

SurFACTS *in Biomaterials*

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SurFACTS *in Biomaterials* Goes Exclusively On-Line

by Joseph A. Chinn, Executive Editor

Volume 8 Issue 1 marked the beginning of the exclusively on-line format for SurFACTS. In response to reader concerns that the hard copy of the newsletter always seemed to arrive “late”, we moved to a more timely format that allows readers anywhere in the world to download the newsletter in Adobe Acrobat format. While some will miss the glossy hard copy, most will appreciate the convenience of reading the e-copy or being able to print a hard copy while its content is still current. Members and other readers with current addresses on file with the Foundation will be notified by e-mail when new issues are posted to the website. Please send your comments on the new format to director@surfaces.org. We are committed to making SurFACTS meet the needs of its readers.

The new on-line format provides an excellent advertising opportunity for companies serving Foundation members and other SurFACTS readers. Between April 29, 2003 (when Volume 8 Issue 1 first appeared on the Foundation website at <http://www.surfaces.org/publications/v8i1.pdf>) and June 30, 2003, the newsletter received 3324 hits. Our readers represent a focused target group interested in biointerfacial phenomena, and ways to affect, measure, and apply these phenomena to medical diagnostics and devices. Member companies and others interested in advertising are welcome to contact visibility@surfaces.org.

Volume 8 Issue 2 brings more changes to SurFACTS as we welcome Phil Triolo as Regulatory Editor and Min-Shyan Sheu as Surface Modification Editor. Phil has over 18 years of hands-on industrial experience in the design, development, evaluation, and approval of medical products. He is co-inventor of 8 design patents for medical products ranging from bioluminescent detectors to drug delivery catheters, demonstrating an ability to make significant, original contributions to the development of a wide array of medical devices and diagnostic products. Min has extensive experience in surface modification

(SurFACTS continued on page 3)

Foundation News

Whitaker Foundation Grant Received

The Surfaces in *Biomaterials* Foundation was recently awarded a Whitaker Foundation Grant in the amount of \$5,000 to support the BioInterface 2003. Its particular emphasis is to encourage the participation of biomedical engineering students during the Annual Symposium. This grant will support an additional David J. Lee Student Award and a Student Town Hall Meeting. This Meeting will enable students to network with industry experts, inquire about opportunities in their organizations, and discuss the future of the surface science industry.

SurFACTS 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, or diagnostic research.

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FDA Approves Landmark Treatment for Coronary Artery Disease

press release

Cordis' CYPHER™ Sirolimus-eluting Coronary Stent Dramatically Reduces Reblockage of Coronary Arteries

Cordis Corporation, a Johnson & Johnson company, reported April 24, 2003, that it has received approval from the U.S. Food and Drug Administration (FDA) to market its CYPHER™ Sirolimus-eluting Coronary Stent, making it the first U.S.-approved combination drug device intended to help reduce restenosis (reblockage) of a treated coronary artery. Restenosis is one of the greatest challenges in long-term patient treatment in interventional cardiology.

“Cordis is very pleased to bring this remarkable and innovative treatment to patients, hospitals and interventional cardiologists,” said Johnson & Johnson Company Group Chairman Robert Croce, who has worldwide management responsibility for Cordis Corporation. “Clinical evidence and experience with more than 50,000 patients treated to date in nearly 60 countries, suggests the CYPHER Stent represents the beginning of a new era in interventional cardiology — an era in which the combination of drugs and devices substantially improves patient outcomes.”

Jeffrey W. Moses, M.D., of Lenox Hill Hospital, New York, a principal investigator in the U.S. clinical trials for the new device said: “The CYPHER Stent clinical trials set a new standard in coronary artery stent investigation. No other stent in this category has been studied so

extensively in such a wide range of high-risk patients with difficult-to-treat lesions. Clinical evidence is clear that cardiologists can use this new stent with confidence.”

Mr. Croce explained that the FDA approved the CYPHER Stent under an expedited review for use in native coronary arteries with reference diameters of 2.5 mm to 3.5 mm and lengths in 8, 13, 18, 23, 28 and 33 mm. This covers the majority of stent cases performed today.

“Our main objective is to make the CYPHER Stent available to all patients in need of this medical technology as quickly as possible,” Mr. Croce said.

The CYPHER Stent was first introduced by Cordis in April 2002, and is now available throughout Europe, the Middle East, Canada, Asia-Pacific and Latin America.

Combining Drug and Device for a New Era in Interventional Treatment

Combined with the pharmaceutical agent sirolimus*, the CYPHER Stent is placed into a human coronary artery to prevent restenosis (reblocked arteries). Sirolimus, marketed as Rapamune by Wyeth Pharmaceuticals, is a commercially available drug developed from a naturally occurring substance first isolated from soil samples in Easter Island in the South Pacific.

“Years of research and development involving hundreds of drugs led to our

(FDA continued on page 5)

(SurFACTS continued from page 1)

technologies for biomedical applications, including medical devices and implants, diagnostic devices, cell cultureware, biosensors, and biochips. His expertise includes plasma surface treatment and deposition, parylene and silane CVD coatings, biocompatible polymer coatings, biomolecule immobilization, and surface characterization of biomaterials.

Section Editors are critical to the success of the SurFACTS *in Biomaterials* Newsletter. While the positions are voluntary, Section Editors take great pride in promoting knowledge in their respective fields of expertise. They are the ones responsible for soliciting and reviewing the articles you see in each issue. Often, Editors themselves are the authors of the most interesting articles, as they quickly gain insights into their fields after reviewing many other authors' articles. Their time commitment is minimal, but they have maximum impact on the success of SurFACTS. Regular Editors' teleconferences help to ensure the cohesiveness of each issue. The Foundation would like to thank Byron Shen (Modification Editor), Daniel Mooradian (Biology Editor), and Elaine Duncan (Regulatory Editor), all of whom have been Section Editors for several years, for their many contributions to SurFACTS. They have stepped down as Section Editors to devote their time to other interests and to give others the chance to experience the rewards of these important positions. Members interested in serving as Biology Editor should submit a current resume or CV to director@surfaces.org at the Foundation office.

Member News

President moves to new organization...

Mark Moore, current President of the Surfaces in *Biomaterials* Foundation Board of Directors, has moved on in his career to join LifeNet, headquartered in Virginia Beach, VA, as Director, Research and Development.

Mark left his former position with CarboMedics in Austin, TX where he was employed for 13 years. LifeNet (<http://www.lifenet.org/>) was founded in 1982, employs over 375 people, and operates an

organ and tissue donation program as well as being "one of the nation's largest full service non-profit tissue banks" providing various organs as well as musculoskeletal and cardiovascular tissues. Mark's new contact information is mark_moore@lifenet.org and he can also be reached at 757-464-4761, Ext. 4409.



Mark Moore

Other members on the move...

Joe Chinn, SurFACTS Editor, joined SurModics as Director, Hemocompatibility this past spring, Ken Ryder recently joined Johnson & Johnson's Cordis division as Director, New Product Development-Core Products, Tim Baldwin recently joined the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) as Health Scientist Administrator, Mike Casanova recently joined Bard Peripheral Vascular as Director, Research and Development, Tim Kelley recently joined Medtronic Cardiac Rhythm Management Division as Principal Reliability Engineer, and Andy Campbell recently joined Medtronic Heart Valves as Senior Director, Research and Development, each after many years at CarboMedics. They all miss the Tex-Mex.

Foster the education that drives the research and technology of surface science!

The Surfaces in *Biomaterials* Foundation is looking for companies and organizations who are dedicated to exploring creative solutions and technical challenges presented in the surface science community. The Foundation needs your support to continue to foster education and multidisciplinary cooperation among industrial, academic, clinical, and regulatory communities.

Support the surface science community through an Enhanced Symposium Sponsorship at BioInterface 2003. The Surfaces in *Biomaterials* Foundation is proud to announce the all-new "Pick and Choose" sponsorship program. With this program, companies can design their own sponsorship package based on their visibility needs and budget. Visit the Corporate and Member Support Opportunities section of www.surfaces.org for the 2003 Marketing Prospectus and details on the new sponsorship program. Show your support to the surface science community today!

Pulsed Laser-Assisted Surface Modification / Functionalization

James D. Talton¹, Barbel Eppler¹, and James M. Fitz-Gerald²

¹Nanotherapeutics Inc, Alachua, FL

²University of Virginia, Dept of Materials Science and Engineering, Charlottesville, VA

Surface modification is not only a method to differentiate a medical device in the marketplace, but also a requirement for market success. Manufacturers must determine not only the mechanical properties of devices such as stents, catheters, vascular grafts, contact lenses, ocular implants, oral implants, hip implants, pacemakers / defibrillators, and bone fixation devices, but also the desired surface properties. Several techniques such as gamma irradiation [1], plasma treatment [2], radio-frequency magnetron sputtering [3], dip-coating [4], and chemical modification techniques, have been tested to produce biocompatible coatings onto medical devices. Perhaps best known is the success of Cordis™ coronary stent, which uses a SurModics drug-eluting coating to deliver Rapamycin. Unfortunately, many of these processes are limited by poor control of adhesion and composition, rigorous processing conditions, and long reaction times, limiting their manufacturing and commercial potential.

A new method for producing biocompatible thin-films is under development at Nanotherapeutics called pulsed laser-assisted surface modification, or PLASM™.

PLASM™ has been developed to prepare surfaces that are coated with ultrafine layers of materials, such as hydrophilic or hydrophobic polymers, applied through a non-aqueous, non-solvent process near atmospheric pressure. PLASM™ offers several advantages such as control of both the thickness and uniformity of the coating on the substrate surface, as well as process times of seconds to minutes.

Laser desorption at atmospheric pressure is well known as a method to introduce analytes for mass spectrometry [5, 6], as well as laser etching without vacuum [7]. MALDI, or matrix-assisted laser desorption ionization, is also utilized to analyze complex mixtures such as a drug or protein embedded in a polymer matrix.

Additionally, surfaces can be functionalized to improve attachment of proteins, such as enzymes, to further design surfaces with complicated structures or needs.

Percutaneous (through the skin) access devices, such as intravenous and peritoneal dialysis catheters, often fail because the lack of tissue bonding leads to the invasion of bacteria and subsequent infection at the access site, leading to removal of the implant and further patient discomfort. Using PLASM™, a 5 to 10 micron thick poly(tetrafluoroethylene) (PTFE) coating was applied to glass slides in under 10 minutes. Coated and uncoated slides were then seeded with DH5a E. coli in Brain Heart Infusion (BHI) broth to test for reduction of bacterial adhesion. Compared to uncoated glass slides (FIG. 1A), the PTFE-coated glass slides (FIG. 1B) demonstrated reduced adhesion onto PTFE after one hour incubation (FIG. 2).

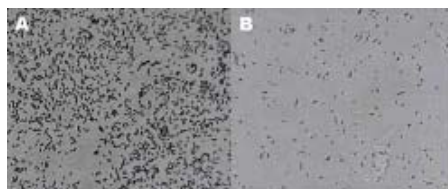


FIG. 1 Microscope images of (A) uncoated glass slide seeded with E. coli and (B) PTFE-coated slide showing reduced bacterial adhesion using PLASM™ process.

Tetracycline-loaded resorbable membranes [8] and fibers [9] have been investigated for local delivery to prevent bacterial growth following periodontal surgery. In addition, laser-deposited bioceramic coatings onto catheters have also been proposed as a method of reducing bacterial attachment [10]. Using 12.5% tetracycline mixed with poly (lactic-co-glycolic acid) (PLGA), 1 minute PLASM™ coatings produced a characteristic yellow spot (tetracycline coloration) on glass cover slips. To measure the release-rate of tetracycline, coated cover slips were placed into plastic Petri dishes with phosphate buffered saline, and UV absorption at 360 nm was measured for one week. After one week incubation, the absorbance spectra of the released tetracycline compared to standards were similar, demonstrating that the drug was not thermally damaged during the deposition process.

Finally, a related technique called pulsed laser-assisted surface functionalization, or PLASF™, involves modifying a surface for attachment of other molecules in a second step. For example, a functionalized coating of poly(dimethyl siloxane) (PDMS) was

(Laser continued on page 8)

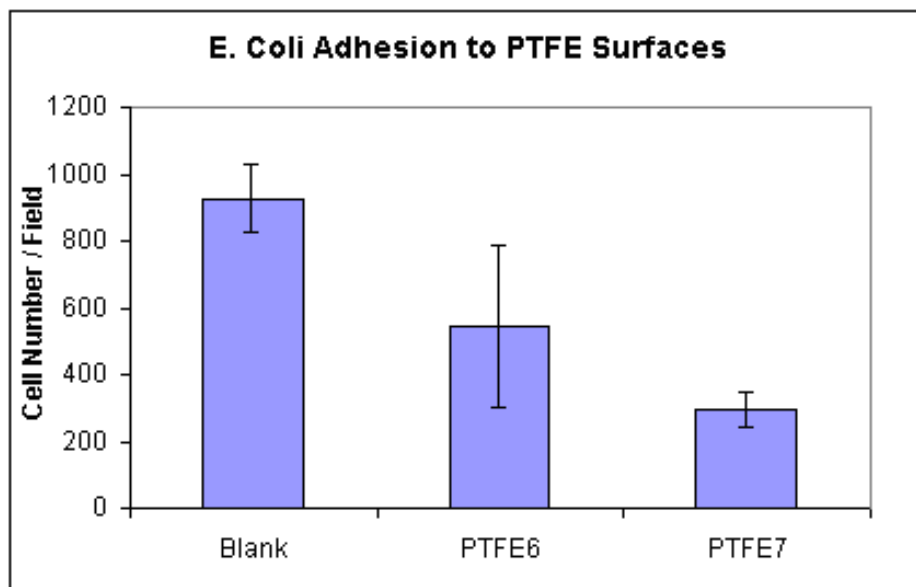


FIG. 2 E. coli adhesion to uncoated and PTFE-coated glass slides (mean ± SD).

CALL FOR NOMINATIONS

Deadline: August 29, 2003

Nominations for President-Elect, Vice President, Treasurer, and Secretary are requested by August 29, 2003. An officer must be the voting representative of a Supporting Member corporation in good standing. Terms are for one year. Below are descriptions of these positions adapted from the bylaws.

President. The President shall be the principal executive officer of the Corporation and shall in general supervise and control all of the affairs of the Corporation. The President shall preside at all meetings of the Board of Directors and shall be the Chairman of the Board.

President-Elect. The President-Elect shall assist the President with scientific program details as requested and shall automatically become President. The President-Elect shall become President at the Annual Business Meeting.

Vice President. The Vice President shall assist the President and the President-Elect with scientific program details as requested and shall automatically become the President-Elect. The Vice President shall become President-Elect at the Annual Business Meeting.

Treasurer. The Treasurer shall have charge and custody of and be responsible for all funds and securities of the Corporation; receive and give receipts for monies due and payable to the Corporation from any sources whatsoever, and deposit all such monies in the name of the Corporation in such banks, trust companies or other depositories as shall be selected in accordance with the provisions of

these by-laws; and in general perform all the duties incident to the Office of Treasurer and such other duties as from time to time may be assigned to him/her by the President or by the Board of Directors.

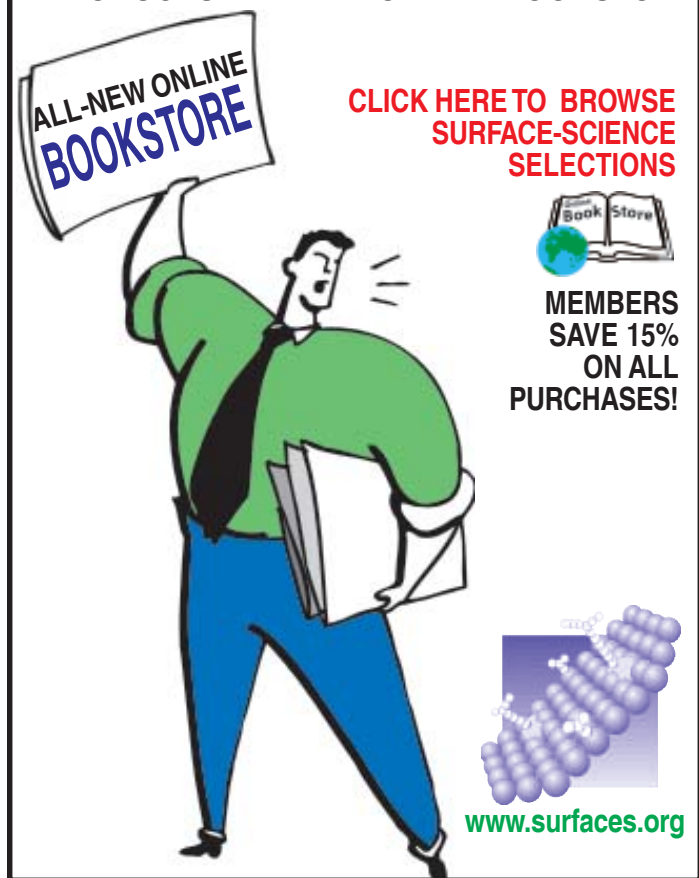
Secretary. The Secretary shall keep the minutes of the meetings of the Board of Directors in one or more books provided for that purpose; see that all notices are duly given in accordance with the provisions of these by-laws or as required by law, be custodian of the corporate records, the by-laws, and of the seal of the Corporation and see that the seal of the Corporation is affixed to all documents, the execution of which on behalf of the Corporation under its seal is duly authorized in accordance with the provisions of these by-laws; and in general perform all duties incident to the Office of the Secretary and such other duties as from time to time may be assigned to him/her by the President or by the Board of Directors.

Nominations should include a letter of support and recommendation, and an application which includes name, address and contact information of both the nominator and the nominee.

Nominations and applications with all supporting materials should be submitted to President-Elect Jim Brauker at vicepresident@surfaces.org for receipt by August 29, 2003.

Nominations will be considered for individuals from non-Supporting member companies pending the company becoming a Supporting Member prior to the individual standing for election.

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Boston Scientific Submits Fifth and Final Module of PMA for its TAXUS™ Express2™ Paclitaxel-Eluting Stent System

press release

Boston Scientific Corporation announced that it has submitted to the U.S. Food and Drug Administration (FDA) the fifth and final module of its Pre-Market Application (PMA) for its TAXUS™ Express2™ paclitaxel-eluting coronary stent system. Submission of the final module starts the official regulatory review process of the PMA at the FDA.

“We are pleased to have submitted our PMA on schedule and to have marked another major milestone in our TAXUS program,” said Jim Tobin, President and Chief Executive Officer of Boston Scientific. “We are looking forward to bringing the benefits of this breakthrough technology to clinicians and patients in the United States, as we have done for those in Europe and other international markets. The TAXUS technology is being enthusiastically embraced in those markets, and we are looking forward to a similarly strong reception in the U.S. Boston Scientific has been a pioneer in the development of drug-eluting stent technology, and today’s submission is a significant achievement for which the entire TAXUS team deserves congratulations.”

The TAXUS technology is Boston Scientific’s proprietary polymer-based, paclitaxel-eluting stent system for reducing coronary restenosis, the growth of neointimal tissue within an artery after angioplasty and stenting. Boston Scientific launched the TAXUS™ Express2™ paclitaxel-eluting coronary stent system in Europe and other international markets in February.

(FDA continued from page 2)

selection of sirolimus for the CYPHER Stent,” Mr. Croce said. “Our collaboration with Wyeth resulted in this significant medical advancement in coronary care, opening the door to future drug-device therapies.”

Mr. Croce added, “The clinical benefits of our CYPHER Stent are compelling. We are seeing solid clinical results, out to three years in our initial pilot study. These results will have an increasingly positive impact on patients.”

“It’s gratifying to see the impact Rapamune (sirolimus) has had in treating patients with coronary artery disease, and its potential for an even broader application in other parts of the vasculature,” said Robert R. Ruffolo, Ph.D., President, Wyeth Research. “The use of Rapamune has had a significant impact on the field of transplantation, and now we’re seeing its potential to help the hundreds of thousands of patients who receive cardiac stents each year.”

Setting a New Standard

The stent’s treatment process, or mechanism of action, is controlled by a polymer coating that gradually releases the drug sirolimus into the vessel lining to prevent scar tissue growth, a frequent reaction that leads to re-blockage following current treatment procedures.

“Reblockage of coronary arteries has remained a stubborn obstacle to successful long-term patient treatment,” said Dr. Moses. “Currently, restenosis occurs in as many as 30% of patients who receive a bare metal stent.

“Our goal is to treat a blockage one time, and one time only,” Dr. Moses added. “This is our patients’ expectation. Now we have a treatment that can significantly reduce the incidence of re-blockage, potentially sparing tens of thousands of patients the need for repeat interventions, including bypass surgery.”

The CYPHER Stent is the only drug-eluting coronary artery stent whose performance is supported by two large-scale, randomized, double-blind, controlled clinical trials.

“These trials, involving approximately 1,400 patients, continue to support the long-term unprecedented results for the CYPHER Stent,” said Dr. Moses.

Data from the two-year follow-up on the pivotal European RAVEL trial and the one-year follow-up on the landmark U.S. SIRIUS trial were presented at the American College of Cardiology’s 52nd Scientific Session in March. The CYPHER Stent data showed sustained reduction in the incidence of re-blockage by more than 90% as compared to a conventional bare metal stent, with a greater than 95% chance that patients can avoid retreatment. The outstanding results were achieved in a broad range of patients, including those with complex lesions and at high risk for reblockage.

Public and Private Coverage for Drug-eluting Stents

Recognizing the medical value of drug-eluting stents, the Centers for Medicare and Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services, moved

forward in August 2002 with approval of incremental reimbursement for the new medical device, effective April 1, 2003. This new policy provides significant incremental reimbursement over and above the current bare metal stent reimbursement levels. Cordis is also actively engaged with Medicaid and private insurance payers to grant coverage and incremental reimbursement for drug-eluting stents.

A recent independent economic analysis of the SIRIUS trial performed by David J. Cohen, M.D., Harvard Clinical Research Institute, showed that the CYPHER Stent was cost-effective at one-year post treatment and will enable payers to recoup virtually all costs associated with the CYPHER Stent within 12 months. The analysis looked at actual hospital in-patient and outpatient cost data, beginning with the period of initial hospitalization and ending one-year following stent implantation.

For every 100 patients treated with the CYPHER Stent, there were 19 fewer revascularizations and 25 fewer hospital admissions than with the conventional stent, translating into substantial post-treatment healthcare savings.

**Cordis has entered into an exclusive worldwide license with Wyeth for the localized delivery of sirolimus in certain fields of use, including delivery via vascular stenting. Sirolimus, the active drug released from the stent, is marketed by Wyeth Pharmaceuticals, a division of Wyeth, under the name Rapamune®. Rapamune® is a trademark of Wyeth Pharmaceuticals.*



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BioInterface 2003

Mark Moore, Program Chair and President

We are very excited about the upcoming BioInterface 2003 to be held in Savannah, GA October 22-24 (<http://surfaces.org/meetings/2003/index.htm>). We have received an unprecedented number of abstracts and are looking forward to a great meeting. The meeting will focus on Tissue Engineering, Hemocompatibility, Drug Delivery, Immunology, and in vitro and in vivo Model Systems. We will also have a Student Poster award competition, and a special debate session related to Hemocompatibility testing models that promises to be entertaining and lively.

Congratulations are also in order to the Foundation for receiving a student support grant

from the Whitaker Foundation. We are going to use the funds to support an additional student award as well as hosting a Town Hall meeting for the students where they can “meet the industry” while enjoying refreshments. We plan for this session to be an informal process for students to interact with those from a variety of companies and to ask questions about life in industry. We were able to promote this news prior to the abstract deadline resulting in a record number of student abstracts.

I hope you plan on attending the meeting and I am confident you will enjoy the science, the beautiful city of Savannah, the debate session, and our unique blend of industry, academic, regulatory, and clinical attendees. See you in Savannah!

Dynamic Coronary Stent Market In For More Changes

By Paul Consigny

On April 24, 2003, the Cordis Division of Johnson and Johnson received FDA approval of the CYPHER™ drug eluting stent for the treatment of de novo atherosclerotic lesions in native coronary arteries. This is the first drug-eluting stent to be approved in the U.S. The CYPHER™ stent had previously received European CE approval in April, 2002.

The CYPHER™ stent system comprises a stainless steel BxVelocity™ stent that is coated with a non-degradable co-polymeric matrix developed by SurModics that controls the elution of the drug sirolimus. Sirolimus is an antifungal drug, originally developed by Wyeth Pharmaceuticals, that inhibits vascular smooth muscle cell proliferation and migration and, in doing so, inhibits the intimal thickening that is responsible for vessel re-occlusion (restenosis) that occurs subsequent to stent placement. The CYPHER™ stent has been tested in several clinical trials including the RAVEL and SIRIUS trials. The SIRIUS trial revealed that 8 months after stent placement, the CYPHER™ stent had reduced in-stent restenosis from 35% in the control arm to 3% in the treatment arm. Similarly, target vessel revascularization was reduced from 21% to 9.6%.

Since its initial approval in April over 50,000 CYPHER™ stents have been implanted in the U.S. Currently, there are several issues related to the use of the CYPHER™ stent including cost, limited availability, limited stent diameters and lengths, poorer performance in insulin-dependent diabetics, and a sufficient number of subacute thromboses to warrant Cordis sending an advisory letter to physicians.

Currently, the CYPHER™ stent is the only drug eluting stent on the market. This should change in the next few months after the anticipated FDA approval of the TAXUS™ paclitaxel eluting stent

manufactured by Boston Scientific Corporation. The TAXUS™ stent previously received European CE approval in January, 2003.

The TAXUS™ stent system comprises a stainless steel Express2™ stent that is coated with a non-degradable polymeric matrix, developed internally by Boston Scientific. The TAXUS™ stent elutes paclitaxel, the active component of the chemotherapeutic agent TAXOL, that inhibits cell division by preventing the dissolution of microtubules. Currently there are two types of TAXUS™ stents, one that elutes paclitaxel at a slow rate and one that elutes paclitaxel at a moderate rate. The TAXUS™ stent has been tested in several clinical trials including the TAXUS I, TAXUS II, TAXUS III, TAXUS IV, and TAXUS VI trials. The TAXUS II trial revealed that 6 months after stent placement binary in-stent and in-segment restenosis rates for the patients treated with the control stent were 17.9% and 20.1%, respectively, while for the patients treated with the slow release stents, the rates were 2.3% and 5.5%, respectively. Total lesion revascularization rates for the control and slow release formulation were 12.0% and 4.6%, respectively, while major adverse cardiac event rates for the control and slow release formulation were 19.5% and 8.5%, respectively. Comparable rates were seen for the stents with the moderate release formulation.

Other drug eluting stents currently being developed include Cook's paclitaxel coated stent (ASPECT and ELUTES trials), Guidant's everolimus eluting stent (Future I trial), and Medtronic and Abbott's ABT-578 eluting stents (ENDEAVOR and PREFER, trials respectively).

(Additional information can be obtained at the Drug Eluting Stent Center at <http://www.tctmd.com>.)

(Laser continued from page 3)

deposited onto similar PDMS samples to improve the chemical attachment of an enzyme to an implant surface. Biocatalytic coatings of hydrolytic enzymes with PDMS have been previously proposed using sol-gel entrapment and covalent attachment for paints [11]. Because silicone, which is currently used in urological stents [12], produces a nucleation site for oxalate crystal formation after implantation, the attachment of oxalate degrading enzymes to prevent encrustation was investigated. PDMS sheets were coated for 10 minutes using PLASFTM, producing a white spot. The modified PDMS samples were then reacted with a coupling agent (AMEO, Sigma) and rinsed, and similar samples were formed under different conditions using radio-frequency plasma discharge (RFPD) as controls. While surface modification by both RFPD and PLASFTM resulted in a more hydrophilic surface, XPS studies showed that the PLASFTM surface deposition followed by AMEO functionalization resulted in a slightly greater increase in surface nitrogen content, indicating a higher level of AMEO attachment. Oxalate-degrading enzyme, oxalate oxidase (OXO) and oxalate decarboxylase (OXDC) were then covalently bound to the RFPD and PLASFTM-modified silicone elastomer samples through glutaraldehyde bioconjugation. PLASFTM immobilized OXDC retained more enzymatic activity (0.784 U/mg) compared to RFPD-immobilized OXO (0.038 U/mg). The results, in collaboration with Ixion Biotechnology, showed that by optimizing the choice of enzyme and method of attachment substantial improvement in the functionality of the surface may be realized. Further studies with PLASFTM and PLASFTM are currently being conducted on different implant surfaces and biosensors.

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“From Atoms to Anatomy...”

By Steven Goodman and Jim Brauker, workshop chairs

Biomaterials Scientists and Engineers understand the necessity of carefully characterizing their devices and material structure, and their interactions with the biological environment. This is one of the reasons why we read this newsletter. To fully understand biological and material interactions requires a multimodal approach over several scales and several characteristics. Speakers in this workshop, “From Atoms to Anatomy,” will introduce new materials and biological characterization tools and techniques, beginning with atomic structure and ending with whole body anatomical physiology. The goal of these presentations will be to provide insight into recently available technologies that biomaterial scientists can presently apply to address their 3-D structural, compositional, and/or bio-functional questions, and to provide a glimpse into newer, not yet commercialized technologies that will likely be available in the near future.

In the first presentation, Steven Goodman, representing Imago Scientific Instruments Corporation, will introduce an innovative atomic resolution imaging mass spectrometer instrument, the local electrode atom probe or LEAPTM. The LEAPTM determines material structure by literally taking it apart one atom at a time, atomic layer by atomic layer. Unlike current instruments, LEAPTM maps out all elements and isotopes with sub-nanometer resolution. In the last presentation, Edward LaFaso of Full Body Scanning Management, Inc., will examine the “Use of electron beam tomography in the clinic.” In between these two presentations, a number of presenters will focus on the methods and instrumentation for determining material and function. These presentations will include methods to image composition of biological and organic materials at the micron scale; “Imaging Raman and IR applied to tissues and polymers” by Patrick Treado, Chemimage Inc.; 3-D biological function with “Light microscopy/gene expression/organ function/bioinformatics” by Andres Kriete, Tissue Informatics Inc.; a newer method to image tissue and scaffold structures hundreds of micron deep into tissue without staining using a confocal-like instrument, “3-D imaging of protein structure and function using simultaneous second harmonic generation and multiphoton fluorescence microscopy” by Paul Campagnola, Center for Biomedical Imaging Technology at the University of Connecticut; the latest development in an optical technology that can non-invasively examine interfaces such as extracellular matrix structures and blood flow deep within living tissues; “Applications of optical coherence tomography in clinical medicine and biomaterial science” by Johannes de Boer, Harvard University and Mass General Hospital; and “Molecular Imaging in the Health Sciences Using Positron Tomography” by Tom Hook, President, CTI Molecular Imaging, Inc. As you can see, this promises to be an exciting, educational workshop.

Savannah, Georgia's First City

By Kristin Horstman, Meetings & Conferences Manager

Savannah is a city rich in history, Southern charm and old-fashioned hospitality. The city has one of the largest historic districts in the United States, with thousands of architecturally-significant buildings nestled under giant oaks hung with Spanish moss. Often referred to as the Hostess City of the South, Savannah is rich in architectural splendor, natural beauty and ever present Southern charm.

Savannah is home to a multitude of cosmopolitan award-winning restaurants and low country cuisine! Excite your taste buds with a bowl of creamy lobster bisque, a sweet pecan pie, a crispy platter of fried chicken, fresh collard greens, a hot bowl of grits or a delicate scored flounder tempered with an apricot glaze with baby carrots and wild rice. If down-home favorites are not your forte and it's international flare you seek, Savannah is filled with eclectic restaurants featuring Italian, Asian, Southwestern, Caribbean, French, English, Irish, Greek and Moroccan cuisine. There is a restaurant to satisfy everyone's pallet.

In the Historic District, the cobblestones that line River Street are ready for visitors to explore the candy shops, art galleries and a number of nautical-themed apparel and gift stores. Move a couple of blocks south from River Street to City Market where art studios, galleries and specialty shops fill the two-block space. Discover Broughton and Bull Streets, the heart of Savannah's antique district, where treasures of old are awaiting your unearthing. Whether you're in search of unique treasures or the ultimate bargain, you'll discover just what you're looking for in Savannah.

If golf is what you're looking for, look no further than Savannah with its many golf courses to delight the amateur or the seasoned golfer. Due to its temperate seasons and evergreen conditions, Savannah offers a perfect place to tee off, drive and putt the day away.

By day, Savannah is a scenic city full of history, romance and charm. After the sun goes down, the nightlife heats up in



Savannah, with a variety of clubs, pubs and options for every taste. From downtown Savannah to the beaches at Tybee Island, you'll find a wide range of happening hot spots. Whether you enjoy dancing 'til the wee hours, listening to live bands or sampling a locally-brewed beer, you'll find that Savannah comes alive after dark in Irish pubs, rustic bars and high-tech dance clubs. Don't miss all the fun!

Visit www.savannahvisit.com to learn more about this enchanting city. See you in Savannah October 22-24, 2003

FDA/ODE Vendor Day

By Lise W. Duran, 2002-2003 Past President

The FDA is developing a Vendor Day program on coatings/surface modification for the Office of Device Evaluation (ODE), Center for Devices and Radiological Health (CDRH). ODE developed the Vendor Day Program in 1993. It is an educational activity that allows device manufacturers to display and provide to FDA reviewers a product demo highlighting the scientific basis for their product. The Vendor Day is held at ODE headquarters in Rockville, Maryland where scientific reviewers visit industry displays and demos that include devices and related videotapes and simulators. Reviewers also have the opportunity to query the manufacturers' scientists and engineers about the product design and its operation and application, providing them with useful information about the device.

Aside from the educational benefits afforded FDA reviewers, the Vendor Day Program also engenders improved communications between industry and the FDA and

provides both groups with better understanding of the health issues involved with the medical device technology highlighted at that Vendor Day. Several medical device associations (such as HIMA, NEMA, OSMA, AMDM) have participated with ODE in hosting several Vendor Days covering such topics as: Orthopedic Implants, Endoscopes, Ultrasound, Sterilization and Packaging, DNA Amplification, Diagnostic and Safety Devices, Orthopedic and Spinal Devices, Patient Monitoring Devices, New Technology, and others. The Surfaces in *Biomaterials* Foundation will be facilitating the Vendor Day program on coatings/surface modification.

Although no date has been set, the Vendor Day will likely take place sometime from mid-September through mid-November or mid-January through June. The Vendor Day is normally one day from 9:00 a.m. to noon with as few as three vendors and up to fifteen depending on the device area. It

could be split into two days for a large device area with multiple companies (i.e. orthopedics).

Announcement of the Vendor Day will be sent out to all FDA employees. There are usually about 100-200 employees (mostly CDRH) that participate. During Vendor Day, the reviewers will spend from 15 minutes to a half an hour at each company exhibit. Normally, companies send representatives from within their company from different areas (regulatory, technology, marketing, etc.) to show and explain to the reviewers the science behind the device and to answer any questions that they may have.

If you are interested in participating, please call me, Lise Duran, at (952) 829-2745 or contact me by e-mail at lduran@surmodics.com. Once we determine the level of interest among our members, we will work with the FDA to schedule a day and provide all participants with more defined details.

Calendar of Events

The Institute for International Research Minimizing Liability Risk in Clinical Research

August 25-27, 2003
Hyatt Regency Cambridge
Cambridge, MA USA
212-661-3500-x-3069
www.iirusa.com

2003 NESAC/BIO Workshop Surface Characterization of Biomaterials

August 25-27, 2003
National ESCA and Surface Analysis Center
for Biomedical Problems
University of Washington
Seattle, Washington USA

The UWEB 7th Summer Symposium Biocompatibility

August 27-29, 2003
University of Washington
Seattle, Washington USA
<http://www.uweb.engr.washington.edu/news/summersymp.html>

ACS Division of Polymeric Materials: Science and Engineering Symposium on Polymeric Drug Delivery: Science & Application

226th ACS National Meeting
September 7-11, 2003
New York, New York USA
<http://www.chemistry.org/portal/a/c/s/1/acdisplay.html?DOC=meetings\newyork2003\homepage.html>

American Society for Metals International Materials & Processes for Medical Devices Conference

September 8-10, 2003
Anaheim Hilton Hotel
Anaheim, CA USA
+1 (440) 338-5151
www.asminternational.org

TCT 2003 Conference

September 16 - 21
Washington, DC USA
<https://www.one-stop-registration.com/tct/>

BMES 2003 Annual Fall Meeting

October 1-4, 2003
Renaissance Nashville Hotel
Nashville, TN USA
www.bmes.org

European Society for Biomaterials ESB 18th European Conference on Biomaterials

October 1-4, 2003
Millennium Hotel and Resort
SI Centrum, Stuttgart, Germany
+49 (0) 711-9340-216
+49 (0) 711-9240-261
www.conference@esb2003.org

National Institute of Standards and Technology, and ASTM Symposium on Metrology and Standards for Cell Signaling: Impact on Tissue Engineering

October 14-15, 2003
Hilton Washington DC North/
Gaithersburg
Gaithersburg, MD USA
301-975-3124
<http://www.cstl.nist.gov/biotech/cellsignaling>

Surfaces in Biomaterials Foundation BioInterface 2003

October 22-24, 2003
Savannah Marriott Riverfront
Savannah, GA USA
+1 (763) 512-9103
register@surfaces.org
www.surfaces.org

MD&M Minneapolis

October 28-30, 2003
Minneapolis Convention Center
Minneapolis MN USA
<http://www.devicelink.com/expo/minn03/>

American Heart Association Scientific Sessions 2003

November 9-12
Orange County Convention Center
Orlando, FL USA
<http://www.scientificsessions.org/portal/scientificsessions/ss/generalinformation>

Australian Society for Biomaterials 7th World Biomaterials Congress

May 16-21, 2004
Sydney Convention and Exhibition Centre
Sydney, Australia
+612-9262-2277
biomaterials@tourhosts.com.au
www.tourhosts.com.au/biomaterials

AO Research Institute ECM V: The Cell Biomaterial Reaction

June 28-30, 2004
Congress Centre, Davos, Switzerland
www.aofoundation.org

Surfaces in Biomaterials Foundation BioInterface 2004

October 27-29, 2004
Wyndham Baltimore Inner Harbor
Baltimore, MD USA
+1 (763) 512-9103
register@surfaces.org
www.surfaces.org