SOCIETY OF PLASTICS ENGINEERS

Medical Plastics Division

2014 – First Quarter

Letter from the Chair:

Dear Friends and MPD Members,

Happy New Year! I hope everyone had a great and relaxing Holiday season. It seems like months ago rather than weeks. It is always exciting to start a new year and 2014 is already shaping to be a great year for Medical Polymers throughout the world.

Since I last wrote before the holidays, the Medical Plastics Division and Injection Molding Divisions put on the first ever TOPCON in China, at the Marriott City Center in Shanghai. The event was a great achievement and success with many international speakers, panels, sponsors, and attendees. I would like to extend a special thanks to Ali Ashter, Len Czuba, Steve McCarthy, and Harrison Yu for their exemplary work, countless conference calls, and hours helping to make this conference the great success that it was. In addition to giving some great presentations at the conference, Len, Ali, and Harrison where instrumental in organizing and Chairing the MPD portion of the program. It was a privilege to participate in this first ever TOPCON in China. Based on the initial feedback, it was an overwhelming success. Working with all the SPE staff and IMD made this event something we look to build upon in the upcoming years. I think Len will also be sharing some photos with us.

As we begin 2014, and coming off the TOPCON in China, I am reminded about how great a role education, continuing education, and networking play in the fabric of our industry. If we are to maximize our impact, one thing we all must continue to do is to learn and to expand our knowledge in our professional worlds. With technological advancements and the fast paced changes of global markets, it is more important than ever to stay engaged and to participate in continuing education.

The SPE is a great way to make this a part of your 2014. While providing numerous forums for education and great content, the different SPE sections and divisions provide some great venues for networking among our industry peers. I encourage everyone to make SPE part of your 2014 resolutions.

In addition to the Medical Plastics Division, the SPE has other sections and divisions that offer additional opportunities for you to network and learn.

One great example is the upcoming ANTEC 2014 at the Rio All-Suites Hotel & Casino in Las Vegas this April 28-30, 2014. Plan to join close to 2,000 industry professionals, exhibitors, and presenters for a great Technical Program and networking. Visit www.4spe.org for more information and registration information.

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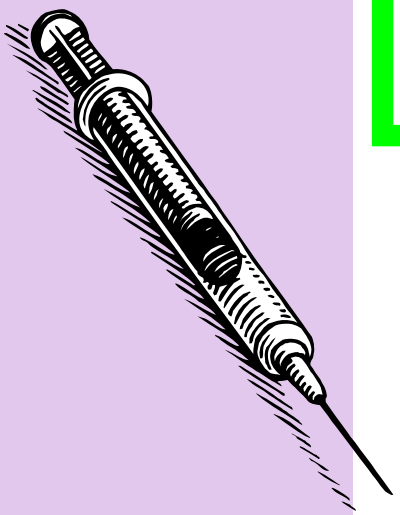
We have an open invitation for any of our members to attend our Board Meeting during ANTEC 2014. We are finalizing the exact times. Please drop me a line at mark@bonifacioconsulting.com if you are interested in learning more. We are always welcome to members of the division or anyone who may be interesting in joining our Division.

If 2013 was any indication, I think we can expect some great advancements in the field of Medical Plastics and Polymers in 2014, whether it be in materials or advanced processing and manufacturing methods. I believe 2014 has some great things on the horizon. With more of our Dollars being spent on Healthcare, plastics are leading the way in providing some of the most effective and cost effective solutions for patients worldwide.

I hope to see you at one of our events, ANTEC, or anyone of the numerous other events SPE or our great industry has to offer. Once again, Happy New Year to everyone.

Mark Bonifacio
2013 – 2014 Chair



Upcoming Conferences
- ANTEC DUBAI -

Inside

Technical Presentation

MD&M West Conference

Recent Conferences

Society of Plastics Engineers (SPE) Medical Plastics Division (MPD) held its first ever technical conference (TOPCON) in Shanghai, China on Dec 11-12, 2013. Titled "Global Advances in Plastics for Medical Devices and Packaging," the conference was well attended with over 200 attendees including 40 plus students. A total of 25 technical papers were presented during this two day conference, either in English or in Chinese. Headsets were provided to each attendee to listen to the presentation translation. The conference was divided into four sessions - Advanced Materials and Packaging, Biopolymer in Focus, Biopolymers/Processing, and Advanced Technologies. Each session started with a keynote speaker followed by technical presentations. Some of the keynote speakers who were able to draw audience were Stephen McCarthy, Len Czuba, and Mark Bonifacio. Prof. McCarthy talked about "*Biodegradable polymers in medical applications*" while Len and Mark presented their views on medical devices and their markets in China. In order to engage the attendees and answer some of their question, the last session on each day was focused around panel discussion. In this discussion, leading experts discussed some of the challenges and advantages in medical industry. They also answered to questions from the attendees.

Ali Ashter

11 DECEMBER 2013
Moderator: **Jon Ratzlaff**

8:20 **Willem Devos** *Conference Open and Welcome (DAY 1)*
CEO, Society of Plastics Engineers (SPE)

8:30 **Helmar Franz** - Chief Strategic Officer/Executive Director, Haitian International Holding Ltd.
Some Thoughts About Trends and Challenges in the Injection Molding Industry

9:00 **Zheng Kai** - Vice Chairman/Secretary General, China Synthetic Resin Association
Update on the Chinese Plastics Industry

9:30 **Stephen McCarthy** - University of Massachusetts Lowell
Biodegradable polymers for Medical Applications

MEDICAL PLASTICS SESSION
Advanced Materials and Packaging
Moderator: **G.T. Lim**

10:20 **KEYNOTE -** *Polycarbonate Resins for Medical Applications: Today and Tomorrow*
R. Wong, Bayer Material Science

10:50 *Thermoplastic Polyurethanes as Medical Grade Thermoplastic Elastomer*
C. Yan, Lubrizol Advanced Materials

11:15 *Soft Styrenic TPEs for Medical Devices*
G.T. Lim, Exponent Science and Technology Consulting (Hangzhou) Co. Ltd.

11:40 *Practical Alternatives to DEHP Plasticized PVC for Medical Applications Growing Negative Momentum - Real or Imaginary*
E. Pritikin, Teknor Apex Asia Pacific Pte. Ltd.

12:05 *Effect of Photo-Oxidative Degradation on Environment Stress Cracking Behavior of Polycarbonate Injection Molded Parts*
J. Han, Zhengzhou University

JOINT SESSION I
Bio-Polymers in Focus
Moderator: **M. Bonifacio**

13:30 KEYNOTE - *Natural Antimicrobial Protections in Injection Molded Plastics*
T. Ellefsen, CEO, Life Material Technologies Ltd.

14:00 *ECOZEN®, A New Bio-based, BPA-Free and High-Tg Copolyester*
J.R. Kim, SK Chemicals Research Center, Korea

14:25 *Behavior of Banana Natural Fiber Composite Under Odor Test in the Automotive Industry*
M. Monzon, Las Palmas de Gran Canaria University

14:50 *Investigation of Blending Methods and Phase Morphology of Poly(lactic acid)/ Polystyrene Blend*
J. Han, Zhengzhou University

JOINT SESSION II
Bio-Polymers in Focus
Moderator: **L. Czuba**

15:35 KEYNOTE - *Biopolymers: Impasse and Breakthrough*
H. Yu, Bondable Biopolymers LLC.

16:05 *Antimicrobials for Medical Textiles and Plastics*
V. Kulkarni, Americhem Inc.

16:30 *Optimization and Characterization of Electrospun Fiber Mats for Cell Seeding Scaffold Applications*
A. Ashter, EMD Millipore Corporation

16:55 *Biodegradable Hollow Nanospheres (TBC)*
S. McCarthy, University of Massachusetts Lowell

12 DECEMBER 2013
Moderator: **Jon Ratzlaff**

8:20 **Willem Devos** *Conference Welcome (DAY 2)*
CEO, Society of Plastics Engineers (SPE)

8:30 **Michael Taylor** - Senior Director International Business SPI
Global growth markets in medical devices

9:00 **Yang Weimin** - Distinguished Professor of Chang Jiang Scholars Program, Beijing University of Chemical Technology
Advances in Polymer Processing Principle and Equipments

9:30 **David Kusuma** - VP Product Development and R&D Worldwide, Tupperware Brands Corporation
Building a Culture of Innovation in the Development of Plastic Products

MEDICAL PLASTICS SESSION
Biopolymers/Processing I
Moderator: **S. McCarthy**

10:20 KEYNOTE *Changes and Challenges in Global Medical Device contract manufacturing and outsourcing – 2014 Outlook and beyond*
M. Bonifacio, Bonifacio Consulting Services

10:50 *Benefits of Servo-Driven Ultrasonic Welding for Critical Assemblies*
S. Zhang, Dukane Corporation

11:15 *Plasma-assisted Processing of Polypropylene/Clay Nanocomposites*
R. Magaraphan, Chulalongkorn University, Bangkok, Thailand

11:40 *Characteristics of Processing Thermoplastic Polyurethanes Resins into Medical Devices*
W.B. Qiu, Lubrizol Advanced Materials

12:05 *An Experimental Investigation of the Residence Time in Micro Extruders and Its Effect on Molecular Weight*
K. Slusarz, American Kuhne

MEDICAL PLASTICS SESSION
Biopolymers/Processing II
Moderator: **K. Slusarz**

13:30 KEYNOTE *The Driving Factors Shaping the Device and Diagnostic Industry for Global Healthcare Distribution*
L. Czuba, Czuba Enterprises, Inc.

14:00 *Advanced Shape Memory Technology (ASMT) for Medical Device/Medicine Packaging*
W.M. Huang, Nanyang Technological University

14:25
The Evaluation Methods for The Processing Thermal Stability of Degradable PPC
P. Shi, Hunan University of Technology

14:50 *Preparation and Characterization of Ethyl Cellulose-based Core–shell Microcapsules Containing Argy Wormwood Solution*
P. Jiang, Hunan University of Technology

MEDICAL PLASTICS SESSION
Advanced Technologies
Moderator: **A. Ashter**

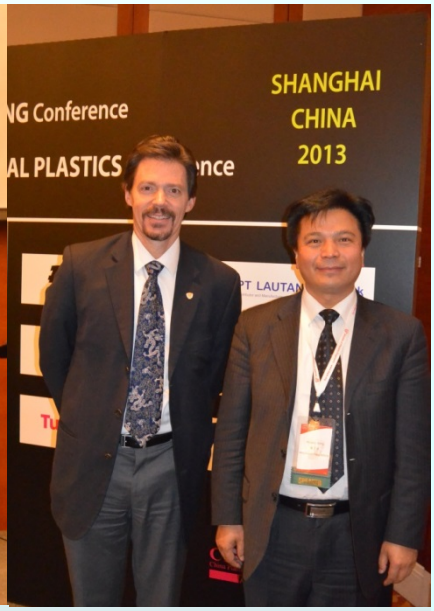
15:35 *Specialty Plastics in China - A Market "Look Up"*
W. Qiang, Solvay Specialty Polymers

16:05 *The Disturbing but Growing Trend to Reuse Single-Use Medical Devices: A Recipe for Trouble*
L. Czuba, Czuba Enterprises, Inc.

16:30 *Polymer Application Center UniPACE of The University of Kassel*
R.U. Giesen, University of Kassel

16:55 Panel Discussion - Question and Answer Session - Open Discussion

Steve McCarthy and Kevin Slusarz



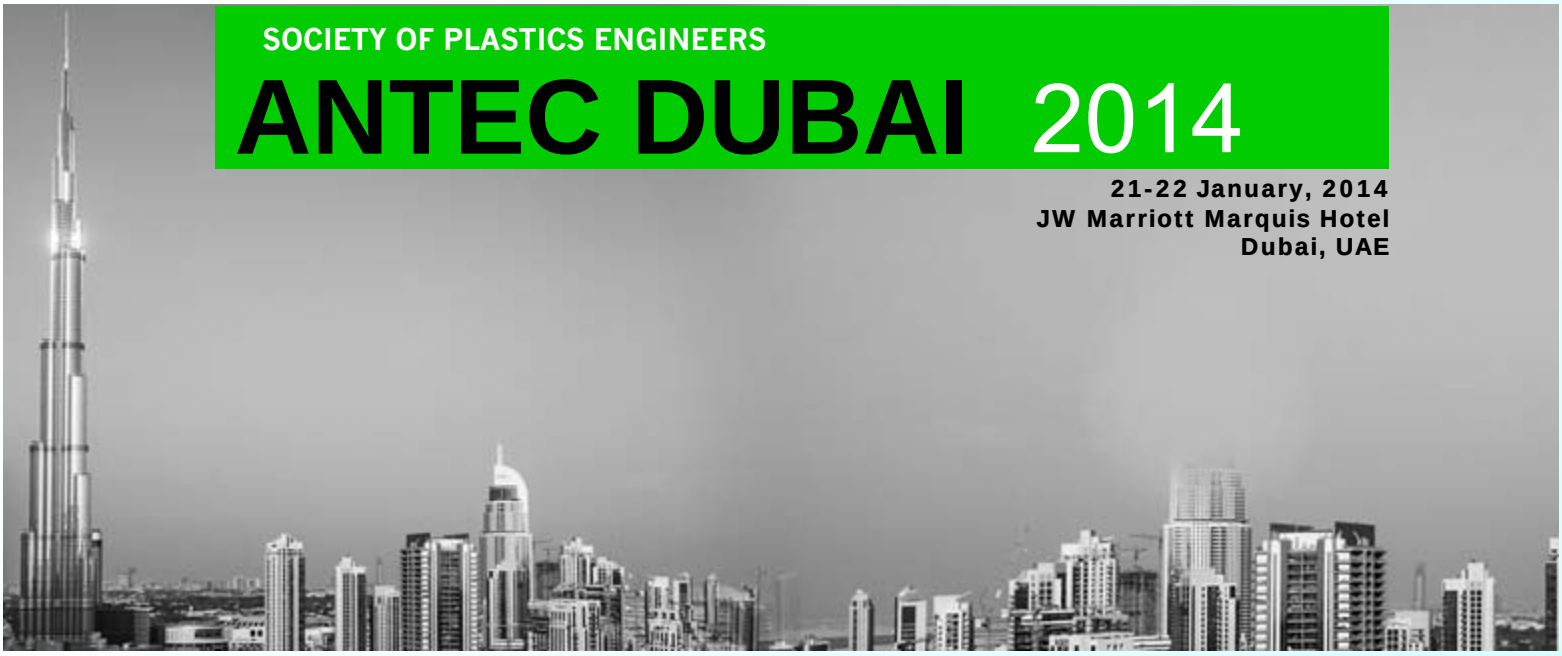
Jon Ratzlaff and Weimin Yang

Maria Wang, Sofie Peeters, Sue Wojnicki, and Ali Ashter

Will Qiang

Goy Teck Lim and Elliott Pritikin

Upcoming Conferences and Activities



Advances in Processing – Materials (Room 1 Day 1 / am)		
The Impact of Plug Material Selection on Overall Part Cost	Mr. Conor Carlin	CMT Materials, Inc.
New generation of potable water certified Noryl™ grades for Water Management	Mr. Christ Koevoets	SABIC Innovative Plastics
Thermoplastic Prepreg Fabrication Technology Using Induced Vibration Techniques	Dr. Mohammed Alghamdi	Yanbu Industrial College
Development of Superhydrophobic Surface using Ultrasonic Imprinting	Dr. Keun Park	Seoul National University of Technology
FAILURE ANALYSIS OF PVC AFTER EXPOSURE TO HEAT	Dr. Christian Stapfer	Metrastat
Importance of Electron Beam Radiation Technology for Polymer Industry	Dr. Subhendu RayChowdhury	Bhabha Atomic Research Centre
Thermoplastic Prepreg Fabrication Technology Using Induced Vibration Techniques	Dr. Mohammed Alghamdi	Yanbu Industrial College
Advances in Materials - New Materials (Room 2 Day 1 / am)		
Inorganic additives for Laser applications in the Plastics Industry.	Mr. Gordon Ernest Price	Merck KGaA
High Performance Nanocomposites using Ionic Liquid as Novel and Efficient Dispersion-Curing Agent	Mr. Nishar Hameed	Deakin University
A New High Clarity Peel Seal Resin	Dr. Rajen M. Patel	Dow Chemical Company
Influence of melt viscosity on the properties of polypropylene/carbon nanotube nanocomposites obtained by melt mixing process	Alessandra Lorezetti	University of Padova
Effect of Amphiphilic Surfactants on the Properties of Polyethylene – Graphene Oxide Nanocomposites	Dr. Vikas Mittal	The Petroleum Institute
Accurate simulation for multi-phase materials in the Industries	Dr. Roger Assaker	E-Xstream Engineering
Developments in the Global Polyolefin Business	Sheth Utpal	I H S Inc.
Advances in Machinery (Room 3 Day 1 / am)		
Plastics Food Global Regulations and Packaging Compliance	Dr. Naeem Mady	Intertek
Advanced Material Preparation with Co-rotating Twin-Screw Extruders	Rob Roden	SteerAmerica Inc.
The Co-Rotating Twin Screw Extruder ZSK Mc18 for Compounding of Polyolefins	Mr. Frank Lechner	Coperion Werner
Comparing High-Tech Twin Screw Extruders with 1.5 and 1.66 OD/ID Ratios	Mr. Michael Thummert	Leistritz Group
USE OF MODERN PRE-HARDENED TOOL STEEL IN MOULDING APPLICATIONS	Dr. Per Hansson, Ph.D.	SSAB

Advances in Materials - Sustainability I (Room 4 Day 1 / am)		
New resources from waste recovery: synthesis and properties polymer based composites containing innovative inertized fly ash from municipal solid waste incineration	Stefano Besco	University of Padova
Investigation of feasibility of Compounding and Processing Lignin as Additive and Colorant with Polypropylene	Mr. Kevon Tabrizi	University of Wisconsin-Platteville
Strain hardening: Fast test for long term properties	Mr. Abdulaziz Alsayyari	SABIC, Saudi Basic Industries Corporation
Preparation and Biocompatibility Evaluation of Compatibilized blends of Thermoplastic Polyurethane (TPU) and Polydimethyl Siloxane Rubber (PDMS)	Mr. Krishnaprasad Rajan	Yanbu Industrial College
Plenary Session (Ballroom Day 1 / pm)		
Welcome and Introduction	Willem De Vos	CEO, Society of Plastics Engineers
KEYNOTE	Dr. Abdulwahab Al-Sadoun	Secretary General, Gulf Petrochemicals & Chemicals Association (GPCA)
Impact of Shale Gas on US Plastic Resin Produers and Converters	William Carteaux	President & CEO, Society of Plastic Industry Trade Association
To be announced		Tasnee
Enabling Down Stream Plastic Conversion: the PCC Integrated Industrial Park Model	Dr. Raed Al Zu'bi	Petrochemical Conversion Company
How the Composite Industry Approaches the Automotive Challenge	Prof. Jan-Anders Manson	Ecole Polytechnique Fédérale de Lausanne (EPFL)
Challenges for a Local Converter	Geert Haentjens	Director New Businesses, Mattex Group
Closing Remarks	Jon Ratzlaff, President	Society of Plastics Engineers

Upcoming Conferences and Activities

SOCIETY OF PLASTICS ENGINEERS

ANTEC DUBAI 2014 *(con't.)*

21-22 January, 2014
JW Marriott Marquis Hotel
Dubai, UAE

Advances in Materials - Sustainability II (Room 1 Day 2 / am)		
Cyclised Soyabean Oil as Plasticizer for PVC for replacing Di- octyl phthalate	Mr. Bhakti Mehta	Institute of Chemical Technology
IMPROVING FIRE BEHAVIOR OF POLYURETHANE RIGID FOAMS BASED ON POLYOLS FROM RENEWABLE RESOURCES	Mr. Michele Modesti	University of Padova
Novel nanoblends prepared from simultaneous in-situ polymerization and compatibilization of bio-based plant oils and thermoplastic polymer	Professor Samy A Madbouly	Iowa State University
Oxo-biodegradable plastics	Mr. Michael Frederick Stephens	Symphony
Advances in Materials Performance - Resins I (Room 2 Day 2 / am)		
New generation of potable Noryl resin grades for Fluid Engineering	Mr. Christ Koevoets	SABIC Innovative Plastics
STANDARDIZATION OF GEL/DEFECT MEASUREMENT BY RIBBON TEST METHOD	Tariq Syed	SABIC
EFFECT OF OCTENE CONTENT ON THERMAL AND MECHANICAL PROPERTIES OF CROSSLINKED ETHYLENE-OCTENE COPOLYMERS	Dr. Rajesh Theravalappil	King Fahd University of Petroleum and Minerals
The New Frontier of Z-N Catalysts for PP polymerization: CONSISTA(tm) catalyst. Commercial status and fundamentals	Mr. Jose M. Rego	W.R. Grace & Company
Hydroxyapatite reinforced chitosan composites: Preparation and characterization	Dr. Selvin Palakattukunnel Thomas	Yanbu Industrial College
Developing High Melt Flow Polystyrene Grade for Extruded Polystyrene foams with Carbon Dioxide Blowing Agent	Dr. Ghurmallah H Al-Ghamdi	SABIC
Biaxial deformation behavior of PP films	Dr. Vassilios Galiatsatos	Borouge Pvt Ltd
Advances in Processing - Extrusion, Injection Molding, and Thermoforming (Room 3 Day 2 / am)		
Plastic Recycling on Co-Rotating Twin Screw Extruders	Mr. Noah Grade	Krauss Maffei Berstorff
Perfect injection molding wth fluid assisted technologies	Mr. Ulrich Stieler	Stieler Kumststoff Service GMBH
SANDWICH MATERIAL FROM PP BLENDS SKIN AND X-HDPE CORE MANUFACTURED BY CO-INJECTION MOLING	Dr. Utai Meekum	Schooll of Polymer Engineering, Suranaree University of Technology
Flowability of Bulk Solids during the Extrusion Process	Dr. Jaime Gomez	Coperion
3rd Generation Thermoforming	Mr. Ralph Mayer	ILLIG Maschinenbau GmbH & Co. KG
Advances in Rheology, Modeling & Simulation – I (Room 4 Day 2 / am)		
Reactivity Ratios Estimation Model and Parameter Uncertainty Quantification	Dr. Mohammad A. Al-Saleh	Kuwait Institute for Scientific Research
Effects of Rheological Behaviour on Colour Matching of Two Polycarbonate Resin Blends	Dr. Ghaus M. Rizvi	University of Ontario Institute of Tech
Melt Flow Rate, Molecular Weight and Rheological properties	Tariq Syed	SABIC

Advances in Materials - New Applications (Room 1 Day 2 / pm)		
SABIC SOLUTIONS FOR RAIL INTERIOR APPLICATIONS MEETING THE REQUIREMENTS OF THE NEW EUROPEAN EN 45545 RAIL STANDARD	Mr. Mark van der Mee	SABIC
Advances in Microcellular Plastics	Mr. Vipin Kumar	University of Washington
New paradigm of space exploitation: large size space constructions	Dr. Alexey V. Kondyurin, Ph.D.	University of Sydney
Mucell(R) Foamed Film Applications	Mr. Luis Zalamea	Dow Europe GmbH
The reports on the adverse effects of BPA are greatly exaggerated and Polycarbonate does not need to be eliminated from medical devices	Len Czuba	Czuba Enterprises Inc
Development of resins and specialty film types for high performance biax-film machines – practical approaches and available solutions	Mr. Andreas Blin	Bruckner Group
Accelerate Innovation of Advanced Polymer Materials	Mr. Frank Huijnen	Intertek Polychemlab BV
Advances in Materials Performance - Resins II (Room 2 Day 2 / pm)		
Metal replacement: A holistic look at the entire process	Mr. Marc Mezailles	PolyOne Corporation
Ultrahigh Performance Pigments & IR Reflectivity	Mr. Tom Mestdag	The Shepherd Color Company
EFFECT OF MATRIX AND PROCESSING METHOD ON PROPERTIES OF POLYMER GRAPHENE NANOCOMPOSITE	Dr. Ahmed A. Abdala	The Petroleum Institute
TECHNICAL PERSPECTIVES OF PLASTICIZERS PERFORMANCE FOR DIFFERENT PVC APPLICATIONS	Dr. Abdulhadi Saeed Alshehri	SABIC
Mineral Modifiers for Polyolefin Applications	Dr. Michael Tinkl	Omya International AG
XPS Alternative foaming agent study	Mr. Muteip Bin Saif	SABIC
Polylactic Acid for Durable Applications	Dr. Sushant Agarwal	West Virginia University
Surface Damage Behaviors of Urethane-Acrylate Coatings for Aesthetic Assessment	Mr. Jongil Weon	Dongguk University
Advances in Materials Performance - Composites and Blends (Room 3 Day 2 / pm)		
New Push-up to Water Business with Components of Blow Moulding and Composites Technology	Mr. Jukka E. Silén	Acqua Plastica - R&D and Business Consultancy
Superior Properties and Sophisticated Design to Industrial Applications with Plastics and Composites	Mrs. Karita Silén	abc-Acqua Business Consulting
Biopolymer – Graphene Oxide Nanocomposites: Structural Characterization and Properties	Dr. Vikas Mittal	The Petroleum Institute
Preparation of Polypropylene/Montmorillonite (MMT) nanocomposites for food packaging applications	Dr. Abdirahman A. Yussuf	Kuwait Institute for Scientific Research
Studies on the Properties of Polypropylene Composites with Modified Bio-Filler (Wood Fiber& Wheat Husk) by using Modified Surface Treating Agents	Dr. Pradeep Upadhyaya	CENTRAL INSTITUTE OF PLASTICS ENGINEERING ANN TECHNOLOGY
Sustainable Composite: High Strength Polypropylene Fiber Composite for Metal to Plastic Conversion for Automotive Application	Mr. Brajesh Kumar Singh	Mahindra & Mahindra
ELECTRICALLY CONDUCTIVE AND MECHANICALLY ENHANCED BIOPOLYMER-GRAPHENE NANOCOMPSITES	Dr. Ahmed A. Abdala	The Petroleum Institute
Does Graphene Increase Tg of Polymer Nanocomposites?	Dr. Christopher W Macosko	University of Minnesota
Advances in Rheology, Modeling & Simulation – II (Room 4 Day 2 / pm)		
Using Design through Moldex3D Simulation to understand Flow Ability	Mr. Teng Yang	University Of Wisconsin Platteville
CALIBRATED CFD-BASED CALCULATION OF COLOR AND MATERIAL CHANGES IN EXTRUSION DIES	Levente Szöke	University of duisburg-essen
An Alternate Method to OIT for Determination of Thermal Stability in HDPE Resin"	Dr. Poondi Srinivasan	Equate Petrochecmical Company

Upcoming Conferences and Activities

MedTechWorld M&M WEST

Exposition: February 11-13, 2014

Anaheim Convention Center
Anaheim, CA

Conference: February 10-13, 2014

DAY 1 - Monday, February 10th

INSPIRING DESIGN, PROTOTYPE & USABILITY

9:00 AM	**The consumer electronics movement to the medical device space** **Dr. Peter Tippett**, Chief Medical Officer & VP of Innovation Incubator, Verizon Enterprise Solutions
10:10 AM	**WORKSHOP** **Using design thinking methodology to discover creative solutions to your device development challenges** **Stacey Chang**, Associate Partner and Director, Health and Wellness, IDEO **Brian Mason,** Lead of Medical Products Group, IDEO
1:00 PM	**Using software design to drive medical device differentiation** **Christopher Miles**, Vice President, Consulting Services, Foliage
1:30 PM	**Using a customer value-centric perspective to dissect customer expectations and transform them to exceed commercial expectations** **John Crombie**, Principal Engineer, Ethicon
3:00 PM	**Innovation beyond concept creation - Bringing medical devices to market** **Sanjay Shrivastava, Ph.D.**, Director, Global Marketing, Covidien
3:45 PM	**Ensuring a successful launch with a new product design** **Tom Kramer**, President, Kablooe

DAY 1 - Monday, February 10th

INTERPRETATIONS AND GUIDANCE ON REGULATORY UPDATES

9:00 AM	**The consumer electronics movement to the medical device space** **Dr. Peter Tippett**, Chief Medical Officer & VP of Innovation Incubator, Verizon Enterprise Solutions
10:10 AM	**What are the expectations of the regulatory agencies?** **Steven Niedelman**, Lead Quality system & Compliance Consultant, King & Spalding LLP **Tim M. Lohnes**, Senior Regulatory Consultant, Orchid Ortho **Michael Morton**, Vice President, Regulatory Affairs, Medtronic
10:45 AM	**Exploring FDA initiatives for FY 14** **Michael Morton**, Vice President, Regulatory Affairs, Medtronic
11:15 AM	**How to reapply FDA feedback: Measure twice, cut once** **Tim M. Lohnes**, Senior Regulatory Consultant, Orchid Ortho
1:00 PM	**UDI: Keeping with the compliance timeline and implementation plan** **Dawn Fowler**, Senior Manager, Labeling & Documentation, Endologix
1:45 PM	**Uncovering the advantages and disadvantages of GS1 and HIBCC UDI identification** **Dr. Anne Marie Belteu**, Senior Business Analyst, Beckman Coulter
3:00 PM	**Regulatory strategy for promotional marketing** **Wilmar Estrada**, Director, Advertising & Promotional Compliance, US Regulatory Affairs, Allergan
3:45 PM	**Responding to warning letters** **Jonathan M. Lewis**, Principle, Advanced Biomedical Consulting

DAY 2 - Tuesday, February 11th

ACCELERATING SPEED TO MARKET THROUGH EFFECTIVE PROTOTYPING AND 3D PRINTING

9:00 AM	**The entrepreneurial journey** **Rudy Mazzochi**, CEO, Elenza
10:10 AM	**Prototyping workshop - Building to Think** **Stacey Chang**, Associate Partner and Director, Health and Wellness, IDEO **Brian Mason,** Lead of Medical Products Group, IDEO
11:15 AM	**From making 1 prototype to manufacturing 1 million products: How to scale up your prototype** **Hugh Ferguson**, Director of New Product Development, Nonin Medical
11:50 AM	**Trends in 3-D Printing in Medical Technology** **Michael Drues, Ph.D.**, President, Vascular Sciences
1:00 PM	**3D printing for medical device applications** **Roger Narayan**, Professor, Joint Department of Biomedical Engineering, North Carolina State University
1:45 PM	**Utilizing 3D printing in your design stages: Are you there yet?** **Greg Olsen,** Director of Industrial Design, Cercacor
3:00 PM	**The next steps in rapid manufacturing** **Bruce Bradshaw,** Director of Marketing, Stratasys
3:45 PM	**Conference VIP Exhibition Tour: 3D Printing**

DAY 1 - Monday, February 10th

EFFECTIVE QUALITY CONTROL IN ACTION

9:00 AM	**The consumer electronics movement to the medical device space** **Dr. Peter Tippett**, Chief Medical Officer & VP of Innovation Incubator, Verizon Enterprise Solutions
10:10 AM	**Discussing compliance audit management trends and best practices to meet local, international regulations and notified body expectations** **Marcelo Trevino**, Senior Regulatory Compliance Manager, Medtronic
11:00 AM	**The mistakes to avoid during an FDA inspection** **Denise Dion**, Vice President, Regulatory & Quality Services, EduQuest
1:00 PM	**Successfully executing ISO 13485 and establishing your QMS criteria** **Bob Mehta**, Principal Consultant, GMP & ISO Expert Services
1:45 PM	**Updates on the implementation of IEC 60601-1 3rd Edition** **Dan Modi**, Director R&D Surgical Instrumentation (Standard Certification), Alcon, a Novartis Company
3:00 PM	**Using statistical methods to fulfill quality and regulatory requirements** **Gary Chung**, Statistics and Data Management Manager, Covidien
3:45 PM	**Integrated Process Excellence for Medical Device Development** **John Crombie**, Principal Engineer, Ethicon

DAY 1 - Monday, February 10th

EFFICIENT SOURCING AND SUPPLIER MANAGEMENT

9:00 AM	**The consumer electronics movement to the medical device space** **Dr. Peter Tippett**, Chief Medical Officer & VP of Innovation Incubator, Verizon Enterprise Solutions
10:10 AM	**Rating and evaluating vendors and suppliers** **Jonathan M. Lewis**, Principle, Advanced Biomedical Consulting
11:00 AM	**Unlocking value through effective supplier relationship management** **Christine Bynarowicz**, Senior Manager, NPI Sourcing, Contract Manufacturing, Covidien
1:00 PM	**Aligning operations with strategy in medical device manufacturers** **Michael Connerty**, Managing Director & Partner, L.E.K. Consulting
1:45 PM	**Peer to peer benchmarking on supplier management best practices** **Venket Rajan**, Industry Manager – Medical Devices, Frost & Sullivan
3:00 PM	**Best practices in supply chain and procurement** **Vinay Asgekar**, Senior Director, Global Supply Chain, Edwards Lifesciences
3:45 PM	**Smart sourcing: Capitalizing on new opportunities** **Geetha Vaithyanathan**, Domain Lead – Biologics and Medical Devices, Beroe

DAY 2 - Tuesday, February 11th

IMPROVING RISK MANAGEMENT STRATEGIES AND PROCEDURES

9:00 AM	**The entrepreneurial journey** **Rudy Mazzochi**, CEO, Elenza
10:10 AM	**Impact of EN/ISO 14971:2012 on how you implement risk management** **Kevin Posey**, Director of Quality, CardiacAssist
10:45 AM	**Applying risk management throughout the product cycle** **David Vogel, Ph.D.,** Founder and President, Intertech Engineering Associates
11:20 AM	**Risk management for gamma radiation sterilization** **Emily Craven**, Manager, Sterilization Science & Production Irradiator Engineering, Nordion
1:00 PM	**Building a shatterproof CAPA system: It does exist!** **Dawn Haake**, Senior Director Quality Assurance Compliance, NuVasive, Inc
1:45 PM	**Successfully auditing quality processes by applying risk management principles to ensure adequate CAPA systems** **James Wabby**, Director Quality Systems and Risk Management, Allergan
3:00 PM	**A live dissection of a risk assessment gone wrong: Could this happen in your department?** **Rita McIntyre**, Head, Compliance Standards & Alliances, Janssen Research & Development LLC

DAY 2 - Tuesday, February 11th

NAVIGATING THROUGH THE PMA AND 510(K) SUBMISSION PROCESSES

9:00 AM	**The entrepreneurial journey** **Rudy Mazzochi**, CEO, **Elenza**
10:10 AM	**Uncovering the blind spots in 510(k) submissions** **Marjorie Shulman**, Director, Premarket Notification (510(k)) Section, CDRH, **FDA**
11:00 AM	**Deciding when to submit a new 510(k) for a modified device – is a new regulatory approach needed?** **Mark DuVal**, President, **DuVal & Associates**
1:00 PM	**Frustrations of inconsistencies within FDA for Class III product updates** **Donald J. Sherratt**, Director Regulatory Affairs and Compliance, QRA Management, Respiratory Ventilation, **CareFusion**
1:45 PM	**Competitive regulatory strategy: Acting as a barrier to entry for your competitors** **Michael Drues, Ph.D.,** President, **Vascular Sciences**
3:00 PM	**Getting FDA approval for changes to PMA products** **Janet D. Benson**, Director Regulatory Affairs, US Post Approval and Core Products, **Abbott Vascular**
3:45 PM	**PMA submissions and approvals: Not a cookie cutter approach** **Peter Knauer**, Senior Consultant, **MasterControl**

DAY 2 - Tuesday, February 11th

MEDICAL DEVICE POLYMERS AND PLASTICS

9:00 AM	**The entrepreneurial journey** **Rudy Mazzochi**, CEO, **Elenza**
10:15 AM	**Absorbable polymers for drug delivery** **Vipul Davé, Ph.D.** , Research Director, Fellow Global OTC Technology, **McNeil Consumer Healthcare, Johnson & Johnson**
10:50 AM	**New research on Polycarbonate and BPA: Safe for continued use in medical disposables** **Len Czuba**, President, **Czuba Enterprises, Inc.**
11:30 AM	**Ultra high molecular weight polyethylene: Material properties and applications** **Anthony Verrocchi,** **Celanese Textile Fibers and Medical Fabrics**
1:00 PM	**Textile fibers and medical fabrics** **Todd Blair**, Director of Marketing, **Biomedical Structures**
1:45 PM	**Conference VIP exhibition tour: Polymers**
3:00 PM	**Laser micromachining of polymer based medical devices** **Glenn Ogura**, Executive Vice President, Business Development, **Resonetics**
3:45 PM	**Challenges of medical device contract manufacturing** **Mark Bonifacio**, Principle and Owner, **Bonifacio Consulting Services**

DAY 3 - Wednesday, February 12th

APPLYING PRACTICAL HUMAN FACTORS ENGINEERING AND IMPROVING USABILITY

9:00 AM	**Keynote Address** **Yan Chow**, Director of Innovation and Advanced Technology, **Kaiser Permanente**
10:10 AM	**From hospital to home: The switch from technical user to non-technical user** **Andy Schaudt**, Director of Usability Services, **MedStar Health** **Korey Johnson**, Vice President, UX, **GfK Custom Research, LLC** **Daniel L. Mooradian, Ph.D.,** Founder and President, **The Simpatico Group LLC**, Honeywell/James J. Renier Chair in Technology Management, **University of Minnesota - Technology Leadership Institute**
11:00 AM	**Beyond the basics of Human Factors Engineering 101** **Andy Schaudt**, Director, Medical Device Usability Division, **National Center for Human Factors in Healthcare**
1:00 PM	**Interpreting requirements for Human Factors validation testing** **Korey Johnson**, Vice President, UX, **GfK Custom Research, LLC**
1:45 PM	**Pre-Clinical Program Strategy to Drive Innovative Product Design, Usability & Safety to Support Regulatory Submissions and De-Risk your Clinical Trials** **Daniel L. Mooradian, Ph.D.,** Founder and President, **The Simpatico Group LLC**, Honeywell/James J. Renier Chair in Technology Management, **University of Minnesota - Technology Leadership Institute**
3:00 PM	**Human factors in risk management** **Pat Baird**, Principal Systems Engineer, **Baxter Healthcare** **Sara Waxberg**, Human Factors Engineer, **Baxter Healthcare**
3:45 PM	**The business case for Human Factors** **Pat Baird**, Principal Systems Engineer, **Baxter Healthcare** **Sara Waxberg**, Human Factors Engineer, **Baxter Healthcare**

DAY 3 - Wednesday, February 12th

DESIGN CONTROL FOR QUALITY, SAFETY AND EFFECTIVENESS

9:00 AM	**Trends in mobile monitoring** **Yan Chow**, Director of Innovation and Advanced Technology, **Kaiser Permanente**
10:10 AM	**Anatomy of a successful design plan** **Rob Packard**, Founder and Instructor, **Medical Device Academy**
1:00 PM	**Using design control to manage product and business risk** **Dr. Kevin Ong**, Senior Managing Engineer and Medical Device Consultant, **Exponent**
1:45 PM	**Drug device combination design controls: Regulatory challenges and successful product development** **David Maltz**, Director, Device Technology, **Novartis**
3:00 PM	**Audit and compliance adventures in design control with a software twist** **Eric L. Henry**, Director, Quality Systems (SW Quality, Compliance), **Medtronic**

MedTechWorld M&M WEST

DAY 3 - Wednesday, February 12th

PROCESS VALIDATION PLANNING, EXECUTION & REPORTING

9:00 AM	**Keynote Address** **Yan Chow**, Director of Innovation and Advanced Technology, **Kaiser Permanente**
10:10 AM	**Process validation advanced principles** **Thomas Oesterle**, President, **MedHouse Innovations, LLC**
1:00 PM	**Writing a robust validation protocol and identifying gaps in current validation programs** **Vinny Sastri**, President, **Winovia**
1:45 PM	**Low temperature sterilization process validation** **Rob Packard**, Founder and Instructor, **Medical Device Academy**
3:00 PM	**Conducting the validation protocol, collecting and analyzing the data** **Walt Murray**, Director of Quality & Compliance Consulting Services, **MasterControl**
3:45 PM	**Process Validation - Fundamental Principles and Application of Basic Statistical Methods** **Ken Link**, Medical Research Manager, **NAMSA**

DAY 3 - Wednesday, February 12th

NELSON LABORATORIES CLASSROOM

10:00 AM	**Materials Selection and ISO 10993 Biocompatibility Update** **Thor Rollins**, Biocompatibility Specialist, **Nelson Laboratories, Inc.**
11:00 AM	**Ethylene Oxide Sterilization Validation Overview** **Dan Floyd**, Laboratory Manager, **Nelson Laboratories, Inc.**
1:00 PM	**Radiation Sterilization Validations Overview** **Martell Winters**, Senior Scientist, **Nelson Laboratories, Inc.**
2:00 PM	**Packaging Test Methods for Validation of Sterile Barrier Materials** **Wendy Mach**, Packaging Section Leader, **Nelson Laboratories, Inc.**
3:00 PM	**Process Validations for Newly Manufactured Devices – Is Your New Device Clean?** **Alexa Tatarian**, Study Director, **Nelson Laboratories, Inc.**
4:00 PM	**Managing Human Factors in Reprocessing of Reusable Devices - Validation Considerations** **Emily Mitzel**, Laboratory Manager, **Nelson Laboratories, Inc.**

MedTechWorld M&M WEST

Exposition: February 11-13, 2014
Anaheim Convention Center
Anaheim, CA
Conference: February 10-13, 2014

DAY 4 - Thursday, February 13th

MAXIMIZING OPPORTUNITIES IN eHEALTH IN CONSUMERIZATION

9:00 AM	**Getting beyond the myths, misconceptions, and hype of big data and focusing on actionable data** **Shahid Shah**, CEO, **Netspective Communications** but better known as the **"The Healthcare IT Guy"**
10:10 AM	**The continuing rise of mHealth** **Mark R. Anderson**, FHIMSS, CPHIMS , CEO, **AC Group**
11:00 AM	**New technology driving the consumerization of medical devices** **Cameron Brackett**, Director of R&D, **Honeywell**
1:00 PM	**Unraveling the changing FDA and FCC wireless regulations** **Eben Gordon**, Senior Director, Regulatory, **Sotera Wireless** *FCC invited, FDA invited.*
1:45 PM	**Wireless technology in a hospital setting: Cutting the cord** **Stephanie Kreml, MD,** Principal, **Popper and Company**
3:00 PM	**Overcoming the present and future constraints of wireless medical device technology** **Jeffrey Johnson**, CISSP, Solution Engineering Manager, **Hospira**
3:45 PM	**Security concerns of cloud connected wireless medical devices** **R&D Expert speaker from medical device manufacturer**

DAY 4 - Thursday, February 13th

TESTING METHOD VALIDATION PROTOCOLS AND SOLUTIONS

9:00 AM	**Getting beyond the myths, misconceptions, and hype of big data and focusing on actionable data** **Shahid Shah**, CEO, **Netspective Communications** but better known as the **"The Healthcare IT Guy"**
10:10 AM	**Test method validation: A risk based approach** **Mike Silverman**, Reliability Engineering Consultant, **Ops A La Carte**
1:00 PM	**Qualification of laboratory test instruments based on FDA and USP requirements** **David W. Vincent**, Chief Executive Officer, **Validation Technologies**
1:45 PM	**Conducting accelerated - aging tests to provide experimental data in support of performance and shelf-life claims** **Karl Hemmerich**, President, **Ageless Processing Technologies**
3:00 PM	**Meeting your electrical safety testing and quality requirements** **Peter Havel, Ph.D.**, Senior Vice President, Global Medical Health Services, **TÜV SÜD**

DAY 4 - Thursday, February 13th

GLOBAL PRODUCT DEVELOPMENT AND REGULATORY REQUIREMENTS

9:00 AM	**Getting beyond the myths, misconceptions, and hype of big data and focusing on actionable data** **Shahid Shah**, CEO, **Netspective Communications** but better known as the **"The Healthcare IT Guy"**
10:10 AM	**Harmonizing international regulations: The challenges and realities**
11:00 AM	**Breaking into the Brazilian market: Key product development and regulatory drivers in this Latin American medical device market** **Derek Archila**, Director Research & Analysis, Medical Devices, **GlobalData**
1:00 PM	**Moving engineering and R&D to India and China** **Gunjan Bagla**, Managing Director, **Amritt**
1:45 PM	**Medical device registration in South Korea** **Bruce Wang**, Managing Director, **Nova Global**
3:00 PM	**Gaining insight into changing EU medical device regulations** **Chris Sarner**, Project Manager, Medical Device Certification, **DEKRA**
3:45 PM	**Changes with global CAPA: What are the standard bodies looking for?** **Steve Niedelman**, Lead Quality Systems and Compliance Consultant, **King & Spalding LLP**

DAY 4 - Thursday, February 13th

CHOOSING MATERIALS FOR MEDICAL DEVICES

9:00 AM	**Getting beyond the myths, misconceptions, and hype of big data and focusing on actionable data** **Shahid Shah**, CEO, **Netspective Communications** but better known as the **"The Healthcare IT Guy"**
10:10 AM	**Material selection: Finding the balance between properties, performance and cost**
11:00 AM	**Material selection: Finding the balance between properties, performance and costs** **Shane Mao, Ph.D., MBA**, Director of Project Management and Raw Material Development, Global R&D, **Coopervision**
1:00 PM	**Implementing RoHS compliance** **James P. Vetro**, Global Engineering Manager - RoHS & Substances, **GE Healthcare**
1:45 PM	**Developing novel materials for medical devices** **Dr. Thomas Dietrich**, Chief Executive Officer, **IVAM**
3:00 PM	**Manufacturing and designing antimicrobial medical devices** **Dr. Rakesh Kumar**, Vice President Technology, **Specialty Coatings Systems**

Conference

Networking

Exhibition

Upcoming Conferences and Activities

International Polyolefins Conference 2014
"The Polyolefin Renaissance" at Hilton Houston North
February 23 - February 26, 2014, Houston, Texas

From The Editor:

We need you. And, frankly, I think you need us.

Nominations for the Medical Plastics Division Board of Directors are now open and will remain open until 14 FEB 2014. The elections will be conducted via email and be finished in early March.

The function of the Board is described on page 13 and Goals and Objectives for 2014 on page 15. The list of current Board members on page 17 shows the areas where the members contribute – conference planning, finance, communications. If you would like to know more, just ask. There are five positions to fill this year.

And why do you need us? Of course there is networking. However, it is not just networking at SPE but being able to call a friend for help or advice. The scope of networking goes outside of SPE as well because MPD often organizes conferences with other groups. You can meet professionals at very different levels of industry than your own and share their experiences. Stretch your skill set – learn things you would not learn at your day job and get experience with something different (I am a chemist who learned to assemble a newsletter).

In an old issue of the MDP newsletter, I found this quote from Winston Churchill:

"We make a living by what we get, we make a life by what we give."

And (my favorite) you get to attend the annual MPD dinner at ANTEC.

Happy New Year.

Norris M. Tollefson *January 2014*

Also From The Editor:

A Technical Presentation in the Medical Plastics Division Newsletter

I would like to invite any member of the Medical Plastics Division to submit an article or paper that has been published or presented elsewhere for reprint in the MPD newsletter.

The intention is to provide a diverse selection of subjects over the year that are intersting to our members and important to our medical plastics industry.

Please submit an article or paper in a pdf format to the newsletter editor Norris M. Tollefson (norris.tollefson@alcon.com). At your discretion, you may also include a brief biography (less than 50 words) and a photo. Not all submissions may be used.

Please make submission to the newsletter editor
Norris M. Tollefson (norris.tollefson@alcon.com)

Upcoming Conferences and Activities

SOCIETY OF PLASTICS ENGINEERS
ANTEC 2014

Rio All-Suites Hotel & Casino
April 28–30, 2014
Las Vegas, Nevada, USA

TENTATIVE PROGRAM FOR THE MEDICAL PLASTICS DIVISION

Wednesday Morning, 30 APR 2014

• Plenary Speaker	Steve McCarthy
• Polyurethanes in Cardiac Device Leads: Effect of Morphology on Performance	Ajay Padsalgikar
• Polypropylene and Polypropylene-SEBS Blends for Medical Films	Martina Sandholzer
• Chemical Resistance Evaluation Of Medical Grades Eastman Tritan™ Copolyester And Polycarbonate	Steven Givens
• Chemical Resistance Advantages of TRITAN™ Copolymers for Medical Applications - Oncology Drug Case Study	Yubiao Liu
• Modified PEBA for Direct Adhesion to EFEP	Sabine Fleming
• High Flow Polycarbonate Copolymers for Medical Appilcations	Malvika Bihari
• Hydrogels for Arterial Modelling and Tissue Scaffolding	Austin Coffey

Wednesday Afternoon, 30 APR 2014

• Gas Plasma for Molecular Re-engineering of Microfluidic Devices	Mikki Larner
• Radiation Sterilization of New Medical Resins in Oxygen-Free Packaging	Pierre Moulinie
• Benefits of Servo-Driven Ultrasonic Welding for Critical Assemblies	Kenneth Holt
• Polymer-Based Microfluidics Chips: The Engine That Drives A New Class of Medical Devices Called Prognostic Devices, Medical Devices That Predict Diseases Rather Than Just Diagnose Disease	Rey Parel
• Radiopaque Filler Enhances Nanocomposite Catheter Shaft Performance	Amar Nilajkar
• Maximization of Hydraulic Flow In Small Flexible Polymer Tubing by Stiffness and Wall Thickness Optimization Utilizing Hardness and Glass & Carbon Nano Tubes Fillers	Alan Boardman
• Moisture Determination of Specialty Resins Using Relative Humidity Sensor Technology; a Solvent-free Alternative to Karl Fischer Titration.	James Moore

All interested people are invited to attend the Medical Plastics Board of Directors meeting, the business meeting, the Division dinner, and the co-sponsored social reception. Make plans to attend the Student Luncheon on Wednesday as well. Details next issue.

Nominations are now open.

Board of Directors for the Medical Plastics Division

Elections will be held in February 2014.

The Board of Directors is the governing body of the Medical Plastics Division. Its responsibilities include election of MPD officers, establishing division rules and operating procedures, appointing committee chairs, establishing a budget, and fundraising, as well as authorizing, negotiating, and planning topical conferences (TOPCONs).

The Board of Directors is made up of approximately 20 elected members that generally serve three year terms in a staggered fashion so that each year we elect five new board members. Officers serve one or two year terms while also a member of the Board. Our Councilor to the SPE serves a three year term.

Requirements and Responsibilities of Board Members for the Medical Plastics Division

►Candidates for the SPE Medical Plastics Division Board of Directors must be active members of the Society of Plastics Engineers and of the Medical Plastics Division.

►Members of the Board should be involved in or have interest in some aspect of the Medical Plastics Business or a related academic field.

►Board members are expected to participate in bimonthly 1-hour teleconference meetings and annual in-person Board of Directors and Business meetings at SPE's Annual Technical Conference (ANTEC).

►Willing Board members will assume specifics roles in leadership positions, such as Secretary, Newsletter, Web-Site, Social Activities, Technical Program Chair, Membership, Student Activities, Treasurer and SPE-Council Representative.

►Board members are expected to participate in committees in some capacity to support activities such as Technical Conferences, Membership Group Activities, Financial oversight, BOD nominations, etc.

►We encourage an active membership so any one individual doesn't carry too much of a load.

All nominations are due before 14 FEB 2014.

If you are interested in participating in the Medical Plastics division as a member of the Board of Directors, please submit a short biography and a recent picture to Mark Bonifacio (mark@bonifacioconsulting.com) or John Thomas (Johnt@bonifacioconsulting.com).

SOCIETY OF PLASTICS ENGINEERS INC.

MEDICAL PLASTICS DIVISION

Sponsors…

We are now seeking Sponsor Display Ads for our Award -winning Division Newsletter! To show your support of the Society of Plastics Engineers and in particular, the Medical Plastics Division Newsletter, please consider taking part in this important communication effort.

Sizes Available (Full year amount, i.e. 3 issues)

Full page (8½" X 11")	$3,000
Half page	$1,600
Quarter page	$900
Eighth page	$500

The newsletter is published electronically at least **three times per year**. Every Medical Plastics Division member, about **1,000**, receives a copy mailed directly to their listed address. And additional copies are also circulated in our continuing effort to reach new and prospective members and other interested individuals.

To show your support please contact Norris M. Tollefson (newsletter editor) at 678-415-3784 (Internet:norris.tollefson@alcon.com) with your copy (jpg preferred) and payment.

Or contact MPD Chair Mark Bonifacio at 310-683-3257 (Internet: mark@bonifacioconsulting.com) for more information.

Thank you for your support!

Medical Plastics Division

Mission Statement

To promote the Medical Plastics Division of the Society of Plastics Engineers through outreach, networking, and education about our fascinating and vital industry. To encourage participation of everyone from the MPD Board and from the Division to help shape our message and to encourage others to join us in this mission.

Goals and Objectives 2013 - 2014

Leadership Development
Communicate about our industry through outreach, education, and networking. Encourage MPD Board members and division members to actively participate in the Division and SPE. Identify new board prospects, mentor those new to the board. Initiating new MPD programs to benefit members and prospective members of SPE. Be respectful of everyone's opinions.

- Fill all positions on board.
- Have each BOD member identify a successor and mentor that person.
- Hold 6 Conference Calls as a Board during MPD 2013-2014 Calendar year.

Technical Programming
Maintain or increase MPD level of participation at ANTEC, including joint sessions with other divisions.
Continue to partnership with UBM Canon for MDM shows.
Develop a speakers list for division.
Continue support of TopCon for 2013.
Support and participate in the EuroTec and AsiaTec conferencing efforts.

Communications Program
Publish at least three issues of the Medical Plastics Division newsletter of high quality content with news of activities and interest to our members.
Use the website for better communication about MPD activities and volunteers.
Utilize SPE monthly email blasts to reach out to members with news and to promote activities.

Finance Committee
Determine effective use of MPD funds to support an operating budget as well as member programs, benefits, and student support.
Develop long-range plans for use of funds including annual budget and to raise income.

Membership
Appoint a membership chair to develop a communication program, to recognize new members, and to reach out to potential new members. Increase division membership by 5%.

Recognition
Use Awards program to recognize contributions from conference speakers and student papers. Work with programming committee to identify and recognize best speaker at each conference.
Nominate and sponsor at least one member for either Honored Service Memeber or Fellow from our division.
Use division awards to recognize significant contributions.

Medical Plastics Division - SPE
Board of Directors for 2013 - 2014

Name	2012-2013 Position	Company
Officers		
Mark Bonifacio	Chair	Bonifacio Consulting
open	Vice Chair	
John Thomas	Secretary	Bonifacio Consulting
Paul German	Treasurer	Kruger Plastics
Margie Hanna	Councilor (2012 - 2015)	Czuba Enterprises, Inc.
Jill Martin	Past Chair (2012 - 2014)	Dow Chemical
Board Members		
Class ending ANTEC 2014		
Norris Tollefson	Newsletter Editor	Alcon Laboratories, Inc.
Jim Madenjian	Membership	J.M. Engineering Associates
Harrison Yu	Website Communications / Pinnacle	Bondable Biopolymers
Jordan Freedman	Technical Program Committee	Biomet Orthopedics
Class ending ANTEC 2015		
Jodie Laughlin	Marketing - To be chartered	GE Healthcare
Maureen Reitman	Awards / Technical Program	Exponent
Ken Breeding	Marketing - To be chartered	Eastman Chemical Company
James Oberhauser	Technical Program Committee	Abbott Vascular
Ali Ashter	Technical Program Committee	EMD Millipore
Class ending ANTEC 2016		
John Thomas	Secretary	Bonifacio Consulting
Ed Fewkes	Technical Program ANTEC	Corning Inc
Ben Poon	Technical Program Committee	Baxter Healthcare
Len Czuba	Technical Program Committee	Czuba Enterprises Inc
Michael Wallick	Awards Committee	Invibio Biomaterial Solutions
Vipul Dave	Technical Program Committee	McNeil Consumer Healthcare
ex officio		
Glenn Beall	Historian (Appointed)	Glenn Beall Plastics
Sarah Sullinger	SPE Liaison (Appointed)	SPE
Vijay Boolani	EC Liaison (Appointed)	Boolani Engineering Corporation
Gerry McNally	EMPD TPC	McNally Associates
Austin Coffey	EMPD Chair & Councilor	Waterford Institute of Technology

If you would like to get in touch with a member of the board, contact information may be found in the SPE Membership Directory.

Meeting Minutes for MPD BOD Conference Call

Date: 11/20/13 11 am EST

Call to order

Roll Call – Margie Hanna, Ben Poon, Steve, Ali Ashter, Jim Madenjian, Michael Wallock, Jim O, Ed Fewkes, Norris Tollefson, Len Czuba, Vipul Dave, John Thomas

1) Confirm email approval of meeting minutes from 6/19 & 9/13 conf calls – Send out minutes with edits.
2) Treasurer/Finance Committee Report
    a. Finance Review
    b. TOPCON China
        i. Ali motion to advance $15K to SPE for TOPCON, seconded
            1. The money is only at risk if there is a loss
            2. What kind of contract is there? - Email exchanges only – was approved in the minutes of the June meeting
            3. We should have assurance that this is not a gift but will be returned before profit or loss. MDP will also share in the profits
        ii. Rebate to SPE – pending balance from TOPCON
        iii. Still looking for Sponsorships?
3) Technical program
    a. MD&M West Anaheim
        i. Len – has submitted proposal for a session of speakers and MD&M should be promoting next week
        ii. Session moderators? Ali has volunteered to moderate or chair
    b. ANTEC 2014 Las Vegas – Ed Fewkes
        i. Problem access to the papers – not emails from SPE for a while
        ii. 14 papers, 2 sessions – review and pick which you like (at least two), reply via email copy other reviewers by 1st week of Dec
        iii. Scheduling- do not want a conflict with the New Technology Forum
        iv. Motion approved to Host reception up to $2,000
            1. Len to ask other division to co-sponsor
            2. JT to contact Barbara & set up
        iv. Polymers for use in hospitals in the human body – Tues during ANTEC
            1. Looking for 6 speakers
            2. Approaching additive organ technology company
            3. Biomometrics
            4. Disolvable implnt circuits
            5. Len will send an email
    b. TOPCON China Update – Harrison L, Len C, Ali A, Vipul D, Steve McCarthy
    c. Polyolefins Conference - Ben
        i. Five Papers - Three resin suppliers, two from Baxter (need 6)

i. Looking for suggestions for speakers – Ed Fewkes will look

b. Mini-Tech Minneapolis, March 2014
   i. Model the same program as Chicago
   ii. Len is working with Ben and would like others to support

c. Potential Medical Plastics Event with Philadelphia SPE

4) Membership
   a. Committee – Jim Madenjian will Lead
      a. How many we have in our division
      b. Use SPE website – work Pedro or Tom Conquin

5) Councilor Report – Margie Hanna: (emailed in after the call)
   a. Committee meetings for councilors were held on Friday, Nov. 15th. CCOW was held in the afternoon followed by the "Meet the candidate" reception that evening.
   b. During both the Sections and the Divisions committee meetings, problems with website and membership reports were extensively discussed and HQ staff committed to resolve these problems as the new website continues to roll out.
   c. During the CCOW, a presentation on the Student Activities at ANTEC 2013 recognized the wonderful financial support from S/Ds and SIGs. The presentation is downloadable from the extranet and details the specific donations from each group and the number of students that participated.
   d. http://extranet.4spe.org/index.php?dir=Council%2F2013-14+Term%2F
   e. At Council meeting on Saturday, election of officers was held. The following members were elected:
      i. As President-elect – Dick Cameron
      ii. As Sr. Vice-President – Scott Owens
      iii. As the elected VP on the EC – Jaime Gomez
      iv. As Chair of the CCOW – Sandra McClelland
   f. SPE CEO Wim DeVos presented a strategic plan in which SPE operations will attempted to be run more like a business and plans have already begun to be implemented.
   g. The Finance committee presented the following report including the budget for 2014.
      i. Full report can be downloaded at the extranet.
      ii. Budget:
         1. Revenues
         2. 2013 forecast – $3.4M 2014 budget - $3.5M
         3. Expenses
         4. 2013 forecast - $3.55M 2014 budget - $3.6M
         5. Total results:
         6. 2012 actual - $61K 2013 – forecast – ($96.5) 2014 budget – ($86.4K)
         7. Rebates for 2014 will be reduced from rate paid in prior years by 25% because of projected loss.
   h. Membership:
      i. During 2013 with a high of about 15K, we are projecting ending the year with about 14.5K members. The new website is expected to help change the downward trend during 2014.
   i. Website reconstruction, redesign and changeover
      i. Included was redesign of SPE logo
      ii. E-connect – method to make SPE info and website link up to social network portals and on universe of mobile devices and apps.
      iii. New logo (Corporate Identity)

i. Branded shirts are available to help communicate the change and all groups (Sections, Divisions and SIGs) are encouraged to consider purchasing a quantity of shirts and selling these at future events.

b. TopCon policy
   i. A reworked policy for revenue sharing with SPE headquarters was presented. As recrafted, essentially HQ will be paid as a percentage of the Gross revenue in return for the services provided. Much discussion ensued but as it is now crafted, the policy will become effective mid-year 2014.

c. By-Law and Policy
   i. The 2nd reading of By-law 7.4.6 was approved and By-law changes 9.2 and 10.2 were read for 1st reading and both were approved for publication and then consideration for 2nd reading at ANTEC.
   ii. Policies 013 and 014 and 002 were approved as presented and policy 009 was withdrawn from consideration because B&P decided that it needed additional work.

d. Report on recent international conferences
   i. ANTEC Dubai is progressing very well with 70+ submitted abstracts, very good exhibit sales, Conference is tracking well and expected to be a big success.
   ii. Eurotec was reported to be a good conference but attendance was light and it ended with a short loss.
   iii. Plans are once again underway for ANTEC Mumbai in December, 2014. The committee decided to wait until after ANTEC Dubai in January 2014.

e. Next generation committee report

f. A report was given about the outreach and activities being done to bring Young Professionals into SPE. See presentation available on extranet. http://extranet.4spe.org/index.php?dir=Council%2F2013-14+Term%2F

g. Parts competition at ANTEC was announced and details available at SPE website.

h. Next meeting in Las Vegas in April 2014

i. Problems with Website and Membership reports – will be resolved in the next few months

j. Rebate Compliance Documents, Leadership Checklist – Marie to follow up

6) Newsletter update – Norris T
   a. Next Pub date: 1st week of Jan – Looking for event reports -
   b. Promote Dubai conference
   c. Assistant, Jordan Freeman?
   d. Great job Norris
7) Liaisons – Sarah Sullinger (part time now), New person – Cathy – not on call
8) Award Nominations Committee – Update – Mike Wallick
   a. Submitted 2 applications
   b. Mike will notify the board
   c. Congratulations to Steve McCarthy for SPE annual Educators Award
   d. Gifts – Ben is working on it and should have them before TOPCON
9) Unfinished business
10) New business
   a. Next meeting & 2014 meeting schedule – JT will work with Mark to set up, similar to 2013
11) Meeting Adjourned

THE DISTURBING BUT GROWING TREND TO REUSE SINGLE-USE MEDICAL DEVICES: A RECIPE FOR TROUBLE

Len Czuba, Czuba Enterprises, Inc. Lombard IL, USA

Abstract

An ominous trend in the health care industry has been gathering momentum in the last 10 to 15 years. Reprocessing and reuse of Single-Use Devices (SUDs) is being promoted as an effective cost saving method and as an environmentally responsible use of resources. However in an industry dedicated to providing safe products that allow life-saving and life-preserving therapies for health-compromised patients, the reprocessing and reuse of SUDs directly violates the principles on which so many manufacturers of SUDs have based their products. Device manufacturers take great care to design, develop and manufacture their products and test and qualify these products to assure safe use (and even abuse). But SUDs are made with the presumption that after use (a single use) the device would be discarded. This paper will present a review of the risks and the consequences associated with this dangerous practice.

Introduction

Before Plastics in Medical Devices

Before plastics were available to make reliable medical devices the materials used were largely glass for intravenous (IV) solutions and metal for instruments. The products made from these materials were limited but because of the properties of each material, glass and metal, they could be cleaned, sterilized and reused. However it soon became apparent that for every institution that treated patients using glass IVs bottles and metal instruments, that they needed a dedicated cleaning and sterilization team in order to prepare these products or instruments for reuse. And for IV solutions it was even more complicated requiring not only cleaning, inspecting the glass for bottle deterioration but also in carefully preparing the solutions that were being used (primarily 0.9% saline) for IV infusion.

For smaller hospitals it was impractical to have their own IV manufacturing lab and even for larger institutions, it became apparent that the variability between how the IVs were being prepared and their quality and ultimately the patient outcomes were being compromised. This led to the development of the first manufactured IV products by Baxter Laboratories in the early 1930s. The consistent safety and effectiveness of these manufactured IV products led to the rapid growth of healthcare institutions using these products.

At the same time, manufactured IV accessories were being developed to allow the safe infusion of IV solutions as well as the collection, storage and infusion of blood. The advantages of sourcing IV solutions from a manufacturing company dedicated to producing safe and effective products proved that improved health care, elimination of dedicated hospital teams and cost savings were all realized by using these new manufactured products.

Selling Safety

The process of making in-hospital IV solutions beyond the questions of inconsistencies of batches, sterility and pyrogenicity and quality of product, the cost to manufacture these products in-house was significant. When medical product companies began to specialize in the manufacture, sterilization and distribution of IV solutions in glass bottles, the overall quality improved, ease of use continued to evolve and the cost per unit dropped. As in any large scale manufacturing operation, resources were dedicated to improving efficiencies of every step of the manufacturing process and the resulting product continued to get better at lower manufacturing cost allowing cost savings to be passed on to the users.

But the real benefit of these products was not just the improved quality and repeatability of performance but ultimately the assurance of quality never before realized with in-hospital manufacturing operations. Large scale manufacturing allowed tracking of performance and quality which ultimately proved sterility assurance levels (SALs) up to and beyond 10^{-6th} (one in a million). This means that the product-line is shown to have less than one non-sterile product in a million units of that product. By eliminating risk of non-sterile and improperly manufactured IV solutions, the IV solution manufacturers filled a niche and made these types of products widely available leading to improved healthcare to the entire country and ultimately to throughout the world.

Replacements for Glass, Metals

Plastics Provided Basis for Growth

Synthetic polymeric materials developed throughout the 20^{th} century made available to the healthcare industry superior quality materials of construction that in some cases could replace the existing products even if used only once and discarded. The cost savings realized from not having an extensive dedicated cleaning and sterilization department coupled with the improved

patient outcomes with fewer patients contracting infections or diseases from cross contamination, led to the widespread adoption of what are now called single use disposables or (SUDs).

Flexible PVC (polyvinyl chloride) IV bags were introduced to the market in the early 1970s and virtually overnight eliminated the glass IV market. Blood bags, kidney dialysis solution containers and the variety of accessories largely relied on plastics of all makes and properties to expand the range of products and therapies that were being used to treat patients during the last third of the last century. Glass syringes were replaced with low cost disposable polypropylene syringes. IV catheters and fluid delivery sets, tubing, catheters, needle hubs, drip chambers, roller clamps, spikes, connectors, injection sites and filters all were developed with polymers selected to provide optimum performance while allowing use as disposable single-use devices.

Metal Replacements

Eventually, polymers were found to have superior engineering properties such as stiffness, high temperature resistance and processability allowing many of these performance polymers to be used as disposable plastic replacements for the formerly metal instruments. Hospital personnel began to realize the benefits of disposable plastic medical devices in providing high quality, dependably functioning products that were used and after use, disposed as spent products.

Patients were not exposed to the threat of infection from their medical devices or instruments since each was a new device carefully made, sterilized and provided for a single use. The industry grew and the range and scope of new medical products from procedural tools for minimally invasive surgeries to cardio-catheterization with balloon catheters to biopsy instruments grew in complexity and capabilities all based on the premise of using low-cost, functional polymers in their construction.

Providing Critical Functionality and Maximum Safety

Engineering design teams responsible for the functionality and efficacy of the medical devices designed and built their products with a large margin of safety in case of inadvertent use (or abuse) wanting to assure their users that their products were safe. If a product such as a medical suture was required to survive a certain level of force to prevent breakage or other malfunction, often design teams worked to design into their products double the necessary tensile strength in order for that product to pass. If an IV bag was required to survive a 2 meter (or 6 foot) drop test, the engineering team would strive to make the product survive a 4 meter (approximately 13 feet). And for critical devices such as new IV containers the goal was raised even higher for example teams tried to make a so-called "unbreakable" one-liter solution container often testing at 6 meters (or 20 feet).

As creative new products continued to emerge to serve new and existing patient populations, there was little thought given to how the spent medical disposables were handled after use. It was assumed / expected that the used plastic medical devices were put in the hospital trash and either incinerated with other hospital wastes or sent to a landfill.

Commercial Reprocessing is Spawned

During the last decades of the 1900's some institutions began taking certain single-use medical products and rather than disposing of them, these products were washed, thoroughly cleaned, tested for efficacy and then packaged and resterilized. Often the products were unused single-use devices that were part of a surgical procedural kit or a catheter or device that was opened in the surgical suite but for one reason or another not used. If the sterile field of a procedure kit was compromised and inadvertently made unsterile, the kit would, if typical practice was followed, be discarded rather than risk causing an infection in the already at-risk patient. It was in instances such as this that some institutions began considering repackaging (after cleaning if necessary) and resterilization of these kits so that they can again be made ready for use.

Other institutions began taking expensive single-use devices used in surgeries or in procedures and evaluating these for their ability to safely reuse on other patients. The practice grew and because there appeared to be an opportunity to grow this practice into a larger scale venture, so-called reprocessing companies were formed. These companies collected used but "good" i.e. non-defective devices and began offering cleaning, repackaging and sterilization service. The reprocessors then sold these reprocessed single-use devices for a much reduced price to the hospitals or institutions, often at half the price of a new device. This practice became a concern for the original equipment manufacturers (OEMs) of the single-use medical devices who petitioned the FDA to regulate reprocessors of SUDs to the same standards that the OEMs are required to meet.

Federal Agency Response

In November 1999, the United States General Accounting Office (US GAO) investigated the practice of reprocessing and reuse of SUDs and in June of 2000, issued a report entitled "Single-Use Medical Devices; Little Available Evidence of Harm from Reuse, but Oversight Warranted".[1] This report details the investigation and research that went into the preparation of this report but in summary it states that with proper oversight, it believes that reprocessing and reuse of certain SUDs should be regulated by the US Food and

Drug Administration (FDA) and that if done properly, the likelihood of harm to patients is low.

An Engineering Perspective

Medical Device Performance
The process of developing a new medical device involves extensive testing of materials of construction, design and functionality of components and complete evaluation of the finished medical device. The materials are evaluated for physical and functional suitability, the suitability via chemical assessment and finally through a thorough battery of biological evaluations. Finished devices are challenged to show reliability when the level of testing is extensive. Each step of the manufacturing process in validated and verified for acceptability. Complete documentation is required and maintained throughout the manufacturing process and through the useful life of the particular medical device.

Given the care and level of engineering effort with which OEMs produce their devices, it is almost contradictory for the FDA to allow any less care be given to the reprocessing of SUDs. Admittedly, there are circumstances where reprocessing is not dangerous and where the reprocessed SUD is apparently safe for use. However, even with devices that have never been used, the very process of resterilization presents a challenge to some components and to many materials. Unless these aspects are taken into consideration, I believe that reprocessing presents a danger to patients when reprocessed devices are used on them.

Concerns

Materials of Construction
The polymers and components of SUDs are selected based on the premise of one cycle: from processing, assembly, sterilization and use. If an SUD is then taken through another cycle in any of the processes, it is difficult to know how the materials will survive this exposure. It is also unlikely that the reprocessing companies have the in depth expertise in polymer science to know and understand the effects of the reprocessing on the materials of construction. Often the OEM has spent years developing the SUD. For a reprocessor to blindly expose the devices and the materials to additional processing steps can adversely affect the properties of the device.

Assembly Methods
Another major concern is the way any of the reprocessing steps can affect the assembled SUD, especially if adhesives are used. Joining science is carefully developed in many medical devices and because the requirements are so very extreme, it is likely that after the first cycle of the SUD, a second exposure including the exposure to the cleaning agent and the disinfecting process can dramatically, adversely affect the properties of the SUD. If the SUD were used before reprocessing, the joints may have been stressed. This could lead to micro-cracks or fissures which can harbor debris. Any contaminant that is not removed has the potential to carry pathogens or prions.

If It is Not Clean, It Cannot be Sterile!
Prions are the abnormal proteins said to be associated with the transmission of Crutzfeldt-Jakob disease (CJD). This brain wasting disease, similar to mad-cow disease in animals is a rare but fatal brain disease caused by abnormal proteins called prions. CJD causes rapid deterioration of the brain, resembling dementia. Patients exposed to CJD can be infected and not manifest the symptoms for years but once the symptoms are observed, the disease progresses rapidly and the average time to death is within four months.

Any medical device exposed to a patient with CJD in the opinion of this author should be discarded. CJD has been found to survive the most rigorous cleaning and sterilization cycles and therefore the risk of infecting other patients is real and should be avoided. About 200 cases a year of CJD are said to be reported in the United States. Reports of recent patient exposure to the deadly CJD stated that they were caused by improperly sterilized instruments.[2] A hospital spokesman said that the procedures necessary to eliminate all traces of the (prion) proteins would effectively render the equipment unusable(!) Emphasis added.

Sub-Microscopic Surface Features
Microfissures, particle discontinuities and rough surface feature are all locations which can contain micro remnants of blood or body fluids that even the most rigorous cleaning cannot remove. Elastomers, expanded balloons, stress-crazed polymers and any mechanically activated joint will have at the microscopic level surface defects. It is unlikely that the surfaces can be absolutely purged of all pathogens.

Mechanical Features Can Harbor Pathogens
Joints, hinges, film fin seals and sharp corners can all be locations where the SUD, once exposed to a patient's blood can lead to contamination of other patients. Some devices of instruments are able to disassembled, cleaned, components replaced and the product reassembled. This option for using SUD may be effective if done properly. The president of the Association of Medical Device Reprocessors (AMDR) indicated that the industry likely did themselves a disservice by calling this process "Reprocessing" rather than more correctly "Remanufacturing". If in fact the SUDs are appropriately disassembled, components cleaned or replaced, reassembled and then tested and sterilized, there would be

much less objection to this type of reuse. However, the recommendation to dispose of any product or material that has had blood contact is still advised.

Concerns Raised by Medical Professionals
I was told by the representative from AMDR that no critical use devices are ever reprocessed.

In a direct contradiction to this statement by AMDR, I was contacted by a technical field representative from a major multinational firm that sells balloon cardio-catheters and surgical instruments. He told me that many of the physicians with whom he meets, do not want to use reprocessed critical use SUDs and although they feel that these products put their patients at risk, the institutions with whom they work do not give them the choice whether or not to use reprocessed SUDs. They are required to use reprocessed devices in spite of them knowing the risk to their patients.

Interestingly, several professional organizations of nurses or physicians have issued statements in support of their recommendations to avoid the use of SUDs. There is the recognition that such devices pose a hazard to their patients both in their questionable function as well as in the likelihood, no matter how remote, of passing along viable pathogens.[3], [4]

Re-Sterilization Can Affect Materials & Functionality
Multiple sterilization exposures have been shown to have an effect on the SUD product particularly if some of the materials used to make the SUD are incompatible with the intended sterilization method. Polypropylene, flurorpolymers and acetal polymers can be dramatically affected by radiation exposure leading to unexpected mechanical and chemical failure. Reprocessors do not have access to the depth of science used in the development of the original SUD and it is unlikely that the product will be handled by the reprocessor in the same way it was done by the OEM. My experience is that even when repeat exposure was done with new SUDs, there would be significant change in material properties directly showing the effect of a second or repeat sterilization.

Controlling Multiple Reprocessing
If SUDs are used and discarded as their manufacturers intended, there would be no need to track the products after use. However, if SUDs are reprocessed, there needs to be well documented and controlled method to know and understand the number of times any one particular device is reprocessed and used and yet assure safety. Furthermore, as the device is reprocessed for the second time and then beyond the first reprocessing, the device must be shown safe and effective.[5] These FDA guidelines offer suggestions on how to effectively handle and treat possibly contaminated devices before reuse.

There have been efforts made by the OEM (original equipment manufacturer) to control the reprocessing as evidenced by the acquisition of Sterilmed by Ethicon Endo-Surgery, Inc., a Johnson & Johnson subsidiary.[6] In this example, the OEM can work closely with the reprocessor and by using the original manufacturing specifications, components and quality assurance measures, work to assure as much as possible that the reprocessed SUD is safer to use than if it was reprocessed without the help of the OEM.

Summary

I believe that as it is now being practiced, reprocessing of SUDs poses an unacceptable hazard to patients. The risk of causing a life-threatening disease or infection exists and this fact has been documented. I believe that any critical use device designed as an SUD should be discarded after it has been exposed to a patient's blood, tissue or body fluids. Whenever this is the situation I recommend the adoption of the so-called Precautionary Principle and err on the side of caution. If there is a chance the patient can be harmed and can contract serious, life-threatening infection from the reprocessed SUD, no matter how low the risk, I recommend that reuse not be done.

Recommendations

Industry experts should work with Federal agencies in assessing the situation in greater detail than is now the case. Changes should be made to eliminate the contradiction of reusing SUDs. And the following recommendations should be considered for adoption.

1. Any single-use device exposed to blood should be discarded. The best current technology cannot provide absolute assurance that reprocessed SUDs can be made sterile and pathogen free. If a device has had blood contact and if that patient is infected with CJD, then that reprocessed device has the potential to infect anyone else on whom the device is used.

2. For products that can be safely reprocessed, regulators should work with OEMs to consider new labeling category other than "single-use devices". If manufacturers were shielded from the liability that comes with the use of reprocessed devices, they may be willing to produce products that can be labeled as "compatible with reprocessing" in accordance with regulations, controls and acceptable practice.

3. The term reprocessing should not be used on devices that are actually remanufactured. Instead, they should be labeled as "Remanufactured" devices and if the reprocessing or remanufacturing companies can properly document that these processes are safe, the devices are

safe and effective to the same level of assurance as the original devices, with proper controls in place and acceptable relabeling, these products should be allowed for reuse. It is important to note however that these are not SUDs but devices designed to be compatible with reuse.

4. Manufacturers of devices and instruments should work to design and make disposables two part assemblies where ever possible where the disposable part is a small part of the instrument and the reusable is easy to clean and sterilize and presents no risk if reused. These have been termed "reposable" devices meaning part or the device is reused and reprocessed but the blood contact end is disposable.

5. Finally, there should be agreement between OEMs and regulators on the use of the term "single-use device". Any device labeled SUD should never be reprocessed or reused. If OEMs were given assurances that no liability would be associated with the OEM for any reprocessed medical device, then new labeling can be adopted such as "conditional SUD" or "appropriate for reprocessing".

Conclusions

The reprocessing and reuse of single-use medical devices is now considered a wise use of resources and a way for the healthcare providers to contain costs. However, patient safety is put at risk and this directly contradicts the entire premise on which the device industry is based which is to provide safe and effective devices for improving the health of the patient. I believe that the reprocessing and reuse of SUDs should be discontinued immediately and if the reprocessing industry is interested in continuing the practice, they should adopt the term "remanufactured medical devices" rather than continuing to use the contradictory term "reprocessed single-use devices". The medical device industry must take the lead and work with regulatory agencies to first protect patients and only after this is assured, work to reduce costs and strive to be environmentally responsible with proper use of all resources. [7]

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Key Words

Medical Devices, Reprocessing, Single-Use, Disposables