Society of Plastics Engineers
Medical Plastics Division
Newsletter
4Q2019

GREETINGS FROM THE CHAIR

Dear Fellow Medical Plastics Division Members:

Welcome to our year-end newsletter!

I hope that everyone is enjoying the holiday season with family and friends.

Elections for the Board of Director positions will be held in January. Please consider running for the election as we are always looking for new talent to serve on our board. If interested, then send your bio and photo to Pierre Moulinie (pierre.moulinie@covenstro.com) so that you can be included in the ballot for the election.

We have two exciting events planned in first quarter of 2020, namely MiniTec during the MD&M Show in Anaheim, and ANTEC in San Antonio. I would like to thank the technical programming committee for organizing both these events with excellent topics and speakers.

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Inside This Edition…

GREETINGS FROM THE CHAIR

Continued from the previous page…

As always, thank you to all our sponsors! We welcome more sponsorship from companies to display their information in our award-winning newsletter. In addition, we can also circulate the information by various social media forums.

We have a strong membership following which has been steadily growing. I would like to make sure that our division becomes stronger so please remember to renew your Annual Membership.

Finally, I am very thankful to all our Board of Directors for working hard to make several contributions for the Medical Plastics Division.

Enjoy the highlights that are summarized in the Newsletter!

Please send me a note if you have any suggestions to improve our division.

Happy Holidays!

At your service,

Vipul

Do you have questions about MPD Membership?

Please email Ravi Ayyar
rayyar@lilly.com

Are you interested in volunteering for the BOD?

Please email Vipul Davé
VDave1@its.jnj.com

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- rayyar@lilly.com

Ed Fewkes, Corning

- Membership Committee
- fewkesej@corning.com

Ajay Padsalgikar, DSM

- MPD Technical Program Committee
- Ajay.Padsalgikar@dsm.com

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- somlai_louis@lilly.com

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- m_hanna@yahoo.com

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- Secretary; Technical Program – Webinars
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- VDave1@its.jnj.com

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- Past Chair
- pierre.moulinie@covestro.com

Len Czuba, Czuba Enterprises

- Councilor
- LCzuba@CzubaEnterprises.com

Kathy Schacht, SPE

- SPE Liaison
- kschacht@4spe.org

Are you interested in volunteering for the BOD?

Please email Vipul Davé
VDave1@its.jnj.com

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Ali Ashter (’21)
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- Webinars & MiniTec Lead: Ned LeMaster (‘21)

Are you interested in volunteering for the BOD?

Please email Vipul Davé
VDave1@its.jnj.com

CALL FOR ELECTIONS

ANTEC 2020 is just around the corner, which means time for elections! An email notice to the MPD membership will be coming out in the next few weeks.

Serving on the BOD is a volunteer position and requires your attendance at monthly teleconferences / meetings, committee service, and attending our annual MPD face to face board of directors meeting at ANTEC.

SPE MPD members in good standing can submit their interest in running for open board of director positions by reaching out directly to Pierre Moulinié (pierre.moulinie@covestro.com).

Are you interested in running for the upcoming election?

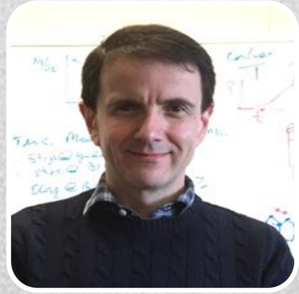
Please email Pierre Moulinié
pierre.moulinie@covestro.com

SPE MPD BY-LAWS REFRESH COMMITTEE

At ANTEC 2019, a Leadership Roundtable organized by SPE Pat Farrey for Division Board Members reviewed obligations required by Divisions as well as elected board members. This training session included reading material to help Board of Directors better understand how to serve in leadership roles in non-profit organizations.

Those in attendance felt strongly that it was time for the MPD Board of Directors to re-examine and update our division By-Laws & kicked off an ad-hoc committee to do a comprehensive review of our MPD existing bylaws & propose updates and amendments or changes, as appropriate.

The ad-hoc committee is composed of Pierre Moulinie (Covestro), Len Czuba (Czuba Enterprises), Maureen Reitman (Exponent), and Louis Somlai (Eli Lilly).




The committee is making excellent progress and is on track to propose a substantive update to the Board of Directors for consideration by the Membership by the end of 4Q2019.

GREETINGS FROM THE NEWSLETTER EDITOR

Greetings fellow MPD Members!

Welcome to the latest edition of our award winning newsletter! I appreciate your efforts to help me improve this communication tool; please send feedback my way: somlai_louis@lilly.com

Once again another year has come and gone! I know it's rather cliché, but time really does fly when you're having fun! I'm shocked to be writing this note to you with the realization that 2020 is just around the corner… which means ANTEC 2020 is coming soon. I look forward to seeing all of you in San Antonio, Texas.

For those members planning to attend the Medical Design & Manufacturing Expo (MD&M West) 11-13 FEB 2020: please consider traveling 1 day earlier to attend our 3rd annual MPD MIniTec. This year's theme is "Emerging Materials & Technologies in Medical Devices" – please see the advertisement within the newsletter!

The 1Q2020 newsletter will be dedicated to the upcoming MPD Board of Directors elections. Are you interested in serving our members on the BOD? We are seeking SPE MPD members in good standing who might be interested in serving on specific committees (finance, education, membership, and awards); if interested, please reach out directly to Pierre Moulinié (pierre.moulinie@covestro.com).

As always, your board has recognized the need to increase sponsorship for the division. If you are aware of a firm or organization that would benefit from sponsoring our newsletter please let them and me know. Please our directly to me (Somlai_louis@lilly.com).

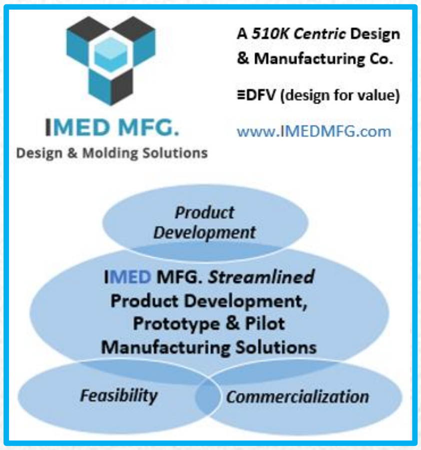
Best regards,

Louis

Newsletter Suggestions? Interested in Sponsorship?

Please email Louis Somlai

somlai_louis@lilly.com



Please welcome IMED Manufacturing
our newest SPE MPD newsletter sponsor!
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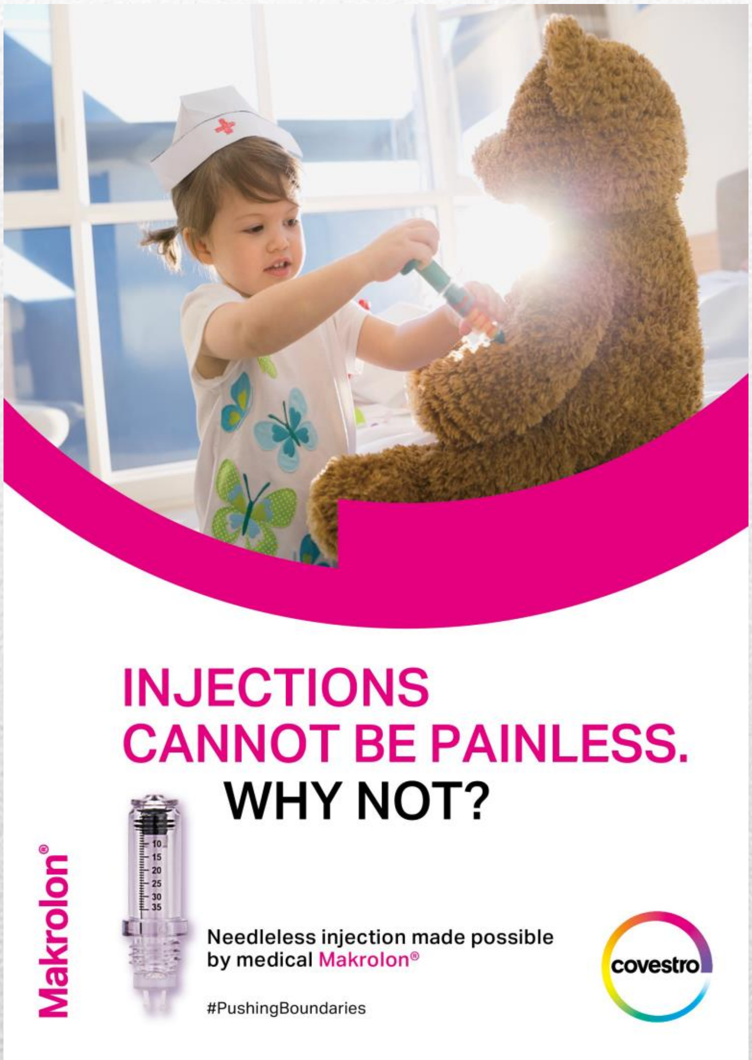
somlai_louis@lilly.com



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MPD NEWSLETTER SPONSORSHIPS

Sponsors…

We are 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, please consider taking part in this important communication support effort.

Sizes Available	(Full Year 2020; 4 issues)	
	Full page (8.5"x11")	*$1,500*
	Half page (4.3"x5.5")	*$850*
	Quarter page (2.1"x2.8")	*$450*
	Eighth page (1.1"x1.4")	*$250*

The newsletter, as scheduled, is prepared and circulated **four times per year** (*quarterly*). Every Medical Plastics Division member receives a copy emailed directly to their listed address. Additional copies are also circulated (via the Chain) and broader social media (LinkedIn, Twitter) in our continuing effort to reach new and prospective members and other interested individuals.

To show your support please contact Louis Somlai at 317.209.4719 (email: somlai_louis@lilly.com).

Thank-you for your support!

Newsletter Suggestions? Want to Advertise?

Please email Louis Somlai
somlai_louis@lilly.com

Medical Plastics Division Councilor Report

Dear Fellow Medical Plastics Division members,

SPE Council met at a face-to-face meeting in mid-November in Bethel, CT. This meeting was held at the new SPE headquarters and coincided with a ribbon cutting ceremony and welcome reception by the local Chamber of Commerce of the area. This new location offers SPE and our various chapters (Sections / Divisions / SIGs, etc.) the opportunity to hold meetings, training seminars and other activities at the facilities available at this new location. I believe that this was a good move and positions SPE for growth for years ahead.

There were 53 Councilors or Councilor proxies in attendance of the 78 chapters in SPE. With 9 of the Executive Board and 4 staff members, the meeting was very well attended. The agenda covered the many activities which we all are involved in including ANTEC, various conference events, communications and membership growth. The EB proposed a governance restructuring but met with concerns voiced by Council. More discussion was held on the need to change in order to streamline decision making and helping SPE become more responsive to needs of our industry. It was finally decided that the existing structure would remain the same while continuing to allow Council to have final authority to reverse decisions made by the EB if deemed unacceptable.

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COUNCILOR'S REPORT

Finances continue to be a challenge and although 2019 is expected to close in the black thanks in large part to investment performance, the 2020 budget was presented showing a projected shortfall of almost $500k. Both staff and the Executive Board with help from Council are looking for ways to close this gap although some spending is related to investment into systems that will offset later expenses such as software upgrades.

CEO Pat Farrey shared his continued challenge to come up with a fee-for-service model that would offer HQ help to Sections and Divisions with a structure that can both support the chapter activities but also not over-charge yet be a reasonable payment for service that HQ staff is providing. Details are still being worked out.

Mr. Farrey also proposed that SPE chapters consider joining the 5-year old program "Plastics for Life" competition that is held every year at ANTEC. This contest could be a significant income stream for SPE but would need involvement from the various Divisions to have local "roll-out" competitions that would then be rolled up into the ANTEC competition for final level of competition. This program will be worked on for implementation in the near future. (I volunteered to be part of the Task Force that would help put this competition together. I am waiting for next step action.)

Continued on next page…

There were a variety of other business topics addressed including minor updates to our Bylaws, updates from Sections and Divisions committees and the chair of the Council Committee or the Whole. We were also given an update on plans for the upcoming ANTEC in San Antonio, TX and various activities being planned for student involvement in both ANTEC and SPE in general.

Copies of all the presentations made to Council are available for viewing by MPD board members on the Chain. (https://community.4spe.org/communities/community-home?CommunityKey=b22502ab-c825-4ec3-ae83-747b7b5175a2). Check on files in the "Latest Shared Files" area near the bottom. There are 12 presentations plus the minutes which summarize the meeting. If you have any questions, let me know. I welcome your feedback, comments or questions.

Our next Council meeting is scheduled the weekend before ANTEC in San Antonio.

Best regards,

Len Czuba
Medical Plastics Division Councilor
SPE President 2005 - 2006
Distinguished Honored Service Fellow of SPE

TREASURER'S REPORT – Ali Ashter
Last Updated 25DEC2019

Balance as of October 17, 2019	$ 27,783.96

INCOME

Income Type	Amount
Newsletter Sponsorship - IMED	$ 386.00
Newsletter Sponsorship	$ 723.75
TOTAL INCOME	$ 1,109.75

EXPENSE

Expense Type	Amount
TOTAL EXPENSE	$ -

FUNDS AVAILABLE AS OF December 25, 2019	$ 28,893.71

Do you have questions about the Treasurer Report?

Please email Ali Ashter
ashter2000@gmail.com

The Medical Plastics Division and Webinar Team plans to host a series of webinars during 2020, with a goal of at least three to four. Some of the topics in consideration include: Advances in Medical Tubing Materials, Drug Delivery and Implantable Materials, Materials for Excipient Release, Relevant Changes in Regulatory Directives, Biodegradable & Resorbable Polymers in Med Device, Best Practices for Introduction of New Polymers in Med Device, Speed to Market through Improved Development, and Advances in Friction Reducing Materials. We are even considering a series on project management.

We welcome your interest to participate, as well as suggestions for topics and/or speakers. Please contact the MPD Webinar team:

Pierre Moulinié (pierre.moulinie@covestro.com),
Victoria Nawaby (nawabyv@hotmail.com)
Ned LeMaster (ned.e.lemaster@dupont.com)

Reaction Injection Molding of Polyurethane Medical Device Components

Ian Pierson and Ajay Padsalgikar, Abbott Laboratories, Rogers, MN

Abstract

Polyurethanes (PU) are widely used in the medical device industry due to their desirable combination of biological compatibility and stability, mechanical durability and processability [1-4]. Components forming a medical device are often small in dimension and intricate in structure, and a common operation in medical device manufacturing is the bonding of different device components to each other or an additional substrate. The manufacture and assembly of these intricate device components requires complex molds and molding methods. The bonding operations can be achieved via a number of methods, including welding processes, adhesive bonding, and thermoplastic reflow. However, these methods have limitations on bond strength and stability, and frequently require the introduction of a new material into the device. In this paper, we examine the potential to use and optimize reaction injection molding of medical PUs to create an intricate part and a bond between multiple components in a medical device.

Introduction

PUs are segmented copolymers, consisting of microphase separated hard and soft domains [4]. The hard segment is typically formed from the reaction of a diisocyanate and a low molecular weight curative. The relatively flexible soft segments typically consist of a higher molecular weight macrodiol or polyol.

The polymerization reaction in PUs can proceed through either a one-step process or a two-step process [4]. In a one-step process, all the raw materials for the synthesis are added at once, whereas, in a two-step process, the polyol is first reacted with an excess of isocyanate to produce an isocyanate end-capped pre-polymer. The pre-polymer is then reacted with a stoichiometric quantity of the short chain curative. The pre-polymer is typically considered the soft segment and the reaction of the pre-polymer with the curative as the formation of the hard segment.

In a reaction injection molding (RIM) system, the curing step takes place inside of a mold, creating the final PU material in a desired shape. Prepolymer and curative are dispensed through a mixer and injected into the mold, remaining liquid long enough to fill the mold cavity (Figure 1). After injection, the liquid mixture finishes curing, often at elevated temperature, creating a solid part in the shape of the mold. Once curing is completed, the mold can be removed and the solid part, made of completely cured PU, is left behind.

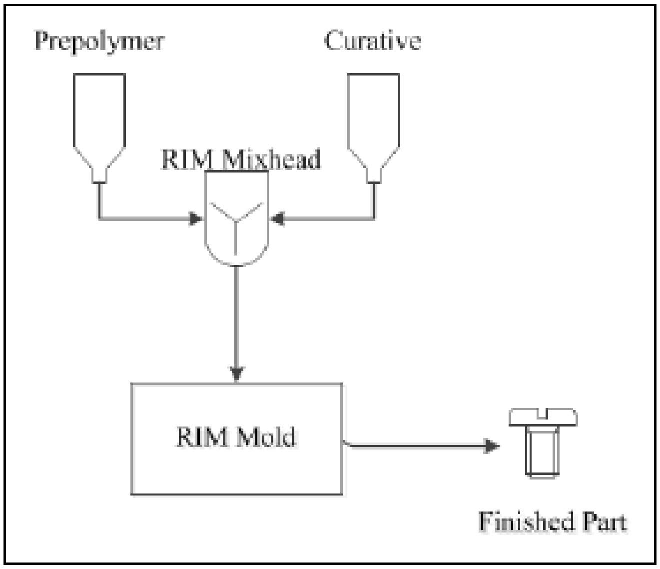


Figure 1: General schematic of a reaction injection molding system.

During the dispensing and injecting step of RIM, it is critical to ensure that the prepolymer and the curative are thoroughly mixed. Due to the high degree of incompatibility between the prepolymer and the curative, the materials do not readily mix into each other. Instead, the reaction happens at the interface of the two materials, requiring thorough mixing to increase the interfacial area [4]. Without thorough mixing, the reaction will either be slow, increasing cycle times for a RIM process from hours to days. Poor mixing may also produce an incomplete reaction, resulting in weakened or unusable parts. In addition, the reaction must be sufficiently completed to allow demolding of a part after injection. Without the proper reaction extent, the part may stick in the mold, creating issues with cleaning and part dimensions.

RIM systems are commonly used to produce large, polyurethane foam parts, particularly in the automotive industry. In the medical device industry, parts are typically solid instead of foamed, as well as much smaller in size. Medical device parts also come with additional requirements, such as biocompatibility and dimensional precision. These requirements add additional importance to confirming that the curing reaction is fully completed, ensuring that the final parts obtain the material properties required for their applications.

As the components are mixed in a RIM mixhead, the viscosity of the mixture is low enough not to require the high clamping forces used in conventional injection molding. Also, the mixture is delivered to the mold at relatively low temperatures allowing the use of temperature sensitive substrates for insert molding. The low viscosity of the mixture allows the manufacture of precisely dimensioned and intricate parts often required for medical applications. Another possible application of RIM to medical device assembly is the creation of a strong, stable bond between multiple parts of a medical device. The process involves the injection of the prepolymer and curative through a high shear mixer and into a fixture surrounding one set or multiple sets of pieces to be joined. The material would flow around the joint and surround the materials to be joined. After injection, the material would react and solidify, bonding the two pieces together. RIM bonding is low pressure and low temperature, allowing for a bonding process that does not damage the components being bonded.

Materials

All testing was performed using a material in the Steralloy™ "E-Series" family, a two part liquid urethane rubber kit (parts A & B) produced by Hapco, Inc. Steralloy is a food and drug grade liquid molding compound, used to create a wide variety of production parts and custom medical devices.

Steralloy™ part A is primarily comprised of the urethane prepolymer which is derived from *dicyclohexylmethane 4,4'-diisocyanate* (hydrogenated MDI or *HMDI*) having two terminal isocyanate groups per molecule and *polypropylene glycol (PPG)* with two hydroxyl terminal groups per molecule. Part B is a mixture of a diol, namely 1,4-butanediol (BDO), and a triol, namely trimethylolpropane propoxylate (TMP) that are commonly used to formulate various urethane elastomer materials. Upon mixing and curing of parts A and B, the material attains a hardness of approximately 90A.

Experimental

Several methods were used to evaluate the polyurethane curing reaction, and the effects of mixing and curing temperatures on the rate of the reaction.

RIM System

The reaction injection molding process was carried out using a Polytec DG-105 dispensing unit. The dispensing unit consists of two gear pumps to accurately dispense prepolymer and curative at the specified ratio into the system mixhead. To ensure adequate reaction and maintain pumping ability, the tank and tubing for the prepolymer are heated to the temperature specified for a given run. The mixhead consists of a tunable air motor, used to spin a high shear rotor up to several thousand RPM inside of the fixed dispensing tube. The mixed material exits the bottom of the rotor, where it is dispensed directly into a mold to create a desired part. For experimentation purposes, the mixed material was dispensed into a small sample cup to allow for direct measurement of material properties.

ATR System

An adiabatic temperature rise (ATR) system was developed to provide a semi-quantitative comparison of reaction speed and extent between various RIM process conditions. An ATR system works by allowing the curing reaction to proceed within a defined space that minimizes heat transfer out of the system. Due to the exothermic nature of the curing reaction, heat is generated and the extent of reaction can be correlated with the temperature rise measured within the system. As the reaction rate increases, more heat is generated in a shorter amount of time. For a given sample size, a more rapid reaction will result in a higher maximum temperature observed in a shorter amount of time.

The ATR system was constructed of several layers of polystyrene foam, to minimize heat transfer to the environment and create near-adiabatic conditions inside the system (Figure 2). After equilibration of the system at the reaction temperature, approximately 20 mL of material was dispensed from the RIM machine and the system was sealed while the curing reaction proceeded. Two thermocouples inside of the system measured the temperature rise, with data recorded via an attached data logger. The reaction was allowed to run until a maximum temperature was reached, then the system was disassembled to prepare for the next test.

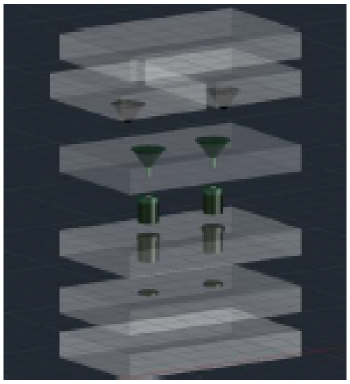


Figure 2: Expanded schematic of the ATR system.

Rheology

Rheological characterization of the curing mixture was performed using a Haake RheoStress 1 rotational rheometer. Immediately after dispensing from the RIM system, a sample was withdrawn from the bulk material using a 1 mL syringe. Approximately 0.4 mL of sample was placed on the preheated stage, and the cone lowered into the sample to begin testing. Using the heated stage on the rheometer, each sample was maintained at the desired curing temperature specified for a given experimental run. Testing was performed at a shear rate of 1/s and allowed to run until viscosity exceeded at least 500 Pa s, then manually halted. Viscosity values were recorded throughout the duration of the testing period.

FTIR

Fourier transform infrared spectroscopy (FTIR) was used to quantitively track the extent of the curing reaction after mixing. A Perkin Elmer Spectrum Two with Attenuated Total Reflection accessory was used for testing of all samples, both liquid and solid. After mixing, a small sample was removed from the bulk sample and placed on the ATR crystal for analysis. If the sample had solidified due to the curing reaction, the bulk sample was cut open with a razor blade and a portion of the exposed surface was analyzed with the FTIR system.

Throughout the curing reaction, isocyanate is reacted with hydroxyl to form the urethane bond; as the cure progresses, the amount of isocyanate is decreased until it is entirely reacted. After measurement was completed for each timepoint, analysis of the extent of reaction was based on the disappearance of the sharp isocyanate peak near 2260 cm^{-1}, as shown in Figure 3 [5]. To ensure accurate analysis, all samples were automatically baseline corrected and normalized to the 1375 cm^{-1} peak, corresponding to the stable alkane C-H bend bond [5]. All analysis was completed within the included Spectrum software.

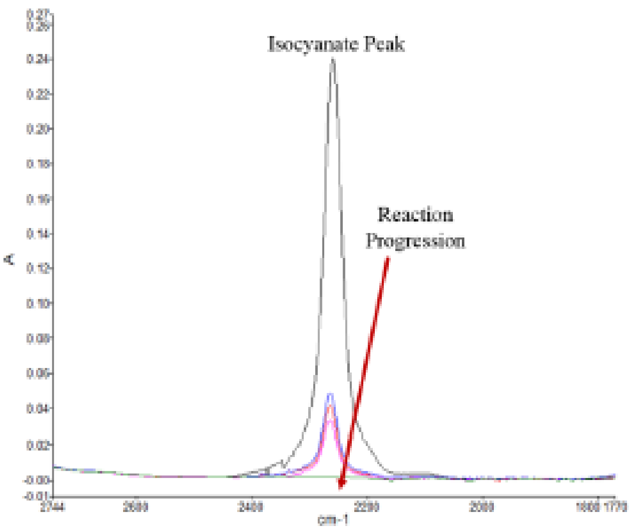


Figure 3: Compilation of FTIR spectra showing the disappearance of the isocyanate peak as the curing reaction progresses.

Results and Discussion

Several variables were modified within the molding process to determine their effect on the curing reaction rate and overall curing time. After experimentation, test coupons were molded to determine the viability of creating complex parts with RIM.

Effect of Mixing Changes

Changes were made to the mixing process to determine the effect on reaction rate and final reaction equilibrium. First, the mixing speeds of the rotor within the high shear mix head were varied, with curing tested at 240, 1550, and 2350 RPM. Rheological testing and FTIR tracking were used to determine the effect of these changes on the curing reaction. Surprisingly, the reaction rate was not observed to be strongly dependent on the mixing speed used. Figure 4 demonstrates a steady, exponential increase in the shear viscosity of the reaction mixture, regardless of which mixing speed was used.

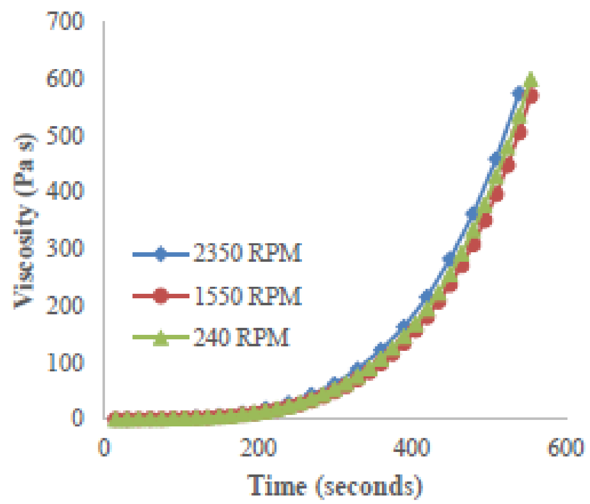


Figure 4: Viscosity of curing material after mixing at different agitator speeds; all testing conducted at 60 °C.

FTIR tracking of the isocyanate peak indicated a similar trend, as shown in Figure 5. During the first 5 minutes after mixing, the higher mixing speed appeared to increase the rate of isocyanate disappearance. However, after 60 minutes, the materials had reached the same reaction point regardless of mixing condition. In addition, all samples reached an absorbance near zero, indicative of complete reaction of the isocyanate, after 24 hours at the curing temperature, as shown in Table 1.

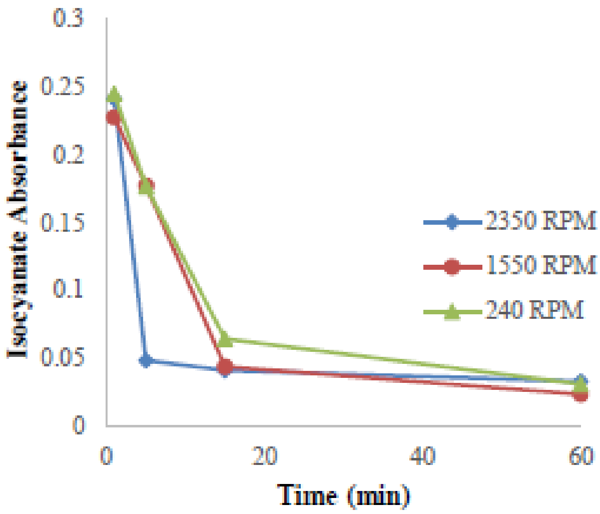


Figure 5: Effect of mixing speed on the reaction of isocyanate, measured by tracking the normalized FTIR absorbance of the isocyanate peak. All samples were cured at 60 °C.

Mixing Speed (RPM)	Isocyanate Absorbance at 24 hours
240	0.0038
1550	0.0034
2350	0.0022

Table 1: Normalized isocyanate absorbance of each sample at the 24-hour timepoint.

Measured FTIR and viscosity data both indicate that the speed of the mixer does not affect the rate of the curing reaction for this urethane system. This likely means that, even at low speeds, the active mixing used creates adequate interfacial area to allow the curing reaction to proceed at its maximum rate. For this material, the reaction rate is limited by the chemistry of the reactants, and not by the mixing and interfacial area limitation observed in some formulations.

In addition to mix speed, two different mixhead sizes were evaluated with ATR and rheological measurements to determine the effect of total mixing time at maximum speed. The nominal mixhead, approximately 4.3 mL, resulted in a shorter residence time for the material as it was pumped through the mixer. The larger mixhead, approximately 18.6 mL, resulted in a higher residence time for the material. With a constant pump speed of approximately 850 mL/hour, residence times were calculated as 0.30 and 1.30 minutes, respectively. Table 2 shows the difference in maximum temperature and time to reach maximum temperature between two samples mixed with the two different mixhead sizes. Material mixed for longer showed a higher maximum temperature in the ATR system, and reached the maximum more quickly, indicating a more rapid reaction.

Mixhead	Mixer Volume (mL)	Residence Time (min)	T_{max} (°C)	Time to Reach T_{max} (min)
Nominal	4.3	0.30	89.2	15
Large	18.4	1.30	113.5	7

Table 2: Data from ATR testing with both nominal and large mixheads.

Similarly, material mixed with the larger mixhead showed a more rapid viscosity rise, as increased interfacial area between the components allowed the reaction to occur more rapidly. Figure 6 shows the viscosity rise measured for both conditions. Also shown is the "corrected" viscosity measurement for the large mixhead, where 60 seconds has been added to the viscosity measurement to account for the extra residence time of the larger mixhead. Even with this extra reaction time accounted for, it is clear that the additional time spent mixing resulted in a more rapid polymerization.

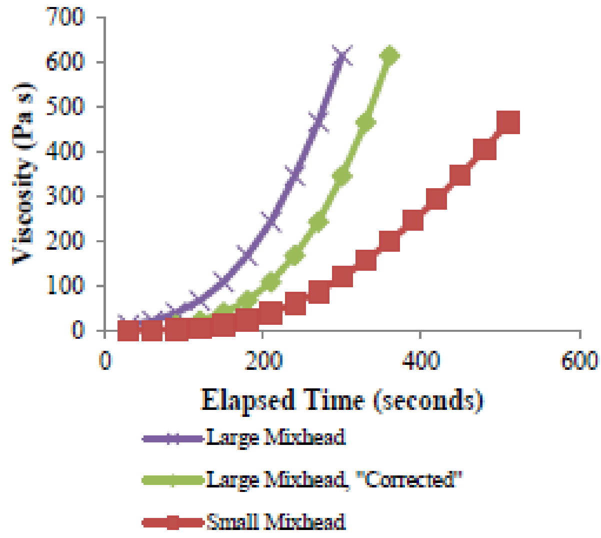


Figure 6: Comparison of viscosity of curing material up to 500 Pa s after mixing with different mixheads.

The observed increases in reaction rate with increased residence time were likely due to an increase in the amount of time that the high shear mixing was maintained between the two components. Although mixing speed by itself was not shown to increase the reaction rate, additional time at the high shear rates can increase the reaction rate by providing more time for the two components to diffuse into each other. As opposed to the increased interfacial area provided by higher speed mixing, additional time in the mixing chamber allows the reaction to proceed more quickly even after exiting the mixhead, because the reactive components have greater opportunity to diffuse into one another.

Effect of Reaction and Curing Temperatures

The temperature of dispensed material and of the curing process were also varied to determine the effect on the rate of the curing reaction. Three temperatures were evaluated: 45, 60 (nominal), and 75 °C. Rheological measurements show a rapid increase in viscosity for all conditions, with higher temperatures demonstrating a more rapid viscosity rise (Figure 7).

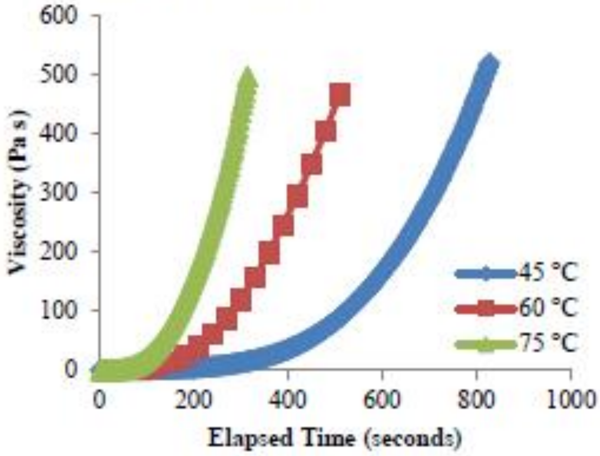


Figure 7: Comparison of viscosity of curing material at different dispensing and curing temperatures.

Similar trends were observed from FTIR data collected during the curing reaction, with elevated temperatures resulting in an accelerated rate of isocyanate disappearance, as shown in Figure 8. At 75 °C, the reaction proceeds most rapidly during the first 5 minutes, before slowing down as isocyanate is consumed. After the 24 hour curing time, no difference is observed between the 60 °C and 75 °C cured material, but a small amount of residual isocyanate remains for the 45 °C cured material, as shown in Table 3.

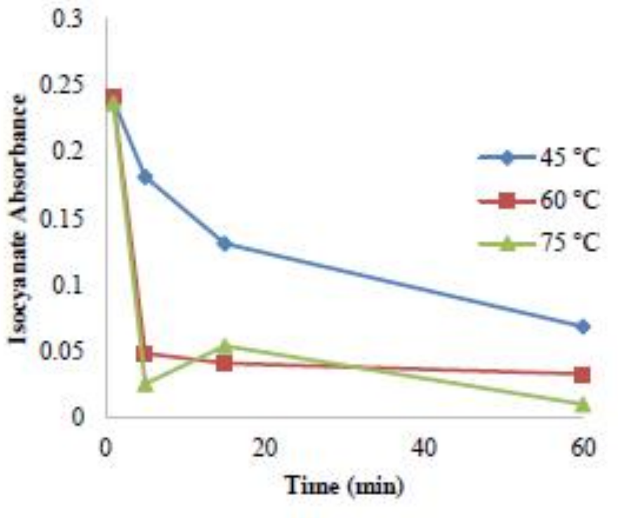


Figure 8: Normalized isocyanate absorbance through time extracted from FTIR data obtained during curing. All samples were mixed at full speed.

Mix/Cure Temperature (°C)	Isocyanate Absorbance at 24 hours
45	0.0062
60	0.0022
75	0.0032

Table 3: Normalized isocyanate absorbance of each sample at the 24 hour timepoint.

During curing at 75 °C, an increase in isocyanate is observed at 15 minutes, but this is likely due to difficulty testing the rapidly cured material with the FTIR system. Isocyanate measurements before and after the 15 minute timepoint show lower measured values.

As the cure temperature increases, the curing reaction kinetics increase as well, resulting in the more rapid temperature rise. At elevated temperatures, the diffusion-limited reaction rate increases because one reactive component can more readily diffuse into the other reactive component. This increase is also observed in the rapid decrease of isocyanate at elevated temperatures. However, for all temperatures tested, the curing material retained a low enough viscosity to allow the RIM process to proceed after mixing.

Example Molded Parts

Based on the settings tested previously, a simple mold was created to demonstrate the concept of RIM molding using a reactive urethane system. High quality, highly transparent parts were produced with the RIM process (Fig. 9A). Part thicknesses below 0.5 mm were achieved in the wing part (Fig. 9B).

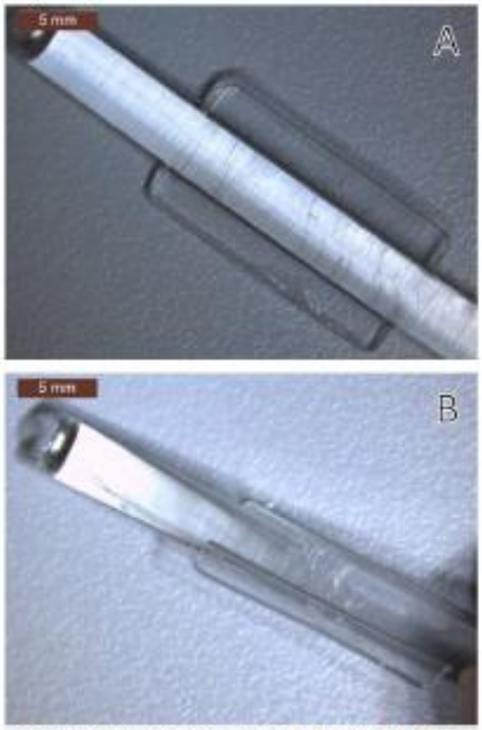


Figure 9: Sample parts produced with the RIM process.

In addition to creating molded parts, the RIM process was used to create a bond between two pieces of an assembly in a mold (Figure 10). These example parts demonstrated no visible weld lines, representing a potentially significant improvement over commonly used joining methods in the medical device industry. Additional testing beyond this sample part will be required to quantitatively compare bond strength to existing methods.

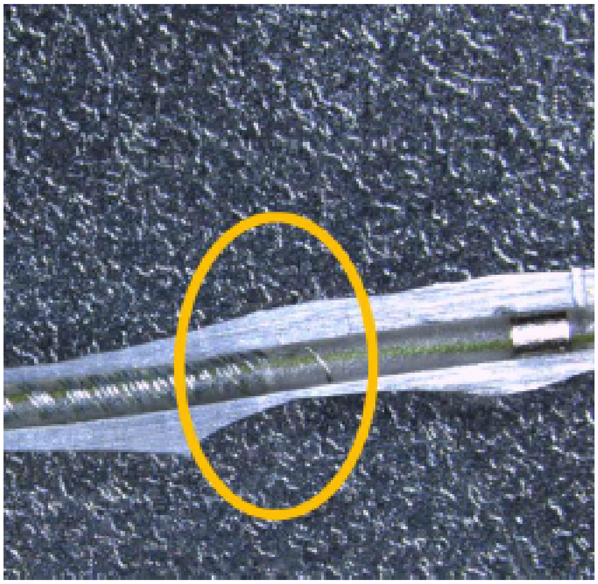


Figure 10: Sample bond created with RIM process. The circle indicates the area where the two pieces were joined together. Flash is present from the molding process.

Conclusions

Reaction injection molding of a polyurethane was proposed as a method to create small, intricate parts for a medical device. The effects of several process variables were evaluated to determine their effect on the reaction injection molding process and the curing reaction speed.

Mixer speed was varied from 240 RPM to 2350 RPM, but was not found to impact the rate of the curing reaction, as measured by both viscosity and FTIR measurements. For the polymer system used, active mixing is sufficient to create adequate interfacial area between the reactive components. Therefore, the reaction rate is controlled by the reactivity of the component materials instead of the mixing speed. Mixing duration, however, was shown to impact the reaction rate. Material mixed using a larger mixhead, with a higher residence time, showed a more rapid reaction when evaluated with viscosity measurement and an adiabatic temperature rise system. Longer mixing times allowed more time for components to diffuse together, allowing the unreacted components to stay in contact for longer and accelerating the reaction rate. Finally, increased reaction temperature was also shown to increase the reaction rate during and after mixing. By holding the material at a higher temperature, the curing reaction can be accelerated.

Initial evaluation of reaction injection molding process shows that the process can be utilized to create small parts with high precision and throughput. In addition, RIM was used to create a quality bond between two parts, with no visible weld line between parts. An improved understanding of the curing reaction can be used to optimize the RIM process to reduce cycle times and improve final part properties, while taking care to ensure that the reacting material remains fluid enough for low pressure injection. RIM production of parts for medical devices allows the creation of intricate parts with low pressure and low temperature, offering the opportunity to use RIM in a wide variety of sensitive manufacturing steps and complex geometries.

References

1. P. Vermette, et. al., *Biomedical Applications of Polyurethanes*, Landes Bioscience, Georgetown, Texas (2001).
2. N Lamba, K. Woodhouse, S. Cooper, and M. Lelah, *Polyurethanes in Biomedical Applications*, CRC Press, Boca Raton, Florida (1998).
3. S. Dumitriu, *Polymeric Biomaterials*, CRC Press, Boca Raton, Florida (1994).
4. M. Szycher, *Szycher's Handbook of Polyurethanes*, CRC Press, Boca Raton, FL (2013).
5. Yilgor I, Yilgor E, Guler IG, Ward TC, Wilkes GL. Polymer 2006;47:4105–14.

Check out what you missed…

Dusseldorf River Front (photo courtesy K-Show)

The K-Show is one of the largest global trade fairs for the plastics and rubber industry. The event was held in Düsseldorf, Germany from 15-23 October 2019.

A few interesting statistics:
- ~3,300 exhibitors from a total of 63 nations
- ~225,000 visitors from 168 countries
- A multitude of plastics technologies & innovations

K-SHOW 2019

Check out what you missed…

K-Show Exhibit Hall Entrance (photo courtesy Lauren Zetts Covestro)

The plastics and rubber industries present their entire performance spectrum and the whole diversity of innovative applications.

The net exhibition area amounts to ~178,000 m^2 (~1,900,000 ft^2) spread through all 19 halls of the Düsseldorf Exhibition Centre.

K-SHOW 2019

Check out what you missed…

Picture from the SPE Booth at K-Show (courtesy SPE)

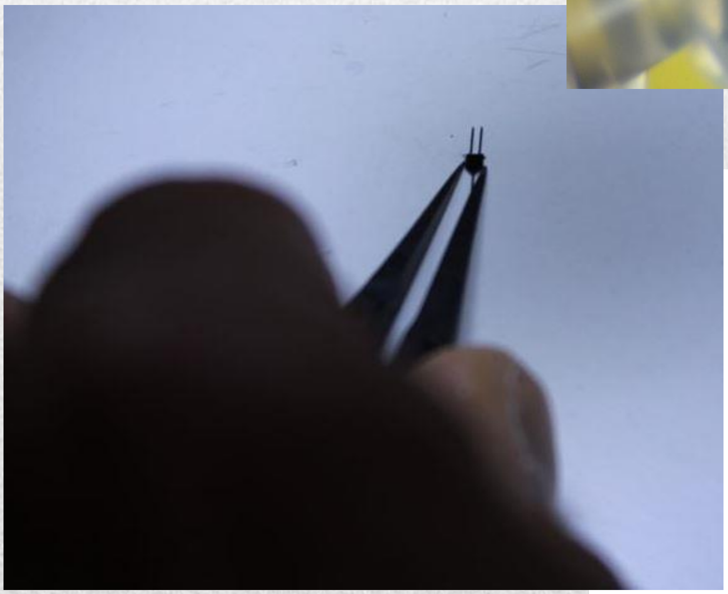
Picture from the SPE Booth at K-Show (courtesy SPE)

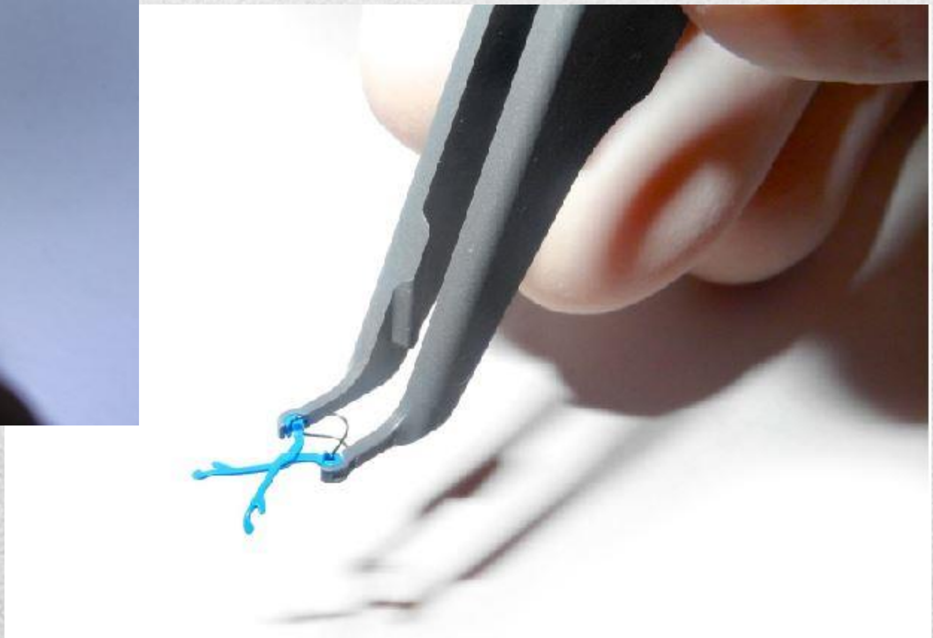
Check out what you missed…

Medical plastics examples from K-Show (courtesy K-Show)

Raw material and auxiliary specialists presented products at the leading edge of polymer science. The focus was on materials with superior resource efficiency that allow a more balanced economic and ecological performance and which can be recycled at the end of their life cycle. Companies offering semi-finished products, industrial components and reinforced plastics products showed a high innovative force and a wide variety of products. Energy- and resource-efficient products have become more important than ever before, as they can meet the most challenging requirements (K-Show Press Release).

Check out what you missed…





Medical micro-molding examples from K-Show (photos courtesy of Donna Bibber, Isometric Micro Molding)

BEST OF 2019 PHOTOS – MPD MiniTec

Check out what you missed…

Expert Panel Discussion (L→R): Len Czuba (moderator); Jamie Orr (PolyOne); Jeffrey Jansen (The Madison Group); Yubiao Liu (Eastman Chemical)

SPE CEO Pat Farrey with the lead organizers of the MPD MiniTec (L→R): Len Czuba (Czuba Enterprises), Ashley Spittle (Horn), Patrick Farrey (SPE), and Ned LeMaster (DuPont)

BEST OF 2019 PHOTOS – ANTEC 2019

Check out what you missed…

L→R: Margie Hanna, Len Czuba, Maureen Reitman (ANTEC 2020)

Len Czuba accepting "SPE Fellow of the Society Award" on behalf of Dr. Thomas W Haas from SPE President Brian Grady

BEST OF 2019 PHOTOS – ANTEC 2019

Check out what you missed…

Leadership Round Table (L→R): Margie Hanna, Len Czuba, Vipul Davé, Jeremy Dworshak, Ned LeMaster, and SPE CEO Pat Farrey

MPD Past Chair's Breakfast (L→R): Vipul Davé, Len Czuba, Glenn Beall, and Pierre Moulinié (designed to help the current chair understand the job and share suggestions)

BEST OF 2019 PHOTOS – ANTEC 2019

Check out what you missed…

SPE MPD Board of Directors Group Photo – Renaissance Center

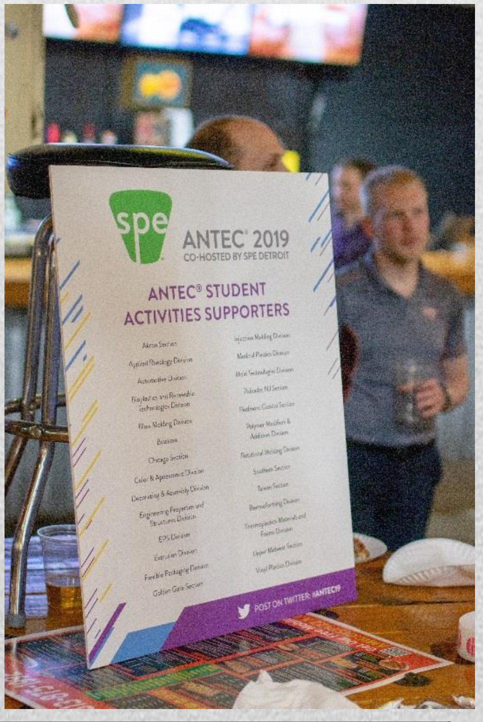
SPE MPD Board of Directors Dinner – Andiamo Riverfront

BEST OF 2019 PHOTOS – ANTEC 2019

Check out what you missed…

The MPD provided financial support to the Student Activities at ANTEC this year.

Part of the funding went to one of the fun activities (Fowling = football + bowling) they planned for the young members and the pictures enclosed were taken at that event.



UPCOMING EVENTS: MINITEC 2020

MEDICAL PLASTICS MINITEC

Anaheim, California • February 10, 2020

Presented by SPE Medical Plastics Division and SPE Southern California Section

EMERGING MATERIALS AND TECHNOLOGIES IN MEDICAL DEVICES

Monday, February 10, 2020

Sheraton Park Hotel at
the Convention Center
1855 S Harbor Blvd
Anaheim, CA 92802

Schedule of Events:

7 – 7:30 am
Registration and Continental Breakfast

7:30 – 8 am
Keynote Speaker

8 am – 6 pm
Tabletop Exhibition

8 am – 4:30 pm
All Day MiniTec
(Lunch and Breaks Included)

4:30 – 6 pm
Cocktail Reception and Poster Session
(Included in Registration)

Register to Attend:

Member (Advanced):	$150
Member (On-site):	$195
Non-Member (Advanced):	$250
Non-Member (On-site):	$300

Info & Online Registration:

www.4spe.org/MedPlasticsMinitec

A one day conference where 15 presentations from the industry will discuss the latest developments in the area of medical plastics.

Keynote Speaker
Maureen Reitman – Exponent

I. MATERIAL SELECTION CONSIDERATIONS WITH REGULATORY CHANGES

EU MDR Compliance for Medical Devices and the Road towards the Adaptation of Medical Grade Material Selection
Jacqueline Anim – Ethicon (JNJ)

How will the new EU Medical Device Regulation (MDR) Affect Material Selection in Medical Device and Packaging?
Tina Barrett - Eastman Chemical Company

II. ADVANCES IN MATERIAL SCIENCE

Beyond the Datasheet - Maximizing the Value Your Material Supplier Can Bring to Your Combination Drug Delivery Device Design for Precision Friction Performance
Don DeMello - Celanese

Variables Affecting Coefficient of Friction Testing in Lubricious Polycarbonate Resins for Medical Applications
Cheryl Weckle - Trinseo LLC

Reducing the Impact of Hydrolysis of PEBA and TPU-based Radiopaque Materials
Selvaanish Selvam - Clariant

III. SIMULATION & SCALE UP

Scale-up of Polymer/Active Pharmaceutical Ingredients (APIs) Compounds via Twin Screw Extrusion
Charlie Martin - Leistritz Extrusion

Application of Simulation Towards Process Development, Optimization and Troubleshooting
John Perdikoulias - COMPUPLAST Intl. Inc.

IV. CHANGE MANAGEMENT IN A DYNAMIC REGULATORY CLIMATE – Lunch Session

The Change and Certification of Materials in Medical Devices Resource Guide
George M. Southworth - Plastics Industry Association

V. INNOVATIONS IN MANUFACTURING TECHNOLOGY & NOVEL TECHNOLOGIES FOR PROCESSING

Merging of Processing Technologies for High Quality Healthcare Devices
Isaac Platte - Covestro

Paste Extrusion, Expansion, and Functionalization of Expanded Polytetrafluoroethylene (ePTFE) for Blood Vessel Grafts
Tom Turng - University of Wisconsin–Madison

Point of Care 3D Printing of PEEK for Orthopedic Applications
Steve Kurtz - Exponent Inc. & Drexel University

VI. VALUE ADDED & POST PROCESSING OPERATIONS

New Technology Advancements in Plastic Welding to Support Medical Device Manufacturers
Alex Savitski, Ph.D - Advanced Technologies

Medium Voltage Electron Beams for The Sterilization of Medical Devices – An Alternative for the Medical Device Industry
Gustavo H. C. Varca, B. Pharm, PhD. - E-BEAM Services, Inc.

VII. END OF LIFE/CIRCULAR ECONOMY

Reprocessing of Multi-Use Medical Devices: Impact of Cleaning, Disinfection, and Sterilization (CDS) on Polymer Properties; and Impact of Polymers on CDS Efficacy
Rob Klein - Stress Engineering

Upcycling Single-use PET Plastic Waste into Durable Materials for Medical Devices
Manish Nandi - SABIC

Reception and Poster Session
(Includes Cocktails and Hors d'oeuvres)

Conference Co-Chairs:
Ned LeMaster, DuPont & Ashley Spittle, Azelis Americas CASE

Moderators:
Len Czuba, Czuba Enterprises, Inc. & Ned LeMaster, DuPont

TABLETOP EXHIBITOR OPPORTUNITIES AVAILABLE

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- Registration includes 1 admission
- Company name recognition published in promotions and on event signage!

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- Breakfast Sponsor: $400 (2 available)
- Reception Sponsor: $300 (2 available)
- Break Sponsor: $100 (6 available)

Contact:
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p: 608-402-3268 e: ned.e.lemaster@dupont.com
Ashley Spittle
p: 562-217-1377 e: aprice1208@gmail.com

UPCOMING EVENTS: ANTEC 2020

ANTEC® 2020
San Antonio, TX • March 30-April 2, 2020

About   Agenda   Exhibitors & Sponsors   Resources

ANTEC 2020 submissions are now closed
Please reach out to the Technical
Programming Committee for future
speaking opportunities.

THE ANNUAL TECHNICAL CONFERENCE FOR PLASTICS PROFESSIONALS

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Why should you attend?
ANTEC® 2020 represents the ideas, research and trends shaping our plastics industry. 420+ technical and business papers, including sessions and panel discussions focused on the biggest questions being asked in the plastics community today — complete with networking, student and young professional events and exhibitor receptions.

Who Should Attend?
SPE is comprised of 22,500+ members, all from diverse backgrounds and careers — ANTEC® is no different. Managers, engineers, R&D scientists, technicians, sales & marketing associates, executives, academics and students are all invited to enhance their career in plastics through this networking and knowledge sharing event.

The MPD TPC welcomes you to submit an abstract

For more information, please email Amin Sedighiamiri
am.sadighi@gmail.com