MEDICAL PLASTICS

MPD NEWSLETTER

NOVEMBER 2015

LETTER FROM THE CHAIR

Hello Fellow Member of the Medical Plastics Division:
The week that I am writing this, National Public Radio (NPR) is holding their fall pledge drive and they keep asking "Why do you listen to NPR?" And so I am asking you a similar question: "Why are you a member of the Medical Plastics Division?" When I first joined SPE (30 years ago!) my answer was for the industry contacts (and I thought it looked good on my résumé). The answer is still pretty much for the contacts, but also for so much more. SPE is one of two professional associations that I have maintained for 30 years and I have been a member of the Medical Plastics Division for all that time. Others have come and gone but MPD gives me things that other affiliations have not. I have called people I met through MPD for expert advice or scientific interpretation or just a second opinion. Attending ANTEC meetings and presentations has helped me solve technical problems. What do you value most about your membership? We would like to hear from you. To mix my metaphors "What's in your wallet?"

Electronic submission of papers for ANTEC 2016 has been open since August but the closing date of 08 DEC 2015 is fast approaching. We invite any and all to submit papers to the Medical Plastics Division for our ANTEC 2016 program. It is an indication of dedication of the MPD members that they will be reviewing submitted papers over the holidays. Help us make it a great program.

Elections for the Medical Plastics Board of Directors will be held in January 2016. There will be five positions open. Candidates must be active MPD members and be interested in helping the Division through the many responsibilities and activities of the Board. We encourage an active membership so that any one person doesn't carry too much of a load. Please contact me if you are interested in serving on the Board.

By our next newsletter, paper submission will be closed and elections will be done. Time goes fast. Don't hesitate. Act now.

Norris M. Tollefson
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ANTEC Abstract Deadline:

DECEMBER 8th, 2015

In This Edition…

It is that time once again to start planning your trip to the ANTEC conference. This is a great opportunity to see familiar faces and expand your network with other medical plastics professionals. As you read in the Letter from the Chair, the abstract deadline of December 8th is fast approaching. We encourage anyone with relevant research to submit an abstract. If you know a colleague that isn't an SPE member but has research to share, please encourage them to submit an abstract too. The strength of the Medical Plastics program relies on your submissions. As part of the technical program this year, the Medical Plastics Board will be handing out awards for best paper and best presentation. For more information on the format and submission process, visit https://www.eiseverywhere.com/ehome/127608. If you have any questions about the Medical Plastics technical program, please contact Pierre Mouline at pierre.moulinie@bayer.com.

This year, ANTEC is coming to Indianapolis, Indiana, one of the hidden gems of the mid-west. It has big city activities with the pace and friendliness you expect in that part of the country. There are great restaurants and activities to keep you entertained after the conference. Go to www.visitindy.com to learn more about the city, where to eat, and what to do if you have some free time.

We look forward to seeing you in Indianapolis!

Word to the Wise…Book Early

This year, ANTEC lands in Indianapolis the week before the Indy 500 runs. With driviers qualifying during the week, there may be more tourists in town than a typical week. We highly recommend getting your hotel rooms early.

MED DEVICE ONLINE

The Technology and News section of this newsletter came from our collaboration with Med Device Online. Our featured article was written by Len Czuba, who is a member of the Board of Directors for the Medical Plastics Division. If you are a subject matter expert on a topic that you think the readers of Med Device Online would be interested in, please send an email to jhfreedm@yahoo.com with a short description of the topic and your contact information.

CAREER CORNER

Career Corner is a new section of our newsletter that will be dedicated space for employers to post career opportunities that will reach the 1,000+ members of the Medical Plastics Division. If you are an employer and would like to use the newsletter to get the word out on potential career opportunities, please contact Jordan Freedman at mailto:jhfreedm@yahoo.com.

EVENTS CALENDAR

ANTEC Dubai	Jan 10-12, 2016
MD&M West	Feb 9-11, 2016
Polyolefin Conference	Feb 21-24, 2016
MINITEC-Charlotte	Spring, 2016
ANTEC 2016, Indianapolis	May 23-25, 2016
MINITEC-Minneapolis	Fall, 2016

If you are interested in promoting your event or webinar in the MPD newsletter, please send an email to mailto:jhfreedm@yahoo.com.

TECHNOLOGY AND NEWS: FEATURE ARTICLE

An Introduction to Emerging Polymers for Medical Devices

By *Len Czuba, President, Czuba Enterprises, Inc.*

I spend a great deal of time with engineers who are working on new medical devices. They often need help selecting the best material for the parts and devices they are developing, a polymer that will make their new product functional and safe. But more frequently the focus is on how much will the material cost and what will be the final cost of the device?

Depending on the type of device they are producing, the importance of material cost varies. For high-volume, single-use, devices, the material cost is of greater importance than in a reusable device or most implanted materials. Additionally, when the device being developed has unique requirements, developers must consider what material will have the necessary physical, chemical and biological properties that will allow its use at the lowest possible cost.

So my work in selecting a material often starts with a series of questions:

- **Cost** — "How much will you use in a year" and "What are you willing to pay for this material?"
- **Physical properties** — "What are the requirements for the material and/or the part made from our selected polymer?" "How will the part be produced from the material?" "Will it be injection molded, extruded or machined?" "What will the component or the device need to do in its final form?" "Will it need mechanical strength?" "Will it need to resist breakage and when exposed to forces during use?" "Does the device or this component need to be transparent or will an opaque material be satisfactory?" "How flexible or stiff does this material and the parts made from it need to be?"
- **Chemical and biologicals properties** — "Will it be exposed to chemicals during assembly (solvent bonding) or in use (disinfectants or cleaners)?" "Will it have any contact with the human body; skin, tissue, blood?" "How will it be sterilized?"
- **Regulatory concerns** — "Has the material been used before in other FDA-cleared devices or approved by foreign regulatory bodies for use in other parts of the world?"

With answers to these questions and, usually, many others that will come up during development, the engineers and development teams can, in a relatively short time, come up with candidate materials.

Some of the newer materials on my watch list include:

- **Ketone polymers –** Polyether ether ketone (PEEK) and some of its copolymer forms
- **Polyethylene and cyclic olefin copolymers (COCs) –** Specifically ethylene vinyl acetate (EVA)
- **Bioresorbables –** Polylactic acid (PLA), polyglycolic acid (PGA), Polycaprolactone (PCL) and the various copolymers that can be made by combining these and other starting ingredients
- **Fluoropolymers** –Specifically,polytetrafluoroethylene (PTFE), perfluoroether (PFA) and fluorinated ethylene propylene (FEP)

Most of these materials have been around for a long time but their suitability for use in medical

devices is only now being recognized and put to use.

PEEK Polymers

When PEEK polymers were first introduced, their high heat resistance, coupled with their remarkable inertness, made them an ideal material for applications that placed a device in contact with tissue and blood. PEEK polymers are not affected by most solvents, lipids or blood, and are completely unaffected by enzymes in the body. These properties make them ideal materials for long-term orthopedic implant applications such as bone screws, plates and pins, tissue anchors and suture screws.

More recently, PEEK has been used to replace metal as a hip stem component. As a metal replacement, the ketone polymers more closely match the flexibility of the native bone, especially when compared to steel or titanium hip replacement stems. That flexibility is vital as the bone into which the hip stem is placed tends to flex; a metal hip stem does not flex, resulting in its loosening over time, while PEEK components are not afflicted by this trait.

Although the PEEK polymers have been available for almost 25 years, it is only in the last 10 years that PEEK has been widely accepted for long-term, in-body applications. One of the reasons for its slow growth is that it is extremely expensive and has been subject to limited availability. Invibio has been the recognized supplier of PEEK since it first appeared in the market. But more recently Solvay and Evonik have emerged as suppliers of this specialty material. I am happy to see that there are more suppliers of such a unique material and expect that, with competition, the cost of the polymer may even moderate from its current pricing.

Polyethylene And Cyclic Olefin Copolymers

Polyolefin copolymers such as EVA and COCs offer new options for products traditionally made from other materials. For only a slight cost increase, EVAs offer many advantages. For example, the flexible grades do not have, nor do they need, plasticizers. Likewise, COCs are a remarkable material spanning a range of flexibility, at a reasonable cost. COCs can be used for containers, replacing glass or polyester and they are inherently cleaner, very clear and solvent resistant.

However, neither EVA nor COCs are readily solvent bondable so assembly to tubing or other polymers - as connectors for fluid administration sets, for example – likely would need to be done with either cyanoacrylates or UV light-cured adhesives. These adhesives are readily available from Dymax, Permabond, Loctite and others. EVA polymers are available from a number of suppliers including Celanese, Mitsubishi and LyondellBasel. C OCs are supplied by Topas and others.

Bioresorbables

One of the most exciting areas of new material development in the device community is bioresorbables. One of the first to be investigated has been PLA. As a suture material, PLA will maintain its strength until the liquids with which it is in contact begin the dissolution process, eventually leading to the PLA's complete elimination from the body.

The other bioresorbables are polyglycolic acid (PGL), polycaprolactone (PCL) and several other copolymers. Together, they offer the medical device community a material that can perform a number of different applications. These materials, too, can be used as bone screws, small orthopedic plates or rods but they typically do not have the physical properties

needed for any high-stress applications (e.g., bone reconstruction).

However, these materials are idea when used as tissue anchors, vascular stents or internal meshes that allow cell seeding and reconstruction of an organ as in repairing a perforated heart. Tissue and organ scaffolding are some of the most recent applications well-suited to these unique materials. Another possible area of increasing use will be drug delivery. These applications comprise some of the most exciting opportunities in the area of medical polymers.

Current suppliers of the bioresorbables include Purac and Boehringer Ingelheim.

Fluoropolymers

Fluoropolymers are wonderful materials that come in many combinations and in many different forms. Most everyone knows about the common fluoropolymer, polytetrafluoroethylene (PTFE) originally marketed by DuPont with the tradename Teflon. In the medical device industry PTFE in its solid form can be used for in-body applications because it is very clean and inert in blood or tissue. But the material is very soft and is not useful for any load-bearing applications.

In forms other than solid, PTFE can be made into porous membranes or rods or tapes. These membranes can be used as filters, non-fouling surfaces or hydrophobic surfaces. Other forms of the fluoropolymer such as perfluoroether (PFA) and fluorinated ethylene propylene (FEP) polymers are melt processable by either extrusion or injection molding. Although the materials are difficult to process, products made from them have interesting properties such as inherently non-stick surfaces, high gas barrier properties and in some, transparency.

Suppliers of these polymers for the medical device industry are Daikin Americas, 3M Corp.and W.L.Gore & Associates.

Other Promising Materials

Among the emerging materials of interest are a few traditional, or legacy materials that are being redesigned to improve their properties for specific applications: These include polyesters, urethanes and improved thermoplastic elastomers (TPEs). TPEs are compounds based on polyolefin technology.

For both polyesters and polyurethanes, the breadth of material properties is dependent on the chemistry used to produce the polymer. Polyesters can be made rigid for bottles and containers, like the widely used polyethylene terephthalate (PET) polymer or made flexible with properties that closely match flexible polyvinyl chloride (PVC). The ability to engineer polyurethane polymers to a wide spectrum of properties allows them to be considered for almost any application. They can be soft enough to replace PVC in tubing or sheeting, or to serve as a soft gel-like wound covering, or they can be extremely rigid, like wheels or bumpers on carts.

Both the polyesters and the polyurethanes offer many of the properties common to some of the more widely used polymers, but at a significant cost penalty – two, three or even four times the cost of the polyolefins or flexible polyvinyl chlorides now being used. Suppliers of polyesters for the medical device market include Eastman and DAK, while polyurethanes are available from DSM (formerly known as PTG) or Lubrizol (formerly known as Thermedics).

The Right Material Requires The Proper Manufacturing Technique

The combination of one or more of these newer, non-traditional polymers coupled with evolving manufacturing methods opens new pathways for sophisticated medical devices. Researchers are working on dissolvable sensors with electrically conductive circuits which function in tissue or the bloodstream for a predetermined period of time before being absorbed into the host tissue and then are eliminated from the body via its normal processes.

Some exciting new processing technologies are also helping change the landscape of new product development. The ability of additive manufacturing to produce functional parts with some of the high-temperature materials such as PEEK or polyphenylsulfone (PPSU) for long-term implantable components is just one such enabling technology. Another additive manufacturing process allows multiple materials, with different colors or different stiffness to be combined into a single part. A third additive manufacturing application takes advantage of high temperature materials making possible new mold-making methods that can incorporate features like conformal cooling in the mold as it is being made. Traditional cooling requires adding cooling channels to a mold after it is made, often resulting in significant temperature differences in non-cooled areas of the mold. The additive manufacturing process also can be used with high-temperature polymers to quickly make entire prototype molds, similar to metal molds, usable for producing limited-run injection-molded thermoplastic parts!

Other new processes that are giving extended properties to molded parts include the powdered metal and powdered ceramics injection-molding processes. By combining these manufacturing techniques with the newest materials technologies, manufacturers can create higher-temperature components that are often more resistant to wear, are more resistant to adverse chemical exposure and are usable in high-temperature environments.

Non-stick surface technology developed at MIT, and now commercially available fromLiquiGlide is made possible by engineering the surfaces in a way that prevents even viscous liquids from adhering to the wall of containers. A similar effect is obtained using a fluoropolymer additive from Daikin America. The additive is used with polymers used to create bottles or other containers for high-value contents such as specialty biopharmaceuticals, (e.g., Botox and similar very expensive fluids) where any residual product in the container is the equivalent of losing hundreds or thousands of dollars of product. This same additive may have applications in medical devices that could benefit from a non-stick or anti-adhering surface, for example, non-fouling catheters to resist thrombus formation or other surface build-up.

Conclusions

There are so many exciting new materials and processing techniques that, alone or in combination, will enable the healthcare industry to create innovative, next-generation products. They will allow more effective treatments and the promise of better patient outcomes.

This article first appeared on
www.meddeviceonline.com.

TECHNOLOGY AND NEWS

What Medical Companies May Be Overlooking When It Comes To Finished Device Assembly

Assembly is an integral part of the device manufacturing process; yet when companies design and develop their devices, assembly is rarely considered. Design for manufacturability and assembly (DFMA) is what sets premier contract manufacturers apart from the traditional medical device "job shops".

Medical Device Industry Playbook: Accelerating Innovation In A Perfect Storm

This playbook explores the medical device industry's most significant challenges and opportunities in innovation while sharing leading practices and key recommendations.

Solvent Tube Bonding

As medical devices become more sophisticated and complex in performance and structural complexity, solvent bonding is used in making permanent connections within plastic part assemblies. This method can dramatically reduce costs while producing aesthetically pleasing joints with low weight and sufficiently strong connections. The process of bonding medical components involves a thorough understanding of the design process, material compatibility, performance testing, assembly methods, and regulatory affairs.

For additional articles and content on medical device news, visit www.meddeviceonline.com

MED DEVICE ONLINE

Want to contribute?

We are always looking for new technologies and new perspectives to present to the MPD membership. If you have an interest in publishing in the newsletter or Med Device Online, please contact our communications team at jhfreedm@yahoo.com.

COMMUNICATION TEAM NOTES….

We hope you enjoyed this November issue of the MPD Newsletter! At the end of this newsletter is the communication plan for 2016. We hope to be more involved with social medial through The Chain and make use of the MPD website more. This plan should help us get on a regular schedule. If you have any suggestions on ways for us to improve the communication, please contact us at jhfreedm@yahoo.com. Until next time, Happy Reading!

MPD Communications Team

MEDICAL PLASTICS BOARD OF DIRECTORS

The volunteers that make up the Board of Directors are listed below, along with their contact information. We appreciate all our volunteers and we thank you for your involvement in the Medical Plastics Division of SPE. If you are interested in participating or would like more information, please reach out to anyone on the board. We look forward to hearing from you!

Name	Position	email
Norris M. Tollefson	**Chair**	norris.tollefson@alcon.com
Mark Bonifacio	Past **Chair**	mark@bonifacioconsulting.com
Ben Poon	Secretary	benjamin.poon@baxter.com
Austin Coffey	EU Rep.	austin.coffey@gmail.com
Pierre Mouline	Tech. Program Com.* **Chair**	pierre.moulinie@bayer.com
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Bob Herman	Education Com. **Chair**	quarkreh1@gmail.com

*Com. Is shorthand for Committee.

MEDICAL PLASTICS DIVISION 2016 COMMUNICATION PLAN

Purpose:

The purpose of this document is to define the elements of the Medical Plastics Division (MPD) communication plan including guidelines for newsletter, e-mail blasts, and website content. This document will also define requested contributions from the other functional groups within the MPD and timelines for receiving said contributions.

Scope:

This plan is limited to the MPD newsletter, the MPD website, and e-mail blasts. Guidelines social media (The Chain) content will be held in a separate document.

Communication Objective:

The objective of the communication vehicles laid out in this plan is to provide current, accurate, and value-add information to the MPD members about advancements in the medical plastics field, upcoming events, and MPD and SPE news. For upcoming events, the content should be geared towards cultivating excitement around the different events that MPD offers and to get people out and involved.

Newsletter:

To comply with SPE rules on member communication, the Communications team will publish a Newsletter every calendar quarter in 2015 with the following target cadence:

Calendar Quarter	Target Publish Date	Target Date for Content
Q1	February 9	January 20
Q2	April 20	April 10
Q3	July 13	July 3
Q4	October 12	October 2

The Newsletter will contain the following sections at a minimum (not necessarily in this order):

- **Letter from the Chair**
- **Table of contents**
- **Feature Event:** This will include either wrap ups from recent events or articles to drum up interest in up-coming events.
- **SPE Event Calendar**
- **SPE News:** This section will be news from the SPE Council Meetings and other SPE highlights (example: Feature on "The Chain")
- **Technology News:** This will be an article about new technology in the medical plastics field. These could be written by anyone in MPD. For the Q2 edition of the newsletter, this section will feature the ANTEC papers that won the "best paper" awards.
- **Board Member List**: This will consist of a list of all MPD board members and their contact information.
- **Get to Know Your Board Members**: With each edition starting in Q2, there will be a small section where a board member will be featured with a small section on their roll in SPE, how many years they have been in SPE, and some information about them.

Additional content can be added on an as needed basis such as announcements for awards, or election results. The newsletter will use a magazine type compact format. The goal will be to keep the content to around 8 pages.

Newsletter Content Timing:
In order to ensure that each newsletter contains the appropriate sections, it is requested that information to be added to the newsletter be provided to the newsletter editor by the target dates listed in the table above.

Website:
A MPD website will be created in 2015 where the content can be edited and controlled by the communications team. The website will house the following information and will serve as the information archive for MPD.

- Copies of the quarterly newsletter
- Board of Director Meeting Minutes
- Past Programs from MPD Events
- Councilor Reports
- Contact information and bios for all MPD board members

Goals for content updates will be set by the webmaster.

E-Mail Blasts:
For contacting MPD members between newsletters, SPE offers E-mail blast services. These are typically short emails that promote an upcoming event, or requests for papers and speakers. If you would like to do an email blast, please email the content of the email to the newsletter editor. E-mail blasts go out every Monday. Each e-mail blast should include the proper SPE logos and heading (provided by newsletter editor).