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# SurFACTS in BioMaterials

Summer 2015 Volume 20 - Issue 2

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## Note to Our Readers

This is the first edition of SurFacts transitioning from our traditional PDF to a web-based format. The reason for this change is to make reading and accessing the newsletter content faster and easier. We have included news and announcements in the body of the newsletter with links to individual PDF versions of the longer technical articles. We hope you like the change. Feedback regarding this new format is encouraged and should be provided to the newsletter Executive Editor Joe McGonigle at [jmcgonigle@surmodics.com](mailto:jmcgonigle@surmodics.com).



## BioInterface Workshop & Symposium 2015

September 21-23 | Fairmont Scottsdale Princess

- Excellence in Surface Science Award Presentation by: Gail Naughton; Histogen Aesthetics, LLC
- Keynote Presentation by: Stu Williams; Cardiovascular Innovation Institute - University of Louisville
- Full Day Workshop on "Hemocompatibility Technologies, Models, and Testing"
- 7 Technical Sessions
- Student Town Hall Meeting & Poster Contest
- Multiple Networking Specific Receptions

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- SurfaceSolutions Labs, Inc.

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## Member News

Welcome to new SIBF member **Brightlands Chemelot Campus**. Brightlands is a collaborative endeavor between researchers, industry and government to develop new technologies. The Chemelot campus is focused on high-performance biomedical materials and regenerative medicine. For more information on Brightlands please see the article in this issue.

**American Preclinical Services** announced the launch of a new online client portal called *My APS FlightLog*. This portal is intended to allow easy and accurate initiation and retrieval of biocompatibility testing data. APS was also a participant in the ISO/TC 194 Biological and Clinical Evaluation of Medical Devices annual meeting. APS will be involved in developing new assays and standards to reduce assay cost and animal utilization.

**Medtronic** received FDA approval in June for the CoreValve® Evolut™ R System. This is the first recapturable transcatheter heart valve to be available in the US. To date the company has treated over 75,000 patients using the CoreValve system and the new product offers several improvements in the procedure. The company also made several acquisitions including RF Surgical Systems, Aptus endosystems, and Cardio/Insight. Medtronic also announced several partnerships in the area of diabetes treatment including Samsung, BD and Glooko. The company also released a new bariatric surgery device called the GastriSail® gastric positioning system to aid surgeons during sleeve gastrectomy for weight loss. Medtronic also announced results from the Citadel/Centurion trial of the TYRX™ antibacterial envelope to reduce infection of cardiac implantable electronic devices (CIEDs). At 1 year after implantation infections rates were 0.44% in 1,129 patients with the TYRX device compared 2.2% in published controls. CIED infections are associated with high risks and are estimated to cost approximately \$50,000 to treat.

**CooperVision** introduced a new silicone hydrogel lens called MyDay®. These lenses are made with Smart Silicone™ chemistry to deliver benefits of hydrogel and silicone lenses. These lenses provide optimal permeability and moisture by reducing the amount of silicone and also offer both softness and strength and handling.

**W.L. Gore** received approval to begin clinical studies of the GORE®EXCLUDER® AAA endoprosthesis in the US and Japan. This device for treating infrarenal abdominal aortic aneurysms should enable treatment of patients previously unqualified for an endovascular approach. Gore also announced final results of a study of its BIO-A® tissue reinforcement mesh for hernia repair. The study showed increased quality of life after complex ventral hernia repair with the mesh material. The BIO-A® mesh is a synthetic degradable material with ideal porosity for repair with the advantage of not being animal or human tissue derived.



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## Brightlands Chemelot Campus: Breath-taking innovation, heart-beating tradition

By Kurt Gielen ([kurt.gielen@brightlands.com](mailto:kurt.gielen@brightlands.com); Tel +31619271669)

Most of our experiences have one thing in common. They are almost always linked to specific places, sometimes very unique ones, all around the globe. If you like gambling, you can do it everywhere, even online. However, when it comes to gambling, deep in your heart you know you have to go to the Strip at Las Vegas at least once. Everything else is secondary. If you are into shopping, you are most probably well aware of the never-ending possibilities of 5th Avenue in New York City. If you are into luxury and elegance, the Champs-Élysées in Paris is certainly hard to miss. If your heart beats for finance, though, Wall Street is your capital street.

[Read More \(PDF\) »](#)

# GREAT THINGS HAPPEN WHEN KNOWLEDGE CROSSES BORDERS

At Brightlands we live to find solutions to the great global challenges in materials, health and nutrition. Leading international researchers, entrepreneurs, and students work together on healthy and sustainable solutions. Collaboration and cooperation that crosses scientific, geographical, and organizational boundaries.

Brightlands Chemelot Campus  
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Brightlands  
Knowledge crossing borders

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## Synthetic Bone Grafts: A Surface Mineralized Approach

*By Jacqueline Harding, Chemical and Biological Engineering Department, Colorado School of Mines, Golden, CO*

Bone is a dynamic system continuously undergoing remodeling with 10% of the skeleton regenerated annually in adults.<sup>1</sup> The existing bone is utilized as a growth template for remodeling and repair alike. As such, in the event of a critical defect in the tissue, natural processes are unable to repair the damaged site. As shown in Figure 1, the use of grafts of natural and synthetic origin are used as regenerative templates in the repair of damaged tissue.

[Read More \(PDF\) »](#)

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## Discerning *in-vivo* corrosion mechanisms and failure modes of explanted prostheses – Part I

*By Norman Munroe, Vishal Musaramthota, Christopher Emerson and Kinzy Jones*

## Introduction

Orthopedic implants have seen a major increase in usage within the US and worldwide. Three decades ago, the average age for a hip replacement was 78 years, while today it is 59 years. The American Academy of Orthopedic Surgeons notes that more than 700,000 primary total hip or knee replacements were performed in the US, with demand doubling in the next decade. However, increased usage has been accompanied by an increase in revision, where the prosthesis is removed. Most joint replacements have been performed primarily on older patients and as such, there is a dearth of information on how these implants would hold up in younger patients over longer periods of time. Despite the advent of new designs and advanced materials, orthopedic surgeons are still concerned that younger knee replacement patients, for example, may need to have replacement in as little as 5 to 10 years, which leads to bone loss every time the surgery is performed.

[Read More \(PDF\)](#)

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## Early Feasibility Studies for Initial Clinical Investigations of Innovative Medical Devices in the US

*By Phil Triolo PhD, RAC*

In response to the offshore exodus of clinical trials for innovative devices, the FDA issued a guidance document in Oct. 2013, Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies, found [here](#). The EFS (Early Feasibility Study) process is especially useful for new, innovative, significant risk devices whose safety and efficacy/performance can only be evaluated by using the devices in the clinical setting, but whose design is still in flux. The guidance document is summarized here because many of my clients and presumably other manufacturers continue to conduct trials overseas, seemingly unaware of the opportunity to conduct an EFS in the US.

[Read More \(PDF\)](#)

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## Membership

The Foundation proudly spotlights your corporate/institutional expertise throughout the Foundation's print and online publications. As a Supporting Member, you are a leader with a voice

in the future development of the surface biomedical community by participating in the governing committee. You will have the opportunity to participate in topic selections for the annual BioInterface Conference. Your company also has a voice in selecting the governing Board of Directors. Each supporting member has one vote. Other Benefits Include:

- Discounted member rates at BioInterface
- Name recognition in Foundation publications distributed to surface science professionals around the world
- One complimentary registration to the BioInterface symposium (does not include the Workshop)
- Complimentary exhibit booth at the BioInterface Exhibition
- 40% discount on all advertisements in SurFACTS newsletter and the Surfaces website
- Logo recognition in the SurFACTS newsletter
- Complimentary listing in the Foundation's Online Member Guide including logo, hotlink, and 50-word description of your company
- Complimentary subscription and online access to SurFACTS newsletter including past issues
- Complimentary full-page, full-color advertisement in the SurFACTS newsletter
- Article visibility in the Member News section of the SurFACTS newsletter (Article is subject to editorial review for space and content)

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## Member Testimonial

"For American Preclinical Services (APS), exhibiting at the [Surfaces in Biomaterials Foundation](#) conference was marketing dollars well spent. The conference attracts a broad variety of biotechnology companies and we felt like there was substantive interaction with the scientists and engineers that would be using our services. These interactions yielded many new leads, more so, than other larger conferences/expos that we have had exhibits"

**Michael Conforti** DVM, MS, MBA , President with American Preclinical Services, LLC

[Join or Renew](#)

## Submit Content for Next Issue by October 9th

### "Surface Highlight"

**The *Surface Highlight*\* is a half-page article dedicated to one company in the surface science industry!**

Your article will be placed in SurFACTS in Biomaterials, the official newsletter of the Surfaces in Biomaterials Foundation! Reach the unique niche the Foundation has to offer with an entire article dedicated to your company, giving potential clients detailed information on your products and services.

For further exposure, place a half-page [advertisement](#) next to your *Surface Highlight* article for even more visibility!

For general information on advertising contact our Business Development Department at (651) 290-6267 for more information.

\*The *Surface Highlight* article is limited to 1500 words and should be submitted to [Executive Editor Joe McGonigle](#) on or before the Submissions Deadline. Article submission does not guarantee publication.

### Submission Deadlines

**Summer** - July 10, 2015

**Fall** - October 9, 2015

**Winter (2016 edition)** - January 8, 2016

This includes stories and advertisements. Most SurFACTS are published a few weeks after the Submission Deadline ends.

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Members are encouraged to submit articles for future editions of SurFACTS. Please email your report (with all appropriate figures and graphics) to Staff Editor Jazzy McCroskey at [jasperm@surfaces.org](mailto:jasperm@surfaces.org) for consideration in a future issue. [Deadlines](#) for upcoming issues are posted.

