Society of Plastics Engineers Medical Plastics Division Newsletter December 2018

GREETINGS FROM THE CHAIR

Dear Fellow Medical Plastics Division Members:

I hope that everyone had a wonderful holiday season with family and friends. I would like to wish everyone Happy New Year and Best Wishes for 2019!

I would like to thank the Medical Plastics Board as they are all are very busy with several activities to make our division stronger. Many initiatives are underway which have been summarized in this newsletter.

The Medical Plastics Division has partnered with SPE's Southern California Section to organize a MiniTec which is going to held on February 4 in Anaheim, CA, before the MD&M show. This is a great opportunity to learn about Medical Materials and Processing with more than 14 presentations given by industry leaders. Please register for this meeting if you are attending the MD&M show.

ANTEC 2019 is going to be held in Detroit from March 17-21, and the Medical Plastics Division Technical Programming Committee has planned another exciting technical program. There are two sessions with excellent papers on Monday and we would like to invite everyone to attend the sessions.

Inside This Edition…

GREETINGS FROM THE CHAIR

We would like to continue the drive to increase membership in the Medical Plastics Division. Our membership committee has developed a strategy to engage members with several initiatives to attract new members to our division. Please reach out to our Membership Committee Chair, Ravishankar Ayyar, to find out the value we are providing to our members and to learn more about the division.

Medical Plastics Division will be having our annual elections by online voting in January, and the candidates on the ballot are complete. I would like to encourage everyone to vote!

We are always in need of passionate volunteers and members to join our division so please reach out to me or anyone on the board if you are interested to help us.

Finally, I would like to Thank You for your membership and look forward to your contributions to make our division stronger.

At your service,

Vipul

Do you have questions about MPD Membership?

Please email Ed Fewkes
fewkesej@corning.com

Are you interested in volunteering for the BOD?

Please email Vipul Davé
VDave1@its.jnj.com

MEET YOUR SPE MPD BOARD OF DIRECTORS

2018-2019 MPD Board Appointments (1-year terms)

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Victoria Nawaby, Patina Solutions

- Education Committee Co-Chair

Anil Mahapatro, Wichita State University

- Technical Programming & Awards Committees

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- Awards Committee Co-Chair

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- Member

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- Member

Why not your colleague?

- Member

Looking for volunteers

- Member

Are you interested in running for the upcoming election?

Please email Louis Somlai
somlai_louis@lilly.com

MEET YOUR SPE MPD BOARD OF DIRECTORS

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- Membership co-chair & Awards co-chair

Ed Fewkes, Corning

- Membership co-chair

Ajay Padsalgikar, DSM

- ANTEC 2019 Technical Program Committee

Louis Somlai, Eli Lilly and Company

- Communications Chair; Newsletter Editor

MEET YOUR SPE MPD BOARD OF DIRECTORS

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- Vice Chair; Treasurer / Finance Committee

Margie Hanna, Czuba Enterprises

- Member - Finance Committee

Ned LeMaster, DuPont

- Secretary; Technical Program – Webinars

Maureen Reitman, Exponent

- Member – Technical Program Committee & Awards Committee

Amin Sedighiamiri, Eli Lilly & Company

- ANTEC 2019 Technical Program Committee

MEET YOUR SPE MPD BOARD OF DIRECTORS

Vipul Davé, Johnson & Johnson

- Division Chair

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- Past Chair

Len Czuba, Czuba Enterprises

- Councilor

Kathy Schacht, SPE

- SPE Liaison

Are you interested in volunteering for the BOD?

Please email Vipul Davé
VDave1@its.jnj.com

MEDICAL PLASTICS DIVISION COMMITTEES

Division Chair **Vipul Davé ('19)**	**Vice-Chair** **Ali Ashter ('21)** • Education Committee Oversight • Membership Committee Oversight	**Past Chair** **Pierre Moulinié** • Awards Committee Oversight • Assistant Treasurer • Nominating Committee
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Education Committee • Co-Chair: Pierre Moulinié • Co-Chair: Victoria Nawaby ('19)	**Communications Committee** **Chair: Louis Somlai ('20)** • Newsletter: Louis Somlai ('20) • Marketing and Outreach: Suneel Bandi ('19) • Historian: Vacant	**Membership Committee** • Co-Chair: Ed Fewkes ('20) • Co-Chair: Ravi Ayyar ('20) • Members: Suneel Bandi ('19)
Awards Committee • Co-Chair: Michael Wallick ('19) • Co-chair: Ravishankar Ayyar ('20) • Member: Anil Mahapatro ('19)	**Finance Committee** **Chair: Bhavin Shah ('19)** • Treasurer: Ali Ashter ('21) • MPD Chair: Vipul Davé ('19) • Ass't Treasurer: Pierre Moulinié • Members: Margie Hanna ('21); • Michael Teahan	

Are you interested in volunteering for the BOD?

Please email Vipul Davé
VDave1@its.jnj.com

GREETINGS FROM THE NEWSLETTER EDITOR

Greetings fellow MPD Members!

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

ANTEC2019 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 you to attend monthly 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 me (somlai_louis@lilly.com).

In an attempt to increase our social media bandwidth and outreach to our members, the MPD Communications Team has acquired the **#SPEMPD** twitter handle. If you are an active or even occasional twitter user: please check us out and connect with us! On our twitter feed you'll find some of the latest articles on medical plastics science and engineering as well as SPE and MPD events being promoted. Please check us out!

Finally, a big thank you to PolyOne Corporation and Eastman Chemical for their sponsorship in 2018. We continue to seek firms interested in advertising in our newsletter. Your board has recognized the need to increase fundraising for the division so we have renewed our efforts towards this funding avenue and sponsorship. If you are aware of a firm or organization that would benefit from advertising in our newsletter please let them and me know.

Best regards,

Louis

Newsletter Suggestions? Want to Advertise?

Please email Louis Somlai

somlai_louis@lilly.com

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 amount, i.e. 3 issues)	
	Full page	*$1,250*
	Half page	*$750*
	Quarter page	*$400*
	Eighth page	*$250*

LISTED ADVERTISING PRICES REPRESENT A 50% DISCOUNT
IN EFFECT UNTIL FEBRUARY 15, 2019
ACT NOW!!!

The newsletter, as scheduled, is prepared and circulated **three times per year** (*plus the occasional 4th or bonus issue*). Every Medical Plastics Division member receives a copy emailed directly to their listed address. Additional copies are also circulated (via the Chain) 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!

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COUNCILOR'S REPORT

Medical Plastics Division Councilor 4Q2018 Report

Dear Friends,

As we turn the calendar from 2018 to 2019, I hope that you have had a wonderful holiday season and we wish you a very good 2019!

The news from Council meetings are that SPE continues to struggle financially and are hoping that by continuing the membership growth seen these last several years, we can close the gap between income and expenses. We are making progress but we need good programs and new members!

Two meaningful areas of interest to all our members is the new webinar program being offered to our industry. A wide variety of topics are being presented in a one-hour format with a reasonable fee being charged to non-SPE members while most are free to members. Check out details of these SPE webinars on the Chain! You can even hear the recording of a recent webinar by our division chairman, Vipul Davé: "Materials for Medical Applications".

The other big effort is the planning for ANTEC 2019 in Detroit in March (17 – 21). There is significant planning going into the ANTEC 2019 technical program as well as all the extra surrounding activities: Opening reception, Student poster session, Plenary speaker presentations, various Social events, Networking parties and many opportunities to meet new friends.

Continued on the next page…

COUNCILOR'S REPORT

Continued from the previous page…

The Medical Plastics Division TPC has been planning another great technical program at ANTEC and hope you can come attend our sessions, both on Monday. See session details in the preliminary "Inspire" program available online at SPE's website. Check it out! But also plan to take in some of the New Technology Forum as well throughout the week.

Finally, SPE Councilors will be having our annual elections for offices of the Society in late January and early February. The nominations are almost complete and the elections will be held all by online voting. One note of interest: Our own board member Ali Ashter is on the ballot for Vice President of Events! Good luck Ali!

Have a great kick off to the new year and I look forward to seeing you at the upcoming MiniTec in Anaheim on 04Feb18 and / or at ANTEC in Detroit in March!

Best regards,
Len Czuba
MPD Councilor
Past SPE President (2005 – 2006)
Distinguished, Honored Service, Fellow of SPE

Do you have questions about MPD Membership?

Please email Ed Fewkes
fewkesej@corning.com

TREASURER'S REPORT

TREASURER'S REPORT – Ali Ashter
Last Updated January 7, 2019

Treasurers report as of January 7, 2019

Balance as of September 28, 2018	$ 20,887.39

INCOME

Income Type	Amount
SPE Rebate	$ 1,035.00
TOTAL INCOME	$ 1,035.00

EXPENSE

Expense Type	Amount
Student Activities	$ 1,000.00
TOTAL EXPENSE	$ 1,000.00

FUNDS AVAILABLE AS OF January 7, 2019	$ 20,922.39

Do you have questions about the Treasurer Report?

Please email Ali Ashter
ashter2000@gmail.com

SPE MPD WEBINARS

The Medical Plastics Division is pleased to announce the success of its second webinar of the 2018 calendar year. A total of 93 participants, out of 199 registrants, were in attendance on December 13th, 2018.

A big thank you to the webinar speaker, and our own chair, Vipul Davé for his excellent presentation on Materials for Medical Applications. Thank you also to Louis Somlai and Ravi Ayyar for supporting as moderators.
Don't worry, if you missed Vipul's presentation or were unable to attend, the webinar can be found in the SPE Library or by following the link provided here: https://www.4spe.org/i4a/pages/index.cfm?pageid=4443

The Medical Plastics Division and Webinar Team plans to host a series of webinars during 2019, with a goal of at least three to four. Tentative timing for the next Webinar is February after MiniTec '19. 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 Pierre Moulinié (pierre.moulinie@covestro.com), Victoria Nawaby (nawabyv@hotmail.com), or Ned LeMaster (ned.e.lemaster@dupont.com) with any suggestions.

CALL FOR ELECTIONS – MPD BOD

ANTEC2019 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 me (somlai_louis@lilly.com).

Are you interested in running for the upcoming election?

Please email Louis Somlai
somlai_louis@lilly.com

ACCELERATED AGING OF MEDICAL-GRADE RESINS: Q10 FACTORS AND MATERIAL AGING MODELS

Robert J. Klein, Martin G. Gibler, Naveen K. Singh, Stress Engineering Services, Mason, OH

Abstract

Accelerated aging is used throughout the Medical Device sector and other sectors to evaluate materials and devices in an accelerated fashion. If used properly, it can shave years off of validation efforts. If used improperly, it can generate misleading or completely incorrect data about the resins and products in question. This paper explores the fundamental principles and provides supporting data. It is critical to understand the four primary modes of aging for polymers: (1) physical aging (embrittlement and loss of free volume); (2) chemical aging, which includes oxidation, chemical damage, sterilization, etc.; (3) sustained strain cracking, creep rupture, and environmental stress cracking; and (4) fatigue. For sustained strain or sustained load environments, stress relaxation and creep are also key factors. A case study is presented for polycarbonate and copolyester resins that are undergoing physical aging, sustained strain cracking, and environmental stress cracking (ESC), and a model presented to account for the various factors.

Introduction

Accelerated aging is used throughout the Medical Device sector as well as other sectors to evaluate materials and devices in an accelerated fashion. If used properly, it can shave years off of validation efforts. If used improperly, it can generate misleading or completely incorrect data about the resins and products in question.

The most common approach is to refer to ASTM F1980 or ISO 11607-1. Both of these specifications utilize an Arrhenius approach to calculate acceleration factors. The concept is that at elevated temperatures, aging will proceed much faster, and therefore the time to reach a certain level of aging can be accelerated significantly. These specifications were originally written for polyethylene packaging, but have been extended to a variety of plastic resins and conditions.

There are significant risks in using acceleration factors to predict failure at lower temperatures. Some of these are covered in the ASTM and ISO specifications, and others have been observed from experience:

1) Some resins do not follow the typical Q10 factor of 1.8-2.0. For example, polycarbonate and amorphous copolyester (such as Tritan®) have been reported to exhibit Q10 factors between 3.5 and 12.
2) If the aging temperature is near or above a transition temperature for the resin, step changes in behavior will occur at elevated temperature such that it no longer represents room temperature behavior. For example, the Tg of polyester is ~70°C, and so aging at 55°C or higher presents significant risks.
3) If there are multiple mechanisms leading to failure, such as chemical damage, physical embrittlement, and stress cracking, accelerated aging may not accurately account for stacked or conflicting mechanisms. For example, a resin under sustained strain may exhibit stress cracking at room temperature; but by heating a part under sustained strain, the stress can be relaxed, which will underestimate the rate of failure.
4) The effects of humidity or chemical concentration must be appropriately accounted for during accelerated aging. For example, 50% RH at 23°C is not equivalent to 50% RH at 60°C.
5) Stress concentrators and defect sites must be appropriately accounted for as part of the accelerated aging testing scope. Weak sites within components will fail first, and may mask other possible failure sites.
6) Most assemblies contain multiple materials and numerous failure modes, and the selection of aging temperature, acceleration factors, and test techniques must be tailored to evaluate key failure modes.
7) Devices may contain materials with different behavior relative to thermal expansion, thermal relaxation, and modulus as a function of temperature, and loading conditions may change with elevated temperature exposure.

Technical Background

There are four primary modes of aging that can be experienced by polymers. It is beneficial to separate them into these modes so that they can be understood mechanistically and modeled appropriately.

Physical Aging, also referred to as embrittlement due to aging. For amorphous thermoplastics aging below Tg but above the beta transition, there is a loss of free volume over time, which often leads to increased stiffness and decreased elongation at yield and break. This effect can be minor or significant depending on the resin and exposure temperature. It can usually be modeled with an Arrhenius relationship because it is primarily based on self-diffusion. The Arrhenius relationship is generally written as [1]:

$$Rate = Ae^{(-E_a/RT)} \qquad (1)$$

where A is a constant, E_a is the activation energy, R is the ideal gas constant, and T is temperature in units of Kelvin.

For two temperatures T_2 and T_1, the Arrhenius relationship can be approximated as [2]:

$$AAF = Q_{10}^{(T_2-T_1)/10} \quad (2)$$

where AAF is the Accelerated Aging Factor ($Rate_2/Rate_1$) and Q10 is the "factor of 10" aging factor. Q10 is dependent on E_a, and therefore changes in Ea can lead to dramatic shifts in Q10 factors. For a typical two-component reaction with E_a= ~52.5 kJ/mol, over 0 to 80°C, Q10 is approximately 2.0. This is a reasonable approximation for many simple reactions occurring in this temperature range, but it is only an approximation and should be experimentally determined for each material.

Chemical Aging, which includes oxidation, hydrolysis, UV-damage, sterilization-induced damage, and other chemical damage to the polymer structure. Chemical aging involves chemical damage to the molecular structure of a polymer through crosslinking, scission, side group modification, oxidation, etc. For some forms of chemical aging, such as oxidation or hydrolysis at constant water content, Arrhenius relationships are fairly reliable because damage modes follow chemical reaction rates.

Sustained Strain Cracking, Creep Rupture, and Environmental Stress Cracking (ESC). These mechanisms involve the development of crazing and cracking in materials exposed to constant stress or strain. Stress cracking and creep rupture may occur in the absence of other factors, whereas ESC damage involves mechanical stress/strain in tandem with fluid or environmental exposure. ESC damage is usually connected to plasticization or solvation of polymer chains, which increases diffusion and the rate of disentanglement, as opposed to chemical damage to the polymer chain. For all three types, the likelihood of damage increases significantly as molecular weight decreases, again indicating that this is usually related to chain interdiffusion and entanglements within the polymer.

Based on prior investigations, we have found that the time to crack by ESC is dependent on sustained stress and temperature. This relationship may be approximated [3]:

$$t_{crack} = k_c \sigma^{-n} e^{(E_a/RT)} \quad (3)$$

with time t, stress intensity factor k_C, stress σ, power law constant n, activation energy E_a, gas constant R, and temperature T. Note that in Equation (3) there is an Arrhenius component to represent the effect of temperature, but this is often complicated by the stress varying with time and temperature. In addition, if chemical concentrations change in the fluid over time, then the relationship must also account for this variable.

Fatigue Damage. Materials exposed to repeated mechanical loads may initiate subcritical damage and eventually fail catastrophically. Fatigue usually involves local regions of the material being repeatedly yielded, which leads to local permanent deformation, enhanced local stress concentration, and ultimately crazing, cracking, and crack propagation. Fatigue damage may also arise due to thermal cycling, which creates local mechanical stresses.

In addition, Stress **Relaxation** and **Creep** often play a significant role in aging and must be accounted for in situations where constant strain or stress is applied to parts. For example, if a part is placed at constant strain, but all the strain relaxes before cracking can initiate, then ESC damage will not be observed.

This list is not meant to be all-inclusive, and other types of aging modes are possible.

Selecting Accelerated Aging Conditions

Selecting appropriate accelerated aging conditions for polymeric components generally requires the following:

1. List of all resin grades involved in a part
2. Weak points within a part due to processing, such as weld lines, high flow regions, etc.
3. Stresses and strains, due to assembly, storage, thermal differential, operation, etc.
4. Storage and operating conditions, including durations, temperatures, relative humidity, chemical conditions, etc.

From this information, the first step is to compile a list of likely failure modes for each of the major components. For example, a hospital-grade reusable device such as a pump will typically have a shelf life of up to 2 years, an operating life of up to 5 years, be stored at room temperature and relative humidity, and be sterilized daily by wiping with hospital cleaners. The primary failure modes for the PC housing on this device would most likely be drop impact, physical aging, and stress cracking and/or ESC due to exposure to chemical cleaners combined with assembly stresses.

The next step to develop an appropriate accelerated aging protocol is to understand how these failure modes link to the polymer aging modes described above, especially in terms of quantifying stresses and strains over the material lifetime. Based on the failure modes noted above, it is recommended to first physically age tensile bars of the material (molded under similar conditions as the real part), and then perform stress cracking and ESC tests that replicate the sustained strain conditions and exposure conditions actually experienced by the part. Physical aging could likely be modeled by thermal Arrhenius methods (see Q10 factors in ASTM F1980; note PC generally has a higher Q10 factor than the typical 2.0), but ESC is best performed at the same strain levels, same chemical concentrations, and same temperatures as used in operation. Attempting to use thermal methods to accelerate aging in PC will likely lead to relaxation of the

strain, which will under-predict failure. The case study below reviews data for this example.

As another example, a single-use surgical device that includes a polyurethane component will typically be sterilized with gamma irradiation, have a shelf life of up to 3 years, an operating life of 1 day, be stored at room temperature and relative humidity, and will be used at 37°C in body fluids. The primary failure modes would most likely be decrease in mechanical properties due to aging or sterilization such that it no longer functioned as intended.

Urethane primarily degrades through chemical aging (hydrolysis). Therefore, coupons of urethane should be molded under representative conditions, sterilized under representative conditions, and then accelerated aged under appropriate temperatures and relative humidity to capture both shelf life and operating conditions. The accelerated aging could be performed using Arrhenius methods (see Q10 factors in ASTM F1980), but it is critical to ensure that the relative humidity is controlled so that the total moisture content remains the same between storage/operating conditions and in the accelerated aging conditions.

Failure modes may be due to stresses and strains during operation. As a third example, a reusable component molded from amorphous polyphenylene sulfone (PPSU) will be used as a load-carrying component within a larger device. It would typically have a shelf life of up to 2 years, an operating life of up to 3 years in room temperature and relative humidity, and be sterilized daily by wiping with hospital cleaners. The primary failure modes would most likely be fatigue damage at stress concentrations within the part. ESC from the hospital cleaners may increase the likelihood of crack initiation and propagation, although PPSU exhibits good chemical resistance to most chemicals.

In this example, the PPSU component will primarily fail due to physical aging and cyclic stress loading, and any stress concentrators will play a significant factor. Therefore, test bars should be molded using representative molding conditions (taking account for orientation), notched to represent crack intensity factors, physically aged using Arrhenius methods using appropriate Q10 factors, and then exposed to fatigue cycles at a similar stress level as would occur in the actual part.

Rather than age components individually, there is an alternate approach to accelerated aging – place the entire assembly or package at an elevated temperature condition and then perform functional tests. The major risk with this approach is that different materials may have different accelerated aging Q10 factors and relaxation coefficients. Secondary risks include: the elevated temperature may relax stresses in some of the parts, introduce new stresses related to thermal expansion or post-molding shrinkage, and/or accelerate other failure modes incorrectly (diffusion, corrosion, damage to electrical components, etc.).

Case Study: Materials and Methods

Medical-grade PC and copolyester resins were respectively obtained from Sabic and Eastman. (Exact grade information withheld due to proprietary information concerns.) Resins were molded into ASTM D638 Type I tensile bars per molding conditions recommended by the manufacturers. Physical aging was performed in calibrated and validated ovens under no strain.

Stress relaxation testing was performed in tensile mode. Two replicates were performed per temperature and strain level. Log-log best fits were obtained for each condition over 20-1000 seconds and these were extrapolated to 10^7 seconds.

Sustained strains were applied using fixtures following ASTM D543. Tensile testing was performed per ASTM D638-14 at 2"/min. Izod impact testing was performed per ASTM D256-10.

Case Study: Results and Discussion

Physical Aging of PC and Copolyester

Prior work has indicated that the Q10 aging factor for polycarbonate is about 3.5 and for copolyester is ~8.0 [4,5]. ASTM D638 Type I tensile bars were aged for the equivalent of 1.5 and 3.0 years at 5°C, assuming these Q10 factors. Tensile bars were then tested at 2"/min.

Results from the present paper are provided in Table 1. The yield stress shows a slight decrease with aging. There are also slight shifts in yield elongation and break elongation. Results are also plotted in Figure 1 along with data provided from historical projects by the authors. These other sources of data include both real-time and accelerated data.

Table 1: Tensile properties before and after accelerated aging.*

Material	Modulus (ksi)	Yield stress (psi)	Yield elongation	Break elongation
PC, as-molded	351 ±5	9030 ±60	6.2 ±0.1%	89 ±17%
PC, 1.5yrs at 5°C	347 ±2	9090 ±20	6.1 ±0.1%	71 ±24%
PC, 3.0 yrs at 5°C	352 ±6	9140 ±30	5.9 ±0.1%	76 ±14%
Copolyester as-molded	237 ±8	6230 ±60	6.7 ±0.1%	148 ±8%
Copolyester 1.5yrs at 5°C	234 ±3	6290 ±30	6.5 ±0.2%	139 ±21%
Copolyester 3.0 yrs at 5°C	233 ±3	6330 ±80	6.5 ±0.1%	133 ±13%

**Slight embrittlement (loss of free volume) is noted. For longer times and higher temperatures, physical aging can be much more severe.*

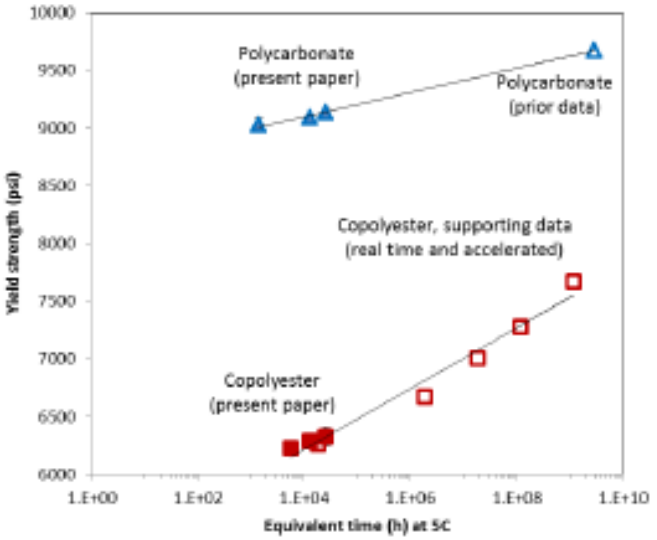

Figure 1: Yield strength as a function of aging time at 5°C, for Q10(PC) = 3.5 and Q10(copolyester)=8.0.

In addition, notched Izod impact testing was performed on specimens aged for the equivalent of 3 years at 5°C. Results are shown in Table 2. There is a significant reduction in notched impact strength after aging for the PC resin. There is a slight reduction in impact strength after aging for the copolyester resin.

Table 2: D256 notched Izod impact properties before and after accelerated aging.*

Material	Notched Izod Impact Strength (ft-lbf/in)
PC, as molded	~12
PC, 3 years at 5°C	1.33 ±0.22
Copolyester, as molded	~18
Copolyester, 3 years at 5°C	15.7 ± 0.5

**PC shows notable embrittlement after physical aging*, whereas copolyester shows only slight embrittlement. Some literature claims that physical aging in PC is actually due to crystallization instead of loss of free volume. The low beta transition of PC also likely leads to a higher rate of physical aging.*

Stress Relaxation and Crazing due to Sustained Strain

Stress relaxation of PC and copolyester is summarized in Figures 2 and 4. As shown, the initial stress as well as rate of relaxation decreases dramatically with increasing temperature. Also, copolyester relaxes much faster than PC at elevated temperatures.

PC and copolyester bars were placed under constant strain conditions at 1.0, 1.5, 2.0, and 3.0% strain levels and -15, 5, 25, and 50 °C temperatures. Examples of crazing are provided in Figures 3 and 5. These multiple temperatures and strain levels allowed the development of a model that incorporates both temperature and strain, using the model described in Equation (3).

Key results from this case study include:

- For sustained strain over time, time to craze and stress relaxation is closely linked through the relationship discussed in Equation (3).
- Best fits to Equations (3), and use of Equation (2), resulted in the following:
  - PC: kc = 2.5e5 s/psi^3, n=3, E_a = 62 kJ/mol/K, $Q10_{crazing}$ factor = ~2.2.
  - copolyester: kc = 7e8 s/psi^2, n=2, E_a = 23 kJ/mol/K, $Q10_{crazing}$ factor = ~1.35.
- copolyester relaxes much faster than PC at elevated temperatures. Therefore, elevated temperature sustained strain experiments will show PC to craze much faster than copolyester, but this may be highly misleading if used improperly.
- Across all the data, below ~1200 psi moderate crazing is unlikely to be observed. This may represent a lower limit below which energy is insufficient to lead to craze development.

Conclusions

If used properly, accelerated aging can be a highly effective tool to shorten material and device testing. If used improperly, the results obtained from accelerated aging can be highly misleading. The case study presented here shows an example of how PC and copolyester can be tested to obtain results for physical aging, stress relaxation, and time-to-craze under sustained strains. PC and copolyester exhibit high physical aging Q10 factors (~3.5 and ~8.0, respectively), but they also relax significantly at elevated temperatures. Even accounting for stress relaxation, time-to-craze results indicate that the $Q10_{crazing}$ factors are ~2.2 for PC and ~1.35 for copolyester.

References

1. P.C. Painter, M.C. Coleman, *Fundamentals of Polymer Science*, Technomic Publishing, Lancaster, PA, 1997.
2. ASTM F1980-07, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*, ASTM International.
3. R.J. Klein, M.J. Gibler, R.M. Jacobs, E.L. Sell, S.D. Lince, *Environmental Stress Cracking of Medical Thermoplastics*, ANTEC 2016.
4. M. Gibler, *Accelerated Aging of Polycarbonate*, Internal SES Report, 2015.
5. *Eastman Tritan™ copolyester: accelerated aging in medical devices and packaging*, Eastman publication SP-MBS-2021, 2016.

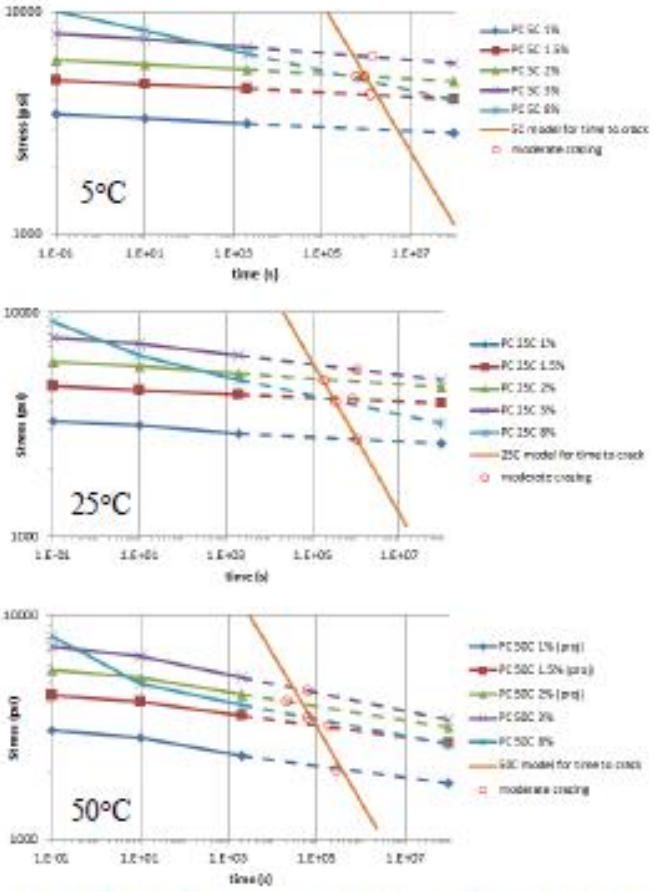

Figure 2: For PC resin at 3 temperatures: relaxation behavior, selected points showing crazing, and best fit model per Equation (3). For times greater than the intersection between stress relaxation curves and the time-to-crack model, crazing is expected to occur.

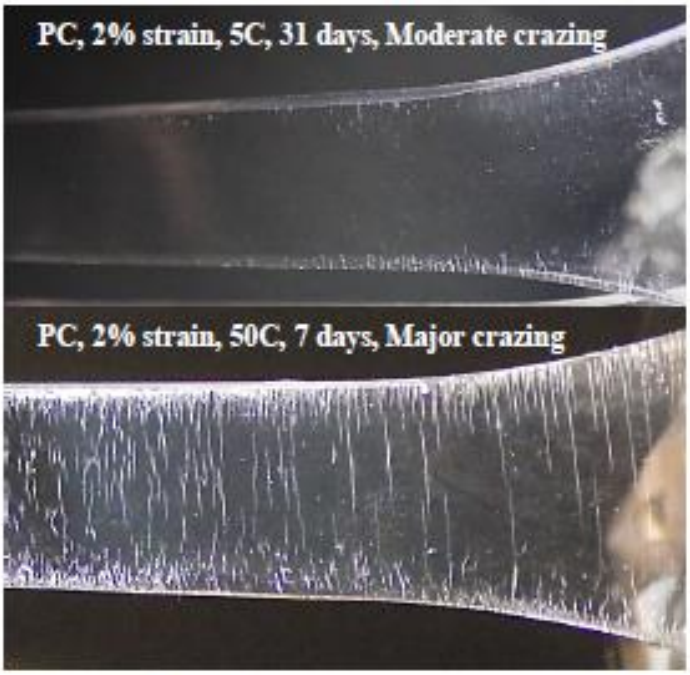

Figure 3: Examples of crazing in PC.

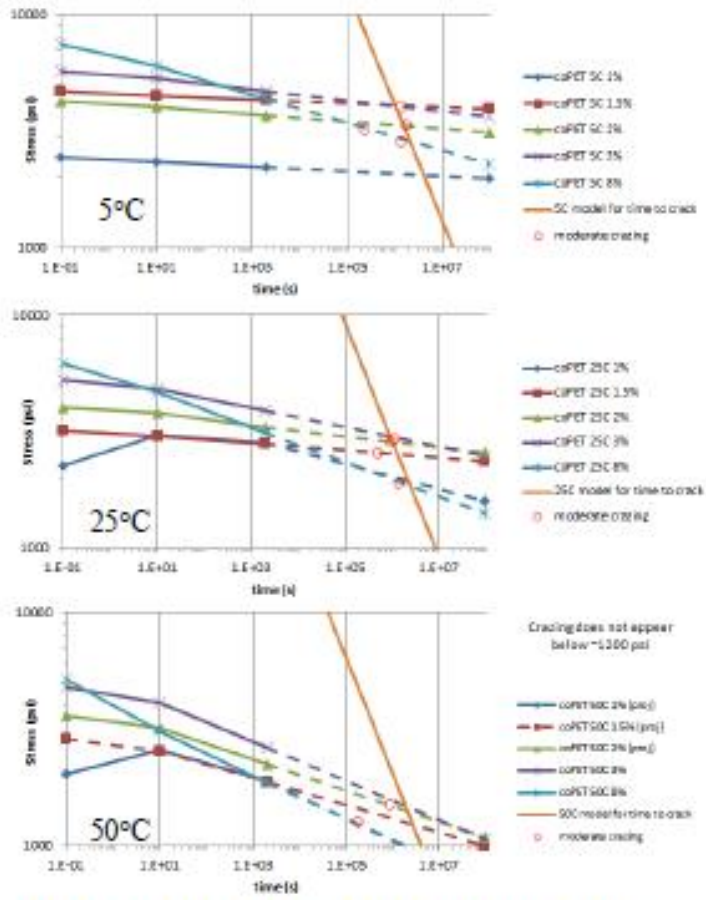

Figure 4: For copolyester resin at 3 temperatures: relaxation behavior, selected points showing crazing, and best fit model per Equation (3). For times greater than the intersection between stress relaxation curves and the time-to-crack model, crazing is expected to occur.

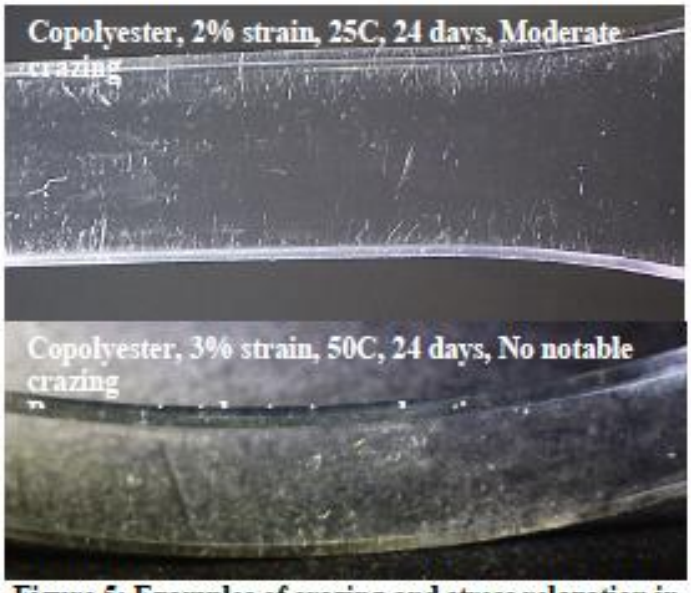

Figure 5: Examples of crazing and stress relaxation in copolyester.

Check out what you missed…

SPE Gold Pinnacle Award 2018:

The MPD was awarded at SPE Gold Pinnacle Award for 2018. Represented left → right: Margie Hanna, Maureen Reitman, Ravishankar Ayyar, Vipul Davé, Brian Grady, Amin Sedighiamiri, and Louis Somlai

COMPAMED 2018

Check out what you missed…

COMPAMED Nov 12-15 2018 - The Medical Plastics Conference in Duesseldorf, Germany. Suneel Bandi with colleagues (top left); Symposium on medical sensors (right top); 3d printed medical possibilities at Formnext, 2018 (bottom left and right)

MPO SUMMIT 2018

Check out what you missed…

October 2018 MPO Summit: a panel discussion on part process development and validation for multiple machines for medical device manufacturing.

From Left to Right: Scott Sully (Terumo Cardiovascular Group), Greg Lusardi (Becton Dickinso), Guthrie Gordon (Nypro), Maureen Reitman – moderator (Exponent), Matt Therrien – organizer (RJG Inc.), Rodney Brown (Eli Lilly and Company), and Paul Robinson (QSCS).

UPCOMING EVENTS

A one day conference where industry leaders and experts will discuss the latest developments in the area of medical plastics.

This MiniTec will be held the Monday, February 4th – the day before the opening of the 2019 MD&M West Expo & Conference in the shadow of the Anaheim Convention Center.

At least ten Speakers will present in two sessions covering the latest technology in Medical Device Materials and Processing. Session breakdown is as follows:

- Morning Session: **Future Polymer Materials Technology**
- Afternoon Session: **Design & Advanced Processing Technology**

Benefits of attendance include:

- Education and exposure to the latest technology in Med Device Design and Processing provided by industry leaders and experts.
- Access to all papers and presentations post show.
- Networking opportunities with peers and colleagues from Med Device OEM, Part Designers, Plastic Engineers, Material Suppliers, Machine and Equipment Suppliers, and more.
- Convenience of location and timing to large Med Device Trade Show.

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UPCOMING EVENTS

A LOOK TO THE FUTURE OF MEDICAL DEVICE MATERIALS & PROCESSING

A one day conference where 14 presentations from the industry will discuss the latest developments in the area of medical plastics.

Monday, February 4, 2019

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

Schedule of Events:

7 – 7:45am
Registration and
Continental Breakfast

7:45 – 8am
Keynote Speaker

8am – 7pm
Tabletop Exhibition

8am – 5pm
All Day MiniTec
(Lunch and Breaks Included)

5 – 7pm
Cocktail Reception and
Poster Session
(Included in Registration)

Register to Attend:
MiniTec (Advanced): $125
MiniTec (On-site): $175

Info & Online Registration:
www.4spe.org/MedPlasticsMinitec

Tentative Morning Session on New Materials & Design

Keynote Speaker
Vipul Davé – Johnson & Johnson

Polymer excipient technology for extended release of API
Greg Moakes and Don DeMello – Celanese

Materials and process technology solutions for designing connected medical devices
Manish Nandi – SABIC

Biodegradable/Resorbable Polymers: Recent Themes and Challenges in the Medical Device Industry
Rob Klein – Stress Engineering Services

Friction-reducing Materials for Medical Devices
Bob Hergenrother BioCoat, Inc.

Design Considerations for Medical Plastics with CAE & FEA
Alan Wedgewood & Helga Kuhlmann - DuPont

Medical Device Plastics and Adhesives - A Design Approach
JoAnne Moody Zeta Scientific LLC

Compounding via Twin Screw Extrusion for 3D Filaments
Charlie Martin - Leistritz

Panel Discussion - Topic to cover Materials and Chemical Resistance to Cleaning

TABLETOP EXHIBITOR OPPORTUNITIES AVAILABLE
Showcase Your Company!

- Registration Fee - $750
- Registration includes 1 admission
- Company name recognition published in promotions and on event signage!
- Booth setup 7 - 8am; requests for electricity accepted

Tentative Afternoon Session on Processing & Applications

Modifications to Medical Cooling and Vacuum Tanks to Minimize Water Issues from Bio-Films, Endotoxins and Pyrogens
Bob Bessemer – Bessemer Consulting/ConAir

Considerations for Extruding Water Sensitive Polymers
Christian Herrild – Teel Plastics

Study of Lamination of PU to FEP for Medical Device Tubing
William Li – Adam Spence

Influence of Stabilizers on Property Retention of Thin Wall Tubing
Chris Moran – Compounding Solutions

Miniaturized medicine on the rise
Donna Bibber - Isometric Micro Molding

Long-Acting Implants: Design for Durable Drug Delivery
Seth P. Forster – Merck

Development of Guidance for the Interconnectibility between Vial Container Closure Systems and Vial Transfer Devices
Naresh Budhavaram – Eli Lilly

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

SPONSOR OPPORTUNITIES AVAILABLE
Company Name Recognition published in promotions and displayed on signage!

- Corporate: $1000 (ncludes 2 admissions)
- Lunch Sponsor: $500 (2 available)
- Breakfast Sponsor: $400 (2 available)
- Break Sponsor: $100 (5 available)
- Reception Sponsor: $300 (2 available)

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SPE Medical Plastics MiniTec '19 – Speaker, Panelist, and Poster Presenter Bios & Abstracts

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Biography for
Vipul Davé, Ph.D.

Dr. Vipul Davé joined Johnson & Johnson in 1996 and held several roles of increasing responsibility within the Medical Device and Consumer Sectors of the company. He is currently a Research Director and Fellow in the Global OTC Technology Group in Johnson & Johnson Consumer Inc. and is responsible for leading the development of novel oral pharmaceutical dosage forms and external innovation. Vipul's research has focused on the fundamental understanding of structure-property-processing relationships of polymers for health care applications. Vipul is an inventor of over 28 granted US patents and 46 US patent applications, authored over 30 publications in journals and books, and presented over 70 papers at technical conferences. Vipul received his BS in Textile Engineering from University of Baroda, an MS in Polymer Science from University of Massachusetts Lowell and a PhD in Materials Engineering Science from Virginia Tech. Vipul is a Fellow of the American Institute for Medical and Biological Engineering and Society of Plastics Engineers, and the current Chairman of SPE's Medical Plastics Division.

Keynote Speaker: "*Materials for Medical Applications*"

Biography for
Greg Moakes, Ph.D.

Dr. Greg Moakes, a physical chemist by training, leads the Field Development team for the Celanese Corporation medical polymers business.

Greg and his team use medical and implant grade products to create technical solutions for the medical device and pharmaceutical industries.

Greg received undergraduate degrees in Chemistry from the University of Leeds in the UK. He also holds a Ph.D. in Electroanalytical Chemistry from the Georgia Institute of Technology, and a Master's in Business Administration from Southern Methodist University.

Morning Session: "*Polymer excipient technology for extended release of API*"

The polymer industry has a crucial role to play in the changing landscape of API delivery. Patient outcomes are strongly affected by compliance. Compliance can in turn be increased by eliminating undesirable elements of drug delivery such as injection site discomfort, incorrect dosage of self-administered therapies, and side effects due to fluctuating blood serum concentrations. Excipient technologies serve to address these concerns while in many cases preventing side effects associated

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with first pass metabolism. This briefing will focus on aligning our polymer excipient technology with evolving small molecule and biologic therapies. This presentation will cover a broad range of literature examples where Ethylene Vinyl Acetate (EVA) is used to create a tortuous path for API delivery. Examples shown will cover subcutaneous, transdermal, oral, and intraocular implant examples.

Biography for
Manish Nandi

Manish Nandi is a Staff Scientist in Healthcare Industry Technology group at SABIC Specialties working on new product and technology solutions for healthcare applications. Prior to joining SABIC, from 2003-2011, Manish worked in area of new technology and product development at W. L. Gore and Associates. Prior to that, he worked for ARCO/Lyondell Chemical for over ten years in various Technology roles in their R&D. Manish received his Doctorate in Chemistry & Polymer Science from the Pennsylvania State University. Manish holds multiple patents and is the author of several technical papers in materials chemistry and polymers.

Morning Session: *"Materials and process technology solutions for designing connected medical devices"*

The future trend for medical devices for diagnostics, monitoring, and drug delivery are miniaturization and wireless connection to mobile phones or other receivers. Designers are often challenged by new needs. This presentation will focus on materials and process technologies SABIC has developed to incorporate connectivity, from antennas to EMI shielding, in these devices.

Poster Session: *"Polymer and Geometry Selection of Injection Molded Microneedles"*

Biography for
Rob Klein, Ph.D.

Dr. Klein is the lead medical polymer scientist/engineer at Stress Engineering and has been with SES for over 4 years. He has more than 10 years of industry experience in activities such as polymer testing, material selection, new material development and validation, accelerated aging and life prediction, and failure analysis.
This has included multiple recent efforts in biodegradable and resorbable material development and testing for medical devices.
In the medical sector, efforts have spanned plastics, thermosets, elastomers, and polymeric fluids for both single-use and reusable devices.
Prior to SES, Dr. Klein worked at Luna Innovations in Charlottesville, VA; and Sandia National Laboratories in Albuquerque.
He holds a B.S. in Chemical Engineering from University of California Santa Barbara, and M.S. and Ph.D. in Materials Science and Engineering

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from Penn State University. He is a current member of the Society of Plastics Engineering and the American Chemical Society.

Morning Session: "*Biodegradable/Resorbable Polymers: Recent Themes and Challenges in the Medical Device Industry*"

The medical device field has a growing number of engineering and specialty resins available for use in biodegradable/resorbable devices. These devices may be used on tissue or organs or be implanted. Devices that often use these resins may include bandages, tissue scaffolds, repair meshes, surgical markers, sutures, screws, and drug delivery devices. These polymer resins face a different set of challenges than typical plastic resins in terms of processing, testing, and performance in vivo. Stress Engineering will review the current state of biodegradable/resorbable medical resins and then provide specific examples from our work highlighting processing challenges, common test protocols, and key performance metrics.

Biography for Bob Hergenrother, Ph.D.

Robert Hergenrother, Ph.D., is Senior Director of Research and Development at Biocoat. Prior to joining Biocoat, he was Director of Medical Technology Development at Southern Research and Professor of Biomedical Engineering at the University of Alabama at Birmingham. Earlier in his career, Hergenrother held multiple positions at Surmodics, Inc., serving most recently as senior director of research and development, and at Target Therapeutics (now Stryker Neurovascular), where he developed endovascular medical devices to treat diseases of the brain.

Hergenrother has led the launch of over 15 new products in the medical device and coatings areas. He has 24 issued U.S. patents and more than 25 scientific publications. Hergenrother holds a Ph.D. in chemical engineering from the University of Wisconsin and Bachelor of Science in chemical engineering from the University of Notre Dame.

Morning Session: "*Friction Reducing Materials for Medical Devices*"

Vascular devices such as catheters and guidewires utilize friction-reducing materials to minimize the friction between vascular tissues or other devices, reduce procedure times and enhance maneuverability. The materials can be additives to the polymer or coatings to the device surface that are either hydrophobic materials, such as polytetrafluoroethylene (PTFE), or hydrophilic coatings. The materials have a range of frictional forces, with hydrophilic hydrogel coatings typically having the lowest frictional forces. Friction evaluations can utilize test apparatus that measure the force needed to move a test item with an applied normal force or in a simulated use model that track the force as a function of insertion length. It is important to measure the foreign material particulate generation from the device movement to understand the potential embolic and other hazards in the vasculature. Performance testing results comparing hydrophilic coatings, fluorinated polymers and other additives to polymers will be shown.

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Biography for
Alan Wedgewood,
Ph.D.

Alan Wedgeweood has over 40 years of experience in product and process development / material testing and modeling. At Dupont, Alan has investigated a wide range of materials, including advanced composites, fiber reinforced engineering polymers, rubbers and nanometals.
His recent work has focused on supporting application developments for the automotive, electronics, industrial and healthcare markets, with advanced testing and modeling. His materials physics understanding of the behavior of these materials has been used to develop unique advanced test methods to elucidate their strain rate dependency, nonlinear viscoelasticity, and progressive damage failure.
These application developments have been further supported with advanced material models for anisotropic micromechanics, fatigue, creep, stress relaxation and failure predictions.

Morning Session: "*Design Considerations for Medical Plastics with CAE & FEA*"

When applied early in the device prototyping, simulation technology can reduce time to market, identify design deficiencies, assess the mechanical performance of a medical device, and enhance design optimization. Several design and simulation approaches are available, including Computer Aided Engineering (CAE) and Finite Element Analysis (FEA). Key to the successful use of these simulation approaches is having accurate mathematical representations of the materials being used. These mathematical representations or material laws allow for accurate simulation of the device's response to applied loads and environmental changes. The data required to generate these material laws, often require the use of advanced test methods. In some cases, simulation of the test itself is necessary to extract the required data. This presentation discusses the application of advance testing in support of the development of these material laws and how they are applied to support the design of medical devices with examples based upon DuPont materials.

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Biography for JoAnne Moody

JoAnne Moody, with 25+ years' experience in medical devices, provides technical expertise, fresh insights, and solutions to challenging adhesive/plastics bonding and joint design problems. As the Principal Consultant and President of Zeta Scientific LLC, Ms. Moody pursues her passion in solving materials science problems from startups to Fortune 500 companies, training teams to overcome hurdles, and successfully moving products forward. Her experience encompasses R&D, process, testing, scaleup, product transfers, and low-to-high volume manufacturing.

Prior to consulting, Ms. Moody's professional employment included 3M, Boston Scientific, EndoSonics Corporation, Raychem (now Tyco Electronics), and Liquidity Nanotechnology Corporation. Ms. Moody is also recognized in Silicon Valley for event planning, nonprofit collaboration, and student outreach. Her degrees include MS in Chemical Engineering and Materials Science (University of MN) and BA Chemistry (Hamline University, MN).

Morning Session: "*Medical Device Plastics and Adhesives - A Design Approach*"

A successful Medical Device development approach for both adhesives and polymers includes a roadmap for product design. Although there are numerous ways to bond materials, often the designer is faced with bonding dissimilar materials and a difficult design where only an adhesive is the right bonding solution. Without a proven methodology to follow, product teams find themselves in a failure loop, without a methodology to resolve bonding challenges and prevent downstream problems. With unsolved failures, often the product team, or company, faces a "shut down" situation. The steps for adhesive/polymer bond success include design evaluation, an understanding of adhesive fundamentals, chemical compatibility, joint design principles, regulatory issues, testing, and processing. A case study of a Medical Device moving from single-use to multi-use requirements will be provided. This design approach includes key factors for success and a roadmap to aid in project management and risk mitigation.

Biography for Charlie Martin

As President/General Manager of Leistritz Extrusion, Charlie is responsible for the management of a company that provides manufacturing equipment and engineering services to the plastics, medical and pharmaceutical industries in the USA and around the world. Extensively published in trade publications, textbooks and journals, Charlie has delivered 200+ technical presentations at wide-ranging international events, and is the co-editor of the textbook Pharmaceutical Extrusion Technology. He has also been awarded 2 extrusion related patents.

Charlie serves on the Board of Directors for the Society of Plastics Engineers (SPE) Extrusion Division, the Polymer Processing Institute @

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New Jersey Institute of Technology, and also on the Technical Advisory Board for Teel Plastics.
Charlie earned his undergraduate degree from Gettysburg College and an MBA from Rutgers University.

Morning Session: "*Compounding via Twin Screw Extrusion for 3D Filaments*"

Twin screw extruders (TSEs) are commonly used to compound plastics formulations to impart desired properties into a 3D filament. Polymers, additives, particulates and active ingredients are metered into the TSE process section, where rotating screws impart shear and energy to facilitate mixing, devolatilization and reactive extrusion. Pellets are often produced that then are fed into a single screw extruder mated to a downstream system that makes a 3D filament. The same downstream system can be mated to the twin screw extruder to make a 3D filament in one-step, which results in the final product having one less heat and shear history. TSE compounding fundamentals and a comparison of direct extrusion versus pelletization and a 2nd stage single screw extrusion operation, with the benefits of each, will presented and explained.

Biography for
Bob Bessemer

Bob Bessemer, currently works as a Downstream Extrusion Consultant with focus on enhancements to equipment and processes.
Bob previously worked for The Conair Group, Inc. as Senior Technical Advisor for Downstream Extrusion Equipment for 26 years. Bob has worked for several other downstream plastics extrusion equipment manufacturers over the past 36 years both with engineering/development and sales.
With major focus on developing, sizing, and cutting equipment specific to medical and pharma applications, Bob has 6 patents.
A major goal has been to better control the variables of the extrusion process and eliminate the so called "Black Art".
He has a degree from Penn State University for business administration, but maintains a focus on engineering and development. Bob has written many papers and delivered seminars to the industry to help advance technology.

Afternoon Session: "*Modifications to Medical Cooling and Vacuum Tanks to Minimize Water Issues from Bio-Films, Endotoxins and Pyrogens*"

Processors who extrude medical tubing, especially those used for in-body procedures, must be extremely aware of processing water conditions and test on a weekly, if not daily, basis. Water circulation tanks and vacuum tanks used for cooling and sizing the medical tubing can benefit from many features, which will be discussed in this presentation.

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Medical tanks should be designed for extreme ease of cleaning. Specialized fittings, known as Tri-Clove fittings, should be used to minimize threads exposed to the process water. The tank and all water contact surfaces must be made of minimally 304-L Stainless Steel and if possible electro-polished to further minimize germ growth. Filtration is extremely important with minimally a 5 micron filter used and an ultra-violet filter as well.

With proper features built into these medical extrusion tanks, water conditioning and the cleaning process can be greatly enhanced.

Biography for
Christian Herrild

Christian Herrild has a diverse background in the plastics and chemical fields. He is Teel's Director of Growth Strategies. He researches and evaluates markets and technologies, manages diverse projects, and helps set Teel's strategic plan. In addition, he manages branding and marketing efforts for Teel. Previously, Christian was Teel's Director of Sales and Marketing and managed its sales and customer service areas. Christian works closely with Teel's technical team, including new product launches with key customers. Christian also serves as in-house counsel for Teel.

Christian graduated cum laude from University of Wisconsin – Madison Law School in 2012 and earned his MBA from the UW School of Business in 2011. He has a strong technical background, with undergraduate degrees in both Mathematics and Chemistry from Marquette University, where in won several awards for his chemistry work as an undergraduate. Prior to his advanced schooling, he spent two years as an industrial synthetic chemist.

Afternoon Session: "*Considerations for Extruding Water Sensitive Polymers*"

There is growing interest in the medical market for polymers that can be used as drug delivery vehicles or other highly specialized applications. Many of these materials are water soluble or experience significant physical changes on exposure to water. The extrusion cooling process usually requires some amount of water contact for tight tolerance control. Using water for these materials can be accomplished, if the process is thoughtfully designed and carefully controlled. Considerations for setting up such a process will be discussed.

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Biography for
Tom Meehan

Tom Meehan is a technical service representative for Eastman Chemical Company. In this role, he is responsible for supporting North American medical device designers and manufacturers who are considering the use of Eastman Tritan™ copolyester in addition to those already using the material. Assistance with pretrial preparation, on-site sampling support, and postsampling testing comprise the bulk of his responsibilities.

Tom joined Eastman in June of 1985, working in a variety of technical service and application development positions supporting Eastman polymers in injection molding, blow molding and extrusion. He joined Intralox, LLC in 2000, serving as process development manager and senior polymer engineer. Then, in 2013, he re-joined Eastman, supporting the medical device market for Eastman copolyesters in a technical support capacity.

He holds a B.S. in chemical engineering from Tulane University and a M.B.A. from the University of New Orleans.

Afternoon Session: *"Scientific Screening Methods for Medical Polymers Demonstrating Compatibility with Drugs and Disinfectants"*

Biography for
Chris Moran, Ph.D.

Chris Moran is a R&D Engineer at Compounding Solutions. He earned his BS from Clarkson University and Ph.D. from Colorado School of Mines, both in Chemical Engineering.
Chris Became interested in polymers and medical devices during an internship at InVivo Therapeutics where he developed PLGA scaffolds for a tissue engineering application. His thesis work focused on understanding chemical structure, morphology, and physical property relationships in bio-based polymer blends and composites.
Several projects that Chris led include determining the miscibility of blends between polyamide-4,10 and polyamide-6,10, elucidating stereocomplexation phenomena in PLA and PMMA and using it in fiberglass reinforced composites.
Chris began his career at Compounding Solutions in January 2018, shortly after finishing his thesis. He is dedicated to formulation development and is eager to bring his knowledge of polymer science and chemistry to the medical plastics industry.

Afternoon Session: *"Influence of Stabilizers on Property Retention of Thin Wall Tubing"*

Degradation on the surface of thin wall medical tubing influences bulk mechanical properties more so than in standard test specimens. This study aims to characterize the degradation behavior of

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tubing with 0.004" wall thickness made from PEBA and TPU, with and without stabilization packages. Tubing is aged under various conditions to elucidate the relative contributions of thermal-oxidation, photo-oxidation, and hydrolysis degradation mechanisms on mechanical performance. Tensile testing and GPC are used to observe degradation over time of stabilized and non-stabilized tubes, and to relate their molecular weight distributions to their mechanical integrity. To calculate the Arrhenius parameters of this system, in which multiple reactions occur with spatial variability, time-temperature superposition is shown to be a superior to the typical approach of using Q10 factors. Compounding stabilizers into PEBA and TPU resins prior to extruding tubing is shown to drastically improve shelf life and resistance to oxidation and UV light.

Biography for
Donna Bibber

Donna Bibber is the Vice President of Business Development at Isometric Micro Molding, Inc. She earned a Bachelor of Science in Plastic Engineering from the University of Massachusetts-Lowell in 1988.

Donna has assisted in over 1,000 micro molding and assembly device programs. Ms. Bibber's plastics engineering background, expertise and unique problem-solving skills earned her an excellent reputation and is recognized nationally and internationally for her work in micro manufacturing. Her expertise in intraocular implants, bio-resorbable polymers, and PEEK implants gave rise to many new devices commercially available today.

She is affiliated with several professional organizations and is a board member for SPE's Micro/Nano SIG. Donna has multiple technical publications, and has won several industry awards including being Voted on the List of 100 Notable People in Medical Devices in 2008.

Afternoon Session: "*Miniaturized Medicine on the Rise*"

It doesn't take a brain surgeon (wait, yes it does) to understand the need for tiny devices that can maneuver in delicate tissue, tiny arteries, rigid ligaments, or membrane-like scaffolds. The trend continues and corresponding need for micro components and assemblies that enable devices across all medical and drug delivery market segments including: Neurology; Endocrinology; Oncology; Ophthalmology; Cardiology; Orthopedics; Pediatrics; Urology; ENT.

These tiny devices are being designed for futuristic exploration and treatments through tiny tubes and lumens via veins, arteries, capillaries, digestive systems, and natural orifices. These miniature devices are required to be both collapsible and expandable, flexible yet strong, rigid yet dissolvable. These are not simple challenges, however they are being met with an elite group of micro molders who dedicate their lives and company solely on enabling these extremely tiny and tight tolerance devices. The miniaturization trend will continue with devices even smaller and with immediate diagnostic capabilities- a unique value chain, creating mutual value in the medical and drug delivery device industry.

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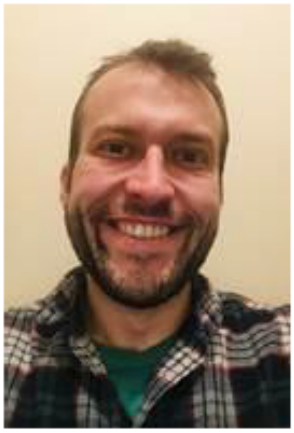

Biography for
Seth Forster

Seth Forster is part of the Specialty Dosage Forms Formulation team at Merck Research Laboratories in West Point, Pennsylvania, focused on novel pharmaceutical dosage forms and process technology. He has more than 12 years of experience developing pharmaceutical products. For the last three years, he has been focused on long-acting drug-eluting implant formulation and process development.
Seth has a BS in Chemical Engineering from Purdue University in West Lafayette, Indiana, and a MS in Pharmaceutics from Temple University in Philadelphia, Pennsylvania.

Afternoon Session: "*Long-Acting Implants: Design for Durable Drug Delivery*"

Patient access, compliance, and appropriate dosing of therapies are essential to the success of any treatment. The currently used standard oral tablet administered daily requires extensive supply and distribution networks, frequent access to trained medical care, and consistent patient diligence. If technically feasible, long-acting implants are likely a better way to reduce patient, caregiver or doctor intervention and overall health care costs.
To successfully develop a long-acting implant, potent and stable active pharmaceutical ingredients (APIs) are required but not sufficient. Drug release will be impacted by the design of the implant, the physical and chemical properties of excipients, especially rate-controlling polymers, and the manufacturing process, often co-extrusion or injection molding. Drug rates from micrograms to milligrams per day can be achieved, controlled by drug loading, polymer chemistry, and product design.

Biography for
Naresh Budhavaram

Naresh Budhavaram, is a Senior Consultant Engineer in the Device Division at Eli Lilly. He leads material selection and evaluation efforts for new products within R&D division. He is also a materials SME (plastics and elastomers) for compendia and other regulatory activities. Before joining Lilly, Naresh worked as a product development engineer at Celanese. In this role his main focus was developing engineering thermoplastic and bio-based grades for

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automotive, consumer and electronic applications. Naresh obtained his bachelors in chemical engineering from Osmania University, Masters in chemical engineering from University of Mississippi and has a Doctorate in Biological Systems Engineering from Virginia Tech.

Afternoon Session: "*Development of Guidance for the Interconnect-ability between Vial Container Closure Systems and Vial Transfer Devices*"

Vial transfer systems are increasingly being used by Health Care Providers (HCP) during the administration of therapeutic agents in vial presentations. The main reason being safety improvement to the HCP from needle sticks. This, however, has led to an increase in complaints from the HCPs (Ex: High Push force, Stopper getting pushed into the vial). Considering that vials and transfer devices are produced by separate manufacturers, manufacturers are experiencing difficulty in resolving complaints directed to their firm. In effect, any one manufacturer can only control the half of the connection that it has designed and produced. Variations in design, materials, and functional performance on the 'other' mating half cannot be controlled even though it may play significantly into the faulty connection. This occurs despite manufacturers utilizing design controls and exercising testing with known and available associate devices, usability testing, etc. To address this issue, members from pharmaceutical, elastomer and transfer device companies formed a consortium and reached out to a Product Quality Research Institute (PQRI). One of the primary goals of this work is to establish standards for the evaluation of the connection between vial systems and vial transfer devices.

Biography for
Don DeMello

Don is a Principal Field Development Engineer with the medical polymers business of Celanese Engineered Materials. Celanese is The Chemistry Inside Innovation™ and has been providing polymer solutions to the medical device industry for decades.
Don has a BSME from Worcester Polytechnic Institute and since university, has worked in the engineering resins industry for almost 30 years in a variety of application & market development roles across a wide range of markets.
He enjoys working with customers on the forefront of new & improved product developments where resin specification decisions are made based on design & performance needs.

Poster Session: "*Advantages of Liquid Crystal Polymers for precision thin-wall design & molding of combination drug delivery device components*"

Liquid Crystal Polymer (LCP) thermoplastics are well-known in the consumer electronics industry for tight tolerance designs with high stiffness and strength, plus rapid cycle times and extreme flow to fill sub-mm wall sections. Processing benefits allow for micromolding replication of details and economical device volumes in the millions of units. These same advantages are translatable to precision

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combination drug delivery devices which incorporate complex mechanisms and wireless connected electronics for pharma prescription adherence goals.

Specifically, LCP resins can help designers and engineers achieve more compact, intricate components thru thinwall molding even as low as 0.3mm (0.012in) nominal wall without sacrificing mechanical stiffness and strength as LCP polymer chains are inherently stiffer & stronger than many other neat thermoplastics. This can be an advantage in wearable/on body devices where light weighting, compact form factors, and liberating more internal space for pharma dose & components are critical.

Biography for
Yubiao Liu, Ph.D.

Yubiao Liu, Ph.D., is the global technical platform lead in Eastman specialty plastics medical device segment at Eastman Chemical Company, in Kingsport, Tenn., USA. Liu supports medical customers globally with a greater focus on developing new products to address previously unmet needs for medical device housings and electronics. With over 12 years of experience in the medical industry specialized in polymer synthesis and material evaluation, Liu is an authority in the field.

He joined Eastman in 2012 as the medical application development representative, specializing in Tritan™ copolyester for applications in the medical device industry. Prior to his time at Eastman, in 2006, Liu was a research scientist at Greatbatch Medical, working on the development of biomimetic coating and on an antimicrobial coating project. He has eight years of medical industry experience in polymer and biomaterial synthesis and polymer material evaluation, and has provided support to 510(k) submissions.

Liu earned a bachelor's degree in material science and engineering from the University of Science and Technology of China and a doctorate in chemistry from the University of Akron. He conducted his postdoctoral research at the University of Akron and Emory University School of Medicine, focusing on polymer synthesis and biomaterial surface modification.

Panelist & Poster Session: "*New generation flame retardant materials - exceptional compatibility with most healthcare disinfectants*"

Healthcare-associated infections must be decreased for healthcare systems to continue being reimbursed for care. This means disinfecting protocols encouraged by the Centers for Disease Control must be followed and are more aggressive than ever before. Plastics in healthcare, especially those used in housings and hardware of electronic equipment have begun to fail over the last 10-15 years at an alarming rate. Better, more disinfectant ready plastics are required to give durability over the expected life of the device. Polymer scientists discovered that Eastman Tritan™ copolyester has excellent chemical resistance in the dishwasher, and later determined that the same polymer chemistry was even more beneficial in plastics used in medical equipment where resistance to most healthcare disinfectants is crucial. This presentation will substantiate the material performance, especially

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chemical resistance claims with disinfectants, when Tritan™ is used in compounded flame retardant materials for medical equipment.

Biography for
Rodger Hendrick

Roger Hendrick has more than 25 years of experience with Dow Corning Corporation, Dow Chemical and DuPont. He is currently an application engineer and technical service representative for Dow Silicones Corporation, as well as a Six Sigma Black Belt. He has devoted his entire career to healthcare, working in manufacturing and quality engineering roles prior to his current Science & Technology responsibilities.
He has significant experience in application and process development as well as product commercialization of silicone elastomers used in medical devices for molding and extrusion. In 2015, Dow Corning recognized his contributions with the prestigious Application Engineering Excellence Award.
Roger earned his bachelor's degree from Saginaw Valley State University in 1992.

Poster Session: "Healthcare Liquid Silicone Rubber for Low Temperature Overmolding Applications"

Liquid Silicone Rubber (LSR) refers to injection moldable thermosetting elastomeric products. The development of LSR products suitable for overmolding onto thermoplastic components such as those made from copolyester has been accomplished with new LSR technologies broadening medical device design options. In consideration of thermoplastic heat deflection temperatures it is necessary to rapidly cure suitable LSRs at temperatures less than 110 °C whilst delivering physical properties such as tensile, tear, clarity, and mixed pot-life typical to standard LSR. Characteristics such as these along with compliance to medical device requirements as defined by USP Class VI make them suitable for medical applications like respiratory care, medical housings and external communicating devices.

Biography for
Selvaanish Selvam

Selvaanish Selvam is a Business Development Engineer at Clariant. He is a recent graduate from Case Western Reserve University with a Master's Degree in Biomedical Engineering and a minor in Chemistry. In addition to his degree, Selvaanish was on the Dean's Council at Case Western and a past President of their Biomedical Engineering Society. As an intern for over 4 years at the Cleveland Clinic, Selvaanish participated in the development of a portable air-oxygen blender for neonates. This unique device has been applied for patent protection.

Poster Session: "*Shaken not stirred? How will USP661.1 and ICH Q3D impact your pharmaceutical packaging materials cocktail?*"

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USP661.1 is a new standard for pharmaceutical packaging and drug delivery devices that doesn't take effect until May 2020, when it will impact all current and future drugs on the US market. In addition, the ICH-Q3D guideline strengthens the risk assessment process by evaluating packaging to ensure it is not the source of elemental impurities in drugs.

During the transitional period, the FDA allows the industry to make new filings under the older <661> or the new <661.1> standard, but in 2020, all existing and new drug/package combinations will need to be tested and compliant to the new standard.

Compliance with <661.1> involves a significant modernization of test methods and a more robust risk assessment process. The major consequence of this change is that in 2020, the 'food contact statements' that have supported the use of many materials in drug packaging will be deemed 'insufficient' to support their future use.

Biography for
Brad Davison

Brad Davison is a Plastics Engineer who has been working in the plastics industry since 1998. Brad earned his Plastics Engineering degree from Penn State Behrend's PLET program in 1999 and has held various positions within the automotive and material industries including; Product Development Engineer, Program Manager, Senior Process Engineer, National Technical Service Rep, and National Application Development Engineer. He is currently the Engineering Manager for PolyOne's Specialty Engineered Materials business. Brad is a member of SPE, Penn State's PLET advisory board and American Injection Molding's advisory boards. He has also created several injection molding training modules to enhance plastics processing knowledge within PolyOne. Brad resides in Ohio.

Poster Session: "*Medical Material Selection – It is More Than Just Materials*"

As the medical industry continues to evolve, patient demand is putting increased pressure on medical device manufacturers to bring innovative technologies to market. These technologies are enhancing device functionality by changing how and where healthcare happens. Selecting the right materials for the application requires more than just a supplier, it requires a partner that can help throughout the process from concept to production, enabling speed to market. Engaging a partner early in the design process ensures the material will meet the functional requirements of the design, will utilize the optimal manufacturing process, and withstand the demands of the end application. Determining the right material and process from the start means reduced design iterations, risk mitigation during the regulatory approval process and improved manufacturability, allowing manufacturers to get their devices to market on time and on budget.

UPCOMING EVENTS

spe ANTEC® 2019
Detroit, MI • March 18-21, 2019

CALL FOR PAPERS

ANTEC® is the largest international technical meeting of individuals representing industry, government and academia, providing a broad perspective on the science, engineering and business of plastics.

Submission deadline has passed speaker submissions now being accepted for ANTEC 2020

YOU ARE INVITED TO SUBMIT A PAPER FOR PUBLICATION & PRESENTATION

- Podium and poster presentations showcasing the latest in industrial, national laboratory and academic work
- Share your findings in polymer research or new and improved products and technologies

TOPICS WILL INCLUDE

- Additive Manufacturing/3D Printing
- Automotive
- Bioplastics
- Blow Molding
- Building and Infrastructure
- Color & Appearance
- Composites
- Decorating and Assembly / Joining
- Electrical & Electronic
- Engineering Properties & Structures
- Extrusion
- Failure Analysis
- Flexible Packaging
- Foams
- Injection Molding
- Medical Plastics
- Mold Technology
- Plastic Analysis
- Sustainability
- Plastic Pipe and Fittings
- Plastics Recycling
- Polymer Analysis
- Polymer Modifiers & Additives
- Product Design & Development
- Rheology
- Rotational Molding
- Thermoforming
- Thermoplastics Materials
- Thermosets
- Vinyl Plastics

UPCOMING EVENTS

Medical Plastics Division

ANTEC® 2019 CALL FOR PAPERS

Submission Deadline: October 19, 2018

Type of Papers/Presentations:

- Submission deadline has passed
- speaker submissions now being accepted for ANTEC 2020
- content will be reviewed before acceptance

Topics of Interest Include:

- Novel Materials/Chemistries
- High Performance Materials/Composites
- Implantable Materials
- Absorbable Materials
- Drug Delivery Devices
- Medical Devices for Different Applications
- Additive Manufacturing
- Micro-molding
- Medical Textiles and Woven Structures
- Surface Modifications, Coatings and Additives
- Diagnostics Devices and Methods
- Modeling and Characterization Methods
- Bio-Derived Materials