Holiday Season Special Edition Newsletter

2021

Inside This Edition…

SEASON'S GREETINGS FROM THE CHAIR

Fellow Medical Plastics Division Members:

Hope you and your family are safe. While we all hoped to get back to pre-pandemic normal, it seems that we may have to wait a little longer because of the highly transmissible COVID variant spreading across the United States.

I would like to start by thanking our past Board members Michael Wallick and Victoria Nawaby for their exemplary service and contribution to the Medical Plastics Division. Mike was the chair of the awards committee while Victoria spearheaded MPD's webinar program. On behalf of the MPD Board of Directors, I wish them success in their next roles.

While we spent most of 2021 virtually, Medical Plastics Division leaders successfully organized events, both in-person as well as virtual. I would like to share some of our accomplishments:

a) MPD webinar series on topics relevant to medical device industry was a huge success.

b) The Virtual Technical Forum and Networking event series was organized to bring plastics professionals virtually together once a month for a technical presentation by guest speaker followed by a networking event.

c) Medical Plastics Division teamed up with Informa Markets to organize one-day MiniTec conference "Medical Plastics to Help Save the World" on August 10, 2021 at Anaheim Convention Center in Anaheim, California. The conference was held in conjunction with MD&M West with podium and poster presentation and panel discussion on sustainability.

SEASON'S GREETINGS FROM THE CHAIR

I would like to recognize Len Czuba and Ned LeMaster for their leadership in planning and organizing MiniTec event; Ravi and Gregorio for driving membership activities; and Louis Somlai and the entire communication team for the MPD newsletter and other outreach activities.
Finally, I would like to acknowledge all our sponsors including Celanese, Avient, Evonik and many more for supporting Medical Plastics Division.

As we close out 2021, I would like to end by wishing everyone happy holidays. Stay safe and enjoy time with your families. I look forward seeing everyone in the new year.

Cheers
Ali Ashter

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Vijay.Kudchadkar@westfall-technik.com

Selvaanish Selvam

Selvaanish.Selvam@avient.com

SEASON'S GREETINGS FROM THE NEWSLETTER EDITOR

Greetings fellow Medical Plastics Division Members. 'Tis the season to be jolly and I would like to wish you and your family joy and peace, this holiday season and always.

In this newsletter, we are featuring posters from the SPE MiniTec that was organized in Anaheim, CA in August 2021. A number of interesting technical topics were presented in these posters and we trust you will find them educational and informative.

We have several events lined up in 2022. Please visit our website for more details. https://www.4spe.org/i4a/pages/index.cfm?pageID=3559

Merry Christmas and Happy Holidays! Have a magical holiday season!

Best wishes, Vijay Kudchadkar

Newsletter Suggestions? Interested in Sponsorship?

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We would like to thank our generous sponsors for supporting our "Medical Plastics in Manufacturing: The Virtual Edition" virtual conference.

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MiniTec 2021
Anaheim, CA • August 10, 2021
Presented by SPE Medical Plastics Division

POSTERS DISPLAYED AT THE SPE MiniTec IN ANAHEIM, CA AUGUST 10-12, 2021

THE EVOLUTION OF THERMOPLASTIC POLYURETHANES FOR MEDICAL DEVICES

LUBRIZOL LIFE SCIENCE

SPE MEDICAL PLASTICS

Medical Grade Material

Lubrizol's Promise of Quality and Reliability

- ✓ Manufactured Under ISO Certified Facilities
- ✓ Change Notification Policy
- ✓ Quality Audit Program
- ✓ Regulatory Assistance
- ✓ Record Retention Procedures
- ✓ Biocompatibility Evaluation

1920-1940

The invention of synthetic polymers.

1950

1960

Polyester urethanes tested in bone grafts, but found to degrade hydrolytically.

BFGoodrich invents thermoplastic polyurethane (TPU).

1970

Polyether TPU developed and commercialized as Pellethane®.

Pacing lead insulation developed using Pellethane® as a silicone replacement.

Tecoflex™ tested in atomic heart.

1980

Tecothane™ developed as Pellethane® alternative.

- Rigid TPU commercialized as Isoplast®.
- Aliphatic polyether TPU commercialized as Tecoflex™.

1990

Polycarbonate polyurethanes commercialized for improved *in vivo* stability.

2000

Commercialization of aromatic hydrocarbon ester TPU, Tecothane™ Soft.

Commercialization of Tecophilic™ aliphatic hydrophilic TPU for molecular transport applications.

2010

Introduction of GMP manufactured TPUs for drug eluting devices.

Lubrizol acquires Dow and Thermedics TPU products, creates Life Science group.

Expansion of Lubrizol medical TPU portfolio with Pellethane® 5863, 5855 series and regional specific products.

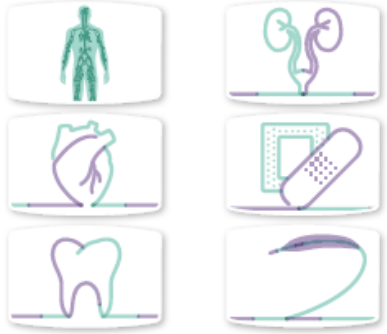
2020 - FUTURE

Commercialization of non-softening resilient TPU, Tecobax™.

Lubrizol Medical Grade Portfolio

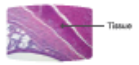
- **Carbothane™**
  - Aromatic and aliphatic polycarbonates
- **Tecoflex™**
  - Aliphatic polyethers
- **Tecothane™**
  - Aromatic polyethers
- **Pellethane®**
  - Aromatic polyethers and polyesters
- **Isoplast®**
  - Rigid aromatics
- **Tecophilic™**
  - Aliphatic polyethers (hydrophilic)
- **Tecobax™**
  - Aliphatic polyethers (non-softening)
- **Tecothane™ Soft**
  - Aromatic bio-based hydrocarbon-esters
- **Tecoplast™**
  - Rigid aromatics

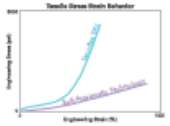
Application Areas

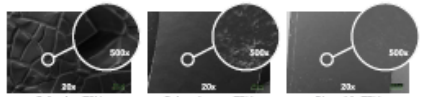


Future Innovations

- Sustainable Raw Materials & Manufacturing
- Antifouling Technology
- Antimicrobial Technology
- Soft Atraumatic Technology
- Enhanced Biostability
- Coating-Free Surface Modification
- Self-Healing Characteristics







Oxidative resistance (8 weeks, in vitro assay) SEM surface images

HEALTH

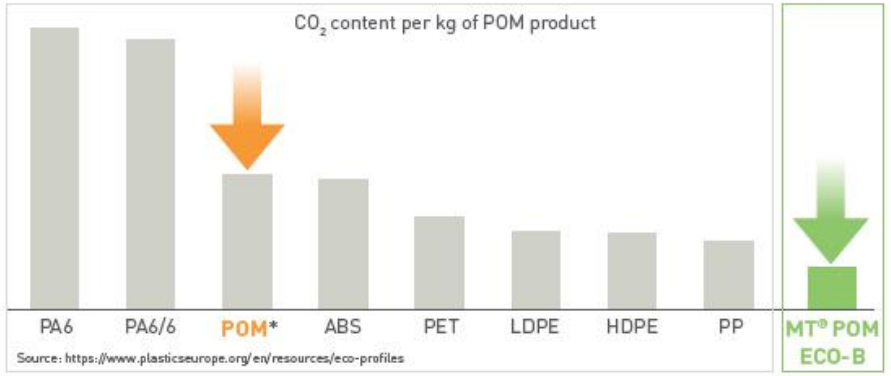
For more information on Lubrizol Life Science's Medical Grade TPU Portfolio please visit **Booth 2401** or **www.Lubrizol.com/Health.**

Celanese
The chemistry inside innovation™

spe MEDICAL PLASTICS

Proven, Versatile and Environmentally Sustainable

Functionally identical to conventional POM, Celanese Hostaform® MT® POM ECO-B offers top-tier performance with a significantly lower CO_2 footprint.



- CO_2 footprint per kilogram of polymer is less than half that of conventional POM
- Manufacturing processes are unchanged so no product requalification or performance sacrifice
- Contains up to 97% bio-content via a mass-balance approach: fossil-based and bio-based feedstock are mixed in the process but accounted for separately
- ISCC+ certified approach and in compliance with the EU Renewable Energy Directive

Influence of Pellet Size on Medical Tubing Extrusion Process Stability

Chris Moran, Ph.D.

c.moran@compoundingsolutions.net

Summary

- Tubing was produced on a ¾" extruder, varying pellet size while holding all other parameters constant.
- Die pressure and tubing diameter were more stable when using smaller pellets of Nylon-12 and HDPE.

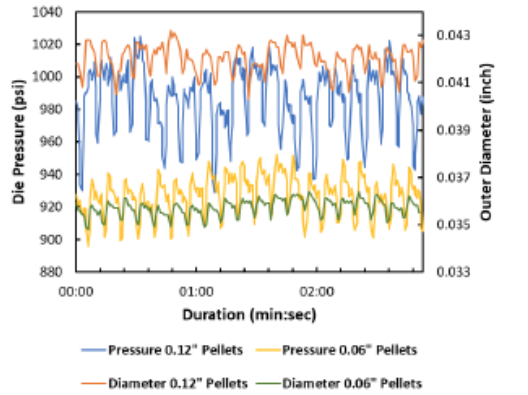
Background

The standard thermoplastic pellet size of roughly 0.12" is well-suited for most melt processing equipment. However, as the medical industry continues to call for more minimally invasive devices, micro-tubing extrusion technology continues to answer by pushing limits of processing extremely thin-wall and small-diameter products with tighter dimensional tolerances. Producing such tubing requires smaller single screw extruders, where smaller than standard pellet sizes can improve process stability and dimensional tolerances by reducing feed rate fluctuations.

Methods

Compounding Solutions produced pellets with sizes of 0.12", 0.10", 0.08", and 0.06" using several common thermoplastics: TPU, Nylon-12, and HDPE. Medical Extrusion Technologies extruded tubing using a ¾" single screw extruder. All compounding and extrusion parameters were optimized for each material and maintained constant throughout various pellet sizes. Each pellet size was purged for at least 5 minutes prior to monitoring drive motor load current, die pressure, and tubing diameter for at least 35 minutes of extrusion.

"Screw Beat" Fluctuations Aligning With Screw RPM in Nylon-12 Extrusion



Results

During extrusion, die pressure and tubing diameter exhibited shorter timescale repetitive fluctuations and longer-term, more random drift. We attributed drift to the system moving towards equilibrium, and we therefore chose to focus on the short repetitive fluctuations.

The phenomena known as "screw beat" was observed, where cyclic die pressure and tubing diameter fluctuations correspond to screw speed (7RPM as shown for Nylon-12). The magnitude of screw beat fluctuations was found to depend on pellet size, with smaller pellets allowing for less fluctuation. This improvement in stability is quantified by the relative standard deviation and range of all data points within 3-minute windows. Stability improved with smaller pellet sizes of Nylon-12 and HDPE, but the correlation was not strong for TPU.

We postulate that smaller pellet sizes reduce the magnitude of cyclic screw beat fluctuations in smaller extruders because they fill each screw channel with more pellets, allowing for more consistent packing. As the screw turns and pellets are conveyed down the barrel, the force of gravity arranges pellets naturally to fill the void of the next channel. Due to the discrete number of pellets, a whole number of pellets must fill each channel. Stochastic packing fraction fluctuations lead to a variable number of pellets filling each channel. There is an inherent variation of +/- 1 pellet. As the pellet size approaches the screw channel depth, variations in channel-to-channel packing accounts for a much larger percentage of total mass filling each channel. Mass flow rate variations in the feed zone manifest into melt pressure fluctuations further downstream.

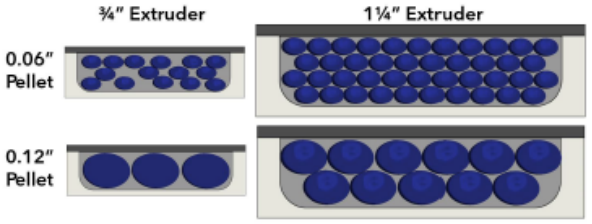
The overall mass flow rate, known as throughput, was calculated based on measured diameters and puller speed. There was a clear trend in all materials with smaller pellets slightly reducing throughput. Such a slight reduction could easily be compensated for by increasing screw RPM when using smaller pellet sizes to maintain manufacturing efficiency while improving dimensional tolerances.

Conclusions

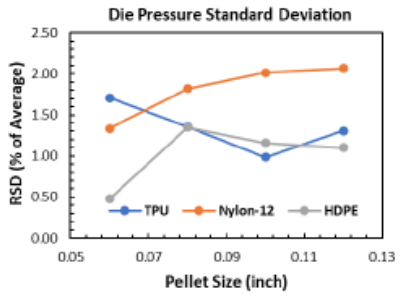
Cyclic fluctuations corresponding to screw rotation speed were observed, confirming the "screw beat" phenomenon caused by void formation and packing fraction fluctuations in the feed zone. Smaller than standard pellet sizes were proven to improve die pressure and tubing diameter stability in Nylon-12 and HDPE using a ¾" extruder. It is not clear why these trends were observed for Nylon-12 and HDPE but not for TPU. Investigating surface interactions such as friction and adhesion at the pellet-pellet, pellet-barrel, and pellet-screw interfaces could provide additional insight.

Pellet Size	Number of Pellets per Screw Channel		
	¾" Extruder	1" Extruder	1 ¼" Extruder
0.06"	485	1159	2263
0.08"	205	489	955
0.10"	105	250	489
0.12"	61	145	283

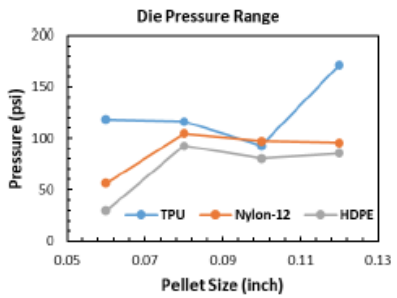
Screw Channel Cross-Section



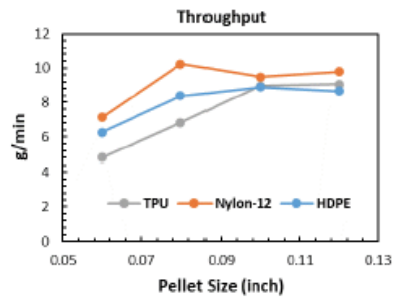
Die Pressure Standard Deviation



Die Pressure Range



Throughput



The Complexity of E&L Testing : Effectively Assessing Biological Risks for Devices that Interact With or Deliver Drugs

Rigwed Tatu, Ph.D., Laura Beringer, Ph.D., Matt Heidecker, Ph.D., Tera Alabran, Michael Alabran

Background

- The recent September 2020 updates to the publication of 'Use of the International Standard ISO 10993-1' by the FDA has brought extractables/ leachables (E/L) testing and chemical characterization to the forefront of medical device biocompatibility evaluations.
- While there are international standards that address E/L testing methods, it remains a challenge for the medical device industry to *interpret and assess biological risk from these experiments to establish compliance*. This includes devices which interact with drugs.

Problem Statement

- Choosing appropriate solvent systems per ISO 10993-18:2020 that mimic lipophilicity and hydrophilicity of drugs, *without degrading the polymer* utilized in medical devices is a challenge.
- The solvents should be capable of exaggerating the analytes to encompass worst-case toxicological risk, without degrading the polymers or artificially introducing analytes that are not clinically relevant.

Market and Opportunity Gap

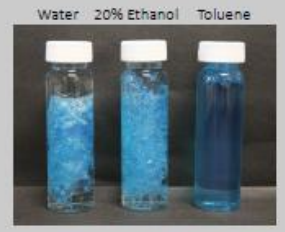
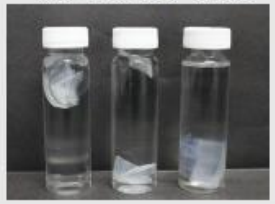
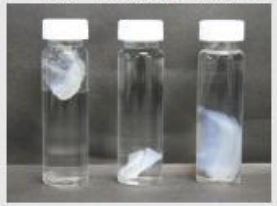
- PSN is uniquely positioned to create custom drug analyses for those devices that interact with or deliver drugs - this includes polarity index (PI) and log P research.
- Solvent feasibility studies are conducted with PI and log P drug characteristics to determine which solvents with lower PIs (toluene, hexane, 100% IPA) are appropriate.
- Custom scientific justifications are written for the medical device and specific drug profiles to demonstrate which solvents were chosen and why they are appropriate.

References

- ISO 10993-18:2020 – Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
- ISO 10993-12:2021 – Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

Proof of Concept Work

Objective: Study the interaction and response of different materials to solvents of varying polarities.
Approach: Common polymer material families utilized in a variety of medical devices were selected and exposed to solvents of varying polarities, as shown in the table below. Polymers were extracted at 50°C for 72 hours, per conditions referenced in ISO 10993-12:2021.

Material Family	Baseline Image	Image after 72 Hours at 50°C
Polyester and Ethyl Vinyl Acetate		
Silicone and Polypropylene		
Polycarbonate Urethane and Polyamide		

Key Takeaways and Recommendations

Evaluation: Each extract was evaluated for condition and clarity.
Results: The non-polar solvent toluene, and some semi-polar solvents lead to visible changes, to include discoloration, swelling, and a change in turbidity of extracts. Solvents which interact with the polymer in these ways, often indicate degradation and chemical changes being introduced, and can lead to an inaccurate E/L profile. To be in compliance with ISO 10993-18:2020, it is critical that discoloration, swelling, and degradation does not occur - therefore solvent feasibility studies are necessary, even when the medical device interacts with lipophilic drugs, in order to determine the most appropriate solvent.

About PSN Labs

- PSN is an ISO 9001:2015 certified engineering firm, providing services in all areas of product development. PSN has three main business units:
  - *Engineering Design Center*
  - *Materials Processing Lab*
  - *Testing Lab (ISO/IEC 17025:2017 Accredited)*
- Our teams of scientists, engineers, and SMEs work cohesively to be your full-service development partner.

"Our focus is providing world class engineering services and innovative solutions with one goal in mind – our clients' success"

- Michael Alabran, President

- Services offered by PSN:
  - Extractables and Leachables Testing (ISO 10993-18)
  - VOC and Particulate Testing (ISO 18562-2, ISO 18562-3)
  - Biocompatibility Evaluations and Toxicological Risk Assessments
  - Material Selection and Development
  - Resin/material Equivalency Testing
  - Design/Simulation Services
  - Failure Analysis
  - Regulatory Testing
  - Expert Witness Services
  - Training Seminars

Polymers in Ultra-Cold Environments in Packaging and Devices

Dan Gorsky P.E. – Senior Associate
Jeremy Hemingway P.E. – Senior Associate
Rob States – Principal
Stress Engineering Services
Booth #2097

Abstract: Determining Viability of Polymers in Packaging and Products at Ultracold Temperatures through Analytical Modeling and Lab Testing

The role of polymers in the successful implementation of new pharmaceutical drugs and medical devices/packaging is increasing as products become more sensitive to environment. To manage stability and integrity, products are stored and shipped at ultra-cold temperatures (<-40°F); a temperature range at which many traditional polymers are not well understood at an application level. This poster highlights the level to which polymers can be characterized and analyzed to understand from a fundamental physics perspective whether there is a technical right for success of these applications. Through characterization testing at ultracold temperatures (below), TMA and Analytical modeling (Left), and instrumentation to identify necessary temperature constraints (right), packaging and products can be de-risked prior to shipping valuable product.

Case Study 1: Evaluation of Cryogenic CCS Seal Integrity using an Incremental Computational Approach

Can Seal Integrity be maintained at cryogenic storage for a 'typical' plastic 2ml Vial and standard assembly lines?

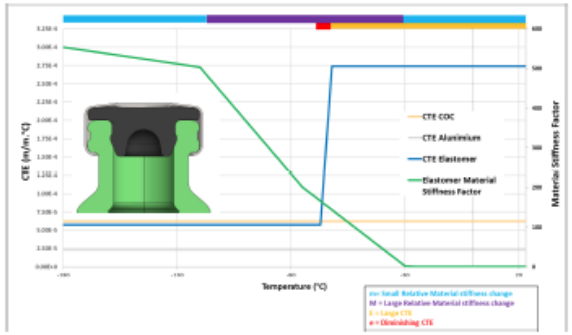


Figure 1: Seal Contact Pressure through Temperature Ramp

Seal integrity can be defined by the sealing contact pressures. Advance material characteristics are necessary and must include more than the typical CTE and varying modulus inputs, especially as temperatures approach and surpass T_g.

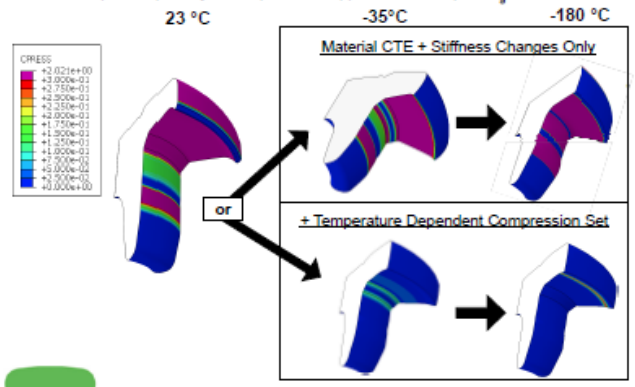


Figure 2: Stopper Seal Contact Pressures vs Temperature | CTE and Stiffness only, vs additional temperature dependent compression set

Case Study 2: Lab Characterization and Design Considerations

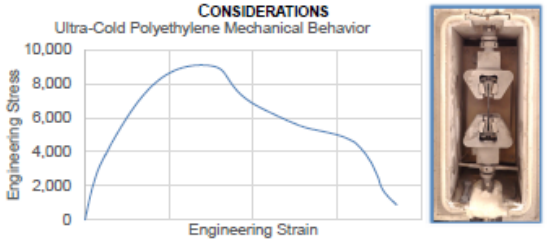


Figure 3: Polyethylene Ultracold Mechanical Characterization

- PE mechanical properties show some ductility and elevated strength at ultracold temperatures
- Adhesive joints may suffer, not all pharmaceutical products are ideal for Ultracold.

Figure 4: Adhesive Failure of Plastic Pallet with Adhesive Joint after Vibration

Case Study 3: Ultracold is a Transient Environment

It is important to understand the true temperature excursions expected during shipping to ensure proper and efficient safety and efficacy evaluations.

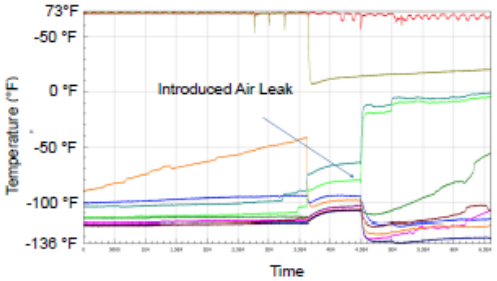


Figure 5: Thermocouple Instrumentation of Dry Ice Package

A common assumption for dry ice packages is that the temperature of products inside of the box cannot go below –109.3 °F. As shown in Figure 5, instrumentation of a dry ice shipper, shows that the air temperature can drop below the temperature of dry ice. To date, the lowest measured by SES has been -136 °F, but this is in a controlled lab environment. Future evaluations of transit scenarios could show more temperature range. The packaging approach can affect the temperature inside of the shipper, but methods must balance regulatory standards for shipping dry ice.

Figure 6: Vaccine Temperature Anomaly New Article
Covid vaccine: U.S. quarantines Pfizer shipments in California, Alabama after transit 'anomaly' (cnbc.com)

Figure 7: Dry Ice Instrumented Package

Manufacturing of Micro Medical Parts Without Cold Runners

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High Costs of Cold Runner Scrap

In conventional micro molding with cold runners, the weight of a cold runner system can be 2-50 times the weight of the part. It is an excessive amount of waste - especially when the cold runners cannot be recycled, and the resin is expensive. Even when regrind is permitted, the entire mass of cold runner scrap produced will not be reused since the part volumes are so small compared to the cold runner volumes. The vast amounts of cold runner material that cannot be reused, must then be disposed or sold, or in the worst-case scenario ends up in land-fills.

Figure 1: Material worth 55 parts is scrapped every cycle.

Cold runners require handling which increases the number of steps in the process and increases production costs. Millions of parts must be detached from millions of cold runners. Labor and energy is required to regrind the cold runners, when regrind is permitted. Unused cold runners must be disposed, which again, consumes labor and energy.

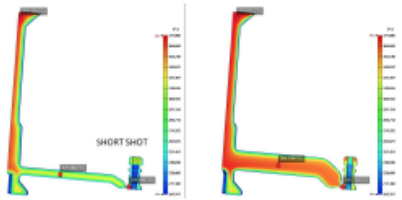


Figure 2: Cold runner diameters often need to be increased to fill and pack micro parts which increases material consumption and cycle time.

Cold runners increase the cost of production by increasing the cycle time. In injection molding, the required cooling time (for plates) is directly proportional to the second power of the thickness of the plastic. If the thickness of the cold runner is 3 times more than the thickness of the part, the required cooling time for the cold runner would be 9 times more that the cooling time of the part. In other words, if the micro-sized part cools in 0.5s, the molder would be waiting an additional 4s for the cold runner to cool down. If it took 43 days to produce 1.5 million micro parts on a 4-cavity cold runner tool, approximately 26 days would be wasted waiting for the cold runner to cool down.

Conventional hot runner technology often fails in micro molding applications due to long residence time, melt compressibility, and shot size control.

Proprietary M3 ISOKOR Technology that Enables Direct Gating of Micro Parts

A new molding machine (M3) and molding process (ISOKOR) were invented to overcome the challenges of conventional hot runners. The fundamental idea behind the new machine and process is to be "kind" to the polymer until it reaches the gate. In this process, a low-shear screw first gently melts the polymer. The temperature of the material is gradually increased inside a temperature-controlled runner that is engineered to provide a high level of temperature control and temperature uniformity. The material is only brought up to its processing temperature when it is near the gates, which significantly reduces the time melt is exposed to high processing temperatures and shear heat, minimizing melt residence time and maintaining the integrity of the resin. To inject the material into the cavity, valve-gates are opened, and the material is injected directly into the cavity using plungers. This process is significantly gentler to the polymer when compared with conventional injection molding. A proprietary molding technique ensures that the allowable residence time of the melt is increased.

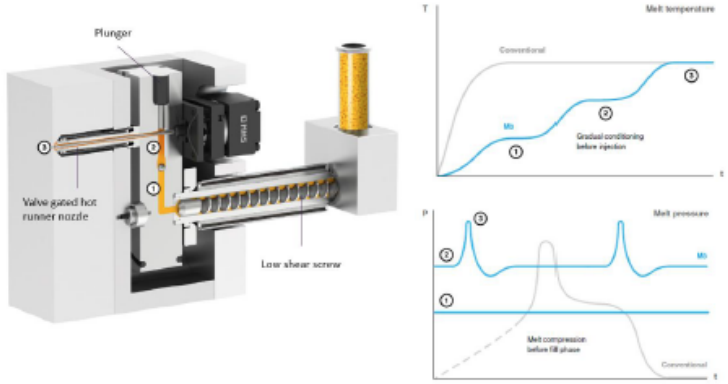


Figure 3: Proprietary ISOKOR injection unit and process

Cycle times are also significantly reduced by eliminating/reducing cold-runners. In the ISOKOR process, the molder must wait only for the part to cool to its ejection temperature. Micro parts cool within 0.5 to 2s. The molder does not have to wait an additional 4-10s for the cold runner to cool below its ejection temperature. Fill times are also reduced since the molder does not have to wait for the cold runner to fill and pack during each cycle. This results in nearly 50-75% reduction in cycle time, which adds up to a significant reduction in production time. Clamp tonnage is directly proportional to projected area and the melt injection pressure. In cold runner micro molding, the projected area of the cold runner dictates the size of the molding machine. Increasing the tool number of cavities results in increase projected area of the cold runner. As molding machines get bigger, the molder loses the ability to control filling of micro parts. In the ISOKOR process, the clamp tonnage is dictated by the projected area of the micro-sized parts only thereby making it easier to scale up production and still maintain a high degree of control over the molding process.

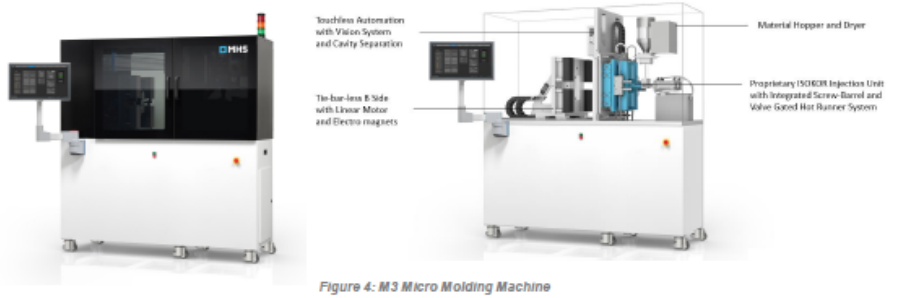


Figure 4: M3 Micro Molding Machine

Savings Realized by Eliminating Cold Runners

The costs of cold runner scrap can add up quickly. Consider an application where the production goal is 120 million micro polycarbonate parts per year. In this application, the part weight is 0.0958g and the material cost is $10.5/lb. If you attempt to make these parts with a 8-cavity cold runner mold, the cold runner to part weight ratio would be 4:1. This would mean that in each cycle, 8 useful parts would be produced and material worth 32 parts would be scrapped. During the course of a year, 101,377.45lbs of resin worth $1,064,463.22 would be wasted. On the other hand, if you make these parts with direct gating, 100% of these costs would be avoided and 50.68 tons of resin would be saved.

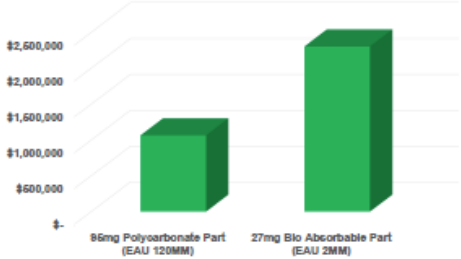


Figure 5: Annual savings in polycarbonate and bioabsorbable applications, by eliminating cold runners.

In bioabsorbable applications, the runner to part volume tends to be higher to reduce the shear stresses and shear rates the material experiences. If the part weight is 0.027g and the runner to part weight ratio is 9:1, 1,071.45lbs of resin would be wasted while making 2 million parts. If the cost of the resin is $2,1500 per lb, the cost of the resin wasted would be $2,303,612.06. These costs can be eliminated by direct gating.

Benefits of Direct Gating Micro Parts

- Higher quality, direct gated parts without wasted cold runner material or secondary processes
- Cleaner gate vestige
- Reduction/elimination of sink marks
- High process consistency
- Faster cycle times for small parts ranging from 0.001 - 0.400g
- Extremely high production outputs
- Increased allowable melt residence time
- High cavitation in a low tonnage machine – smaller footprint.

WESTFALL TECHNIK

Reverse Engineering a COVID-19 Testing Swab

Abstract

As the COVID-19 pandemic intensified in spring 2020, Teel Plastics was approached by a customer with an urgent need to reproduce a test swab known to work in detecting the virus. A limited number of commercially purchased samples of the swab were available, so it was necessary to identify the material of the swab to back-up source the swab.

Teel utilized ISO 17025-accredited Teel Analytical Laboratories to reverse engineer the swab to identify the material and confirm its functionality for COVID-19 testing. After conducting and comparing tests for a variety of materials, Teel identified key characteristics and determined the material was most likely a Tritan copolyester.

Sample of the reverse engineered swab.

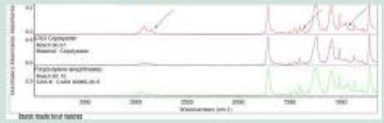
Objective

Teel's objective was to identify the material used in the swab stick by comparing it with other materials exhibiting the characteristics that made it particularly suitable for COVID-19 testing. These included the material's stiff but flexible quality, smooth and high gloss surface, injection molding compatibility, biocompatibility, medical device compatibility, and its ability to be flocked and broken at a fracture point.

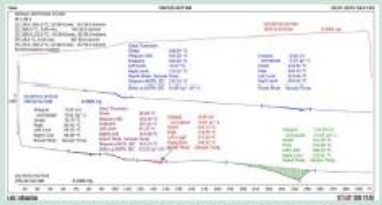
Teel conducted four phases of testing and analysis. The first included Fourier Transform Infrared Spectroscopy (FTIR) and Differential Scanning Calorimetry (DSC) analysis for initial material identification and confirmation of families of materials. The second phase included another round of comparative FTIR and DSC tests based on conclusions reached during initial testing to further home in on the material. The third phase included a flex modification to confirm material functionality for stiffness. A final step included a data sheet review for medical uses and material compatibility.

Results

Teel's initial FTIR samples determined the swab material was a close match to a PETG copolyester. However, peaks in the data showed significant areas of deviation that indicated potentially additional aliphatic groups, a potential alternate alkane chain in part of the structure, and a benzene ring structure. This suggested the material was likely a polyester-based material. DSC data showed the material was amorphous with a glass transition around 102°C. Differing DSC melt data indicated the material potentially had a heat stabilizer or secondary polymer, possibly from a colorant.

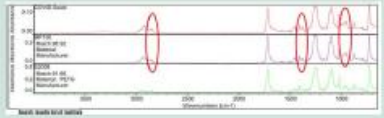


Initial FTIR comparison showing areas of deviation from PETG and PBT.

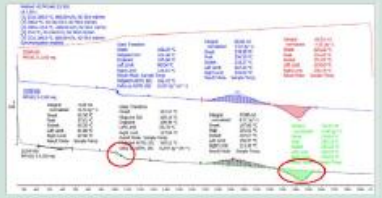


Initial DSC sample data showing first melt at ~130°C and more pronounced melt at ~245°C. A second sample did not show the initial melt at 130°C.

For its second phase of testing, Teel sought out more copolyesters for additional FTIR and DSC tests and comparison with the swab sample. PETG was dismissed from this round of tests due to thermal results, but an alternate material, a Tritan copolyester, was determined to be a substantial material and thermal property match. It showed the additional aliphatic groups present in the sample, the alternate alkane chain in part of the structure, and a potential benzene ring structure. DSC data also confirmed the material would be capable of flocking based on glass transition.



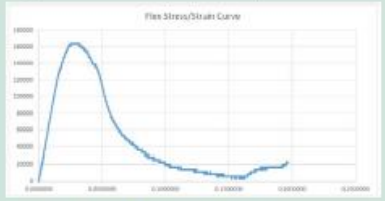
FTIR comparison showing aliphatic groups and other features present in sample were absent from PETG



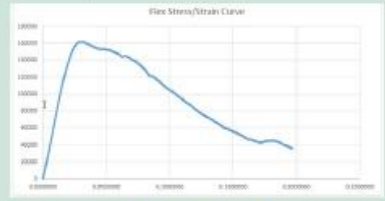
DSC data showing Tritan copolyester first and second heat at essentially the same results as sample.

During the flex mod Teel conducted for its third phase, the stress/strain curve for the sample part exhibited a sufficient match to the Tritan copolyester, demonstrating the material to be functional for its end use.

The last step was to conduct a data sheet review of the Tritan copolyester. Teel found the material was suitable for pharmaceutical and medical packaging, could withstand ETO sterilization, was amorphous with a glass transition at 110° C, and had melt processes at 260-280°C. The material was also suitable for injection molding with high flow rate and low mold shrink, all close matches to the sample and customer requirements.



Swab sample stress/strain curve



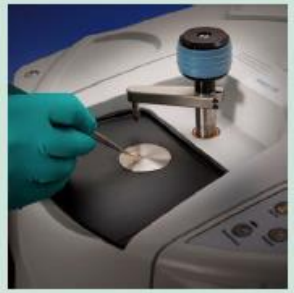
Tritan copolyester stress/strain curve

Conclusion

Teel concluded the material used in the swab sample was most likely a Tritan copolyester. The FTIR match was high and DSC data confirmed the grade selected was close. The stress/strain curve confirmed the material should be functional in end use. DSC data further confirmed the material should stand up to flocking. The customer was satisfied and began development of the swab for COVID-19 and other disease-testing applications.

Contact

To schedule lab testing services from Teel Analytical Laboratories, contact Lab Manager Dan Clark 608-355-4626. The lab offers a variety of testing services in addition the FTIR and DSC, including thermogravimetric analysis, melt flow rate testing, High-Performance Liquid Chromatography (HPLC), and much more.



Wearable Device Skin Patches that Stay Put

Joanne Moody - Principal Consultant - Zeta Scientific LLC

Wearable medical devices are skyrocketing based on sensor developments and remote monitoring by both consumers and medical professionals. FDA's 2020 emergency regulations assigned reimbursement codes for telemedicine which provides an incentive for wearable device growth. Many new wearable devices use skin adhesive patches. Direct contact via a skin adhesive provides more accurate measurements of parameters such as heart rate, temperature, blood glucose, electrocardiogram, and oxygen saturation.

New wearables must consider adhesive selection early in the design phase. Key factors for wearable device skin adhesives include device design, skin factors, biocompatibility, and design integration. Skin adhesive patches have challenges, including sticking firmly to the human skin, removal without skin irritation, and leaving no residue.

What is a wearable device?

What is a wearable device?

❒ A wearable device is an electronic device that is worn close to skin or on the skin to measure and collect real-time data. Multiple functions may be built into a wearable device. Data may be wirelessly transmitted to smart phones and the cloud. From factors include bands/straps and wearable device patches attached to skin with biocompatible adhesives. Sticky, or pressure sensitive adhesives (PSAs), bond skin and dissimilar surfaces with the application of light pressure.

❒ Wearable devices are widespread in the lifestyle and fitness markets. This poster will focus the medical applications. See Figures 1-4 for wearable device examples.

Examples

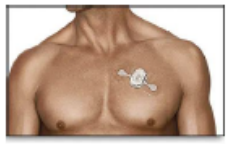


Figure 1. EKG Patch (1)

Figure 2 Temperature Monitoring (2)

Figure 3 Corrective Therapy Device (3)

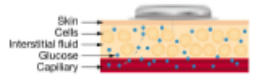


Figure 1. Continuous Glucose Monitoring

Wearable Product Development Checklist

- ❒ Application requirements
- ❒ Size and weight of the device
- ❒ Skin area, age, and location
- ❒ Flexibility
- ❒ Wear duration
- ❒ Breathability
- ❒ Backing/adhesive/liner
- ❒ Regulatory compliance
- ❒ Test Criteria
- ❒ Environment
- ❒ Mock-up devices
- ❒ Manufacturing
- ❒ Sterilization and packaging
- ❒ Costs

Mock-up Device for Adhesive Screening Testing

- ❒ Create a mock-up device (Figure 5) for adhesive screening tests.
- ❒ Obtain biocompatible adhesives tapes for evaluation.
- ❒ Setup protocol with test criteria such as wear time, skin type, irritation, and trauma.
- ❒ Test on human skin or other low energy substrates.
- ❒ Measure and rank adhesives.

Figure 5 Mock-up Device

Wearable Adhesive Comparison

Table 1. Adhesives Benefits and Limitations

Adhesive Type	Benefits	Limitations
Acrylic	Low to high tack, breathable, long duration, repositionable, low cost, long durability, low cost	Potential trauma
Silicone & Gels	Low trauma, good initial tack repositionable	High cost, shorter wear time, low breathability
Synthetic Rubber	High tack, long duration	Potential trauma
Hydrogel	High initial tack, stretchable, repositionable	Week adhesion properties
Hydrocolloid	Adheres to wet skin, high tack, repositionable, low trauma	Low mechanical strength
Polyurethane & Gels	Breathable, absorbent, repositionable, low trauma	Low tack

Skin Factors & Trauma Issues

Skin factors
- ❒ Cell renewal
- ❒ Sensitivity
- ❒ Surface conditions
- ❒ Texture
- ❒ Surface energy
- ❒ Flexibility
- ❒ Location

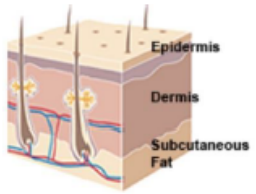


Figure 6 Skin Layers (4)

❒ Skin patch adhesives directly attached to the skin and device construction adhesives may cause allergic reactions.

❒ Manufacturers to produce designs and processes to mitigate these issues.

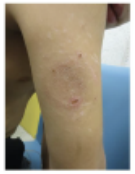


Figure 7 Skin Trauma (5)

Take Aways

❒ Wearable medical devices with adhesive patches are skyrocketing and achieve accurate measurements .

❒ Skin adhesive patches have challenges, including sticking firmly to the human skin and removal/removing without skin irritation or leaving residue.

❒ During the Covid-19 pandemic, wearable devices provided critical remote monitoring with added protection to patients and hospital staff.

❒ Reimbursements of devices will further increase device development and demand.

❒ Skin sensitivity from adhesives will remain a complex part of the design and challenge that should be addressed early in product development.

Contact

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www.zetascientific.com
joanne@zetascientific.com

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Delrin® Renewable Attributed:

Advancing Sustainability through Leading Environmental Impact Profile

Ned LeMaster, Application Development Consultant for Medical Markets, DuPont Mobility & Materials (+1-608-402-3268)

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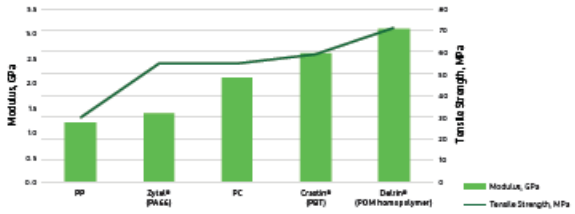
Delrin® Renewable Attributed and Delrin® acetal homopolymer generate superior environmental and financial benefits while demonstrating sustainable advantages. Delrin® as a naturally resilient and self-lubricated polymer enables:

- Low maintenance cost
- Longer service life
- Reduced lubricant and energy consumption
- Improved safety



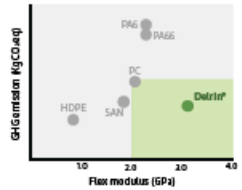
Delrin® Renewable Attributed: The new portfolio of Delrin® with advanced sustainability

Base polymer produced from 100% bio-feedstock according to mass balance and 100% renewable energy

Identical mechanical properties and processing compared to fossil base alternatives

Bio-feedstock from waste, not in competition with food chain, certified by ISCC

Leading eco-profile



Delrin® Renewable Attributed has one of the lowest GWP among all the engineering resins.

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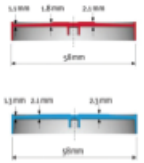
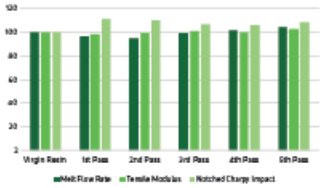


20% Lighter parts

11% Cycle time reduction during molding

Optimize design to produce parts that are lighter, more durable and require less energy during molding.

Enable circularity



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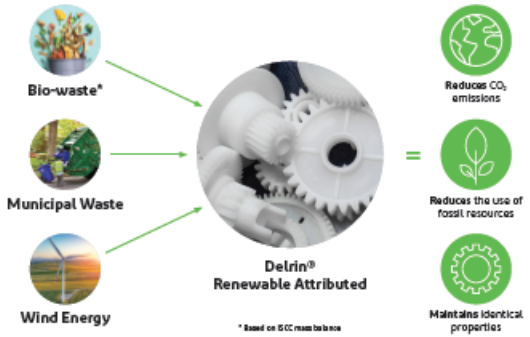

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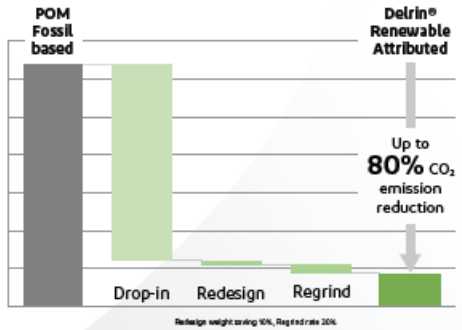

Taking Steps to Optimize Performance, Precision and Availability of Prosthetic Knees

Recently company LIMBS began the process of designing a new knee and adopting a new manufacturing method based on injection molding rather than machining, using Delrin® Renewable Attributed.

- Reduced production time
- Part-to-part consistency
- Faster, easier assembly
- Low CO_2 emission

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Focus on the Latest Regulatory and Risk Management Requirements for Medical Plastics

Vinny Sastri, Ph.D.
President
Winovia LLC
WINOVIA

ABSTRACT

THE LAST FIVE YEARS HAVE BROUGHT ABOUT SIGNIFICANT CHANGES TO GLOBAL REGULATORY AND RISK MANAGEMENT REQUIREMENTS FOR MEDICAL DEVICES, INCLUDING STRINGENT CONSIDERATIONS FOR THE PLASTICS USED IN THESE APPLICATIONS. THE REQUIREMENTS STEM FROM THE EUROPEAN MEDICAL DEVICE AND IN-VITRO DEVICE REGULATIONS (EU MDR AND EU IVDR), THE BIOCOMPATIBILITY STANDARD ISO 10993:2018 AND RISK MANAGEMENT FOR MEDICAL DEVICES ISO 14971:2019. THE GENERAL SAFETY AND PERFORMANCE REQUIREMENTS IN THE EU MDR AND EU IVDR STIPULATE SEVERAL REQUISITES (INCLUDING RISK MANAGEMENT) WHEN CONSIDERING PLASTICS FOR MEDICAL DEVICE APPLICATIONS. IN ADDITION, BIOCOMPATIBILITY MUST BE LINKED TO THE RISK MANAGEMENT PROCESS. THE FDA HAS ALSO PUBLISHED A GUIDANCE DOCUMENT ON BIOCOMPATIBILITY AND RISK MANAGEMENT REQUIREMENTS. THIS POSTER HIGHLIGHTS HOW USERS AND PATIENTS CAN BE EXPOSED TO POTENTIAL HAZARDS AND RISKS ACROSS THE SUPPLY CHAIN WITH PLASTICS USED IN MEDICAL DEVICES.

INTRODUCTION

After a one-year delay due to the global coronavirus pandemic, the European Union Medical Device Regulation (EU MDR) 2017/745 went into effect on 26 May 2021. The European Union Invitro Diagnostics Regulation (EU IVDR) 2017/746, goes into effect in May 2022. These regulations were introduced to resolve and address a number of deficiencies in the Medical Device Directives (MDD). The EU MDR 2017/745 and the EU IVDR 2017/746 are legally binding regulation across the EU member states. In addition, 1SO14971:2019 was released in December 2019. The following table provides a list of current regulations, standards and guidance documents that specify risk management requirements for medical devices and thus, plastics used in medical device applications.

Chronology of Risk Management for Medical Devices and Medical Plastics

Year	Medical Device Regulations and Standards with Risk Management Requirements
1997	21 CFR Part 820 Quality System Regulation
2016	ISO 3485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes
2017	Regulation (EU) 2017/745 of the European Parliament and of The Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC - European Union Medical Device Regulation (EU MDR) Regulation (EU) 2017/746 of the European Parliament and of the Council Of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU - European Union Invitro Diagnostic Regulation (EU IVDR)
2017	ISO/TR 10993-22:2017 Biological evaluation of medical devices — Part 22: Guidance on nanomaterials
2018	ISO10993-1:2018 Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process
2019	ISO14971:2019 Medical devices — Application of risk management to medical devices
2020	FDA Guidance Document - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" September 4, 2020

RISK MANAGEMENT REQUIREMENTS AND PROCESS

Risk Management for medical devices is focused on the use of the device and the risks associated with that device to the user and/or patient. Therefore, the hazards and risks during normal use must be identified, evaluated, and removed or reduced to acceptable safety levels. Risk Management focuses on:

- Normal use conditions,
- The use environment, and
- Users

This is important because the supplier of a plastic resin may be far removed from the production of a finished device, and may not know whether or not their product could potentially contribute to a hazardous situation leading to patient harm. The risk management process includes the following steps:

- **Identification of hazards** associated with the use of the device
- Determining the **sequence of events that could lead to a hazardous situation** (all the way from design, raw materials, production, packaging, sterilization, storage, distribution and use)
- **Evaluating the risk and harms to patient or user** resulting from the hazard and hazardous situation
- **Removing, reducing, mitigating and/or managing the risk** via design, material, production and other relevant risk control measures
- Determining that **the residual risk is acceptable**
- Monitoring the **effectiveness of the risk controls**

POTENTIAL HAZARDS ASSOCIATED WITH PLASTICS

Potential hazards with respect to plastic materials are related to the ability or inability of the material to reduce or protect user and patient from:

Energy hazards like:

- Acoustic energy (infrasound, ultrasonic)
- Electric energy (electric fields, current leakage, magnetic fields, static discharge, voltage)
- Mechanical energy (heavy/falling objects, moving parts, vibrating parts)
- Potential / stored energy (bending, kinking, compression, cutting, shearing, suspended mass, tension, torsion)
- Radiation energy (gamma, X-Ray, infrared, laser, microwave, ultraviolet)
- Thermal energy (high temperature, low temperature)

Biological and chemical hazards like:

- Biological agents (bacteria, fungi, parasites, prions, toxins, viruses)
- Chemical agents (acidic, alkaline, oxidants, flammable, combustible, solvents, cleaning agents, heavy metals, particles)
- Biocompatibility (toxicity, carcinogenicity, allergenic, immunosuppressive, irritants, sensitizing)

Environmental hazards like:

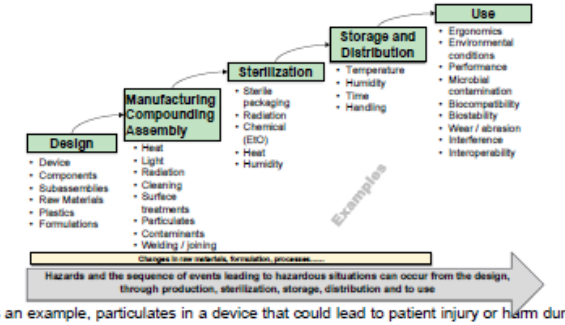
- Particulates
- Temperature
- Humidity

Usability hazards like:

- Slips (using soft-touch, flexible materials)
- Use of wrong-sized device (by using color coding)
- Use of excessive force (by using material that have lubricity)
- Misguiding of devices during procedures (by using radiopaque materials)

SEQUENCE OF EVENTS LEADING TO HAZARDS SITUATIONS DURING DEVICE USE

Hazards and the sequence of events leading to hazardous situations can occur anywhere from the design, through production, packaging, sterilization, storage, distribution and to use as shown in the figure below. This is also true of biological hazards. No matter where the hazard originated, the user or patient is exposed to the hazardous situation that could lead to harm including death or serious injury.



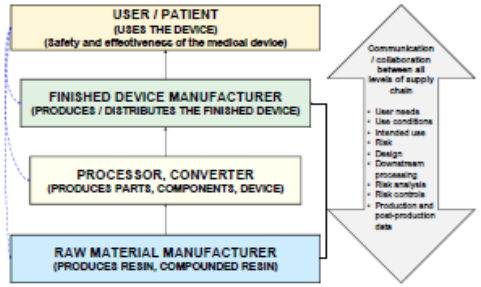
As an example, particulates in a device that could lead to patient injury or harm during the device's use could come from:

1. The raw material resin itself
2. During production
3. During packaging
4. During use with the abrasion of material with another product

Depending upon where the source of the particulate came from, appropriate controls need to be implemented. These controls could be on the material cleanliness itself, controls in production processes or the production environment, controls in material packaging or the packaging environment or the use of non-abrading devices or procedures.

EFFECTIVE COMMUNICATION BETWEEN THE SUPPLY CHAIN

In order to design and manufacture safe and effective devices, medical device OEMs must communicate effectively across the entre plastics supply chain to ensure all suppliers know and understand what they need to do to ensure that their products or processes do not expose the user and/or patient to any hazardous situations.



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The Challenge of Transition to Single-Use Systems for Bio-Pharmaceuticals Manufacturing

Len Czuba
Czuba Enterprises, Inc.

ABSTRACT:
Three Case Studies Show When the Wrong Materials are Used!

The medical device industry has largely grown because of the availability of reliable and effective single use devices built with superior low-cost polymers that provide safety and ease of use in sophisticated, low-cost medical devices. The bio-pharmaceutical industry has traditionally relied on glass and stainless steel reactors, containers and transfer piping as their materials of choice for the production of some of the world's most important medicines, vaccines and health treatments. But there is a growing trend to replace the durable glass and stainless steel equipment with polymeric single-use-systems as production equipment.

However when the specialists in bioprocessing and microbiology are tasked with the selection of materials for their manufacturing operations, **they frequently choose the wrong materials**. This poster shows three examples of how the wrong material or component was used in one of the processes involved. My presentation & slides explained the case studies and reviewed lessons learned.

Introduction

Traditional Systems

Largely based on glass and stainless steel

Single-Use Systems

Primarily made using plastics

Case One – Gel Residue in Graduated Cylinder

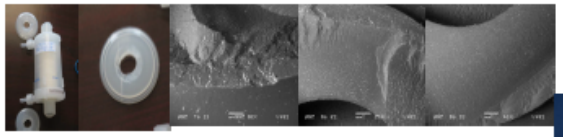
Bio-pharma manufacturing company found about 3 to 5 ml of gelatinous residue at the bottom of one of its measuring/processing vessels. $25 million batch of product was on HOLD pending chemical identification of gel & determining safety or risk to patient.

Chemical analysis found source was the polypropylene Graduated Cylinder and that extractable was an antistatic additive, an **Ethoxylated Fatty Acid Amide**.

Toxicologist was consulted and after investigation, rendered opinion that the risk to safety of patients was very low further analysis of patient exposure was done. It was determined that any patient getting the neurotoxin (a Botox analog) would only be getting about 25 ppm of the antistat per total number of injections (10 injections) per treatment. Even with 10 treatments per year (if done approx. monthly) total exposure was deemed **not a problem**.

Recommendations

Company was cautioned that when steam sterilize is used, empty vessels such as beakers, graduated cylinders and bottles should be positioned with opening down to avoid similar problems in future. In addition select plastic equipment intended for steam sterilization. In this case a graduated cylinder was used even though it clearly indicated "Not for steam sterilization"! An unfortunate decision which could have been avoided.



Case Two – Breakage of Batch-Protective Filters

Storage systems after manufacturing batch of bio-pharmaceutical were having problem with filter flanges breaking when moving in freezer. Filters were housings made of PP material that was fracturing at the flange.(See photos above.)

Vessels needed to be vented during frozen (≤ -40°C) storage but when moved filters broke at flange.

Optical microscopy and SEM was done on the broken surfaces but showed no obvious cause.

Then by examining cross-section of filter in the flange area showed problem. The PP plastic filters were made using the same flange and housing design as used for the SS filters. The inner radius connecting the filter body to the flange did not have the necessary radius to distribute the stresses of handling leading to it being a **stress concentration area.**

In addition, PP material is not well suited to use in frozen environments. Its glass transition temperature is in the range of zero degree C. Therefore at -40°C the filters are glassy and very brittle. Not surprising that they break!

Recommendations

Company was advised to contact filter supplier and ask for redesign. Instead unfortunate decision which could have been avoided.

Case Three– Storage / Transfer Systems Breakage

Broken caps jeopardize quality / safety of product

Caps were breaking while storage containers were in frozen storage waiting safety release. Cause of breaks was not clear.

Examination of fractured caps showed no obvious cause of breakage but several factors gave indication that could have contributed to failure.

- Caps were made of PP and not designed to support weight.
- Accessories allowing fluid flow into & out of jugs with filters added stress to cap.
- Drop tube sized to press against bottom of jug to allow complete fluid recovery.
- Storage done at or below -40°C again working with PP caps in a very brittle state.

Recommendations

Suggested that a HDPE cap be used.
Avoid PP if storage system is radiation sterilized before use.
Ultimately a different system entirely would help eliminate these material & design problems.

Conclusions/Recommendations

Choose Compatible Materials and
Get Help If You Don't Know Which Materials are Suitable & Best!

The medical device industry has grown in large part because of the remarkable and extremely wide range of polymeric materials suitable for almost every possible application that has found the need for a polymer. The Bio-Pharma industry can take advantage of the experience learned by the med device industry by relying on polymer experts in the industry. Both suppliers and med device engineers will help define the requirements and find a suitable material that can meet the requirements and avoid dangerous and costly problems such as those described in this poster.

Users can also consult with suppliers, consultant specialists and resources such as BPSA (Bio-Process Systems Alliance), the SUUR (Single-Use User Requirements) Toolkit as well as Checklist for consideration before making final selection of materials.

Selecting the right materials up front saves $ & time later!

LCzuba@czubaenterprises.com

SPE Poster

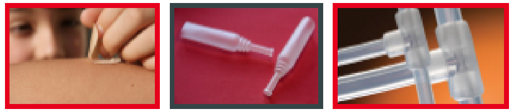
Comparison of Silicone Adhesives in Skin Contact Applications: How Material Properties Influence Adhesive Performance and Wear

Stephanie Steichen, Roger Gibas, Stacey Benemann, and Sweden Yocom
DuPont LIVEO™ Healthcare Adhesives
Midland, MI, USA

Medical Silicones

Silicones have numerous unique and beneficial properties that have enabled their widespread use in medical applications ranging from device attachment to catheters to tubing for biopharma processing to contact lenses to transdermal drug delivery patches[1].

- Biocompatible
- Biodurable
- Flexible and conformable
- Clear and translucent
- Highly permeable to gas/vapor
- Low surface energy
- Versatile chemistry and material properties
- Thermal and chemical stability



LIVEO™ Silicone Adhesives

	SSA *Soft Skin Adhesive*	HASSA *High Adhesion Soft Skin Adhesive*	PSA *Pressure Sensitive Adhesive*
Chemistry	▪ Lightly crosslinked elastomer ▪ Result of Pt catalyzed hydrosilylation cure ▪ 2-part cure ▪ Thermoset	▪ Result of Pt-catalyzed hydrosilylation cure ▪ 2-part cure ▪ Thermoset	▪ Bodied resin-in-polymer ▪ Result of polycondensation ▪ 1-part system ▪ Thermoplastic
Processing	▪ Solventless dispensing ▪ Direct coating ▪ Heat curing ▪ Substrate treatment can be required ▪ LDPE release liner	▪ Solventless dispensing ▪ Direct or transfer coating ▪ Heat curing ▪ Substrate treatment not required ▪ Fluoro-silicone release liner	▪ Solvent-based or hot-melt ▪ Transfer coating ▪ Drying or cooling to set ▪ Substrate treatment not required ▪ Fluoro release liner
Benefits and Use	▪ Use on fragile skin ▪ Atraumatic upon removal ▪ Advanced wound care ▪ Scar care	▪ Use on healthy skin ▪ Device attachment	▪ Use on healthy skin ▪ Device attachment ▪ Ileostomy ▪ External prosthetic ▪ Drug delivery
Products	▪ MG7-9800 ▪ MG7-9850 ▪ MG7-9900 ▪ MG 7-9960	▪ HASSA#1* ▪ HASSA#2*	▪ MG-2401 ▪ MG-2402 ▪ MG-2410 ▪ MG-2502

Gentle adhesion → Secure adhesion

Adhesives Evaluation

Adhesion Testing				
Instrument	**Measurement**	**Interpretation**	**Sample**	**Substrates**
Texture Analyzer TA XT Plus 180° Peel	Measure the force required to remove an adhesive layer from the adherent/substrate	Higher force value indicates increased adhesion and greater ability to hold device	Adhesive coated onto polyester film at defined thickness	Stainless steel (ASTM D3300), frosted Lexan™ polycarbonate (lab standard), and others

"Stick" to Skin

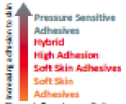


Figure 1. Based on qualitative observations when adhesive is placed in contact with skin.

Stainless Steel ASTM Method[2]

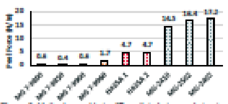


Figure 2. Method was able to differentiate between, but not within, families of formulations. Values, for SSAs, did not align with actual feel of adhesives to skin.

Lexan™ Polycarbonate Method

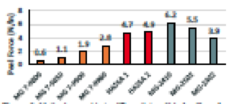


Figure 3. Method was able to differentiate within families of adhesives and aligned with the actual feel of SSAs and HASSAs to the skin.

Penetration Testing			
Instrument	**Measurement**	**Interpretation**	**Sample**
Penetrometer 62.5 g hollow cone, 5s	Measure the depth the tip/cone penetrates a known mass of material over a specified time	Higher penetration indicates a softer material	80g SSA cured in a cup (1h @130°C)

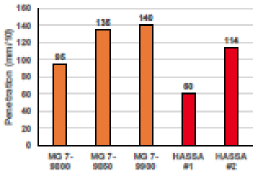


Figure 4. Penetration test method is a way to characterize SSA adhesives, but is non-applicable to PSAs. The SSAs are, in general, softer than the HASSAs. HASSA 2, however, is softer than both MG 7-9800 and HASSA 1. The softness, consequently, is a parameter that can be manipulated by adjusting the formulation. Within material families, the softer the material, the higher the adhesion.

Key Learnings

- Adhesion to stainless steel, although the ASTM standard, does not accurately predict adhesion to skin for SSAs and HASSAs. It is, however, a more representative substrate for PSAs
- Polycarbonate more accurately represents the adhesion to skin, according to qualitative assessments, than stainless steel
- Within product families with similar formulations, increasing penetration increases adhesion to PC

Wear Studies

Adhesion Testing			
Participants	**Measurement**	**Interpretation**	**Sample**
Healthy volunteers between the ages of 18 – 60 years	Evaluate the skin adhesive performance directly on human subjects (chest, back, arms or abdomen)	"Real-life" assessment of adhesive performance	Adhesives coated onto a polyurethane substrate, at defined thickness, with/without weights

Formulations:
MG 7-9900
HASSA #1
HASSA #2
MG-2402

Figure 5. (Above) Representative weighted patches of four different formulations. (Right) Exploded side view of the patch construction.

Formulation	Wear (days)	% Day 7
MG 7-9900	9.2 ± 4.58	63
HASSA #1*	5.38 ± 3.20	25
HASSA #2	8.8 ± 3.71	56
MG-2402	12.8 ± 1.04	100

*Weighted Patches worn on back of arm instead of on chest

Key Learnings

- Increased adhesion to a test substrate does not directly correlate to increased wear on skin
- Patch construction, placement, and weight can all affect wear
- To conduct the most robust comparison, adhesives should be evaluated within the same wear study, with the same participants, within a similar time frame
- Skin is a highly variable substrate and wear depends on participant age, activity level, etc. and other environmental factors, e.g. temp, humidity, etc.[3]

Repositionability

Objective: The results from the wear studies, as well as feedback from customers, revealed that increased adhesion to polycarbonate is not a direct predictor for increased wear time on skin. Repositionability, or the ability of the material to re-adhere after being removed from the skin, is another factor that could, when considered with adhesion, predict wear time.

Repositionability Evaluation			
Instrument	**Measurement**	**Interpretation**	**Sample**
Texture Analyzer TA XT Plus 180° Peel with TA-306A-TC Lid Peel Rig – Top Clamp	Measure the force required to remove an adhesive from the skin after initial and subsequent contact	Retained adhesion force indicates improved repositionability	Adhesive coated onto polyurethane reinforced with polyester at defined thickness

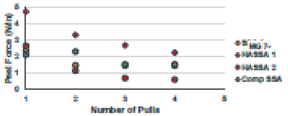


Figure 6. The raw peel force values of the evaluated formulations from the forearm, as measured with the Texture Analyzer TA XT Plus 180° Peel with TA 306A-TC Lid Peel Rig – Top Clamp. Each pull was performed after a 15 minute residence time of the adhesive on the skin.

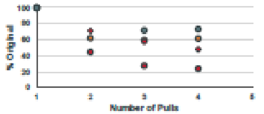


Figure 7. The % of original adhesion retained after multiple peels of the adhesive formulations from the forearm. Each peel was performed after a 15 minute residence time of the adhesive on the skin.

Key Learnings

- Repositionability evaluation shows that there is a tradeoff between increasing initial adhesion and decreasing repositionability
- SSAs retained more adhesion (as a % of initial) than the HASSAs and PSAs
- A softer material with similar initial adhesion and chemistry will be more repositionable

Conclusions

Improved Performance →

Adhesion	SSA	HASSA	PSA
Repositionability	PSA	HASSA	SSA
Wear on Skin	SSA = HASSA		PSA
Penetration	HASSA 1	HASSA 2	SSA

To gain a true insight into how an adhesive will perform in a particular application, an understanding of skin adhesion fundamentals along with well-designed wear studies is necessary. This enables the development and selection of the best adhesive system for the complex and variable substrate that is human skin.

- Skin is a complex, highly variable, and challenging substrate to fully recapitulate
- It is critical to have understanding of what parameters affect material performance to better predict their behavior
- It is equally important to have developmental tools that capture and quantify the parameters that affect material performance
- Increasing adhesion alone (as measured on polycarbonate) does not result in increased wear time to the skin, particularly with weighted patches
- A material's wear time is a combination of initial adhesion to the skin and repositionability
- This work was funded and completed by DuPont LIVEO™ Healthcare Adhesives

References

[1] Curtis, J. & Colas, A. (2004). Medical Applications of Silicones. In Ratner, B.D., Hoffman, A.S., Schoen, F.J., & Lemons, J.E. (Eds.), *Biomaterials Science: An Introduction to Materials in Medicine* (pp. 698 – 707). San Diego, CA: Elsevier.
[2] ASTM D3330/D3330M-04(2010) Standard Test Method for Peel Adhesion of Pressure-Sensitive Tape
[3] Dabrowska, A.K., *et al.* "Materials used to simulate physical properties of human skin." *Skin Research and Technology* 22.1 (2016): 3-14.

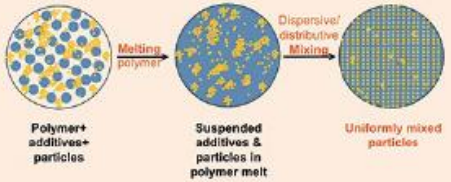
Managing melt temperature (to avoid degradation) in a Twin Screw Extruder

Charlie Martin
cmartin@leistritz-extrusion.com
Leistritz EXTRUSION TECHNOLOGY

Polymer Compounding

The enemy: time @ elevated temperatures!

- Solid additives/particles
- Polymer granules/pellets



Leistritz Extrusion

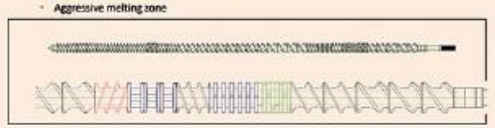
Managing Melt Temperature (and avoid degradation) in a Twin Screw Extruder:

Plastic parts for medical devices require a consistent, high quality homogenous compound with minimal polymer degradation. Degradation occurs due to elevated melt temperatures that emanate for mixing mechanisms and high pressures during processing in a twin screw extruder. Various factors are managed to maintain an acceptable melt temperature in a twin screw compounding system, including operating conditions, screw design, and pressure generation.

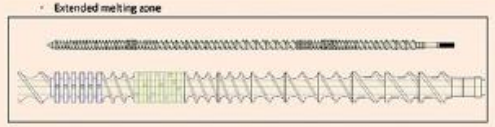
Melt temperature study

ZSE-27 MAXX melt zone designs + 1 mixing element

- Aggressive melting zone

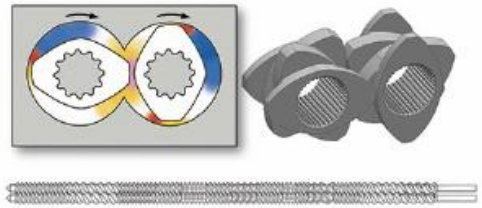


- Extended melting zone

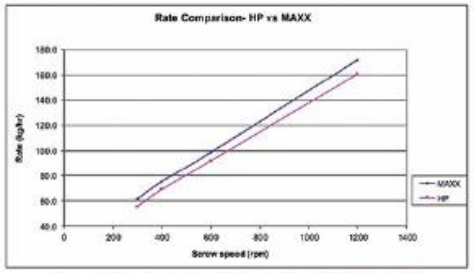


TSEs are continuous mixers

Segmented screws are assembled on shafts



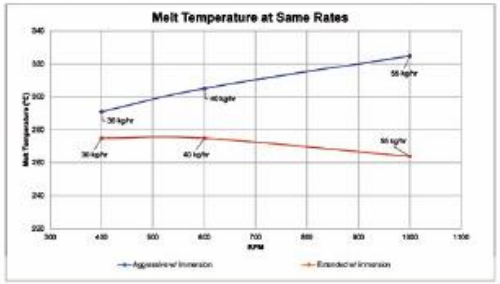
Process Comparison- ZSE 27



PLA- NatureWorks 2002D: what's the residence time?

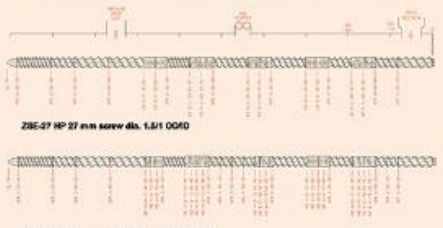
Higher melt temperature with aggressive design

Reverse elements and wide disk/neutral KB's

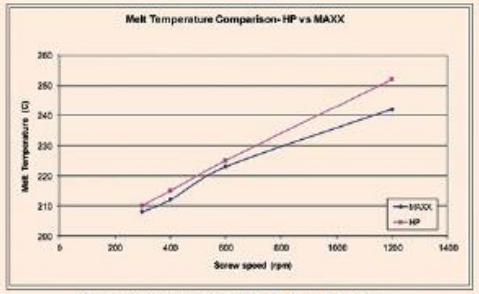


ZSE-27 rate tests

PLA 2002D, rate increased until boundary condition reached



Tests used open end discharge, less than 100 psi pressure

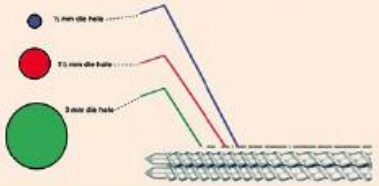


PLA- NatureWorks 2002D: 20, 10 & 5 seconds

Temperature rise during pressure generation

$$\Delta T\ (°C) = \Delta P\ (bar) / 2\ (+/- 50\%)$$

- 40 Bar (580 PSI) Pressure results in a 20°C melt temperature rise (40/2)
- Restrictive front-end designs may adversely effect the product
- RPM, discharge screw elements & materials play a role in Tm



Using water-based hydrophilic coatings to create medical devices for the future

SPE MEDICAL PLASTICS

Surface Solutions Laboratories™

Lubricious

Water-based hydrophilic coatings, such as the biocompatible Coatings2Go® products (see 8-3C lubricity data below), are gentle enough for solvent sensitive plastics yet can retain durability and super-lubricious qualities.
Consistent lubricity can mean decreased surgical duration and surgeon fatigue, reduced tissue damage, shorter recovery times, increased thromboresistance, and overall positive patient health outcomes.

FIGURE 1:
Coatings2Go Patented Hydrophilic

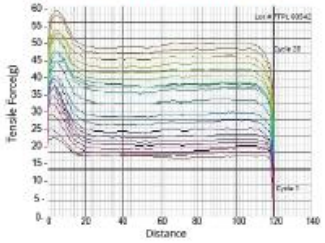
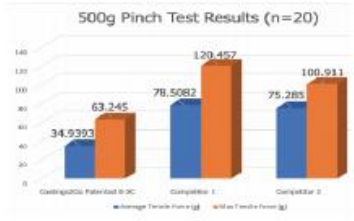


FIGURE 2:
Competitive Analysis



Throughout a third-party pinch test comparison trial (see Figures 1 and 2), the Coatings2Go® Patented Hydrophilic 8-3C exhibited steady and consistent lubricity, visibly representedby the tight range and linearity of the collected tensile force data. Figures 3 and 4 show pinch test data collected from two other industry hydrophilic coatings. Uncoated control showed an overall average tensile force of 460.553g with a max tensile force of 575.084g.

FIGURE 3:
Industry Coating A

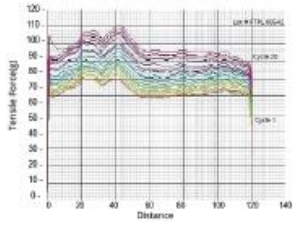
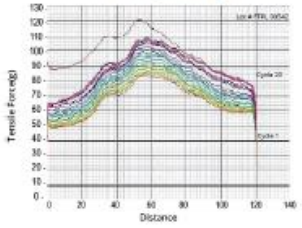


FIGURE 4:
Industry Coating B

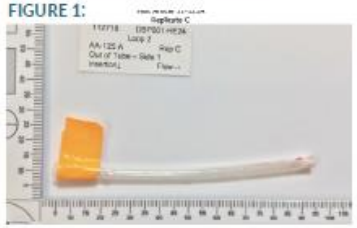


Thromboresistant

Medical-grade Pebax® tubing was primed with Coatings2Go® Primer 5-017 and patented crosslinked hydrophilics.

FIGURE 1:

Sample 11-125A is the hydrophilic coating alone, which shows thromboresistant results (Figure 1).



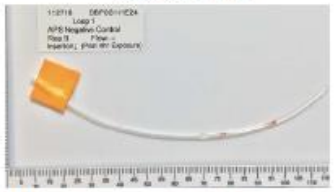
It was noted that these tubes showed less heparin activity in the heparinized blood, post testing. We surmise this is due to aqueous phased heparin absorption into the coating as it hydrates/swells. The 11-125 B (Figure 2) and 11-125 C (Figure 3) are hydrophilic heparin coated. This heparin coating was prepared such that a large part of the heparin would be covalently bound to the carrier resin. The 11-125 B sample may contain more loosely bound heparin since it showed elevation of the post test heparin level.

FIGURE 2:

FIGURE 3:

Positive Control:

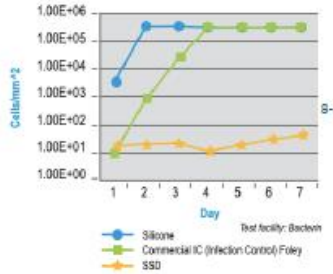
Negative Control:



Summary: Coatings2Go® Patented Hydrophilic Coatings with no antithrombogenic additives showed thromboresistance in this study. This is not a definitive statement for all coated devices, or that the coatings are anti-thrombogenic. Each product must be evaluated for its application.
All test results available upon request.

Antimicrobial

Testing on Coatings2Go® Patented Hydrophilic Antimicrobial 8-63 shows broad spectrum activity against many organisms. Tubes were tested per ASTM E2149-13a Under Dynamic Contact (also called Monovalence test).



Coatings2Go® Patented Hydrophilic Antimicrobial 8-63 Bacterial adsorption–Silicone Foley Catheters

2020 Customer Test Data Per ASTM E2149-13a

Bacteria	Test Result (monobalance %)	Remark
E. coli ATCC 25922	99.9%	-
S. aureus ATCC 6538	99.9%	-
P. aeruginosa ATCC 15442	98.-%	Retest for 99.9%
K. pneumoniae ATCC 4352	99.9%	-

Central venous catheters (CVC's) are implanted for long term access and delivery to the vasculature. Infection is complicated by absorbed blood. Proteins and complexes mask and activate the surface. Commercial products from Biointeractions and Arrow are claiming efficacy against one common bacterium, S. aureus. CVC's were coated, cured, sterilized and tested by microchem for effective log reductions in test media. Arrow and several of the C2G formulations showed good slip and bacterial reductions.

Arrow equivalent CVC catheter sterilized and tested by Microchem in S.Aureus			
Sample		Slip	Log reduction
87A- C2G	Hydrophillic	Excellent	0.16
87D-C2G	Silver	Good	3
87E-C2G	quat	Good	2.29
87F-C2G	Mix	Good	3.39
87G-C2G	Mix	Good	3.87
87H-C2G	Mix	Good	3.1
87J-C2G	Mix	Good	2.81
BioInteractions	Avert	Poor	0.21
Arrow	Control	Good	5.58

Coatings2Go®, LLC., a Surface Solutions affiliate, provides affordable, biocompatible, best-in-class hydrophilic medical device coatings.
You can purchase domestically or internationally through quick and secure online ordering, with no license fees or royalty costs.
Coatings2Go® maintains a Master File with the FDA (1335) and an ISO 13485:2016 certified Quality Management System.
www.coatings2go.com

MEDICAL PLASTICS

MiniTec 2021
Anaheim, CA • August 10, 2021
Presented by SPE Medical Plastics Division

Speakers and Presenters at SPE MiniTec IN ANAHEIM, CA AUGUST 10-12, 2021

“Saving the World through Medical Plastics and Sustainable Solutions”

Conference Co-Chairs & Moderators: Ned LeMaster; DuPont & Len Czuba; Czuba Enterprises, Inc.

Keynote Speaker
Vicki Carr-Brendel – GVP Cochlear Implants of Sonova and President of Advanced Bionics

I. IMPLANTABLES AND WEARABLES

Polyurethanes used as Excipients to control the release of Active Pharmaceutical Ingredients (APIs)
Anthony Walder – Lubrizol, Inc.

The Influence of Polyurethane Chemistry and Microstructure on Surface Phenomena and Their Role in Implantable Applications
Ajay Padsalgikar – DSM Biomedical

Wearable Device Skin Patches that Stay Put
Joanne Moody – Zeta Scientific LLC

II. SUSTAINABILITY

Medical Packaging and the Circular Economy
Andrew Green – Eastman Chemical Company

Hostaform® MT® POM ECO-B Co-Polymer - Proven, Versatile and Environmentally Sustainable
Rob Haley – Celanese

Embracing Sustainability in the Healthcare Sector
Michelle Irvine – Trinseo, LLC

III. SUSTAINABILITY PANEL

Allison Lin – VP Procurement & Sustainability, Westfall Technik, Inc.
Peylina Chu – Executive Director, Healthcare Plastics Recycling Council & VP Antea Group
Koen Janssen – VP Innovation, R&D and Sustainability - DSM Biomedica

IV. NEW PROCESSING TECHNOLOGY

Managing Melt Temperature (and Avoiding Degradation) in a Twin Screw Extruder
Charlie Martin – Leistritz Extrusion

Freeform Injection Molding – the Ultimate Medtech Development Platform
Carsten Jarfelt – AddiFab ApS

Manufacturing of Micro Medical Parts without Cold Runners
Vijay Kudchadkar – Westfall-Technik, Inc.

V. REGULATORY AFFAIRS (DURING A GLOBAL PANDEMIC)

Reverse Engineering of a COVID-19 Testing Swab
Christian Herrild – Teel Plastics

Focus on the Latest Regulatory and Risk Management Requirements for Medical Plastics
Vinny Sastri – Winovia LLC

The Transition to Single-Use-Systems for Bio-Pharmaceuticals Manufacturing
Len Czuba – Czuba Enterprises, Inc.

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“Saving the World through Medical Plastics and Sustainable Solutions”

Len (moderator) presenting Thank-You certificate to our keynote speaker,
Dr. Vicki Carr-Brendel, President of Advanced Bionics

Len presenting certificates of appreciation to speakers
Tony Walder & Nick DeFranco from Lubrizol

Len presenting certificate to speaker
Ajay Padsalgikar from DSM Biomedical

Len presenting certificate to speaker
Joanne Moody of Zeta Scientific

“Saving the World through Medical Plastics and Sustainable Solutions”

Len presenting certificate to speaker
Michelle Irvine from Trinseo

Len presenting certificate to speaker
Rob Haley from Celanese

Ned (moderator) presenting certificate to speaker
Carsten Jarfelt from AddiFab

Ned presenting certificate to speaker
Vijay Kudchadkar from Westfall-Technik

“Saving the World through Medical Plastics and Sustainable Solutions”

Ned presenting certificate to speaker & panelist
Andrew Green from Eastman

Ned presenting certificate to speaker & panelist
Allison Lin from Westfall-Technik

Ned presenting certificate to speaker & panelist
Michelle Ortiz from DSM Biomedical

Ned presenting certificate to speaker
Charlie Martin from Leistritz

“Saving the World through Medical Plastics and Sustainable Solutions”

Ned presenting certificate to speaker **Vinny Sastri from Winovia**

Ned presenting certificate to speaker **Len Czuba from CEI**

Socially distanced conference attendees

Interested in Sponsorship?

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