

Donald E. Stephens Convention Center

June 20-21, 2007



ADVANCE PROGRAM

The 3rd Annual

Orthopaedic Manufacturing & Technology

Exposition and Conference

PANEL OF ADVISORS

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Quality/Regulatory Affairs

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Purchasing Manager



CONFERENCE MESSAGE

Dear Orthopaedic Professional,

You are cordially invited to attend The 3rd Annual Orthopaedic Manufacturing & Technology Exposition and Conference (OMTEC) sponsored by The Institute for Orthopaedics™.

We anticipate hundreds of product development and procurement professionals from across the globe. Don't miss the opportunity to attend relevant and timely educational sessions focused on **optimizing supply chain performance and profitability, minimizing product development cycle times and maximizing speed to market**. Whether learning how FDA expects you to manage outsourced suppliers or hearing about the latest innovation in product design, you'll find that presenters will provide tools designed to help you compete and win.

The exhibit floor boasts access to the industry's top orthopaedic suppliers, allowing you to view the latest technologies and capabilities in testing, fabrication, materials, equipment and more. The floor will again provide you complimentary meals, snacks, drinks and access to email. The Welcome Reception offers a unique opportunity to network with your peers and meet prospective suppliers. **Registration is free for OEM personnel** and includes two days of admittance to all educational sessions, the exhibit hall and the Welcome Reception.

On behalf of Knowledge Enterprises, Inc. and The Institute for Orthopaedics, I encourage you to attend OMTEC 2007 with your colleagues. I look forward to seeing you in Rosemont!

Sincerely,

April C. Bright Marketing Manager

In 2000, Knowledge Enterprises founded The Institute for Orthopaedics™ to provide timely, accurate, strategically oriented information resources to the various sectors of the orthopaedic community. The Institute is comprised of an elite group of thousands of individuals from all civilized nations of the world.

PRELIMINARY SCHEDULE OF EVENTS

Wednesday, June 20		Thursday, June 21	
Breakfast	7:30 - 8 a.m.	Breakfast	7:30 - 8 a.m.
Breakfast Address	8 - 8:50 a.m.	Breakfast Address	8 - 8:50 a.m.
Exhibits Open	9 a.m.	Exhibits Open	9 a.m.
Keynote Address	9 - 9:55 a.m.	Educational Sessions	9 - 9:55 a.m.
Refreshment Break	10 - 10:55 a.m.	Refreshment Break	10 - 10:55 a.m.
Educational Sessions	11 - 11:55 a.m.	Educational Sessions	11 - 11:55 a.m.
Lunch	12 - 1:30 p.m.	Lunch	12 - 1:30 p.m.
Educational Sessions	1:30 - 2:25 p.m.	Exhibits Close	1:30 p.m.
Refreshment Break	2:30 - 3:25 p.m.	Keynote Closing	1:30 - 3 p.m.
Educational Sessions	3:30 - 4:25 p.m.		
Exhibits Close	4:30 p.m.		
Exhibits Re-open	6 p.m.	Friday, June 22	
Welcome Reception	6 - 8 p.m.		
		Titanium Workshop	8:30 a.m 4:30 p.m.

GENERAL INFORMATION

Registration Fees

Registration is free for OEM personnel and includes two days of admittance to all educational sessions, the exhibit hall and the Welcome Reception.

Online registration is available at www.orthosupplier.com. Badges will be available for pickup June 20 at the exhibit hall registration area.

Location

Hall F

Donald E. Stephens Convention Center 5555 N. River Road Rosemont, IL 60018

Hotel Information

Preferred rates have been negotiated with the following hotels:

Crowne Plaza Chicago-O'Hare

5440 N. River Road Rosemont, IL 60018

Rate: \$169

Reservations: 888-642-7344

Doubletree Hotel O'Hare-Rosemont

5460 N. River Road Rosemont, IL 60018

Rate: \$169

Reservations: 847-292-9100

Online hotel reservation links area available at www.orthosupplier.com.

QUESTIONS, COMMENTS & ASSISTANCE

April C. Bright Marketing Manager Knowledge Enterprises, Inc 147 Bell Street, Suite 303 Chagrin Falls, Ohio 44022 440-247-9051 (phone) 440-247-9053 (fax) april@orthoworld.com

EDUCATIONAL SESSIONS

DAY 1

8 - 8:50 a.m.

Orthopaedics Into the Future

Shirley A. Engelhardt President & Founder

President & Founder Knowledge Enterprises, Inc.

Shirley Engelhardt will present a review of the worldwide orthopaedic marketplace, with a discussion of market dynamics and their likely effect on the industry over the next decade. She will shed light on the interaction and impact of the following factors on future growth of the market overall:

- · Procedures, price and mix
- Consolidation along the supply chain
- Population demographics (aging and youth and the demands of both)
- Healthcare providers (hospitals, doctors, payers, etc.) and meeting their needs
- Geographic expansion opportunities in markets from Canada to China
- Traditional and alternative approaches to orthopaedic care

DAY 1

9 - 9:55 a.m.

Wisdom for the R&D Engineer

John P. Collier, Ph.D.

Myron Tribus Professor of Engineering Innovation and Senior Lecturer Thayer School of Engineering, Dartmouth College

DAY 1

11 - 11:55 a.m.

Smart Implants – In Pursuit of Eradicating Joint Replacement Infections

Javad Parvizi, M.D.

Orthopaedic Surgeon Rothman Institute

Biological modifications of conventional devices to counteract current implant-associated problems are underway. Self-protective "smart" implants are examples of such accomplishments. The modification

of the implant surface with a permanent covalent bond and tethering of antibiotics or other biofactors, if proven to be effective, is likely to transform the practice of orthopaedic surgery and other medical specialties.

This presentation will describe the *in vivo* performance of an innovative implant in an animal model. The implant has been engineered to be bactericidal by covalently binding vancomycin to the alloy surface. In comparison with unmodified titanium surfaces, the antibiotic-derivatized surface minimized clinical signs of infection, reduced bacterial proliferation and prevented bone destruction. Preliminary findings are encouraging and hold great promise for the management of periprosthetic infection.

Assessing the Cleanliness of Medical Devices

Stephen Spiegelberg, Ph.D.

President

Cambridge Polymer Group, Inc.

The improvements in medical device design and surgical procedures in the past several years have resulted in a higher standard of clinical success for medical devices. As fewer complications arise from previous issues of material failure, product design or surgical technique, emphasis is now being placed on the cleanliness of medical devices. Ideally, manufacturers would like to produce parts with no contaminants. Practically, this goal is not achievable, and manufacturing costs increase dramatically as manufacturers attempt to reduce the levels of contamination. Two key questions that most quality assurance engineers are asking these days are, "How clean is clean enough?" and, "How does one assess cleanliness?"

Recent product recalls relating to the device cleanliness have helped to spur activities within ASTM. Working with medical device manufacturers, analytical laboratories, NIST, the FDA and medical device consultants, an ASTM task force has been working for the past three years to address issues of cleanliness in biomedical components. Work is being conducted to develop standards for assessing levels of cleanliness in metallic, ceramic, composite and plastic components. The task force is also attempting to determine acceptable levels of cleanliness in the various biomedical devices.

Atomic Oxygen Removal of Organic Contamination from the Surfaces of Orthopaedic Implants

Bruce Banks

Eric Banks, Ph.D. NASA Glenn Research Center

Michael Banks, M.D.

OrthoWest, Ltd.

The Bankses will discuss the generation of atomic oxygen; the effects of atomic oxygen on cells, organic contamination and endotoxins, as well as its interactions with materials; endotoxin removal from orthopaedic surfaces; manufacturing processes for atomic oxygen removal of biologically active contaminants from implant surfaces; and FDA regulation considerations.

*Materials Update I (Speaker TBD)

DAY 1

1:30 - 2:25 p.m.

Smart Implants – Systems on Chip Products Through Integration of Microelectronics and Micromachining

Edward Benzel, M.D.

Chairman

Cleveland Clinic Spine Institute

Doug Lee

President & CEO OrthoMEMS

Shuvo Roy, Ph.D.

Assistant Staff

Department of Biomedical Engineering, Lerner Research Institute

Lean Supply Chain Win/Win Culture Change: Optimizing OEM-Supplier Cash Flow

Andy Novotny

Managing Partner InterPro Group LLC

Speed = Supply Chain Competitiveness. Learn how to speed up the flow of information, materials and cash between operations and businesses in the supply chain. Enable stakeholders in your supply chain to see information in a unified manner and collaborate in the decision making process and make this information globally accessible while lowering costs.

Includes need-to-know information for OEMs, Suppliers, Manufacturing/ Distribution Operations/Information System Users.

Future of Additive Fabrication and Rapid Manufacturing: A Global Update

Terry Wohlers

President Wohlers Associates, Inc.

- · New developments and trends
- · Benefits and limitations
- · Emerging business opportunities
- · Rapid manufacturing
- Applications in the medical industry
- · Research and development
- · Where it's all headed

Additive Metal Rapid Manufacturing Technologies in Orthopaedics

Andrew M. Christensen

President
Medical Modeling LLC

This session will describe commercially available direct metal technologies (particularly EBM) and their application for production of titanium components within the medical device industry. Custom instruments and implants will also be discussed using RP-generated anatomical models.

- Application of direct metal fabrication to the medical industry
- Review of applicable technology and materials

- Considerations for testing and product development
- Case studies comparing this new "digital" technology to existing "analog" technology in terms of material characterization, cost, production time, etc.
- Future steps needed and product categories within orthopaedics affected

*Materials Update II (Speaker TBD)

DAY 1

3:30 - 4:25 p.m.

Innovation in Product Design

Andrew Kusiak, Ph.D.

Professor

Department of Mechanical and Industrial Engineering University of Iowa

Innovation is a key strategy for competitiveness in the global market. The practice of innovation is fragmented and centered on specific cases. This presentation will contribute to better understanding the process of innovation considered from a requirements perspective. This approach extends the practice of integration of users and stakeholders into product and service development activities. The fact that the requirements are elicited from multiple sources and analyzed with the right tools is likely to lead to business success. Methodologies and tools supporting innovation will be discussed, such as data mining, process modeling, dependency analysis and social networks.

Process modeling is a backbone for defining the "best innovation practices." Many of the classical analysis tools, when combined with data and text mining tools, offer a viable innovation toolkit. The material to be introduced in the presentation is directly applicable to medical equipment design and manufacturing. The discussed ideas will be illustrated with case studies.

Outsourced Processes and Regulatory Compliance – How It Works, Where It Fails

Marc-Henri Winter President G-MED North America, Inc.

Laser Marking Using Integrated Through-the-Lens Vision

Faycal Benayad-Cherif, Ph.D. Virtek Vision International Inc.: FOBA/Virtek Laser System NA

Medical devices, such as orthopaedic components and screws, are commonly serialized using laser-marking technology. Generally, parts are marked in the latter stage of production, wherein minor errors can turn into costly repairs or expensive waste.

A new approach relies on image processing technology to laser-mark medical components. This concept differs from existing approaches as the laser automatically aligns itself to the part instead of the time-consuming approach of an operator aligning the part to the laser. The system uses a vision model that verifies the proper device is in place and computes the part position and orientation.

This presentation will address the concept, its medical applications and the product's ability to ameliorate common manufacturing concerns by marking only the correct part; achieving mark placement accuracy <0.001"; reducing expensive waste; and achieving higher throughput, improved production yield and lower cost of operation.

*Materials Update III (Speaker TBD)

DAY 2

8 - 8:50 a.m.

The Future of Orthopaedic Technology

John A. Engelhardt

Chief Executive Officer Knowledge Enterprises, Inc.

The presentation will describe the technology of the future, with a special focus on how the following will affect the technology trajectory, and the design and procurement process.

- · Materials advancements
- · The patient as designer
- · The economics of technology delivery
- · Developments in miniaturization
- Computer control technologies

In addition, Mr. Engelhardt will describe several billion dollar inventions waiting to be realized.

Directing Corporate Innovation: The Next Five Years

Bradford L. Goldense, NPDP, CMfgE, CPIM, CCP President

Goldense Group, Inc.

The Benchmark in Supply Chain Optimization

R. Scott Etlinger

Vice President of Global Operations American Medical Systems, Inc.

Can You Break This for Me? – Non-Standard Mechanical Testing of Orthopaedic Devices

David Spenciner, P.E., Sc.M. Test Facility Manager RIH Orthopaedic Foundation Test Facility

Drawing on his experience from over 1,000 product testing studies, Dave will discuss topics including:

- Determining the correct test methodology for a study based upon your goals
- Choosing an appropriate testing model: mechanical vs. animal vs. human cadaver
- Determining requirements for a product that isn't yet covered by ASTM or ISO
- Testing to draft standards hitting that moving target
- Picking the best test lab to get your study done

Each topic will be heavily salted with pearls of wisdom and recent examples.

DAY 2

11 - 11:55 a.m.

RFID (Speaker TBD)

Advanced Failure Mode and Effects Analysis (FMEA)

Eden Chen, Ph.D. President Chen Consulting

Supply Chain Visibility

Nancy Parmer

Vice President, Healthcare Consulting Services UPS Supply Chain Solutions

Whether your supply chain is lean, just-in-time, demand-driven or a combination of logistics methodologies, one thing remains an essential visibility. This is particularly true if you are internationally outsourcing your manufacturing processes. In this session, Nancy Parmer - a UPS **Supply Chain Solutions Consultant** returning from four years in China will demonstrate via relevant case studies and examples the impact that logistics partners capable of tracking disposition of inventory/goods within the supply chain can make to your customers, your company, and its financial well-being.

Non-Contact Coating Measurement

Jeff Pavelka

Development Manager Sensory Analytics, LLC

This session will describe a new suite of laboratory and in-line measurement systems designed to provide real-time coating thickness and color results for orthopaedic devices including titanium implants, screws and pins. These systems provide results totally independent of substrate thickness, weight or geometry; do not require any correction factors; and provide NIST-traceable results for measurements performed on abstract shapes, holes, curves, edges and miniature components.

The technique incorporates nanometric precision and does not require direct contact with the specimen, broadening the applicability of this system over other currently available contact-based or destructive test and inspection methods.

Using Analysis to Design Better Orthopaedic Products

Vince Adams

Product Manager, Analysis SolidWorks Corporation

Stringent regulatory controls, the use of expensive materials and the need for performance-to-weight ratio

improvement makes use of design analysis technologies such as finite element analysis (FEA) increasingly more important in today's orthopaedic design industry. Participants in this session will learn about the state of the art in design analysis tools and techniques. The relevance of common design analysis practices will be discussed in the context of orthopaedic products and, where possible, will be illustrated with case studies and examples. This session will provide a solid introduction to the fundamentals of this important technology for building better products faster, and will offer participants an opportunity to ask questions related to their particular needs to an industry expert.

DAY 2

1:30 - 3 p.m.

Reduce Supply Chain Risks: How the FDA Expects You to Manage Outsourced Suppliers

Martin Browning

President & Co-Founder EduQuest, Inc.

Martin Browning will draw on his years of experience with the FDA to address:

- How to select outsourcing partners compatible with your standards and integrity
- When and how the FDA must be notified about your suppliers
- Common pitfalls in outsourcing and how to avoid them
- What activities can be outsourced and which should not
- The correct language to include in all contracts and service level agreements (SLAs) to protect yourself and satisfy the FDA
- How to establish a supplier monitoring program with teeth
- What to do when faced with off-spec products, recalls or complaints
- The outlook for increased FDA regulatory scrutiny of suppliers

^{*} Presentations addressing the latest materials-related technologies will be provided for PEEK/polymers, steels/ cobalt-based alloys and titanium.

EXHIBITORS



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BRANSON

Branson Ultrasonics Corporation

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Carpenter Technology Corporation

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Firth Rixson Limited

Firth Rixson Superalloys Ltd.

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gSource

gSource, LLC

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surgical, inc.

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McLean Medical and Scientific, Inc.

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MEDICAL MeDELING

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Precision Metal Products, Inc.

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Seabrook International, LLC

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Sensory Analytics, LLC

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Specialized Medical Devices, Inc.

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Teleflex Medical Products

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Tornos Technologies

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UNITED GRINDING

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OMTEC 2007 Registration Form

Orthopaedic Manufacturing & Technology Exposition and Conference Rosemont, Illinois USA • June 20-21, 2007

Please complete and fax this form to 440.247.9053

Online registration and updated conference information is available at www.orthosupplier.com

Advance Registration ends May 1st. After this date, a \$50 fee applies to late or on-site registration.

Company Information	
Company Name:	
Address:	
City:	
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Country:	
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Fax:	
Comments/Questions:	
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Personal Information Name:	
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Name: Position/Title: Email:	
Name: Position/Title: Email:	
Name: Position/Title: Email: Status:	
Name: Position/Title: Email: Status:	
Name: Position/Title: Email: Status:	
Name: Position/Title: Email: Status:	
Name: Position/Title: Email: Status: OEM Visitor Intentions: I plan to make arrangements at a host hotel I plan to make arrangements elsewhere	

Registration is FREE for OEM personnel and includes two days of admittance to all educational sessions, the exhibit hall and the Welcome Reception.

Payment Information Complete this section ONLY if registering as a visitor. Fee: \$500 Credit Card Type Card Number Name as It Appears on Card Expiration Date Today's Date Signature



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