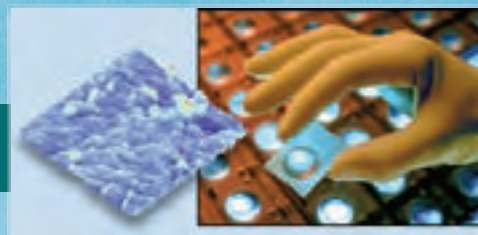
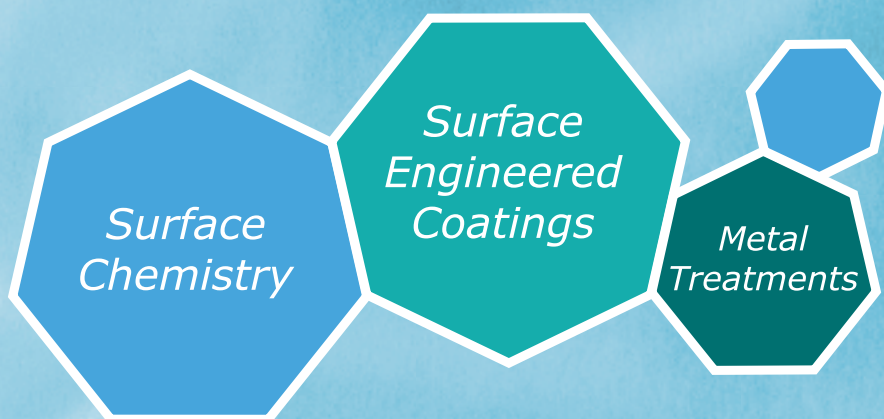
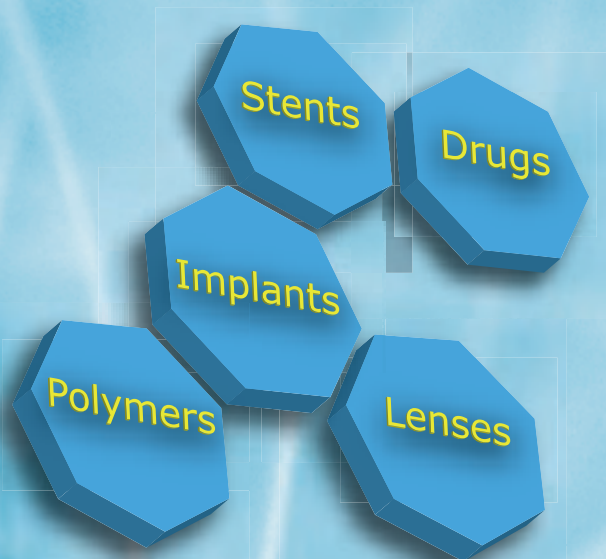
The debate is key to both J&J and Boston Scientific as they compete for \$6 billion a year in sales of drug-coated stents just as doctors are about to hear from Abbott Labs, Medtronic Inc., and other companies with newer stents coated with scar-tissue inhibiting treatments that stop re-closure of the vessel. Stents are tiny mesh tubes that prop open heart blood vessels after doctors remove blockages.

Shares of J&J, based in New Brunswick, N.J., fell 41 cents to \$64.31 in New York Stock Exchange composite trading

Better Stents Continued on Page 6

BioMaterials BioDevices BioSurfaces

Specialists in Materials Characterization



Providing state-of-the-art Surface Analysis at each stage of the product life cycle. We work with our customers to provide answers to problems, not just data. Modern Instruments, Experienced Analysts and Knowledge in BioSurfaces. Rely on Evans Analytical Group*.

For more details call 408 530-3500, visit WWW.EAGLABS.COM or email info@eaglabs.com

*Formerly known as: Charles Evans & Assoc. and Evans East



Rely on the Experts

following the news, while Natick, Mass.-based Boston Scientific shares declined 14 cents to \$17.23.

TAXUS STUDY

The Boston Scientific study involved 536 patients in 15 countries. It found the company's Taxus stents, the biggest seller in the U.S. market, had lower rates of heart attack and renarrowing of blood vessels than bare-metal stents, and no increase in blood clots after four years. The death rates were equal, the study said.

"The Taxus stent system continues to maintain its leadership position in the markets we serve while offering physicians and their patients a best-in-class treatment for coronary artery disease," said Jeff Goodman, president of the company's international division.

J&J, the New Brunswick, New Jersey health products company that makes the world's top-selling Cypher stent, said a study of 352 patients linked Cypher with fewer deaths and heart attacks when compared with bare-metal stents.

The data "reaffirmed the long-term safety and efficacy benefits of the Cypher stent compared with bare-metal stents," said Dennis Donohoe, a vice president of J&J's Cordis stent-making subsidiary.

CYPHER APPROVAL

Johnson & Johnson also announced its Cypher Select drug-coated stent got European approval for the treatment of severely blocked leg arteries. The Cypher stent is the first drug-coated stent approved in Europe for severe blockage of leg arteries, which can lead to pain, skin ulcers and amputations.

Edoardo Camenzind of University Hospital in Geneva reported Sept. 3 that drug-coated stents were no better at preventing heart attacks and death than bare metal stents, according to his analysis of published data. He and colleagues also reported that the Cypher was more likely to cause death or heart attack than the Taxus.

Some analysts said they were concerned about Camenzind's unexpected findings, saying the data suggests that patients with drug-coated stents must take blood thinners, such as Plavix, to minimize the risk of blood clots.

"The conclusion of the docs I've talked to is that you've got to take Plavix potentially forever," said Jan David Wald, an analyst at A.G. Edwards & Sons in Boston. The highest risk, he said, appears to be when patients stop taking anti-clotting drugs because they need normal clotting for surgery or other medical treatments.

Study Suggests Heart Attack Patients Fare Better with CYPHER® Sirolimus-Eluting Coronary Stents than Bare Metal Stents

Study is the first to show potential benefits of a drug-eluting stent in patients experiencing a heart attack

Miami, FL (September 13, 2006) – The CYPHER® Sirolimus-eluting coronary stent reduced the risk of target vessel failure (TVF) by almost half in patients who suffered a heart attack (acute myocardial infarction or AMI) compared to those who were treated with balloon angioplasty and a bare metal stent, according to data appearing in the *New England Journal of Medicine*.

At one year post implantation of the CYPHER® Stent, the study found that patients given the CYPHER® Stent were 49 percent less likely to experience TVF than those given a bare metal stent (BMS). Specifically, patients in the CYPHER® Stent arm of the study had a TVF rate of 7.3

percent compared to 14.3 percent in the BMS arm of the study ($p < 0.004$). TVF is a composite of the need for re-treatment (target vessel revascularization or TVR), recurrent heart attack and death due to cardiac reasons. In addition, the overall mortality rate in both the CYPHER® Stent arm of the trial and the BMS group was exceedingly low (2.2 percent in both).

These data were originally presented at the American College of Cardiology annual scientific session in March 2006.

"The results of this trial provide important information for doctors treating heart attack patients," said Christian Spaulding, M.D., F.A.C.C., professor of

Cardiology, Assistance Publique-Paris University Hospitals, Paris, France. "This study on the CYPHER® Stent is the first to show significant reductions in TVF in a multi-center, randomized clinical trial in patients experiencing a heart attack. Prior to the TYPHOON study, we did not have randomized clinical data to understand the potential use of a drug-eluting stent during the acute phase of a myocardial infarction. Now, doctors have results from a randomized study to help them evaluate the potential role of the CYPHER® Stent in patients suffering an acute heart attack."

TYPHOON (Trial to Assess the
Cypher® Continued on Page 18

Study: New Precision Drug Delivery Method

A new way to release drugs from coronary artery stents can be adapted to release any drug that must be confined to only one part of the body.

Researchers Noah Lotan, Sarit Sivan and Uri Dinnar of the Technion-Israel Institute of Technology were originally trying to find a way to keep coronary artery stents, which are used to keep cholesterol-blocked arteries open after angioplasty, from being reblocked by tissue overgrowth from the vessel walls.

Drug-eluting stents are tiny rigid tubes that are coated with anti-proliferative medications to stop overgrowth from surrounding tissues, which can reblock the artery.

The drug is slowly released from the stent for six months after implantation, when the risk of reblockage is highest. However, the problem has always been controlling the amount of drug that is released.

The Israeli team solved that problem by impregnating the stents with an enzyme that tells the stent to release its drug only when cued by a natural, safe amino acid taken orally by the patient. The amount of amino acid the patient takes determines the amount of drug the stent releases, and when the patient stops taking the amino acid, the stent ceases releasing the drug.

However, the researchers said the new technology is still being developed and would not be on the market for several years. But they added that it could be adapted to any medication that needed to be delivered to only one location, such as chemotherapy drugs.

Stem Cell Hope for Heart Patients

A pioneering stem cell treatment being developed in Yorkshire could see a massive increase in the number of heart patients living longer.

Scientists from Sheffield University are developing the world's first regenerative device to be inserted into diseased arteries. And they believe it could save thousands of lives. Coronary artery disease causes at least 6.9 million deaths worldwide each year and is the leading cause of premature death in the UK.

Stent implantation – where a mini spring-like coil is fitted into furred up arteries in order to widen them and allow more blood through – is now the most common intervention for the disease. But the stent has to be covered with chemicals so the body does not attack it and prevent the heart fully healing. Now researchers at the university's centre for stem cell biology are hoping to stop the defensive reaction by coating the stents with human stem cells. Professor Harry Moore, who is leading the research, said: "The chemical process up to now is very good but it's not helping the heart cells heal. Sometimes, as a result, the artery that is trying to expand constricts again. But, by using stem cells, you can fool the body into thinking it is its own renewal."

"We are hoping this will help us pioneer the next generation of stents which are more sophisticated." Researchers hope the new-style stents will also provide a platform for their wider application in regenerative medicine.

Stem cells are undeveloped cells with the ability to become different kinds of tissue. Those extracted from embryos less than 14 days old can potentially be directed to grow into any part of the body. The stem cells being used in the research are currently being grown at laboratories in Sheffield, which are world leaders in the field, and will be used in animal experiments over the next few years. After that, if everything works, it is hoped human trials can begin.

Wanted: Committee Volunteers

Strong associations are built by strong involvement from volunteers of member companies. The Surfaces in Biomaterials Foundation needs volunteers for the membership committee and the SurFACTS newsletter.

Membership committee volunteers will assist in identifying and soliciting companies that would benefit by becoming members of the Surfaces Foundation. You will work closely with other committee members to develop membership materials and contact prospective companies.

SurFACTS newsletter volunteers will help develop content ideas and gather news and information for the publication. SurFACTS is published quarterly. Volunteers will be asked to share their expertise and experience in areas where they are most familiar.

Please forward the names and email addresses of volunteers to Bill Monn at billm@ewald.com. Your information will be forwarded to the appropriate committee chair.

Boston Scientific and Guidant. We can and we will.

Together, we can partner with clinicians to develop the most innovative and effective medical technologies. Give your doctor new treatment alternatives. Hold the quality of our products to the highest standards. Improve patient care while making it more cost-effective. We can combine two great companies and a powerful shared purpose. Starting today, we can and we will.

See how at bostonscientific.com

**Boston
Scientific**

Delivering what's next.™



ANNOUNCEMENTS

Board of Directors Nominations Open

The Board of Directors of the Surfaces in Biomaterials Foundation will fill the positions of President-Elect, Vice President, Treasurer and Secretary at the annual meeting at BioInterface 2006 in December. Vice President, Treasurer and Secretary are one-year terms. The President-Elect effectively is a three-year term as that person becomes President, then Past-President in succeeding years.

Current officers of the foundation are: Dan Ammon, President; Victoria Carr-Brendel, President-Elect; Daniel Hook, Secretary; Lise Duran, Treasurer; Joe Chinn, Vice President; Jim Brauker, Past President. At the annual meeting, Carr-Brendel will become President and Ammon will become Past-President.

All supporting members and academic members in good standing may nominate candidates for the board. Applications can be found on the website at www.surfaces.org (under Awards & Nominations). Please fill out the application and include a letter of recommendation for the person that you nominate. Nominees must be employed by a supporting member in good standing. Deadline for nominations is December 1. An officer must be from a supporting member of the foundation that is in good standing. Duties of the offices can be found at the website: www.surfaces.org (About the foundation, then by-laws).

Supporting members of the Surfaces in Biomaterials Foundation are:

Angiotech BioCoatings
AST Products
Bacterin International, Inc.
Bausch & Lomb
Boston Scientific
Boston Scientific Cardiovascular
Carbomedics
Carmeda-BDSM
DePuy Orthopaedics
Evans Analytical Group
Genzyme Corporation
Harland Medical Systems
Hysitron, Inc.

IntegumentTechnologies, Inc.
Medical Device Evaluation Center
Medtronic
Physical Electronics
Plasma Technology Systems
Spire Biomedical
Surface Solutions Lab, Inc.
SurModics
University of Arizona
University of Minnesota
University of Washington
W.L. Gore & Associates

Please submit candidates for the Board of Directors by December 1.

Biosurfaces and Bioinventions *Continued From Page 1*

developed in some inventor's garage or basement through sheer guts and determination. However, for the ultimate goal of bringing an idea to the patient, guts are not sufficient. The inventor requires money, and in our business, this can mean *lots* of money. Moreover, most often at some time during development the successful medical device idea will also require partnerships of one sort or another. Exceedingly few, if any, "start-up" companies have the capabilities to navigate regulatory and other issues, nor can they meet the expenses of pre-clinical or clinical testing. At this year's Invention Symposium, the opportunity will be there for inventors and small start-ups to have a few minutes to share their dream with you, the movers and shakers of this industry, as they present their concept to a panel of experienced Venture Capitalist investors. You, the audience, will view this interaction and will have the chance to seek partnerships with these brave souls, and perhaps to consider investments of your own, or simply provide your advice.

As an "inventor" myself (and somewhat embarrassed to say so with the Hollywood images of crazed or not-quite-all-there inventors running through my mind, like the father in *Chitty-Chitty Bang-Bang*), I personally can attest to both the joy and pain of my fellow inventor-entrepreneurs. Getting in front of an audience of seasoned industry professionals to bare your scientific, engineering, and entrepreneurial soul requires extraordinary courage. Perhaps it is my empathy for these brave souls that explains why I allowed myself to be "volunteered" to chair the Invention Symposium. I urge you to stay to the last to see what these inventors have to offer. Perhaps you will find something you were looking for, or perhaps something you weren't looking for, or most importantly, something that you or your firm must have.

**Visit us
online!**

www.surfaces.org

the microelectronics industry for determination of profiles in silicon wafers, but until the advent of C60 ion sources there were virtually no dynamic SIMS biomedical applications since all the molecular information from biomedical samples was destroyed by the sputter profiling process. Thus until recently, the biomedical applications of ToF-SIMS focused on the static regime, where the amount of material sputtered from the sample surface during a ToF-SIMS experiment was significantly less than a monolayer (e.g., a total ion dose of $<10^{13}$ primary ions per cm^2). This provided both excellent surface sensitivity (typically 1-2 nm) and molecular structure information. The introduction of the C60 ion source has shown that organic and biological

samples molecular depth profiling is now possible. Thus, there is currently significant effort being put into developing the biomedical applications of ToF-SIMS for molecular depth profiling and 3-dimensional imaging. Some of the samples under investigation in these new studies include drug-eluting/polymer-coated stents, cell monolayers and tissue sections.

The current generation of ToF-SIMS instruments with Au or Bi LMIGs can generate images with spatial resolutions approaching 100 nm at modest mass resolution and spatial resolutions just under 1 micron at high mass resolution ($>5000 \text{ m}/\Delta\text{m}$). The current generation of C60 ion sources has the lowest sample damage rates and

Physical Electronics

a division of ULVAC-PHI

The Worlds Leading Supplier of Surface Analysis Instrumentation



TRIFT IV TOF-SIMS



Quantera Scanning Probe XPS



700 Scanning Auger Nanoprobe



ADEPT-1010 Dynamic SIMS



1800 MultiTechnique XPS



PHI 06-C60 C₆₀ Sputter Ion Gun

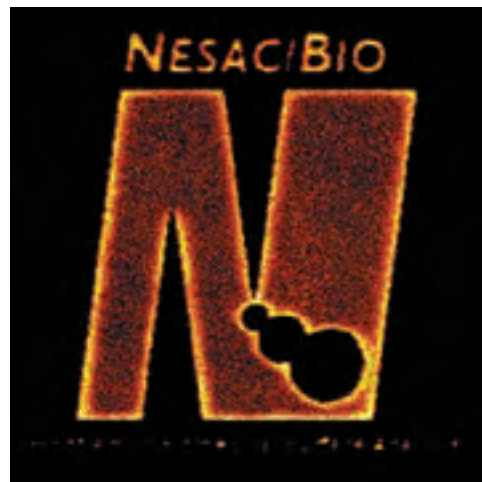


Figure 2. A Na⁺ ion image of the NESAC/BIO logo acquired with an IONTOF instrument using a Bi LMIG. The logo was etched into a Si wafer with a direct current Bi ion beam and then imaged with a pulsed Bi ion beam. The image field of view is 150 μm x 150 μm .

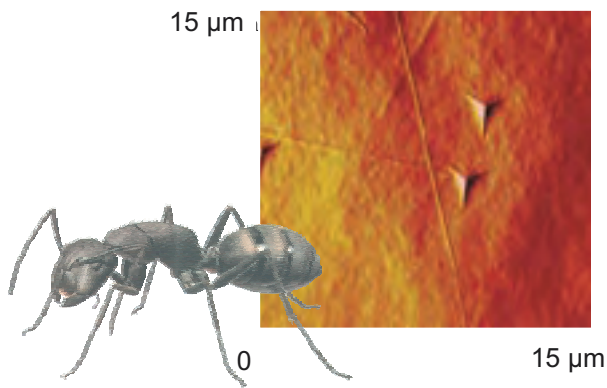
can achieve spatial resolutions of a few microns, but at mass resolutions significantly lower than the Au and Bi LMIGs. Thus, the LMIGs and C60 sources complement each other nicely and open up the possibility of using the two types of ion sources in combination to obtain a high-resolution, molecular depth profile or 3-dimensional image. The low-damage C60 source would be used to sputter through the sample and the high spatial and mass resolution LMIG would be used to image the sample at regular points in the profile. The accompanying images provide examples of the practical (metallic stent) and fun (NESAC/BIO logo) imaging that can be done with current Au and Bi LMIGs.

Acknowledgments. NESAC/BIO is funded by NIH grant EB-002027. Scott Bryan from ULVAC-PHI and Derk Rading from IONTOF are thanked for the images shown in Figures 1 and 2, respectively.

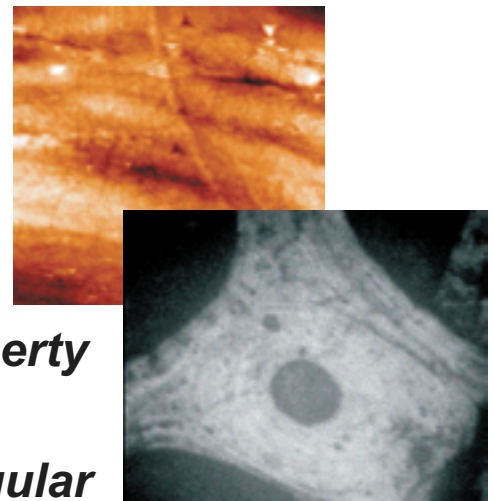
Nano Testing for Natural & Artificial Structures

Hard or Soft Materials Nanomechanical Testing Delivers Results

Hardness of ant mandible



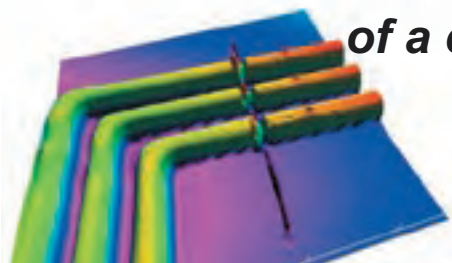
Nanoindentation of the lamellar structure of trabecular bone



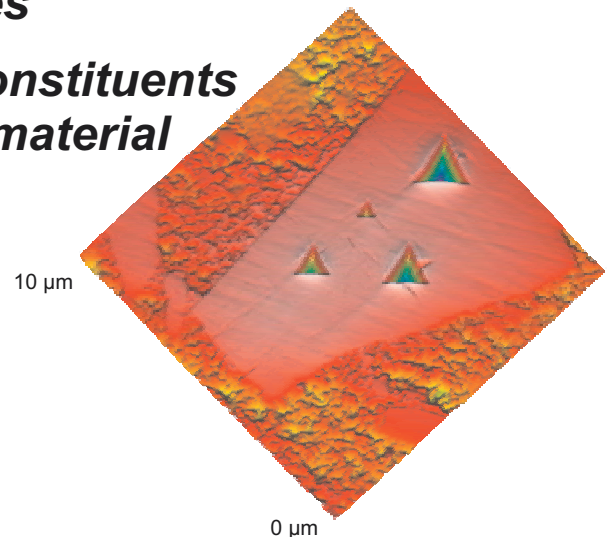
Determine structure-property relationships

Test specimens with irregular geometries

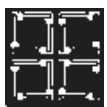
Probe individual constituents of a composite material



Scratch and indents on a MEMS structure



Mechanical properties of individual particles embedded in a matrix



Nanomechanical
Test Instruments

Hysitron, Inc.

For more information please visit our website at www.hysitron.com

Using this, he also developed the first clot-resistant small-bore vascular prosthesis to receive IDE approval.

He founded The Polymer Technology Group in 1989. Since then he has continued to advance the field of biomaterials with new innovations.

STUDENT TOWN HALL MEETING We once again host the popular Student Town Hall meeting where students can "meet the industry" over lunch. This Q&A plus networking session has been a successful introduction for students to industry perspectives over the past few years.

STUDENT POSTER COMPETITION Students are invited to submit a poster into for [a chance to win \\$1,000](#). Submit your intent to present a poster by e-mailing your name, address, school or organization, phone number and topic of presentation to shannonh@ewald.com.

All students submitting posters receive free admission to the conference. You must be present at the conference's poster session to present your poster and be eligible to win. More information, including guidelines for poster submission, is available online at www.surfaces.org.

INVENTION SYMPOSIUM A novel and exciting Invention Symposium session presenting new medical device technologies seeking financing, licensing, and partnerships will close this year's Surfaces meeting. The symposium will begin with a brief introduction on "What Inventors Look for in Investors" by the session chair, followed by "What Investors Look for in Investments" from a panel of experienced Venture Capital investors. Then the excitement begins with early stage firms, start-ups, and other inventors pitching their new biomedical devices and business opportunities to the Venture Capitalist panel, who will then provide comment. For the inventors this is an opportunity to showcase their ideas with the potential of obtaining investments and to obtain valuable feedback on their technology and opportunity. For all attendees, this will be a chance to see how Venture Capital investors view opportunities, and most importantly to see new technologies that may be of interest to you and/or your firm.

WORKSHOP The workshop will focus on Delivery of Therapeutic Biologics. Our technical program will include a session on Orthopedics to highlight important technologies. We have solid sessions in Tissue Imaging, Tissue Engineering, Neurovascular, Orthopaedics and Peripheral Vascular technologies.

In the following pages, you will see the complete schedule as well as a form to fill out and send in if you would like to attend. Hurry! November 13 is the deadline to register at the discounted rates.

Please plan to attend this conference. we are confident that you will be enriched by the science, by the Bay Area, by our debate session and by our unique blend of industry, academic, regulatory, medical and clinical attendees.

Monday, December 4, 2006

7:00 - 8:15 a.m.

Registration & Breakfast

Workshop

Chair: Joe Chinn, SurModics, Inc.

Delivery of Therapeutic Biologics

8:15 - 8:30 a.m.

Welcome and Introduction

8:30 - 9:15 a.m.

Overview of Traditional Drug Eluting

Biomaterials, Kishore Udipi, Medtronic

9:15 - 10:00 a.m.

Overview of Biologic Delivery Systems

Paul Burke, Amgen

10:00 - 10:30 a.m.

BREAK

10:30 - 11:15 a.m.

Drug Elution Kinetics / Bioavailability

Mikael Trollsas, Abbott Vascular

11:15 a.m. - Noon

Characterization Tools

Klaus Wormuth, SurModics, Inc.

Noon - 1:00 p.m.

LUNCH

1:00 - 1:45 p.m.

Combination Devices of the Future

Kevin Healy, University of California

1:45 - 2:30 p.m.

Regulatory Considerations

Joyce Lea Frey-Vasconcellos, Pharmanet

2:30 - 3:15 p.m.

Clinical Study Strategies

Shawn Fuller, SurModics, Inc.

3:15 - 3:45 p.m.

BREAK

3:45 - 4:45 p.m.

Panel Discussion

5:00 - 6:00 p.m.

Applied Technology Workshops

*Chair: Peg Palmer,
SurfaceSolutions Labs, Inc.*

5:00 - 5:30 p.m.

The state-of-the-art surface mechanical properties characterization of biomedical materials

Patricia Lindley, Evans Analytical Group

5:30 - 6:00 p.m.

Nanoindentation of Biomaterials: Novel Applications and Challenges in the Biological Field

Michelle E. Dickenson, Hysitron, Inc.

5:00 - 5:30 p.m.

Surface Modification

Nader Kalkhoran, Spire Biomedical, Inc.

5:30 - 6:00 p.m.

Plasma Surface Modification Meets Nanotechnology

Dr. Terrance G. Vargo, Integument Technologies, Inc.

6:00 - 6:30 p.m.

Welcome Reception

6:30 - 7:00 p.m.

Keynote Topic: PEGylated Surfaces

Alan Hoffman, University of Washington

Symposium

Tuesday December 5, 2006

7:30 - 9:00 Registration
7:30 - 8:00 Poster Session
8:00 - 8:30 Student Poster Session Judging

8:30 Welcome
*Dan Ammon, Bausch & Lomb,
President, Surfaces in Biomaterials Foundation*

8:45 - 11:00 Frontiers in Tissue Imaging

*Chairs: Klaus Wormuth, SurModics, Inc.;
Scott Bryan, Physical Electronics*

8:45 - 9:15 New Techniques for Imaging Drug Distribution in Tissue, Mark Sanders, University of Minnesota

9:15 - 9:45 Imaging and Differentiation of Cells and Tissues by ToF-SIMS, Kuang Jen J. Wu, Livermore National Library

9:45 - 10:05 Imaging Supported Membranes Beyond the Diffraction Limit by Mass Spectrometry, Steve Boxer, Stanford University

10:05 - 10:25 Local Pharmacokinetics of Drug-Eluting Stents, Yen-Lane Chen and Cory Hitzman, Boston Scientific Corp.

10:25 - 10:45 Digital Volumetric Imaging Kip Hauch, University of Washington

11:00 - 12:30 Neurovascular

11:00 - 11:30 Recent Advances in Neurointervention: Endovascular Actuated Micro-Devices in Intracranial Trans-Catheter Therapeutics, Arani Bose, Penumbra Stroke Intervention

11:30 - 11:50 Use of Polyglycolic (PGA) Polymer within Embolic Coils for the Treatment of Intracranial Aneurysms, Dave Watson, Micrus Endovascular

11:50 - 12:10 Enhanced Healing in Aneurysms Treated with PGLA Coated Coils, Stephen Porter, Target

12:10 - 12:30 Neurostimulation Devices, Matt Haller, Advanced Bionics

12:30 - 1:45 LUNCH

Student Town Hall - Carl Turnquist
Business Meeting - Dan Ammon

1:45 - 3:15 Biointerfacial Aspects of Tissue Engineering Applications

Chair: Kip Hauch, University of Washington

1:45 - 2:05 Extracellular Matrix Protein Coatings Accelerate Stent Endothelialization, Dave Babcock, SurModics, Inc.

2:05 - 2:25 Assessment of the Biointerface and Resultant Surface Modifications of a Tissue Engineered Allograft in the Juvenile Sheep Model, Alyce Linthurst Jones, LifeNet

2:25 - 2:45 The state-of-the-art in surface mechanical properties characterization of biomedical materials, Nicholas X. Randall, CSM Instruments

2:45 - 3:15 Design and Synthesis of Biomimetic Materials, Kevin Healy, University of California Berkeley

3:15 - 3:45 BREAK

3:45 - 5:45 Rump Session: Therapies of the Future: Tissue-Based or Device-Based?

Chair: Vicky Carr-Brendel, Boston Scientific

Jim Brauker, Dexcom vs. Gail Naughton, San Diego State University

Wednesday December 6, 2006

8:00 - 4:00 Student Poster Session

9:00 - 10:30 Peripheral Vascular

*Chair: Dave Sogard, Boston Scientific,
C.P. Pathak, C.R. Bard*

9:00 - 9:30 Surface modification for cellular adhesion, Khalid Kader, University of Iowa

9:30 - 9:50 Protein-Modification of Stents Increases Endothelialization, Kristen O'Halloran Cardinal, University of Arizona

9:50 - 10:10 Thrombogenicity of Polymers Commonly used in Blood Contacting Devices, SP Sukanvashvar, Medical Device Evaluation Group

10:10 - 10:30 Cardiopulmonary Bypass Effects on Platelet Adhesion to Biomaterials, Steve Goodman, 10H Technology

10:30 - 10:50 BREAK

10:50 - 12:35 Orthopaedics

*Chair: Larry Salvati, DePuy Orthopaedics;
Peg Palmer, SurfaceSolutions Labs, Inc.*

10:50 - 11:05 The Foreign Body Response to Orthopaedic Implants, Stuart Goodman, Stanford University

11:05 - 11:35 Surface Chemistry and the Biointerface: Beauty and the Beast or Romeo and Juliet? Larry Salvati, DePuy Orthopaedics

11:35 - 11:55 Versatile Fouling-Resistant Coatings Inspired by Marine Mussels, Jeff Dalsin, Nerites Corp.

11:55 - 12:15 Optimizing Wound Bed Recovery with Flexible Device, Steven J. Keough, SurModics, Inc.

12:15 - 12:35 Atmospheric Surface Modification of Polymers for Biomedical Device Adhesion, Rory Wolf, Enercon Industries

12:35 - 2:00 Lunch

Awards Session: Excellence in Surface Science

Chair: Stu Williams, University of Arizona

2:00-4:00 Invention Symposium

BioInterface 2006 Registration

Sponsors to Date

Diamond:

Silver:

Opening Reception:

Rump Session:

Break Sponsor:

Sponsorship opportunities still available! Go to www.surfaces.org for more details!

Exhibitors to Date

Harland Medical Systems
Integument Technologies, Inc.
SurModics, Inc.

There are still opportunities available! Visit www.surfaces.org if you are interested in exhibiting.

Thank You, Program Committee

Carl Turnquist, Chair
Genzyme
carl.turnquist@genzyme.com

Joe Chinn (Workshop Chair)
SurModics
jchinn@surmodics.com

Dave Sogard
Boston Scientific
sogardd@bsci.com

CP Pathak
C.R. Bard
cp.pathak@crbard.com

Klaus Wormuth
SurModics
kwormuth@surmodics.com

Peg Palmer
SurfaceSolutions Labs, Inc.
SurfaceLab@aol.com

Scott Bryan
Physical Electronics
sbryan@phi.com

Larry Salvati
DePuy Orthopaedics
lsalvat3@dpus.jnj.com

Kip Hauch
University of Washington
Hauch@u.washington.edu

Vicky Carr-Brendel
Boston Scientific
victoria.carr-brendel@bsci.com

Before 11/13/06

After 11/13/06

Workshop – Dec. 4 Only (Includes the entire workshop, lunch and breaks)

| | | |
|--------------------|--------------------------------|--------------------------------|
| Member | <input type="checkbox"/> \$195 | <input type="checkbox"/> \$265 |
| Non-Member | <input type="checkbox"/> \$255 | <input type="checkbox"/> \$375 |
| Student Member | <input type="checkbox"/> \$90 | <input type="checkbox"/> \$160 |
| Student Non-Member | <input type="checkbox"/> \$150 | <input type="checkbox"/> \$220 |

Combined Workshop & Symposium – Dec. 4, 5 & 6 (Includes workshop and 2-day symposium, all meals, breaks, an evening reception and the rump session)

| | | |
|---------------------|--------------------------------|--------------------------------|
| Member Combined | <input type="checkbox"/> \$560 | <input type="checkbox"/> \$660 |
| Non-Member Combined | <input type="checkbox"/> \$680 | <input type="checkbox"/> \$780 |
| Student Member | <input type="checkbox"/> \$260 | <input type="checkbox"/> \$360 |
| Student Non-Member | <input type="checkbox"/> \$380 | <input type="checkbox"/> \$480 |

Symposium – Dec. 5 & 6 Only (Includes the 2-day symposium, meals, breaks, an evening reception and the rump session)

| | | |
|--------------------|--------------------------------|--------------------------------|
| Member | <input type="checkbox"/> \$440 | <input type="checkbox"/> \$510 |
| Non-Member | <input type="checkbox"/> \$500 | <input type="checkbox"/> \$570 |
| Student Member | <input type="checkbox"/> \$245 | <input type="checkbox"/> \$315 |
| Student Non-Member | <input type="checkbox"/> \$305 | <input type="checkbox"/> \$375 |

Membership – Join now and save on your Symposium registration. Visit www.surfaces.org/membership/index.cgi for complete member benefit information.

| | |
|---|--|
| <input type="checkbox"/> Individual \$50 | <input type="checkbox"/> Academic \$625 |
| <input type="checkbox"/> Supporting \$2,500 | <input type="checkbox"/> Supporting \$2,000 (50 employees or less) |

TOTAL \$_____

Registration – BioInterface 2006

Name _____
Affiliation _____
Department _____
Address _____
City _____
State _____ Zip _____
E-mail _____
Phone _____ Fax _____
ADA/Special Requests _____

Payment (Payment must accompany registration form to be processed)

- ☐ Check (made payable to Surfaces in Biomaterials Foundation)
☐ MasterCard ☐ VISA ☐ American Express

Name (as it appears on card) _____
Card # _____ Exp. Date _____
Cardholder Signature _____

Send to:

Surfaces in Biomaterials Foundation
1000 Westgate Drive, Suite 252
St. Paul, MN 55114
Fax: 651-290-2266
www.surfaces.org
Phone (651) 290-6267

(For office use only)

| | | |
|-----------|--|--------|
| initials | | acctg. |
| date | | |
| CK/CC | | |
| amt. paid | | |
| bal. due | | |

Cancellation Policy: With written cancellation notice, received by Nov. 20, 2006 you will receive a full refund, less a \$50 administrative charge. Cancellations after Nov. 20, 2006 are non-refundable. Notices of cancellation must be faxed to the Surfaces in Biomaterials office at 651-290-2266. No shows will not receive refunds.

MEMBER PROFILE: PLASMA TECHNOLOGY SYSTEMS

The PS0500 plasma treatment system

For more information, contact
Mikki Larner, General Manager
mikki@plasmatechsystems.com.
www.PlasmaTechSystems.com

The Bay Area is renowned for the semi-conductor industry and biotechnology. The history of biotech and genetic engineering in the Bay Area dates back 30 years. According to BayBio's 2005 report, more than one-third of all domestic public biotech companies are located in Northern California investing close to \$4 billion/year in research. Some say the life sciences were born in the Bay Area. The area is rich in innovation with support from R&D and incubator companies as well as top life science companies and renowned universities.

Our history begins in 1983 in the founding, by Stephen Kaplan, of Plasma Science, Inc. With experience developing primary plasma systems and background in polymer chemistry, Mr. Kaplan saw a niche in exploring the use of plasma for surface modification of plastics in the life science, aerospace and non-semiconductor electronic devices industries. The mission was to provide tools to allow the engineer or scientist to choose a material based on the bulk properties to satisfy the mechanical or optical requirements, and then plasma modify the surface for the surface chemistry requirements. Plasma Science was the first and possibly the only manufacturer of plasma equipment to focus exclusively on the plastics and allied industries.

Marketing to the life science industry started on "Day 1," according to Mr. Kaplan. "Dr. Om Kolluri devoted fifty percent of marketing efforts to that industry." With the growing adaptations of polymers (versus glass) for bioscience laboratory glassware much of the early Bay Area work consisted of modification of plastic roller culture bottles (to ensure that the cultures attached to the walls of the bottles), plastic Petri dishes, titer plates and centrifuge tubes. Plastics such as polypropylene and polycarbonates were modified to mimic the wetting properties of the glass counterparts. Soon thereafter the applications became more sophisticated—such as altering polymers for use in gel permeation chromatography tools and for DNA replication.

In addition to the life sciences industry, plasma is used for aerospace applications. The first Plasma Science purchase order was written by Dupont for the manufacture of small batch (PS0500) and continuous fiber modification (PS1010) plasma systems for use in the development of advanced composite systems. At Plasma Science these systems were used for projects to include the modification of military connectors and Spectra™ (UHMWPE) for Allied Signal. The modification of the connectors involved an activation process to enhance adhesive bonding of molded silicone rubber gaskets. It was one of the first commercial uses of plasma outside the semi-conductor industry.

Fiber treatment continues to the present day for the life sciences industry with modification of UHMWPE for dental applications, polypropylene for suture materials, and various polymer tubing for adhesion enhancement prior to bonding, overmolding and printing.

Another early application (1985) that is still in use today is the activation of Delrin™ for adhesion to polyurethane RIM (Reaction Injection Molding) foams for prosthetics by TruLife formerly known as Seattle Foot. Delrin is used as the mechanical reactive element to thrust the foot forward when weight is shifted. The RIM is a dense foam molded in-place to provide the flesh an aesthetically pleasing, lifelike appearance. Without plasma treatment the RIM would not adhere.



Photo of prosthetic with plasma modified materials courtesy of TruLife

Processes became more sophisticated with applications for plasma enhanced chemical vapor deposition (PECVD) of thin film coatings onto intraocular and contact lenses, to reduce protein adsorption, and development of coatings for blood oxygenation tools. Continuous profile hollow polypropylene tubes were coated via PECVD providing an ultra thin sheath to decrease porosity for controlled oxygen permeation as well as aid in hemophilicity.

With the purchase of Plasma Science by Himont in 1989, focus shifted to the manufacture of large volume reaction chambers for the automotive industries. There was a growing concern in finding environmentally-friendly technologies for primerless adhesion for polyolefins. In addition to the automotive applications, these large systems are used today for treatment of device tubing, large sheets of sintered porous polyethylene media and panels for medi-

Plasmatech Continued on Page 16

cal device equipment. Materials processed for the aerospace community include inflexible Kapton™ assemblies, fluoropolymers and composite honeycombs to enhance adhesion.

The “60 inch web treater” was developed for modification of rolled goods to include wovens, non-wovens, films, foils and membranes. This system allows for extremely cost effective functionalization of films (such as cyclic olefin copolymers and polystyrene) for immunoassay/microfluidic devices and customized modification of membranes and wovens for filtration/separation chemistries. Work continues today for activating Spectra™, Zylon™ and Kevlar™ for the aerospace and defense industries.

Airco/BOC Coating Technology (BOCCT) purchased Plasma Science from Himont in 1994 to create a separate technology center to complement BOCCT's involvement in QLF® (silicon oxide barrier) coatings. PECVD coatings were developed for scratch resistance on ophthalmologic products (as well as automotive glass).

BOCCT's focus, however, was on equipment manufacturing and the customer's interest in process development was not being met. Therefore Mr. Kaplan opened 4th State, Inc. in 1996 to offer Plasma Science equipment owners consulting resources and a lab for research and development projects. The lab has grown to offer customers R&D and contract services in equipment ranging from small batch to 60 inch rolled goods. One of the primary applications at 4th State is activation of fluoropolymer films for adhesion to acrylate and silicone pressure sensitive adhesives (PSAs) for civil engineering projects locally and throughout the U.S.

The story continues with the purchase of Plasma Science's service and support business by Plasma Technology Systems, LLC (PTS). PTS's initial focus was supporting existing equipment owners and renters with spare parts, routine maintenance and calibration services. Since 1999 the services have grown considerably—now offering R&D, training classes and workshops, system upgrades, custom equipment design and development of tools for high temperature monomer delivery. PTS also has alliances with companies offering atmospheric and corona processing services, allowing the team to suggest the most appropriate technology for the application.

Recent Bay Area applications at the PTS lab include modification of silicones, nylons and Pebax® to change surface properties either for adhesion or lubricity and activation of metal



The TC04 system loaded with a tray of pipette tips

stents for subsequent drug loading. Considerable work in the area is conducted for modification of microfluidic tools. Application examples include PECVD polystyrene coatings or creating specific amine functional sites. Additional work of interest is in activation of and even removal of Parylene™ and the deposition of hydrogel-like films.

PTS and 4th State have strong relationships with Stanford and Berkeley (and affiliated research labs) as well as many other academic institutions throughout the U.S. and the world. Students are welcome to work in the labs at a discounted fee.

Continuing work with UCSF/Berkeley bioengineering group includes PEGylation of UHMWPE implants for reducing wear and as presented at the 2005 BioInterface meeting, successful introduction of mercaptosilanes for functionalizing devices for the Stanford Genome Technology Center.

With the strong R&D and incubator environment in the Bay Area, we find continual excitement in being privy to developments in the life science industry. And thanks to involvement in the Surfaces for Biomaterials Foundation, PTS is able to generate contacts with other technologists who share with us their successes and challenges in the industry. This networking greatly aids us in understanding different surface modification requirements, which allows us resources to solve complex customer issues often involving multiple surface modification methods. In addition, understanding other companies' surface modification technologies is critical in ensuring our customers' success using our technology.

To conclude, over the past 25 years and through a few different sets of company eyes, we see that plasma's use has grown from a lab curiosity or simply a wetting tool to a sophisticated method for complete surface re-engineering. Many medical device companies have the equipment in house or are using resources through vendors such as PTS and 4th State.

Plasma processing in the Bay Area has become a critical tool for providing functionality for attaching a myriad of biological coatings; providing tailored nano-scale coatings for chemical resistance and lubricity; continued importance in modification of materials for genomics research; and growing modification of point-of-care diagnostic devices. We anticipate that plasma surface modification will become as important a tool to the biosciences as it has become synonymous to the manufacture of semiconductor devices.

Thank You to Our Members!



MDEC
Medical Device Evaluation Center



THE UNIVERSITY OF MINNESOTA

use of the CYPHER® Stent in Acute Myocardial Infarction Treated with Balloon Angioplasty) is the first randomized, multi-center clinical trial to study the safety and efficacy of the CYPHER® Stent in patients who have suffered an AMI. Data were reported on 712 patients who had suffered an AMI within 12 hours before the stent placement. The TYPHOON trial was conducted at 48 sites across Europe, Israel and Australia.

An angiographic sub-study was conducted in 210 patients who participated in the TYPHOON trial to assess the rate of re-blockage (restenosis) and the amount of tissue proliferation (late loss) within the stent eight months after receiving either a CYPHER® Stent or the bare-metal control stent. The study found that the CYPHER® Stent was associated with an 83 percent reduction in re-blockage rates and an 83 percent reduction in late loss. Specifically, patients in the CYPHER® Stent arm of the study had an in-stent restenosis rate of 3.5 percent compared to 20.3 percent in the BMS arm of the study ($p=0.0010$) and an average late loss of 0.14 mm compared to 0.83 mm in the BMS arm ($p<0.0001$).

Since patients receiving bare-metal stents for the treatment of heart attacks are at an increased risk of stent thrombosis, there was initial concern about the use of a drug-eluting stent in this patient population. Through one-year follow-up in the TYPHOON trial, the stent thrombosis rates with the CYPHER® Stent (3.4 percent) and the bare metal stent (3.6 percent)

arms of the study were comparable (12 events in the CYPHER® Stent group vs. 13 events in the group treated with bare metal stents).

"This study provides important clinical and angiographic evidence about the potential role of the CYPHER® Stent in patients experiencing a heart attack," said Dennis Donohoe, M.D., worldwide vice president of Clinical Research and Regulatory Affairs, Cordis Corporation. "With the TYPHOON data, our clinical body of knowledge for the CYPHER® Stent continues to grow into new areas such as acute myocardial infarction." Cordis Corporation sponsored the TYPHOON trial.

About the CYPHER® Stent

The CYPHER® Stent has been chosen by cardiologists worldwide to treat more than two million patients with coronary artery disease. The safety and efficacy of the device is supported by a robust clinical trial program that includes more than 40 studies, inclusive of independent clinical trials, that examine the performance of the CYPHER® Stent in a broad range of patients. Developed and manufactured by Cordis Corporation, the CYPHER® Stent is currently available in more than 80 countries and has the longest-term clinical follow-up of any drug-eluting stent. The first next generation drug-eluting stent, the CYPHER SELECT™ Sirolimus-eluting Coronary Stent, was launched in Europe, Asia Pacific, Latin America and Canada in 2003. More information about the CYPHER® Stent can be found at www.cyphersusa.com.

Regulatory Continued From Page 3

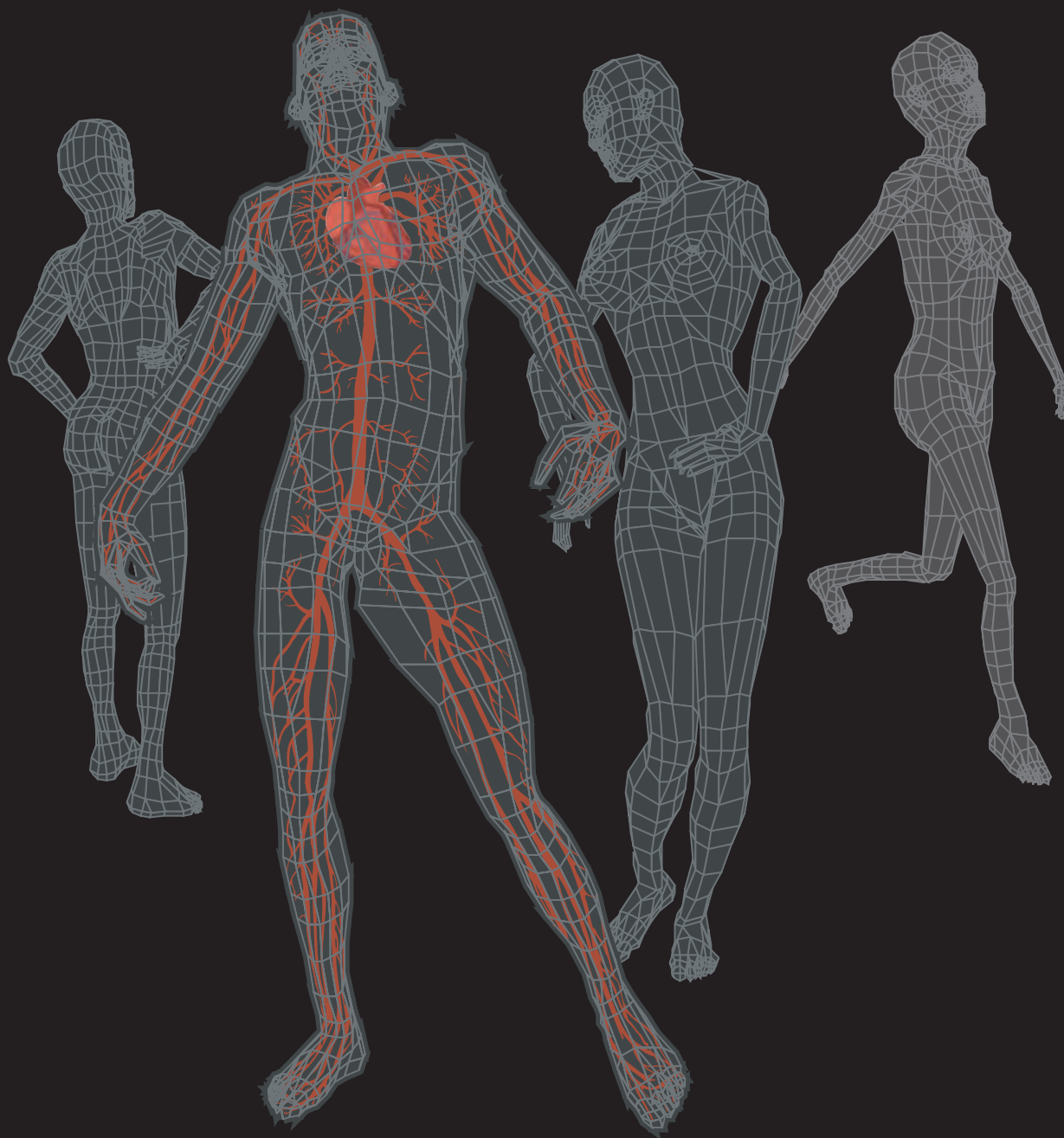
Medical Device FY 2007 User Fee Rates

The FDA announced that the PMA user fee has been increased to \$281,600 for large businesses, and \$107,800 for those qualifying as small businesses (annual gross sales of under \$100 million). The standard fees for 510(k) submissions have increased to \$4158 and \$3236 for large, and small businesses, respectively. The new fees are effective as of October 1, 2006.

Post-market Surveillance

Janet Trunzo, a representative of AdvaMed working on post-market-related issues, indicated in a presentation given at the 2006 Regulatory Affairs Professional Meeting held in Baltimore that the FDA may be planning

to direct some of the user fees it collects to increase staffing for post-market surveillance of medical devices. The Medical Device User Fee and Modernization Act (known by the tortured acronym MDUFMA) will be reauthorized in 2007. Provisions for funding FDA post-market activities were left out of the original act at the request of industry. They will likely surface in the reauthorized bill. Donna-Bea Tillman, Director of the Office of Device Evaluation at CDRH, also spoke at the RAPS conference and indicated that the FDA would place increased emphasis on post-market activities. The reauthorization of MDUFMA could include provisions to fund the staff required for the increased activities. FDA thoughts and guidance on post-market surveillance can be found at <http://www.fda.gov/cdrh/postmarket/mdpi.html>



Working in partnership with physicians for
over 50 years to bring the benefits of biomedical
technology to patients around the world.



Medtronic

Alleviating Pain • Restoring Health • Extending Life

Hysitron was founded in January 3, 1992 as a research facility committed to the development of three-axis positioning transducer technology. Out of this has grown a new level of performance in mechanical property testing at nanoscale with other new instruments based on this technology still in research.

A successful U.S. Army SBIR phase I and II project partially founded the Hysitron transducer into Nanoindentation with in-situ imaging. Further advances in transducer repeatability and resolution, and broader application of use, propelled the commercialization of the Nanoindentation product line in May 1995.

Hysitron has established its leadership position with a strong scientific support group, dedicated customer service and state-of-the-art manufacturing facility. Hysitron offers many test techniques to evaluate the mechanical properties of materials including quasi-static testing, dynamical mechanical analysis as well as scratch and wear testing. In addition to these measurement techniques Hysitron offers the unique capability of in-situ imaging that permits immediate pre- and post-scan-

ning of indent test sites for topographical analysis of the failure mechanism.

Hysitron systems provide multiple analysis techniques for customized materials testing solutions of bulk materials, thin films and nanostructures; from tribological films to biological materials.

With the ability to test at different temperatures and in fluid environments, our systems provide analysis capabilities under realistic testing conditions.

Innovation is the key to our success and we have many new products such as nanoECR™, which permits simultaneous measurements of Current-Voltage and Force-Displacement letting you correlate electrical and mechanical properties of materials at the nanoscale. NanoTensile™ 5000, which redefines nanoscale tensile and pull testing with an extended force and displacement range enabled by dual-mode and dynamic operation.

With our expertise in both material handling and testing, Hysitron has become the world leader in mechanical testing from the nano- to micro-scale.

Hysitron Receives National Recognition at the Tibbetts Awards

Hysitron, Inc. recently collected a national Tibbetts award. The company, along with two other Minnesota-based companies, were recognized in Washington for their success. The Tibbetts Awards, named for Roland Tibbetts, serve as an informal measure of a state's tech-savviness. Presented annually by the U.S. Small Business Administration, they recognize small businesses and the entrepreneurs who started these businesses with nothing more than a good idea. This year, Minnesota's haul was second only to New York, which received four. Nearly 6,000 companies and individuals apply each year, and of them, only 55 companies received the prestigious award this year. Among them, Hysitron supplies nano-mechanical test instruments and services to scien-

tists and engineers conducting advanced research and high-technology product development. Their clients include IBM, the Massachusetts Institute of Technology and NASA. All three companies that received Minnesota's awards received financial backing from the federal Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. These programs provide more than \$2 billion in research and development grants and contracts annually. Hysitron president and cofounder Thomas Wyrobek says SBIR funding was very important in the successful building of his company, which now employs 50 people. Hysitron received two grants from SBIR that totaled more than \$1.5 million.

Wanted: **Members**

To be leaders in the surface science community

- Join a forum that fosters discussion and sharing of surface and interfacial information
- Have your voice heard and your interests represented within the surface science and biomedical community
- Help shape workshops and symposia that further the world-wide education of surface science
- Promote understanding of interfacial issues common to researchers, bio-medical engineers and material scientists.

Benefits of Membership:

- Discounted registration at BioInterface, the annual symposium of the Surfaces in Biomaterials Foundation.
- Your logo and a link to your Web site in the member directory on the official Web site of the Foundation, www.surfaces.org.
- Complimentary full page ad in surFACTS, the Foundation's newsletter and discounts on all advertising.

Join the Foundation that connects the academic, industrial, and regulatory committees within the surface science/biomedical communities!

Visit the Foundation at www.surfaces.org for a membership application or call 651-290-6267.



Surfaces in
Biomaterials
Foundation

Meeting/Conference/Trade Show Calendar

| Meeting/Conference/Trade Show | Place | Dates | Web Address |
|---|----------------------|--------------------------|---|
| American Association of Ophthalmology (AAO) | Las Vegas, NV | 11/11/06 – 11/14/06 | http://www.aao.org/ |
| American Heart Association Scientific Sessions | Chicago, IL | 11/12/06 - 11/15/06 | http://scientificsessions.americanheart.org/portal/scientificsessions/ss/ |
| American Vacuum Society (AVS) | San Francisco, CA | 11/12/06 – 11/17/06 | http://www.avs.org/ |
| American Institute of Chemical Engineers (AIChE) Annual Meeting | San Francisco, CA | 11/12/06 – 11/17/06 | http://www.aiche.org/conferences/spring/index.htm |
| BioInterface 2006 | San Mateo, CA | 12/4/06 – 12/6/06 | www.surfaces.org |
| Biomaterials from 2D to 3D to Larger than Life: A Symposium on the Future of Biomaterials to Celebrate Buddy Ratner's 60th Birthday | Maui, HI | 12/14/06 – 12/17/06 | http://www.uweb.engr.washington.edu/about/2dto3d.html |
| Medical Design & Manufacturing West (MD&M West) | Anaheim, CA | 2/12/07 - 2/17/07 | http://www.deviceink.com/expo/west06/ |

Volunteers Wanted:

If you would like to contribute your talents to the Surfaces in Biomaterials Foundation, we'd love to have you. Let us know if you'd like to help with membership recruitment, writing or editing articles for the SurFACTS newsletter, adding content and interest to the Web site or other areas where your talents could be put to good use. If interested please contact Bill Monn at billm@ewald.com or call 651-290-6295.