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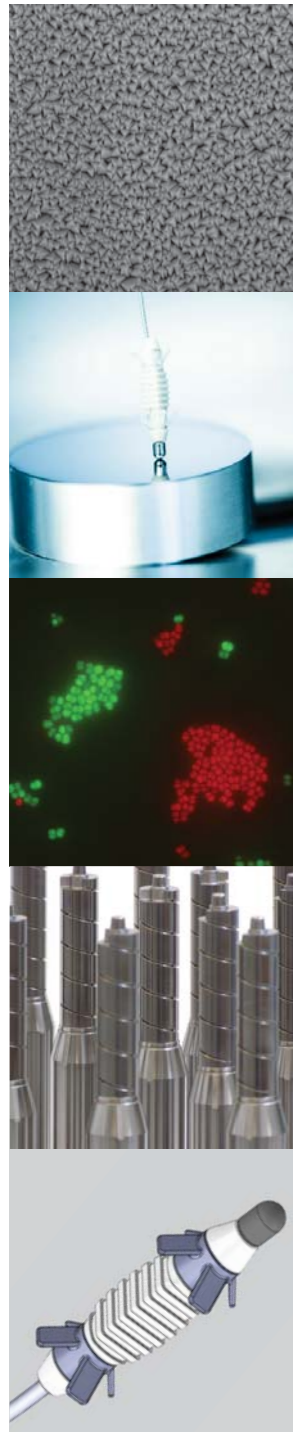


DANISH
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MedTech Innovation

**Danish Technological
Institute**

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Conference Hall, Danish Technological Institute, Taastrup

Conference on New Medical Products and Devices

November 24th, 2016



**Program for the conference – New Medical Products and Devices
24 november 2016, Taastrup, Denmark**

8.30-9.00	Registration and coffee
9.00-	Welcome
9.05	Daniel Delfosse, Mathys; "The Many Hurdles between a Good Idea and a Medical Device".
9.35	Andreas Stavropoulos, Malmö University; "Peri-implantitis: what is it, how much is it, and is it a problem?"
10.00	Bo Hammer, Neurodan; "Pre-clinical and clinical testing of implantable electrode designs".
10.30	Coffee
11.00	Kristian Rechendorff, Danish Technological Institute; "Tailoring surface properties of medical devices using sputter deposition".
11.25	Morten Foss, iNano, Aarhus University; "Steering Cell and Tissue Response by Surface Modifications".
11.50	Ole Zoffman, Elos Pinol; "Surface Technologies for Medical Implants".
12.15	Lunch, network and poster session
13.45	Nicole Ciacotich, Elplatek; "Development of electrochemically deposited surfaces capable of killing bacteria".
14.10	Yijuan Xu, Danish Technological Institute; "Antibiofilm material testing – examples and applications".
14.35	Guggi Kofod, Inmold; "Thermoplastic Parts with Biomolecular Coatings integrated within the Molding Process".
15.00	Coffee
15.30	Annette Rye Larsen, MedTech Innovation; "MedTech Innovation: A tool for innovation projects and matchmaking".
15.50	Jan Lorenzen, Danish Technological Institute; "Biofilm formation - a challenge for many devices".
16.10	Claus Moser, Rigshospitalet; "Novel therapeutic regimens for chronic biofilm disease".
16.40-17.00	Summary and end of conference.

This conference on new medical products and devices is open for companies, specialists, medical doctors, researchers and other people interested in the field.

We encourage people to bring relevant posters, showcases, products and devices, which can be displayed during the poster session (please mention that when you fill in the registration form).

Price: DKK 799 (DKK 400 kr for students), which includes food and drinks.

Sign up for the conference by sending an e-mail to: **Lone Elly Larsen**,
l@teknologisk.dk.

Please state the number and names of participants, and the name of the institute they come from. Let us know if you will be bringing a poster or would like to display your products and devices on a table.

The **deadline for registration** is November 14th 2016.

The number of participants is limited to 150.

Place:

Conference Hall, Danish Technological Institute
Gregersensvej 1
DK-2630 Taastrup

<http://www.teknologisk.dk/kontakt/find-vej/22926,4>

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For further information please contact:

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See abstracts and more details:

[http://www.dti.dk/services/
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DEVELOPMENT OF ELECTROCHEMICALLY DEPOSITED SURFACES CAPABLE OF KILLING BACTERIA

Nicole Ciacotich, Elplatek A/S and DTU Department of Biotechnology and Biomedicine (nicciac@dtu.dk)

Jan Boye Rasmussen, Elplatek A/S (jbr@elplatek.dk)

Lone Gram, DTU Department of Biotechnology and Biomedicine (gram@bio.dtu.dk)

Per Møller, DTU Department of Mechanical Engineering (pm@mek.dtu.dk)

The proliferation and transmission of pathogenic organisms in hospitals and especially in intensive care units is an ever increasing problem. There are many possibilities for bacteria transmission; however, door handles that are touched by all are one of the most likely inevitable vehicles of bacteria spreading. On the basis of the well-known antibacterial capability of copper and silver, a simultaneous electrodeposition process of the two metals has been developed in order to provide common stainless steel surfaces with a unique coating where the dissolution of copper is promoted thanks to the galvanic coupling with silver. Standardized solid surface adhesion tests using *Escherichia coli* as test organism demonstrated the effectiveness of such system as all bacterial cells in a suspension around surfaces coated with the Cu-Ag coating were killed.

Nicole Ciacotich has a Master in Material Science and Engineering from University of Trieste. At present she is an industrial PhD student employed at Elplatek A/S and working in the Bacterial Ecophysiology and Biotechnology group at DTU Bioengineering. The project is in collaboration with the MTU group at DTU Mechanical Engineering and the Panum Institute at the University of Copenhagen.

MedTech Innovation: A tool for innovation projects and matchmaking

*Annette Rye Larsen, Office for Innovation and Sector Services, The Technical University of Denmark
(anryl@dtu.dk)*

The aim of this presentation is to illustrate how MedTech Innovation can aid innovation and growth in SME's. Innovation networks have been established to boost innovation and growth in small and medium-sized enterprises (SMEs) by helping the SMEs to get access to the innovation system. The networks provide a platform within a specific technical or professional area where companies, universities, research institutions and hospitals among others can meet to exchange ideas, knowledge and launching new projects. This lecture will present cases from MedTech Innovation such as innovation projects as well as matchmaking tools used.

Annette Rye Larsen is project manager for MedTech Innovation based at DTU. MedTech Innovation is a Danish innovation network financed by the Ministry of Higher Education and Science. The purpose of the network to increase knowledge sharing, cooperation and exchange of experience between scientist, clinicians and companies, especially SME's

Peri-implantitis: what is it, how much is it, and is it a problem?

Andreas Stavropoulos, Dept. of Periodontology, Faculty of Odontology, Malmö University, Malmö, Sweden (andreas.stavropoulos@mah.se)

Rehabilitation of function with oral implants replacing lost teeth is nowadays a routine treatment and excellent long-term survival rates of implants are reported. Nevertheless, both mechanical and biological complications occur. Biological complications consist of peri-implant mucositis and peri-implantitis, which can be considered as pendants for gingivitis and periodontitis. Thus, peri-implantitis consists of inflammation within the peri-implant mucosa and loss of supporting bone. Recently it is suggested that about 8 – 25% of the implants and about 25 – 45% of the patients will develop peri-implantitis.

This lecture will present relevant similarities and differences between teeth and implants with regard to anatomy, microbiology, and pathogenesis of periodontitis and peri-implantitis, and the challenges associated with prevention and treatment of peri-implantitis.

Andreas Stavropoulos (AS) studied dentistry in Germany and Greece. After graduation worked in private practice in the field of periodontics and implant dentistry. After a few years, he moved to Denmark and got specialty training in periodontology and implant dentistry (1999) at the Dept. of Periodontology, School of Dentistry, Aarhus University, Denmark. He achieved a PhD degree in 2002 and a dr. odont. degree in 2011 from the same University. In 2013 Andreas joined Malmö University as the Professor and Chair at the Dept. of Periodontology.

Novel therapeutic regimens for chronic biofilm disease.

Claus Moser, Department for Clinical Microbiology, Rigshospitalet.

Biofilm infections are clinically important since they are frequent and persistent, they can be focus for systemic spread, they generate pathology and they are tolerant to the host response and antibiotic treatments. Present antibiotic susceptibility testings only partially reflect *in vivo* susceptibility of the microorganisms. They can be difficult to diagnose and treatment response can be a challenge to evaluate. Recently, we have proposed that biofilm infections with their matrix may be regarded as an independent compartment with distinct pharmacokinetic and -dynamic, which has to be considered during handling of biofilm infections.

In the presentation, there will be a short overview of the challenges with biofilm infections and a description of present clinical guidelines on diagnosing, prevention and treatment of biofilm infections.

Finally, a more thorough presentation of new treatment possibilities that are currently in clinical trials will be given.

Claus Moser is a medical doctor who has specialized in clinical microbiology. He has a PhD in immune modulation as a treatment option for biofilm infections. He has supervised several PhD projects within biofilm challenges and his main focus area is diagnostics of biofilm infections, host response as part of the pathogenesis of biofilm infections and new treatment options of biofilm infections.

Clinically he has worked with biofilm infections for around 20 years.

Abstract for Taastrup, Nov. 2016

“The Many Hurdles between a Good Idea and a Medical Device”

Daniel Delfosse, Mathys Ltd Bettlach, Switzerland

The advancement of health care for patients, i.e. for all of us, depends on the continuing accrual of medical knowledge that is made available for doctors and patients as novel medical treatments. While medical science is advancing at a steady speed, the translation into medical devices has become more difficult than ever before. The scandals of late, e.g. the toxic PIP breast implant or the faulty ASR hip resurfacing implant, had a significant impact on the formulation of the new Medical Device Regulation that will come into effect in 2017. The new laws aim at increasing patient safety when novel medical devices are put on the market. Therefore, the demands for proof of safety and efficacy, the prerequisites to obtain a CE-mark, have increased drastically. In short: the hurdles between a good idea and a medical device have never been higher!

How is it still possible to innovate in the field of orthopaedic implants that are labelled “high-risk” class III devices? This presentation will show how high the hurdles have become and how to tackle them. It will also give an indication about the time frame and the costs associated with the introduction of a radical innovation in the orthopaedic field.

Daniel Delfosse is Head of Innovation & Technology of Mathys Ltd Bettlach, Switzerland.

He received the Diploma in Materials Engineering from ETH Zurich in 1985 and the Ph.D. from EPF Lausanne in 1990. During 1991-94 he was at the University of British Columbia in Vancouver, Canada, as a research fellow working with fibre-reinforced materials. Back in Switzerland, he worked on numerous projects with SMEs for the Swiss Laboratories for Materials Testing and Research (EMPA) in Thun. In 2000, he joined Mathys Medical Ltd as head of development for the orthopaedic division. Since October 2007, he is heading the Innovation & Technology department. As Product Safety Officer, he is also responsible for the controlled introduction of innovative medical devices.

Thermoplastic Parts with Biomolecular Coatings integrated within the Molding Process

Guggi Kofod, Inmold A/S, Gregersensvej 6H, 2630 Høje Taastrup (gk@inmold.dk)

The use of biomolecular surface modifications on plastic parts is of great interest to industry and health sectors. Plastic surfaces modified with protein coatings can be used for cell growth containers, detection applications, and in general where the surface of the plastic is not well-suited to bio-applications. Typically, plastic surfaces are modified with proteins by washing steps, which is cumbersome in the lab, leads to weakly bonded biomolecules, and does not allow for radiation sterilization, since free radicals are formed by water during irradiation. Inmold has developed a process by which biomolecules are distributed on an injection mold surface, dried, and then used directly in standard thermoplastic injection molding. The molded part receives all the biomolecules, which are slightly immersed and bound strongly to the plastic surface. The process is relatively simple to automate, leads to strongly bonded biomolecules, and allows for radiation sterilization as water is absent.

Interestingly, as a side development, a few of the injection molding processes could be combined to provide a durable and flexible platform for industrial production of plastics with nanostructured surfaces. This is now marketed as MoldGrfx for plastics with holograms (differentiation and counterfeit prevention).

The presentation will introduce the biomolecular molding process, and briefly describe preliminary results (ELISA; Enzyme-linked immunosorbent assay) on plastic with osteopontin (OPN) coating via injection molding. The presentation will then discuss the process for nanostructured plastic, with possible applications for medical devices.

Guggi Kofod holds a Master in Physics from the Department of Physics at Copenhagen University, and a Ph.D. from the Department of Chemistry at the Technical University of Denmark, for work related to polymer artificial muscles. GK has served as Research Group Leader at Potsdam University. From 2012 GK has worked at Inmold A/S, initially as CTO, since 2014 as CEO.

Biofilm formation - a challenge for many devices

Jan Lorenzen, Biotech, Life Science Division, Danish Technological Institute

As detrimental biofilm may develop on almost any type of medical device, the influence of material selection and finish on the rate and degree of biofilm formation ought to be assessed at an early stage of device development. *In vitro* benchmarking of biofilm formation potential can together with physical, chemical, toxicological and production parameters guide the selection of device material. The selection of the right *in vitro* setup for any medical device application is important, and the translation of *in vitro* data to real life application can be challenging. The pros and cons of various test methods are reviewed in relation to the test materials, their anti-biofilm mode-of-action, and the intended application.

Jan Lorenzen holds a Ph.D. in Biology from Aarhus University. He is acting as senior project manager at Biotech, Life Science at the Danish Technological Institute, where he has been working with biofilm detection and prevention for more than 15 years.

Tailoring surface properties of medical devices using sputter deposition

Kristian Rechendorff, Tribology Center, Danish Technological Institute, Kongsvang Allé 29, Aarhus (krr@dti.dk)

For many medical devices, the surface is critical for proper performance, making the control of the surface properties of great importance. Sputter deposition is an industrially relevant coating technique that allows precise tailoring of surface properties through the growth of layers with thicknesses from a few nm to tens of μm . The technique is versatile, and both chemistry, morphology and topography of the deposited layer can be controlled beyond what is possible with standard “bulk” materials. The presentation introduces the basics of sputter deposition with emphasis on possibilities and limitations. Examples of medical devices where coatings are essential for their performance are given, including examples of coatings developed at the Tribology Center for medical purposes. One example highlights the importance of coating morphology for neural stimulation electrodes for treating incontinence. Another example describes the development of coatings with a well-controlled Sr-release profile for enhanced bone in-growth. In both cases, the coating morphology and chemistry played a central role.

Kristian Rechendorff has been employed as an R&D engineer at the Tribology Center since 2010. He holds a PhD-degree in physics from University of Aarhus.

Steering Cell and Tissue Response by Surface Modifications

Senior Scientist Morten Foss, iNANO, Science and Technology, Aarhus University, Gustav Wieds Vej 14, 8000 Aarhus C (foss@inano.au.dk)

There are several surface modification routes available to guide or optimize cellular response to biomedical surfaces of e.g. implants. In this presentation examples will be given on how surface parameters influence cellular response and how these may be used to optimize the function of biomaterials. Focus will be on bone-tissue and bone-cell contacting devices, but also the additional challenges of producing percutaneous implants, where the soft tissue-implant sealing is of major importance, will be touched upon.

Dr. Morten received his PhD in 1994 and joined iNANO in 2000. His major research interest is the interaction of artificial materials with biological systems with special focus on biomedical surfaces. He has published around 70 articles and has his name on 8 patents. His H-index is 24.

Pre-clinical and clinical testing of implantable electrode designs

Bo Hammer Pedersen (Bo.Hammer.Pedersen@neurodan.com)

Dianna Mærsk Knudsen (Dianna.Maersk.Knudsen@neurodan.com)

Surface treatment of implantable electrodes has a big impact on electrode tissue performance and acceptance. Methods and results from pre-clinical and clinical studies of different anchoring mechanisms and surface treatments will be presented. Results show a greater cell proliferation on microstructured PEEK samples after 96 hrs. Presence of microstructures will accelerate integration of the device into the tissue, decreasing the probability of device migration after implantation.

Furthermore, specific electrode ‘tines’ have proven effective as anchoring mechanisms keeping the electrode in the targeted location for a period of two months.

Finally, the overall plan and status of the implementation and commercialization of the tested technology into a CE-marked product will be presented.

Dianna Mærsk Knudsen, M. Sc. Biomed. Eng. Technical Product Manager at Neurodan A/S. She has been employed at Neurodan A/S since 2008, initially as an R&D engineer with focus on electrode development and pre-clinical testing.

Bo Hammer Pedersen, Msc., MBA. He is Managing Director of Neurodan A/S, which is the developer and manufacture of ActiGait, which is an implantable dropfoot stimulator that is launched in the EU. He has been with Neurodan A/S since 2008 and has hold various positions in the company.

Surface Technologies for Medical Implants

*Ole Zoffmann Andersen, Elos Medtech Pinol A/S, Engvej 33, 3330 Gørløse
(ole.andersen@elosmedtech.com)*

The use of surface modifications in relation to medical implants is of great interest to the industry. Especially in relation to dental implants, surface modifications have been a key feature with respect to gaining and maintaining market shares over the past decades. While there still is room for enhancing the performance of, e.g., dental implants, surface modifications are also of interest for other types of implants and are expected to play an important role in developing novel types of implant solutions. In addition to the technical aspects, the use of surface modifications for non-technical purposes, e.g. for improving esthetics, is currently also a hot topic.

This presentation will treat examples from the dental implant industry where surface modifications have taken part in shaping the current market structure. Moreover, current trends within the medical implant industry will be considered and finally we will have a look at future potentials for surface modifications in relation to developing novel implant technologies.

Ole Zoffmann Andersen (OZA) holds a master in Nanobiotechnology from the department of Physics and Nanotechnology at Aalborg University and PhD in Nanoscience at the Interdisciplinary Nanoscience Center (iNANO) at Aarhus University. Since he completed his PhD, Ole has been employed by Elos Medtech Pinol A/S where he is currently holding the research manager position.

Antibiofilm material testing – examples and applications

Yijuan Xu, Biotech, Life Science Division, Danish Technological Institute

Foreign materials are increasingly used in modern medicine, which results in a raising incidence of biomaterial associated infections known as biofilm infections. Evaluation of biofilm formation potential is therefore of great importance in the process of developing new materials. Models used to study biofilm formation range from simple *in vitro* to complex *in vivo* systems of device-related infections. This talk will introduce some of the *in vitro* models for antibiofilm material testing routinely used in DTI, such as CDC biofilm reactors, MBEC assay, as well as a well-characterized animal model for studying biofilm formation on materials. Selected applications and results will be presented.

Yijuan Xu has PhD in medical biotechnology from Aalborg University, Denmark. She is consultant in Biotech, Life Science, Danish Technological Institute. She primarily works with antibiofilm testing, molecular detection of pathogens, and DNA sequencing.