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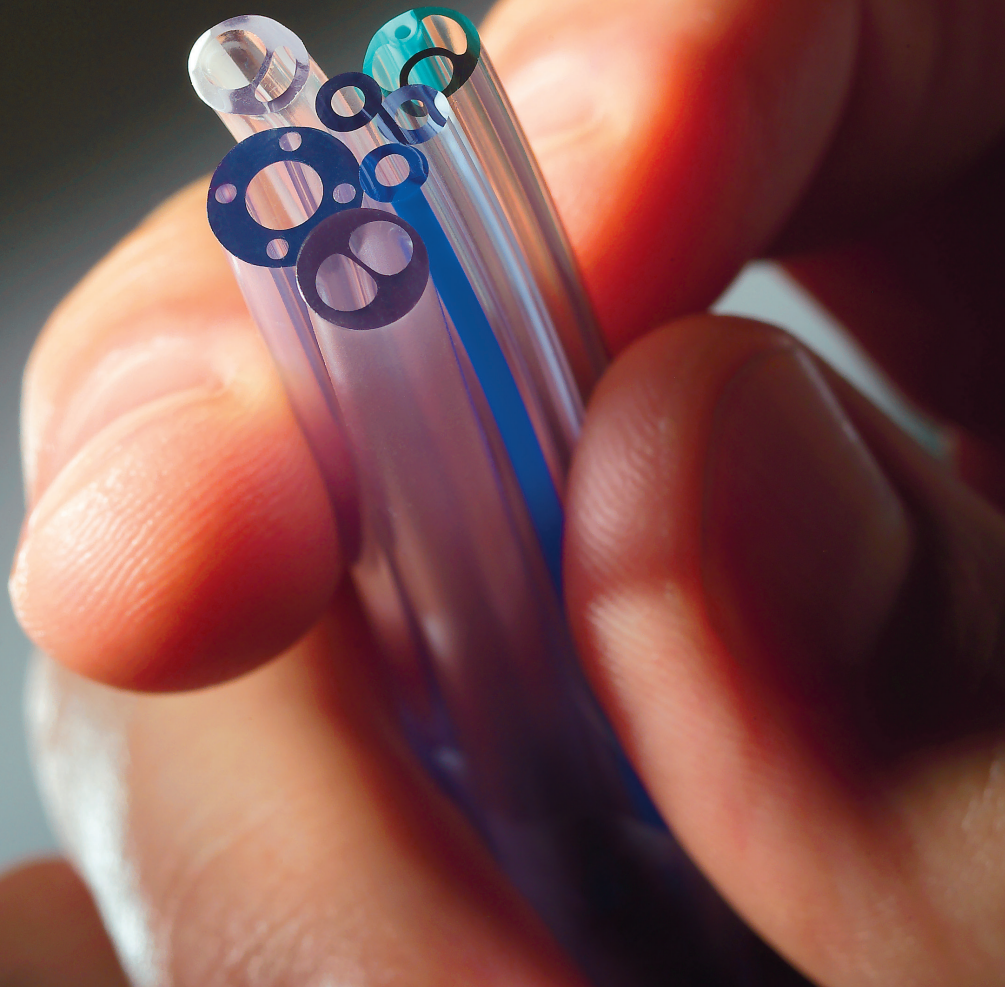
MEDICAL PRODUCT OUTSOURCING

TRAVERSING TUBING TECHNOLOGIES

SOLUTIONS TO MEDTECH'S SOURCING AND MANUFACTURING CHALLENGES



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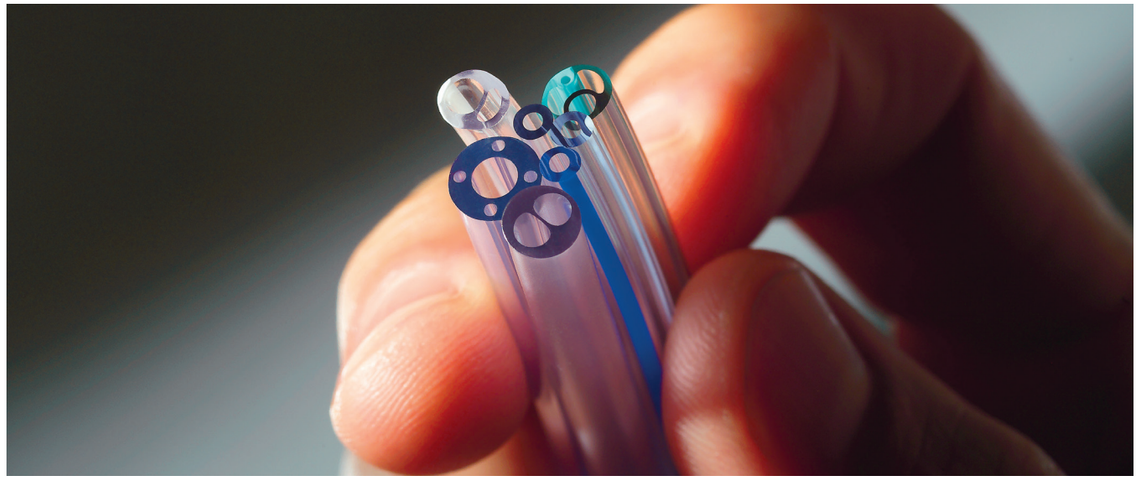

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Pathways to Care: Tubing Technologies

Tubing is incorporated into a variety of medical technologies, which is why the demands on manufacturers of the components are increasing substantially.

Mark Crawford • *Contributing Writer*

Medical tubing is a growing market, with a steadily expanding number of suppliers that extrude commodity resins. Medical device manufacturers (MDMs) are always looking for ways to improve the capabilities of their tubing, which helps differentiate them in the marketplace. In response, a growing niche market has emerged that focuses primarily on specialty tubing, materials, and proprietary compounds for highly specific applications.

Medical tubing is in high demand, especially as medical devices become smaller and more complex. According to Market Watch, the global medical tubing market is valued at $8.4 billion in 2020 and expected to reach $13.8 billion by the end of 2026, growing at a compound annual growth rate of 7.2 percent during 2021-2026.[1]

"The medical tubing market continues to be a dynamic one, primarily because of the variety of pressures on companies within this space to provide cost-effective, high-quality products in shorter time scales," said Joe Rowan, president and CEO of USA and Europe for Junkosha, a provider of peelable heat shrink tubing technologies. "This is mainly driven by the global healthcare market, which continues to demand innovative products and solutions that push the boundaries of what is possible, at a price point that is highly competitive."

As strong as the medical tubing market is, some slowing down is being seen as MDMs and their contract manufacturers (CMs) struggle to apply updated regulatory requirements to new and existing products. Regulatory bodies and new rules, such as the EU Medical Device Regulation and Chinese FDA, for example, are demanding increased risk mitigation for medical devices and their components—a compliance challenge many MDMs expect their supply chain partners, including tubing manufacturers, to help them navigate.

Latest Trends

Technology advances in medical tubing are driven by the demand for smaller wall thicknesses, smaller interior and outside diameters, and tighter tolerances, all while maintaining or enhancing performance. End users are insisting on smaller and more complex medical devices for an increasing number of innovative applications and procedures, many of which require some type of customized tubing.

"This trend toward miniaturization is in response to minimally invasive procedures in areas we did not have devices small enough to access 15 to 20 years ago," said Charles Golub, market development manager for Saint-Gobain Life Sciences, a Northborough, Mass.-based provider of medical tubing. "As a result, the ability to miniaturize medical technology will drive growth in treatments, such as peripheral artery disease and neurology, for years to come."

Demand for silicone is steadily increasing because of its biocompatibility—a property critical for regulatory approval. Smaller and more complex silicone extrusions are also in high demand as devices become smarter and procedures less invasive. "We are seeing growth in the partnerships between the engineering teams of device manufacturers and their suppliers to accelerate the device design and innovation process," said Dan Sanchez, product manager for Trelleborg Healthcare and Medical, a Schaumburg, Ill.-based provider of silicone extrusions for the medical and pharmaceutical markets. "The most successful medical device OEMs are collaborating with innovative manufacturers, early in the concept stage, to move the latest technologies forward."

In the world of neurovascular procedures, clinicians want devices that allow them to perform complex procedures more efficiently, reduce costs, and also relieve surgeon fatigue and improve patient outcomes. Procedures such as delivering stents, coils, and even signals/therapy via catheters are becoming more common.

Every OEM wants to beat the competition, so tubing suppliers are seeing more designs that call for increased functionality, thinner walls, kink resistance, more lumens, less friction, and even the ability to handle hazardous chemicals. For example, one way to add value is the integration of wire conductors into the walls of the tubing, which "saves customers from having to run wires down a tube or lumen, and allows more space for other components within the tubing, which results in more functionality in the same tubular cross-section," said Derek Wilkins, regional sales manager for New England Tubing Technologies, a Lisbon, N.H.-based manufacturer of custom tubing.

What OEMs Want

MDMs' demands for tubing include increased functionality and performance, including more challenging geometries, tighter tolerances, and reduced component size. They especially want superior biocompatibility, which is why they often select silicone and modify it with other materials to improve mechanical performance. Tubing suppliers that can customize tubing materials and shapes to meet specific medical device requirements are always in high demand.

Of course, the number-one priority for MDMs is finding a tubing partner that delivers consistent and reliable quality. As designs become more challenging, and technologies continuously advance, MDMs also want additional services and support, especially regarding customized materials as well as regulatory support and guidance as new regulations come into play.

In short, OEMs are looking for full-service providers to share the burden of medical device design, development, and production.

"Companies that can assist with tubing design and material selection, and provide secondary process operations beyond the tubing extrusion process, are in high demand because they can fill an OEM's in-house extrusion gaps," said Eric Ernst, international territory manager for Fluortek, an Easton, Pa.-based provider of precision fluoropolymer melt and paste extrusions.

"The fact that many device manufacturers have specialized in key areas and cut back their R&D pushes more demand for expertise from their suppliers," added Golub. "Additionally, the ability to offer testing that helps solve a customer's problems is more common. Having an applications or R&D department to help service customers used to be an added benefit—now it is a 'must-have' to effectively compete in the marketplace."

New Technology Advancements

The steady trend toward miniaturization and minimally invasive procedures continues to shape medical device design. End users are demanding catheters that can access hard-to-reach places in the human body, reducing the risk of damaging sensitive or delicate organs or tissues. Applications include neurovascular delivery of stroke or aneurysm therapies and the transmission of signals/energy that support therapies such as neuromodulation or neurostimulation (for example, treatment for Parkinson's disease).

Junkosha's 2.5:1 peelable heat shrink tubing (PHST) provides catheter manufacturers with one of the highest shrink ratios currently possible in peelable fluorinated ethylene propylene (FEP). Its "take up" (the ability to absorb tolerances) allows the use of cost-effective, lower tolerance, baseline materials in the manufacturing process and enables the reflow of these materials easily into a single smooth construct in one step. This reduces total cost of ownership for the catheter manufacturer, increasing the cost margin per construct.

Applications for this high-ratio PHST technology include neurovascular catheters that have tapered diameters for the floppy distal

segments, and proximal sections with larger diameters for pushable support. Because these catheters are mostly braid reinforced proximally and coil reinforced distally, there is a need for a peelable heat shrink solution that can accommodate in a single step the compression required to provide significant bond strength of the materials.

A further trend is the need for increasingly sophisticated "active" catheters that can send diagnostic signals into the body or provide therapy. Ultra-fine cables carry multiple signals through a very small shaft, enabling a new generation of small, flexible, and intelligent catheters that provide increased functionality and capture data from formerly inaccessible areas of the body.

For example, the Multi-Filar active catheter solution from Junkosha is manufactured using precision-engineered polytetrafluoroethylene (PTFE) lamination technology. Single-strand configurations are joined into a multi-filar assembly that can be utilized in electrophysiology catheters for applying pacing and recording protocols from inside the heart, ablation and balloon ablation catheters for atrial fibrillation, as well as cardiac mapping. The multi-filar technique allows for easier assembly of the signal or power wires into the final medical device—cables have a capacity of up to 60 lines, depending on AWG (American wire gauge) size or pitch, and provide multiple signals through the ultra-small shaft.

New England Tubing Technologies' eTubing products incorporate customized wires or cables within the wall of the tubing itself, saving valuable space within the tube and enabling analog and digital transmission of electrical signals for sensor capabilities, powering for devices, and temperature/oxygen monitoring features. Ideal applications include handheld electrosurgical devices, cauterization, ultrasonic devices, monitoring devices, and endoscopes.

Trelleborg's GeoTran technology enables MDMs to design more complex devices with fewer parts by replacing multiple extrusion and assembly components with a single extrusion. Movable die and mandrels allow the production of tubes with transitional geometry—for example, tubes with variable outer diameters and constant or variable inner diameters. This capability expands design possibilities—for example, silicone balloons are common in many medical devices. A preformed balloon segment is typically bonded to a catheter shaft at a position where a small opening allows inflation by saline or air. GeoTran balloons are formed in a single extrusion step as part of the catheter shaft, eliminating the costs associated with secondary operations and inspections. "Ultimately, GeoTran technology leads to higher-quality devices, with fewer failure points and better patient outcomes," said Sanchez.

There is also an increasing trend toward the 3D printing of flexible materials. Digital light processing (DLP) and ink-drop printing methods have been enabled by new chemistry formulations focused on low-viscosity materials. These new methods enable better resolution and the use of elastomers with improved properties. "As a result, there is potential for these printing technologies to be readily adopted for low-volume, intricate multi-lumen or multi-component parts that otherwise would not have been worth the investment in tooling," said Golub. "This could, in turn, push the boundaries for complex, higher resolution, short length tubing, as well as multi-materials systems where there is high value in complex components."

New Material Choices

Most of thermoplastics used in endovascular-related devices are from the nylon, polyether block amide (PEBA), and polyurethane families. Certain grades of these base polymers are partially compatible in that they have similar viscosities and melt temperatures. As a result, they can be compounded together at different ratios to form miscible polymer blends; they can also be co-extruded together to form multi-layer tubing with an outer layer and an inner layer of two different partially compatible polymers. "Polymer blends and multi-layer-extrusion technologies can be used to optimize device performance properties such as strength, flexibility, kink resistance, bondability, burst performance, and trackability for a given application," said Steve Maxson, vice president of sales for Spectrum Plastics Group, an Alpharetta, Ga.-based medical device contract manufacturer, including extruded tubing.

An example of how these partially compatible polymers can be used together is the dual-layer co-extrusion of high-pressure tubing (>600 psi) with a thin nylon inner layer and a flexible polyurethane outer layer for the intravenous injection of contrast media within the vascular system for angiography. "While a bare nylon tube would have a high-pressure burst rating due to its high modulus, it would be too stiff and more prone to kinking," said Maxson. "To combat the kink propensity, a lower-modulus flexible polyurethane outer protective layer is used to resist kinking and to provide greater flexibility of the infusion line."

Lubricity is equally important for catheter tubing, which can be enhanced by specialty coatings bonded to the surface of the tubing. In catheter-based cardiovascular or neurovascular procedures, there are often many twists and turns on the route to the targeted anatomy, so coatings need to be slippery as well as durable. Biocoat, a Horsham, Pa.-based provider of hydrophilic coatings for medical devices, has developed a coating called Hydak that demonstrates durability and lubricity that matches or exceeds other hydrophilic coatings, as well as superior bonding with low particulate counts. In addition, this material is fully biocompatible, made from a compound that already exists in the human body: hyaluronic acid (HA)—a naturally occurring polysaccharide.

OEMs are often unaware of how the formulation of a customized material can solve their technical challenges with medical device design, such as chemical resistance, shelf life, friction, and other general physical properties. For example, Saint-Gobain's Tygon LCF is a custom formulation with a distinct cost/benefit advantage over other low coefficient of friction materials, such as fluoropolymers. LCF is ideal for endoscopy sheaths, soft-touch components for gentle skin contact, and multi-layered systems where the ability to slide components past each other is required. "Additionally, unlike PTFE, the material can be e-beam or gamma sterilized and bonds well to most materials," said Golub.

Creating tubing for the medical industry comes with increasing regulatory and process validation requirements. OEMs are looking for materials that meet these requirements and provide more flexibility in tubing sizes and dimensional tolerances. "There are also expectations that plastic compounds have consistent filler dispersion, melting characteristics, and mechanical properties," said Ernst. "Screw design and compound process engineering also become critical components of material blending that result in consistent and efficient processing of quality tubing and faster entry to market for customers."

Breakthrough Advances

Major advancements in data collection, in-line process and product monitoring methods, and quality inspection continue to be announced. For example, Freudenberg Medical, a Carpinteria, Calif.-based medical device manufacturer, recently announced its Helix iMC system for the inline measurement of inner diameters for silicone tubes. The system uses sensor technology that continuously measures the inner geometry of extruded products such as single- or multi-lumen interior diameter, wall thickness, or concentricity as an inline process. "Until now, it was not possible to measure the interior diameter of silicone tubing without making manual cuts at various cross sections, usually as an off-line process," said Max Kley, CEO of Freudenberg Medical. "With this system, MDMs can monitor data continuously across a complete production run without interruption and sample cuts, reducing validation time and saving money."[2]

Computer-aided engineering (CAE)—including finite element analysis (FEA), computational fluid dynamics (CFD), and multibody dynamics (MBD)—is increasingly used to model end-use tubing applications. "As the knowledge of chemical and physical interactions grows, the ability to model a tube from pellets, through extrusion and cooling, and then through sterilization and end use, is becoming more of a reality," said Golub.

Trelleborg is working on several technologies, including advanced kink-resistant tubing. Trelleborg engineers have developed a process for applying reinforcements within a silicone tube wall, which significantly improves the tube's resistance to kinking; other R&D efforts include incorporating active pharmaceutical ingredients (APIs) into silicone tubing. Silicone composition can hold, and later elute, drugs for localized consistent delivery. Elution rates can be controlled for different applications. "Such APIs include antimicrobials, antibacterials, hormones, and steroids," said Sanchez. "In addition, we are continually looking to increase our quality, decrease the size of our extrusions, and solve unique challenges for our customers."

Freudenberg Medical has also introduced an innovative twisted lumen tubing called HelixTwist. This multi-lumen silicone tubing technology prevents lumen kinks by providing an equal balance of stress across the inner and outer lumens as the tube bends. This tubing is optimal for pacemakers, breathing tubes, neurostimulation, and other applications that require navigation through challenging pathways within the human body.[3]

In R&D news, Fraunhofer Institute for Digital Medicine in Bremen, Germany, is developing an "intelligent catheter navigation" method that uses a catheter equipped with a special optical fiber containing tiny mirrors. When light passes through the fiber, the mirrors reflect a portion of the light. Whenever the fiber bends, the reflected light changes color. Sensors then measure the change in color, which can indicate intensity and direction of the curvature and path of navigation during endovascular procedures. This eliminates the need for X-rays for guidance, thereby reducing radiation exposure for patients and physicians.[4]

Moving Forward

Perhaps the biggest challenge for a tubing manufacturer is understanding how to push the limits of its equipment to meet the performance parameters of the material. "For example, if a product requires very thin walls and the materials chosen cannot be processed at thin-walled tolerances, it is critical to understand why—is [it] truly a limit in the materials, or can the equipment be modified to overcome these material shortcomings?" said Golub.

Tubing manufacturers often play a key role in designing a successful medical device. They use their tribal knowledge to develop custom equipment and innovative manufacturing processes to meet specific demands—this includes knowing how far they can push material processes and equipment (or design their own proprietary methods) to keep pace with the rapid advances in the tubing sector.

Medical device designs will continue to be more complex and multifunctional—for example, mapping catheters, which are used during cardiac and electrophysiological therapies, help physicians discover and evaluate the electroanatomic layout of the heart and surrounding area—something that seemed impossible a few years ago.

As MDMs continue to push the limits of design, they increasingly depend on the know-how and technical expertise of their contract manufacturers to help them deliver the best possible product—often coming up with the critical design or manufacturing ideas that turn an impossible design into a productive device that saves lives.

"OEMs are always looking for improved performance and for suppliers that can provide additional services to get them closer to a finished device," said Wilkins. "They are also looking to partner with suppliers that can provide consistent and reliable quality, as well as documented validation of process qualifications and components."

For example, customers often request tubing flexibility but also need column strength for insertion. "In general, qualities like flexibility and column strength are opposite of one another, so we work with customers to find a balance between all the qualities and features that they are looking for," added Wilkins. "Getting our team involved as early as possible in the design phase is hugely important for meeting MDM performance specifications with a design that is also manufacturable." ❖

References

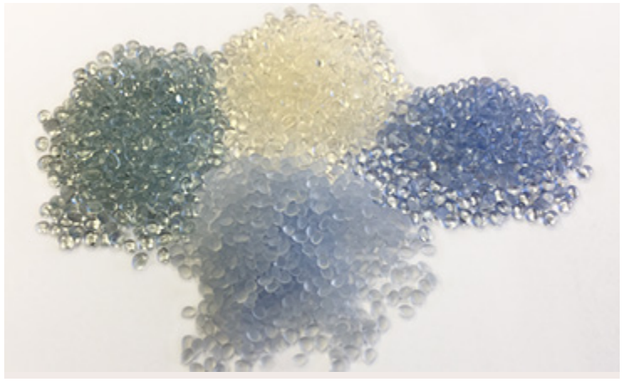
[1] *bit.ly/mpo200461*
[2] *bit.ly/mpo200462*
[3] *bit.ly/mpo200463*
[4] *bit.ly/mpo200464*

Mark Crawford is a full-time freelance business and marketing/communications writer based in Madison, Wis. His clients range from startups to global manufacturing leaders. He also writes a variety of feature articles for regional and national publications and is the author of five books.

Well Over a Decade Later…

The Saga of Non-DEHP PVC and Medical Devices

The story around PVC (polyvinyl chloride) and DEHP (di-2ethylhexyl phthalate)-based PVC in medical devices has been well told. PVC has been a staple in medical products and medical devices since the second world war and today still really has no equal in its widespread use and application. Nevertheless, about thirty years ago, probably in the late 1980s and early 1990s, multiple global health organizations cited DEHP, the most widely used plasticizer in PVC, as a potential health concern.



Flexible PVC pelletized raw material for tubing extrusion.

The plasticizers found in PVC facilitate the softness and flexibility of the chemical and occupy about a third of the compound. Perhaps ten years ago various regulations passed in both North America and in Europe first addressed that DEHP chemical plasticizers may be harmful to people, notably infants and children. Studies suggested that select blood and chemotherapy applications may absorb some of the plasticizer; substances in chemotherapy drugs, for example, elicit or resorb the compound. Most all the studies on DEHP, however, involve rodents, it bears mentioning, and there has yet never been a specific case reported of human health deterioration due to DEHP-plasticized PVC.

Today, there are numerous alternative plasticizers for PVC and significant progress has been made in the evolution of non-DEHP PVC varieties. Cost really is no longer a primary barrier to adopting non-DEHP varieties; the differences in prices often range below 10%. The considered replacements for DEHP all vary based upon application, assembly, among other criteria, including yes, cost.

At Spectrum Plastics, we noticed our customers—medical device OEMs—seriously considering the non-DEHP alternatives about 10 years ago. Largely due to potential health and exposure reasons, as noted above, this conversion seemed to begin with neo-natal and enteral applications to reduce potential exposure. We've since seen a migration across other medical tubing applications, including lower risk drainage and suction tubing applications, where cost management had previously been a mitigating factor in the adoption of the alternatives. It is fair to say that at the present time a substantial and significant majority of our current new product pipeline for PVC extrusions features non-DEHP varieties. We have passed a pivot point world-wide in the adoption of alternatives and there is little on the horizon to see this revert, while surely the EU MDR directive for 2020 is also having a major impact in advancing the displacement of DEHP-based PVC products.

As a tubing extruder and converter/processor of PVC, Spectrum Plastics has had broad and deep experience running the full variety of non-DEHP PVC compounds. There are around eight to nine viable plasticizers to select from at this time, though consensus seems to have been built around three in particular: DOTP, TOTM, and ATBC, with honorable mention to DINCH as technically it is strong but has not caught on commercially. These plasticizers are called di-octyl terephthalate (DOTP), trioctyl trimellitate (TOTM) acetyl tributyl citrate (ATBC), and di-isononyl cyclohexane (DINCH). This consensus largely stems from cost, performance, and chemical compatibility relating to the primary tubing applications for which PVC is targeted.

PLASTICIZER (ranking)	DEHP	DEHT (or DOTP)	TOTM	ATBC (citrate)	BTHC (citrate)	DOA	DINCH
Efficiency Factor	2	4	5	2	7	1	5
Relative Cost (vs. DEHP)	1	1	4	5	7	6	3
Compatibility	3	3	1	6	2	7	3
Chemical Resistance	3	3	1	6	2	6	3
Long term aging	3	3	1	6	2	7	3
Migration*	3	4	1	6	2	7	3
RBC Hemolysis	1	4	4	6	3	6	2

* Actual migration will vary based upon polymer or other material.

When assessing the attributes of the various non-DEHP PVC alternatives, the following appear to be the most fundamental:

- Plasticizer efficiency (how much plasticizer is required to achieve the same hardness and/or flexibility as traditional DEHP)
- Cost (includes both raw material cost and efficiency in final compound)
- Compatibility with other materials (that contact the tubing)
- Chemical resistance
- Long-term aging based on volatility
- Migration resistance to polycarbonate, ABS, polystyrene or acrylic connectors or packaging
- RBC (red blood cell) hemolysis for blood storage

The table summarizes the different properties versus plasticizer type, with DEHP as the standard. This ranking is only for comparison purposes, with (1) being best and (7) being worst. If two items are considered equivalent, they have the same ranking. Actual testing would be required for the specific application to verify the best possible plasticizer solution.

Nevertheless, select alternative plasticizers to DEHP have come to be the expected norm with certain applications. TOTM, for example, appears to be the plasticizer of choice for drug infusion or chemotherapy applications, largely due to its chemical resistance. There is some DOTP used in these applications as well, as it is a very cost effective alternative, but it has been found to have failed some long-term aging and adhesion tests.

ATBC and BTHC are bio-based plasticizers. In terms of sustainability, they are the best plasticizers of the list and they are both biodegradable, too. Both plasticizers exhibit an excellent toxicological and eco-toxicological profile. ATBC is the common plasticizer for enteral applications, whereas BTHC is most often used in blood storage bags and catheters. The BTHC, however, is a very expensive plasticizer.

DOA or dioctyl adipate, has the best efficiency of the common plasticizers and by far the best low temperature properties. Its biggest drawback is the tendency to migrate easily to the surface of the tubing which can cause other potential issues.

Finally, for blood storage, one of the most common applications of PVC, DINCH would appear the best alternative to DEHP at avoiding hemolysis of blood cells. However, despite some recent licensing arrangements and expansion, there remains the potential for supply limitations for this one, and at the present time its availability to the U.S. market may not readily meet demand.

What does the future hold for the PVC plasticizer saga? As noted, we believe we have passed a critical moment for new product development, largely influenced by the focus the EU MDR situation has inspired, but also due to advancement and understanding of the various non-DEHP alternatives. As the largest independent medical tubing extruder in North America, Spectrum Plastics Group is dedicated to advancing the science of tubing extrusion and remaining on the leading edge of plastic conversion. Based on our history and experience with PVC for over 60 years, you can be confident that you have a Trusted Partner available to develop the best technology with the safety of end patients ever in mind. ❖

Illuminating Insights: An eBook Exclusive

Medical tubing experts from Spectrum Plastics share their thoughts on topics from materials to multilumens.

Sean Fenske • *Editor-in-Chief*

Tubing is such a common component in so many medical devices it can easily be overlooked by the design teams developing a device. When that happens, a tubing supplier may not be brought aboard in an ideal timeframe, which can adversely impact the cost and time to market of the final device. It is important for product designers to engage their suppliers early in a project, including components that seem simple, such as tubing.

"It is important for device manufacturers to collaborate with our extrusion engineers and technicians to understand the impact of downstream manufacturing techniques based on the selected tubing design," explained Matt Bills, senior vice president of Spectrum Plastics' Vascular Technologies division, which targets advanced, engineered interventional tubing applications across a variety of catheter and other device platforms. "Factors that impact tubing dimensions include material durometer in relation to tolerances, tubing tolerance in relation to device functionality, and tubing ovality optimization and concentricity. Our technical team participates in a specification review with device manufacturers on design inputs upfront, to minimize cost and scrap, and thus lessening number of iterations."

In this Q&A presentation, Bills was joined by his Spectrum Plastics colleague, J.W. Dalton, senior vice president of the firm's Medical Tubing division, which is differentiated from Bills' segment as the tubing produced is built around broad, large volume fluid management device platforms. Together, both experts took time to address a bevy of questions around the critical component. In this interview, Bills and Dalton speak to material considerations, manufacturing challenges, tubing trends, regulatory concerns, and what expectations they have for medtech down the road.

Sean Fenske: What are the most common tubing challenges medical device manufacturers are bringing to you and how are you helping to resolve them?

Matt Bills: Within Spectrum Plastics Group's vascular technologies division, we specialize in precision, thin-walled tubing at the micro level. As such, we continue to receive inquiries for complex, microbore tubing—everything from large diameter tubing with wall thicknesses below one percent of the outer diameter to multilumens with unique profiles and thin-walled cross-sections. Recently, we have seen an increase in the demand for custom, challenging multilumen designs, including unique profile designs that seek to do the job of a multilumen (separating parts/flow within a tube) without an "outer wall."

J.W. Dalton: It is common for device designers to overlook the humble, flexible PVC tube. That said, currently the highest volume of requests has been concerning regulatory compliance and, most specifically, related to EU MDR. This is a major change to the regulatory landscape in the device industry and a major challenge to overcome for most device manufacturers selling in the EU zone, although the deadline was recently extended. In addition, the majority of disposable tubing for use outside of the body is made from PVC material, which could contain DEHP plasticizer. So we see a lot of requests addressing the conversion from DEHP plasticized PVC to either non-DEHP PVC or away from PVC to another type of polymer.

Fenske: What important considerations do many device manufacturers overlook or forget when spec'ing tubing for a project?

Bills: Multilumen tubing, even some of the configurations that have been on the market for decades, can be deceptively challenging to get right on the first try. Customers often underestimate how long they should allow for the timeline on a new multilumen design; realistically, the sooner the extrusion team gets involved in the conversation, the less likely project timelines and budgets will have to be adjusted because a challenging feature or geometry is already "locked in" by other components, such as injection molded parts.

Dalton: Design for assembly is a common challenge. For example, the tolerancing for a proper fit at one end is different than what is required at the other end and the tolerancing for proper function in the middle is different again. Another consideration involves the potential interactions of different materials. Some materials have ingredients that can craze or cause other materials to migrate and cause failure that is not noticed until extensive aging or shelf life testing.

Fenske: As a company that provides for both ends of the spectrum (pun unintended), what are the biggest differences between providing high volume, "commodity" tubing and specific, custom solutions?

Bills: Spectrum Plastics provides a range of tubing solutions and technical capabilities. We pride ourselves in being a market leader and largest independent tubing manufacturer in North America. Within our Vascular Technologies division, we provide device manufacturers with specific, custom solutions that require tight tolerances and highly engineered polymers, including silicone.

With R&D and small batch custom tubing, which features tolerances ten times tighter than conventional high volume tubing and much thinner walls, generally our biggest priority is getting a job out the door and in-spec parts into the customer's hands as quickly as possible. A lot of the time, we'll get parts to a customer, they'll start doing their testing, and then they'll realize "We need this wall thicker," or "This material is tackier than we thought; we need a little more clearance in this lumen." So rapid iteration, and quick turnaround during the R&D stage of product development is critical. Of course, we can't really treat these as two separate things; ideally every R&D job we bring in the door will become a production job, so while we're doing that rapid iteration work at the start, it's also important for us to be asking ourselves what we can do to make production orders more efficient.

Dalton: At the end of the day for the Medical Tubing division and conventional materials, such as PVC, the engineering requirements and processes are really the same for both categories, so our processes to produce either of these is the same. The materials differ and the tolerances might be less stringent, but the process is the same. What really also differs is the scale of production and the mentality of running a job with millions of feet of tubing versus those in the thousands. For manufacturing higher volume applications, it is imperative to engineer and design a manufacturing process that minimizes costs from the beginning.

Fenske: How important is ensuring the right material is used for the tubing and do you typically aid in that selection process?

Bills: Material selection is probably the single most important choice in this process since it will have effects on everything from our labor and material costs to the actual tubing profile required to meet a customer's needs. Material selection is critical to ensure form, fit, and function of the device. Spectrum Plastics processes virtually every medical grade thermoplastic and silicone available and has the polymer science know-how and extrusion conversion expertise of advanced, specialty polymers. Our technical team frequently assists in material evaluation with our custom-

ers, with the responsibility ultimately residing with the customer to prove its efficacy for the device design.

In cases where customers are unsure of a material, our team often provides meaningful samples of similar parts or run minimum orders of multiple material durometers. Our off-the-shelf tubing products are available via our webstore, in both thermoplastic and silicone form, which provides a great way for customers to jumpstart a project and evaluate material options within days.

Dalton: The material selection for a product contributes substantially to the product's success. This varies by critical nature of the application, but, in general, it is very important and could have a negative effect on the end part functionality, the regulatory compliance, part cost, and also, the project timeline. Material selection considerations include the assembly methods, sterilization, shelf life, compatibility with what is transported through the tube, flex or repetitive motion life, clarity, and more. We use hundreds of material variants and have familiarity with the strengths and weaknesses of most of them, so we can offer insights on material selection.

Fenske: What material advances are you seeing that's enabling more robust tubing solutions?

Bills: Polymer solutions are constantly evolving due to advances in procedures and performance requirements in devices. Most recently, we have seen advances from our vendors that include blending of materials for different compositions; advancements in high temperature, specialty polymers; and an increase of additive usage in base polymers such as low-friction or lubricious additives. ProPell low-friction additive melt blended with low durometer Pebax or polyurethane creates a near tack-free surface while maintaining their elastic properties. The reduced tackiness improves the stability of the extrusion process and results in tighter ID/OD tubing tolerances.

Additionally, the advances in urethane options, while not necessarily visible to the customer, make a big difference in extrusion processing. Changing a urethane material, like Pellethane to Isothane, reduces process variation, and allows for a significant reduction in labor for large volume lots.

Dalton: We serve a broad selection of markets and customers, and each seems to add their own twist. Most material developments we are seeing recently are directed toward reducing risk by ensuring compliance with the latest regulatory frameworks around the world. This allows a customer to stay in the same material in all markets for many years to come. Making products safer and improving the product performance for the patients are the most critical aspects of any new material advances.

The EU MDR requirements have driven some change in the material supply chain and people have had to adapt and make new offerings that are better positioned to succeed in this new marketplace. There are many sophisticated, highly competent material suppliers available with many tools at their disposal to solve specific process or product issues. Some suppliers are differentiating their product line with specific products for medical with varying levels of product regulatory support. Cost management would drive the supply chain toward standard products, but application requirements can drive toward custom solutions. Understanding there are so many options, it helps to have someone like us who can offer expertise and experience in this selection process based on our breadth of products and experience to help identify standard products when possible or when to elevate to custom solutions when needed.

Fenske: Earlier, you mentioned multilumen tubing. Are the demands for multilumen channels increasing and what are the challenges with sending multiple types of media (e.g., gas, fluid, wire) through the same tube?

Bills: We have seen an uptick in demand for multilumen tubing over the last several years, especially for large diameter ones. With the correct selection of material to the end-application use, multilumens are an optimal solution for minimally invasive surgeries. Customers are constantly wanting to pack more into less. Thinner walls of multilumens while maintaining or reducing the OD is frequently explored by device manufacturers.

Dalton: Multilumen channels can be a tool used by designers making out of the body disposable products to reduce the overall footprint of the conveying part of the device, making it more manageable for handheld devices in operating arenas. Tubing management in the user environment aids the user in improving accuracy and reducing touch time. Our multilumen tubing maintains the tubing bundle as a cohesive and easy to manage group. Individual tubes can be striped or colored to aid the user in clearly identifying each tube component.

In this type of application, unless the design uses peelable paratubing, there is a need for a custom design fitting or fittings. The concern here is usually symmetry and specification (or making the part extrudable) from our point of view. The part design may need to have features to tell the different lumens apart to avoid confusion in assembly or at the point of use. There may be additional design features, like flow or pressure and temperature compatibility, to consider as well.

Fenske: With the interest in minimally invasive surgical procedures increasing, how are the demands on tubing suppliers changing or growing to fulfill the needs for delivery systems?

Bills: Again, smaller diameters with thinner walls are one way to tackle this, enabling more functionality through less space. Variable stiffness, steerable catheters for targeted sections of the anatomy are frequently requested.

Dalton: Tubing is often a major part of a surgical kit, from tip protectors to stiffeners and delivery systems. We are seeing demand for printing of navigation marks or inclusion of radio opaque materials as ways the delivery system can help the surgeon deliver items to the targeted spot.

Fenske: What medical device or technology trends are you following so as to be prepared for the needs of the manufacturers of tomorrow's products?

Bills: We are constantly introducing new solutions to the market that customers can utilize to maximize performance; our Apollo Sub-Ultra-Thin-Wall tubing, for instance, is one gateway.

Dalton: There are trends in the industry that we need to keep up with, whether it is new FDA guidance or enforcement trends, EU MDR, the status of EO sterilization, or market trends like cleanability or miniaturization. Then for our plastic processes and products, there are equipment enhancements being introduced by the manufacturers like Industry 4.0. Material enhancements are also being tested or introduced for medical products, like non-PVC materials for applications traditionally made from PVC.

Another trend is in supply chain management. Customers are pushing to shorten the chain, demanding value-add and more comprehensive solutions from component suppliers. So we expect to see a more integrated manufacturing process for devices such that tubing manufactures will be asked to include printing, punching, and even possibly some online assembly as a way to reduce costs and supply chain length. A final trend to note is a desire to ensure every inch of tubing is perfect to specification so more automatic inspection methods for workmanship criteria such as bumps or gels is inevitable.

Fenske: What's on the horizon for medical device tubing? What do you foresee in five to ten years?

Bills: More and more medical tubing is being supplied into the surgical robotics industry. The advances in this space are quite remarkable and I believe the current innovation in this space is just the tip of the iceberg.

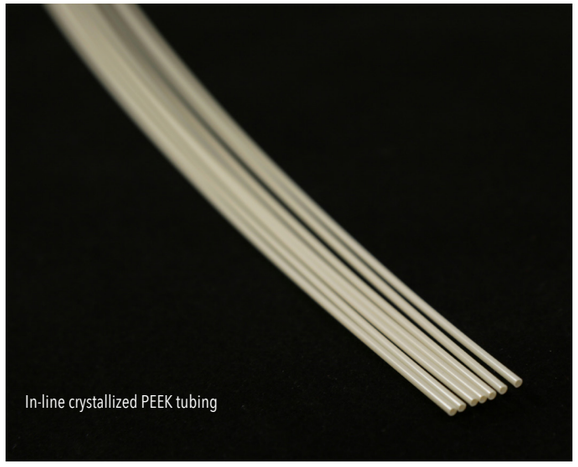
Dalton: At the moment, it is really hard to see ahead with clarity due to the COVID-19 crisis. We might see reshoring driven by regulations to protect our medical supplies infrastructure or by continued tariffs. Again, we will see more interest in the supply chain robustness coming out of this challenge. If we look before the current crisis, cost, speed, and speed to market seemed to be the key drivers.

Fenske: Do you have any comments about medical tubing device manufacturers should keep in mind?

Bills: I would say the importance of material selection and the impact it has on the device, combined with tolerances, tolerance stack-up and design criteria related to the function of the tube and the device—these are the most important things to keep in mind, in my opinion. Our expertise and iterative approach, combined with our quick-turn extrusion process enable us to provide customers with parts rapidly, within days.

Dalton: I would agree with what Matt has to say here—in the end, tubing design can contribute to the success of your product. ❖

The Effect of Crystallinity on PEEK Performance in Extrusions


In-line crystallized PEEK tubing

There are many semi-crystalline polymers used in medical device applications today, but PEEK (Polyether ether ketone) is fairly unique among them for two main reasons. First it can be extruded by a variety of methods that can produce either amorphous or fully crystalline tubing, and second, every single one of PEEK's performance test values are affected by its crystallinity levels. In most cases, it requires specialized in-line processing or secondary operations to achieve fully crystalline PEEK parts. Our engineering team performed a study to quantify the performance differences not only between amorphous and fully crystalline PEEK tubing but also between different methods of tubing crystallization. In this article, we will describe the values tested and the results of these tests below.

There were a few reasons why doing this test is important and should be shared with engineers and consumers alike. First, it is not explicitly clear on easily available documents what the default state of a PEEK part should be, amorphous or crystallized, or that it can even be either one. The material data sheets for PEEK grades from the major manufacturers all mention the semi-crystalline chemistry of PEEK but none state what the samples are for the tests. This ambiguity is not helpful. It is not until one digs into more detailed material information that it becomes clear that the preferred state of PEEK parts is fully crystallized. Moreover, the effect on performance of the crystallinity level often goes unmentioned.

Second, since this information is either lacking or unclear, engineers and consumers may not understand that there is a difference, PEEK parts can be made amorphous or fully crystalline, or somewhere in between, and therefore processors may not go through the extra effort to provide a fully crystalline part. Ultimately, the impact of this ignorance is that the end-user unknowingly receives a part that will not perform to the level that is required and expected.

Finally, the result of all of the above may be to yield failures in the field, something each and every one of us in the medical device industry wishes to avoid. Our goal is that the information provided here will help end-users in specifying extruded PEEK components as well as aid them in the selection of extruders that are experienced with PEEK and can deliver optimized parts.

For this test we extruded two sets of tubing, one set amorphous and one set crystallized in line. We then took some of the amorphous tubes and annealed/crystallized them post extrusion in an oven, which is a common method to achieve full crystallinity in PEEK parts. All extruded tubing was manufactured on the same day on the same extrusion line using the same tooling. The tube size was 0.060" OD x 0.050" ID and was manufactured using recommended processing temperatures and raw material preparation were used for this test. The secondary annealing step was done in an oven.

There are many property values that are contained in material data sheets, but we did not test for all of them for simplicity sake. The properties we did test for--tensile, elongation, flexural and crystallinity-- represent most of the performance characteristics that end-users are mainly concerned with. As we stated earlier, the crystallinity levels of PEEK tubing affect all performance characteristics, including the ones we did not test for, such as electrical, chemical, thermal, density, compression and coefficient of friction.

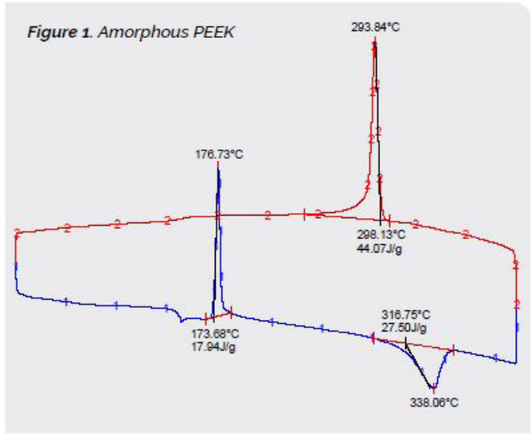


Figure 1. Amorphous PEEK

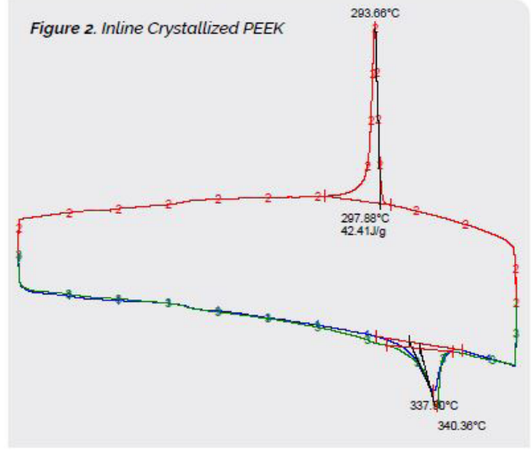


Figure 2. Inline Crystallized PEEK

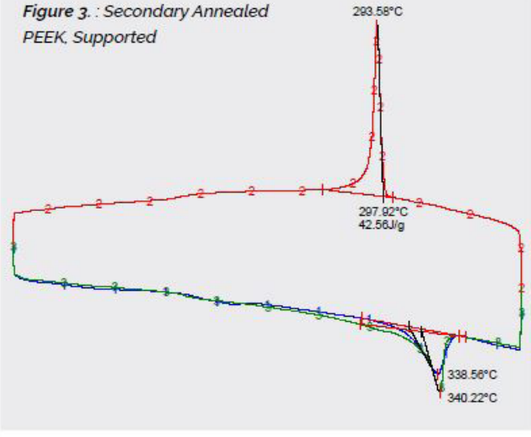


Figure 3. : Secondary Annealed PEEK, Supported

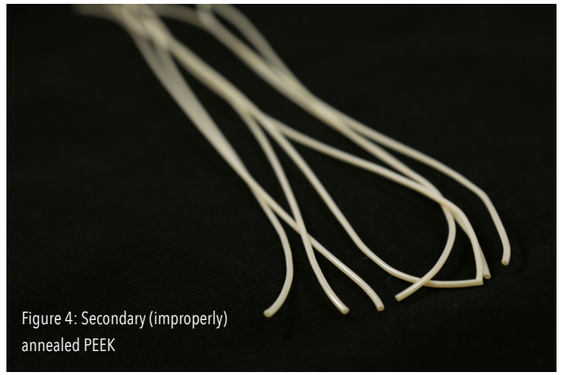
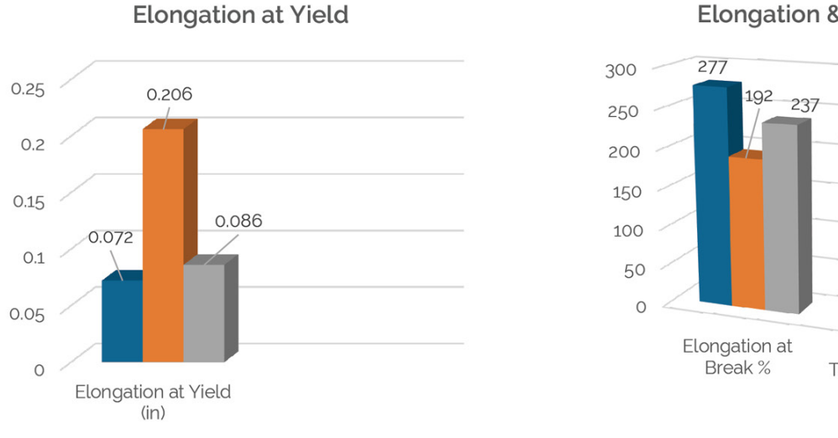


Figure 4: Secondary (improperly) annealed PEEK

A differential scanning calorimetry (DSC) test was done on all samples to determine the crystallinity levels of the samples. The DSC graph for the amorphous tubing can be seen in Figure 1. The peak at 176.76°C indicates that the sample was not crystalline and that there was a lot of heat flow activity in the samples at this temperature. This is also the temperature range of PEEK's Tg and HDT. In Figures 2 and 3 are the DSC graphs for the in-line crystallized samples and the secondary annealed samples.

We can see neither of them shows the peak at about 175°C that the amorphous tubing shows and that they are essentially identical. This tells us that both samples are fully crystallized and that both crystallization methods can make fully crystalline parts. Additionally, these two graphs show that there is no significant heat flow activity until the 340°C melting point is approached, which is why PEEK is known for such high heat resistance. All the heat flow activity that is shown at the 175°C mark on the amorphous samples highlights a very big issue with amorphous PEEK. Crystallinity is achieved by the PEEK molecules moving and aligning and forming crystals when the polymer is soft enough for the molecules to move. This molecular movement after the part has been formed causes the shape and dimensions to change, and when not properly annealed there can be irregular deformation and movement of the parts as seen in Figure 4. This represents a potential mode of failure for PEEK parts that are not fully crystalline. Higher heat sterilization methods that are well within PEEK annealing temperatures as well as heat from tool friction and electro-cautery can produce enough heat to release these internal stresses and uncontrollably anneal parts. Aggressive cleaning chemicals and harsh drugs can also release these internal stresses and cause stress cracking. These are some reasons why fully crystallized PEEK extrusions are so important.

Tensile and elongation properties were tested on these samples and we provided values that correlated to the values typically found on material data sheets. In the Elongation and Tensile chart, elongation at break percentage was lowest for the in-line crystallized sample and highest for amorphous. Amorphous PEEK is more ductile allowing for more stretching before failure, and crystalline samples do not allow as much stretching. The tensile modulus correlates to elongation values in that higher tensile modulus leads to



lower elongation in the in-line crystallized samples and the high elongation of amorphous PEEK leads to lower tensile modulus. In the Elongation at yield chart we found some very interesting information that points to situations where elongation at yield performance is critical: in-line crystallized samples have more than twice the performance of the secondary crystallized samples. Additionally, the amorphous and secondary crystallized values are very similar suggesting that crystallinity by itself is not affecting the performance, but rather the crystallization method. A possible explanation for this difference is that the molecules are already aligned in the direction of flow for all extrusions, so all PEEK extrusions, amorphous and crystalline, will have this same level of alignment at their base. The difference with the in-line crystallization process is that the crystals will also be aligned in the direction of flow because they are being formed during the extrusion process and while the material is being drawn down. Crystals that form during the secondary annealing process could be more random and multi directional, which may be beneficial in some applications but has a negative effect on tensile properties.

Flexural properties were also tested, maximum flexural load and flexural modulus. As expected, both types of crystalline samples had higher flexural values than the amorphous sample. The flexural properties for in-line and secondary crystallized samples showed no significant difference in performance. Whatever molecular change or alignment that resulted in higher tensile performance for the in-line crystallized tubing had essentially no impact on flexural properties. Overall, this does show a consistent performance advantage of fully crystallized PEEK parts over amorphous parts in regards to flexural performance.

In conclusion, the objective of this study was to determine whether a condition of full crystallinity be the default state for all PEEK extrusions. The data and test results answer that resoundingly in the affirmative. The data and test results demonstrate that fully crystallized PEEK extrusions will have higher heat stability, increased tensile properties, and increased flexural properties. Consequently, the performance characteristics will yield their "peak" and will match the levels stated on manufacturer-supplied literature and provide more predictable performance for all end use applications.

Many process variables play into what is required for an extrusion to be fully crystallized: size, geometry, line speed, etc. As mentioned, manufacturer literature tends to be somewhat ambiguous regarding the default state of PEEK material and offers little insight into how to achieve full crystallinity with the extrusion process. In order to receive the most consistent, highest performing PEEK extrusions, the processor must be able to understand this concept of crystallinity, how the molecules function and how to interpret all the project variables while transferring this knowhow into a process that will yield the best possible extrusion for the application. Being armed with and aware of these insights permits end-users that need PEEK extrusions to find a processor that will be able to best meet these needs. ❖

Challenging Channels: Tubing Innovations Enable Greater Device Capabilities

Technical innovations provided by tubing suppliers fulfill the various needs of medical device manufacturers.

Mark Crawford • *Contributing Writer*

Extruded tubing and steel tubing are key components in medical devices today. Tubing applications continue to grow as medical device manufacturers (MDMs) create next-generation devices to improve a wide range of medical procedures. Medical instruments used in surgery today require more elaborate features and added functionality than they did in the past. As a result, product design and development have become more complex, including tubing components. The thermoplastic tubing market continues to expand due to the rapid growth of minimally invasive interventional therapies such as endovascular, cardiovascular, diagnostic, endoscopy, electrophysiology, structural heart, and other delivery systems. For example, such procedures often require catheters with multiple capabilities, such as sending electronic signals to smaller and harder-to-reach parts of the body.

According to a January 2019 report by Grand View Research, the value of the global medical plastic tubing market is expected to reach $11.95 billion by 2025 at a compound annual growth rate of 9.1 percent over the forecast period.[1] The company predicts silicone polymers will be the fastest-growing segment, thanks to beneficial properties such as hydrophobicity, chemical resistance, and thermal stability. Silicone polymers are increasingly used in diagnostic guidewires, defibrillators, suture sleeves, and heart pumps.

"Silicone is being used in new and innovative ways in the medical device industry, such as overmolded tips, reinforced components, and novel extrusion profiles," confirmed Paul Melnychuck, senior director of business development and innovation for Xeridiem Medical Devices, a Tucson, Ariz.-based supplier and a Spectrum Plastics Group company that manufactures silicone-based catheters and other components for medical devices.

Metal tubing is frequently used for the shafts of disposable and reusable medical instruments. OEMs want customized steel tubing with special properties for complex articulating instruments that enable easier access into the body during minimally invasive laparoscopic, endoscopic, and arthroscopic procedures. Making tubing components for these devices typically requires a variety of tubing technologies and processes to manipulate metals into different formations.

Robust growth in the extruded and steel tubing markets parallels the increased development of more complex, miniaturized, and multifunctional medical devices. New innovations in medical technologies and applications are forcing tubing providers to keep pace, where perhaps the greatest challenge is not technical but operational—how to add quality and functionality and still keep costs down. Advances in technology are enabling new procedures that were not possible before—as a result, OEMs are demanding creative, customized, thermoplastic and steel tubing solutions, especially for minimally invasive procedures.

"The market for medical tubing will continue to grow as more open surgical procedures are converted to less-invasive interventional procedures," said Robert LaDuca, CEO of Duke Empirical, a Santa Cruz, Calif.-based manufacturer of catheters and precision medical tubing extrusion. "The rate of this conversion is limited by a lack of suitable, procedurally specific instruments that device developers actively pursue in areas of strategic interest, such as catheter-based mitral valve repair and replacement therapies."

Extruded Tubing

OEMs are asking for smaller inner and outer diameters, multiple lumens, thinner walls, tighter tolerances, and color matching. They seek increasingly functional capabilities and greater performance from their tubing. These demands are pushing technological limits for new devices and next-generation redesigns—for example, OEMs want precision tolerances as small as ±0.0005 inches for outer diameter, inner diameter, and wall thicknesses.

Extrusion technology is being especially challenged by smaller and less invasive procedures that require very thin walls or smaller diameters (multi-lumen within smaller, tighter-tolerance tubes). This is driven primarily by the need for neurovascular techniques and below-the-knee procedures. To meet these demands, "catheter manufacturers are calling for innovations that reduce the wall thickness of the catheter liners to as small as 0.0006-0.0008 inches to free up real estate within the manufacturing of the catheter and to enable the efficient delivery of procedures such as a stent, balloons, coils, or ultrasound to the patient," said Joe Rowan, president and CEO of Junkosha USA, an Irvine, Calif.-based provider of tubing and other products for medical devices.

OEMs are asking for customized tubing solutions with very precise material characteristics and performance parameters. Some tubes are designed to resist temperature and hazardous chemicals or reduce friction between the different catheter components. These challenges typically require the development of hybrid tubing innovations, whereby different layers of material serve different functions, or create variable properties along the length of the tube.

"There is always ongoing development on engineered polymers to provide specific performance characteristics, whether it is flexibility, biocompatibility, lubricity, or tensile," said Tommy Thao, business development manager for Flexan, a Lincolnshire, Ill.-based provider of thermoplastic extrusions with bump tubing, tri-layer, coextrusion, and multi-lumen capabilities.

"Many new materials have been introduced over the last several years," added Tim Steele, president and CEO of Microspec Corporation, a Peterborough, N.H.-based provider of custom extrusion for the medical device industry. "Some of these materials are formulated in the lab, specifically for one part and one application."

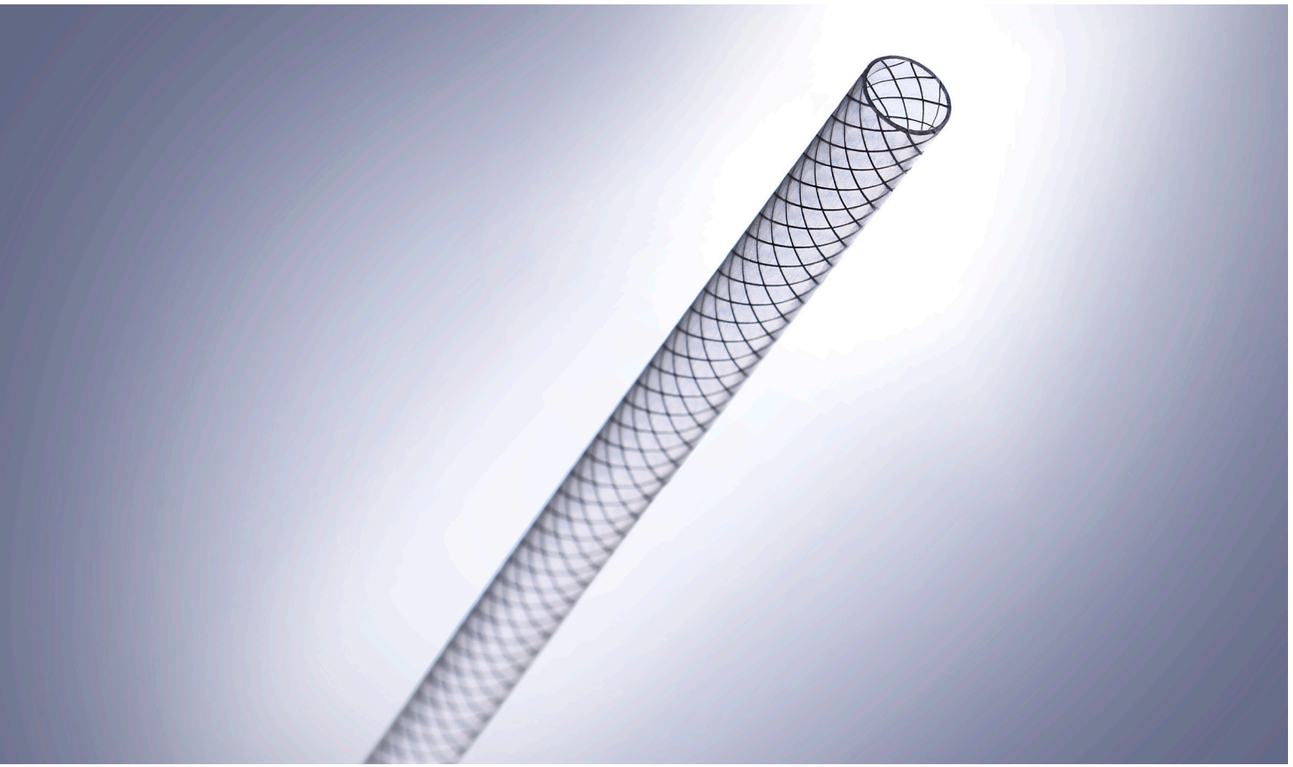
The development of less-invasive heart valve repair and replacement technologies are driving the demand for catheter systems which meet demanding specialized requirements for transmitting forces to deploy implantable devices or to structurally modify the valve or its surrounding anulus while the practitioner operates the system a meter away using the catheter interface. Tubing for these applications has very specific requirements—for example, enough column strength to support "pushability" and navigation to the target anatomy through 3D access routes, while also having an axial stiffness that is sufficiently flexible to traverse tight radii without undo force being exerted on the access vessels. Similarly, once the device reaches the targeted anatomy, it must be stable during actuation and deployment forces, which may involve torque stability as well as in-plane stability, while still allowing motion to take place in only limited planes of motion. "Multi-material, multi-layer, deflectable, coil/braid/laser cut reinforcements, and lubricious liners and hydrophilic coatings are some of the more sophisticated tubing requirements OEMs are designing in order to achieve these goals," said LaDuca.

As exciting as these enhanced capabilities are for these smaller and more complex devices, manufacturing costs can be expensive. MDMs exert great pressure on their tubing suppliers to control costs—a difficult challenge considering design and testing continue to become more elaborate, and often use more expensive advanced materials. Therefore, to keep costs down, suppliers are constantly looking for ways to increase efficiency across their operations, such as streamlining workflows. Junkosha has developed a 2.5:1 peelable heat shrink tubing (PHST) that provides catheter manufacturers with the highest shrink ratio currently possible in peelable fluorinated ethylene propylene (FEP), which reduces the number of shrink processes down to one. Thanks to its "take up," 2.5:1 PHST allows the use of cost-effective, lower-tolerance, baseline materials in the manufacturing process, enabling easy reflow into a single smooth construct. Applications where this high-ratio PHST technology enables improved processes and cost savings include neurovascular catheters that have tapered diameters for the floppy distal segments and proximal sections with larger diameters for pushable support.

Tubing suppliers must also be up to date on regulatory requirements that pertain to their manufacturing processes and tubing products. More OEMs expect documentation that their tubing components meet ISO 13485:2016 standards for quality management, including validation and traceability. "As part of the development process, OEMs want process validation, which demonstrates statistically the part is what it's supposed to be," said Steele. "Delivering this type of service requires a highly-trained and reliable customer service department."

Steel Tubing

Steel tubing for medical devices is typically manufactured using drawn tubing or a stamped and rolled technique. Selecting the most appropriate method depends on a number of factors, such as the medical device and its purpose, the size of the tubing required and its functional properties, and thickness and tolerance. Some OEMs are moving toward single-use surgical instruments and tubing components that can be discarded following a procedure, part of an approach to reduce the frequency of hospital-acquired infections (HAIs). Single-use instruments and tubing offer a safer



approach to preventing transmission of infections, compared to reusable instruments that undergo repeated use and sterilization.

An increasing number of OEMs are being more selective in choosing raw materials. In the past, device engineers typically requested off-the-shelf catalog tubing because they could get it quickly. The downsides to this approach were the design compromises and the time it took to make the mating components work correctly. "Today, device engineers collaborate directly with our technical staff to design custom tubing that will improve device performance," said Jeffrey Crane, application engineer for K-Tube Technologies, a Poway, Calif.-based producer of miniature stainless-steel tubing.

Orders for stainless-steel tubing are increasingly customized. Design teams seek specific physical properties in their steel tubing that can be achieved by using different alloys or by specifically engineered physical properties such as hardness, tensile strength, and stiffness, often in smaller dimensions with tighter tolerances and improved surface finishes. Ultra-small diameter tubing can have outer diameter sizes as small as 0.02 inches and inner diameter sizes as small as 0.005 inches.

Engineers want application-specific physical properties that give them a competitive advantage. This usually translates into using different alloys, but sometimes, it also involves pushing capabilities in manufacturing. "For example," said Crane, "if we are tailoring properties for a catheter-based delivery system, we might recommend tubing with very high yield strengths, and then manufacture concurrent lots in Co-Cr alloys [MP35N, L605] or other precipitation-hardened alloys, such as 17-7PH or 1RK1, so the OEM can test torquability and pushability using different materials. Our teams are sourcing alloys that were once only available to the wire industry such as Co-Cr alloys, Ni-rich super alloys, and high-strength, precipitation-hardened alloys. We are actively researching and qualifying metal suppliers who can offer raw materials suitable for the manufacturing process."

OEMs are also asking for shorter lead times for custom-designed tubing.

"Development requests are handled through our discover center, which is usually an engineer-to-engineer transaction that results in shorter manufacturing lead times," said Crane. "Supply chain or operations professionals also need greater consistency from lot to lot, combined with risk-based regulatory compliance and lower costs. For these requests, we create proposals that increase lot sizes while balancing demand and supply, which often reduces variation and lowers manufacturing costs."

Today, device engineers tend to collaborate directly with a tubing supplier's technical staff to design custom tubing that will meet specific dimensions, tolerances, surface finishes, and physical properties like hardness, tensile strength, and stiffness. The best way for an OEM to secure the shortest possible lead times for custom-designed tubing is by working with a contract manufacturer (CM) that offers a full range of cost-effective, high-quality tubing solutions for the medical device industry, noted Steve Santoro, executive vice president for MICRO, a Somerset, N.J.-based manufacturer of medical devices featuring stainless steel tubing components. "OEMs that develop high-volume products are especially interested in innovative technologies that provide value and help them achieve more advanced features that are also cost-effective and efficient to produce," said Santoro.

Design for manufacturability (DFM) services are an effective way to identify potential problems early in the design stage. DFM reduces prototyping iterations and smooths out the manufacturing process by eliminating unnecessary steps, which saves production time, money, frustration, and wasting valuable resources—all while speeding up time to market. "Being sensitive to pressures that design engineers face with cost targets, time to market, and other factors is critically important," said Santoro. "We can step in during DFM when design engineers dismiss important manufacturing considerations, such as an overdesigned or under-designed product—which can prove detrimental to the successful production of parts."

Technology Advances

Although advancements by tubing manufacturers are continuously being made, they are often proprietary in nature and deliberately kept off the radar. Continued research and development with existing extrusion technologies and/or new materials sometimes results in an effective new process, which remains in-house. This is true for both extruded tubing and stainless-steel tubing.

For example, OEMs want higher-quality cutting of burr-free ends on harder, thick-wall polymer tubing, compared to what standard rotary blade cutter/pullers can provide. Such tubing may be a hard polycarbonate or polyetheretherketone (PEEK) extrusion, which will be subsequently bonded. The cut ends on both sides must be perpendicular, without chips, cracks, loose debris, or flash, and with a cost that requires in-line cutting be performed during the extrusion process for efficiency at higher-volume requirements. To address this need, Duke developed an in-line precision radial cutting machine that moves along at the line speed while the cut is performed.

Medical device designers continue to be challenged to produce smaller and thinner micro catheters and guidewires, which provide clinicians with the ability to reach and treat previously inaccessible anatomical targets. Junkosha has developed an ultra-small PHST tubing suitable for laminating jacket coating to tiny guidewires with diameters as small as 0.011 inches. These miniature guidewires are ideal for applications such as navigating vessels to reach a lesion or vessel segment within the brain or heart.

Data collection and greater in-depth inspection requirements are becoming more prevalent for tubing. Control systems and in-line inspections are key to high-precision tubing production. "Control systems include better motors, servos, controls, feedback loops, and monitoring systems such as air, speed, and pressure," said Thao. "In-line inspection is key because it reduces inspection, has real-time data/analysis, and provides feedback to the process for adjustments in process."

Another technology improvement is the development of active catheters, which are being accepted more widely. Junkosha's multi-channel transmission (MCT) catheter uses a cluster of simple microwires that are individually insulated with an innovative shielding/grounding construct, thereby increasing its signal capacity for a given size. Traditional catheters require four coaxial cables that run in parallel, carrying four individual signal streams; the MCT catheter enables multiples of four signals to be brought together in one cable, thereby quadrupling the capacity while still reducing the size of the catheter. MCT provides increased functionality compared to twisted pair coaxial and flexible printed circuit (FPC) technologies. MCT data-rich signals are especially beneficial for procedures such as intracardiac echocardiogram, ultrasound endoscopy, and intervascular ultrasound.

Inspection technologies must also advance to keep up with the increased number of smaller, more detailed features and components in medical devices, as well as manufacturing speed. Inspection equipment has come a long way in the last few years. Although pin gages and micrometers can still be useful, non-contact measurement both on-line and off-line is the preferred approach. Automation of measuring parts is advancing rapidly. "Some of the tubes we extrude have more than 100 points to measure," said Steele. "Today's programmable systems can inspect in minutes what would take an inspector all day to inspect and do it without subjectivity."

Duke Empirical has invested in a new technology for automated defect detection from Taymer International that identifies, and sorts in-line for, visual defects as small as 0.05 mm. This system provides 100-percent visual inspection performed in-line at the extrusion line speed with programmable defect criteria and automatic data capture for all defects detected. The defect detection equipment sends a signal to the puller cutter, which then eliminates the defect in real time—for example, gels, bumps, particulate, grooves, scratches, and pinholes.

Steel-tubing manufacturers often work on new development projects with tolerances and sizes that are on the edge of current inspection equipment capabilities. K-Tube Technologies continues to improve its inspection capabilities by investing in new equipment such as multi-axis laser micrometers and ultra-sensitive material testing machines. The company is also developing a method for in-process, high-speed defect testing on straightened tubing of all sizes, which will improve tubing quality and reduce the non-conformance risk to customers. "Even with these advances, we spend a lot of effort working directly with our customers to correlate or create new inspection methods," said Crane.

Innovation in Action

Growth in the tubing sector is fast-paced, with new, exciting innovations that drive OEMs to believe the impossible is actu-

ally possible. Medical device designs increasingly call for more functionality in smaller packages with thinner tube walls, more lumens, and even electrical transmission capabilities, with wires or cables embedded in tube walls. "A good example is our eTubing line," said Derek Wilkins, regional sales manager for New England Tubing Technologies, a Lisbon, N.H.-based provider of tubing solutions and custom OEM components for medical devices. "Conductors with specific electrical requirements are built into the walls of tubing. This increases functionally of the design, reduces device footprint, and can reduce assembly time."

The tubing can incorporate other components to meet specific OEM needs, such as ultra-miniature coaxial cables, high frequency cables, thermocouples, and high-strength/high-flex alloys to provide more functionality in the same tubular cross-section. Applications include analog and digital transmission of electrical signals for sensor capabilities, powering devices, and temperature/oxygen monitoring features.

Duke Empirical engineers faced the challenge of making a polytetrafluoroethylene (PTFE)-lined implant delivery catheter, where the distal section was required to be a soft 35D Pebax; however, because of the high radial force of the self-expanding nitinol implant, the catheter tip elongated when the sheath was retracted against the implant pusher during deployment. Wall thickness of the PTFE-lined, braid-reinforced distal section was 0.006 inches, with no allowance for increasing the outside diameter. "Since the design did not have sufficient room for axial aramid fibers, we instead developed a striped coextruded jacket that had a portion of the circumference in a harder durometer and stronger 72D material," said LaDuca. "This solution did not increase the wall thickness and provided the additional strength needed, which then avoided the elongation previously seen during implant deployment."

K-Tube Technologies was asked to develop a tube that could retain its cutting edge longer for multiple-use applications. Through material selection and processing, the engineering team was able to provide a tube that increased the hardness by 35 percent compared to conventional 304 stainless steel. For another application, a customer required tubing with a smooth interior-diameter surface finish to reduce the insertion forces on their stylet. "We recommended our plug-drawing process that supports and smooths the interior diameter during manufacturing, followed by testing different tolerance bands to find the right cost/benefit balance," said Crane. "These process changes reduced insertion forces by over 50 percent."

MICRO's own tube mill for raw material and its patented rolled tube technology allow the company to reduce tubing costs (and shorten lifecycle) on disposable instruments through machining, bending, flaring, flanging, piercing, laser cutting, and other processes. An MDM approached MICRO to develop a cost-effective, disposable surgical device to be used in minimally invasive surgeries. MICRO used its proprietary process to manufacture a rolled tube in a progressive die that replaced traditional drawn tubing. This process streamlined secondary operations and reduced production time and component costs. "A finished tube can now be stamped in one second," noted Santoro.

Moving Forward

Medical devices will continue to become smaller and more sophisticated, especially as new technologies expand the design options for medical device engineers and designers. OEMs want high-performing products with more challenging design features that make them stand out from the competition, all at a lower cost. To manufacture these new designs efficiently and cost effectively, tubing suppliers often make their own specialized equipment. For example, New England Tubing Technologies has built a custom machine and developed a unique process to support one item for one customer, as well as regularly develop unique tooling solutions to meet strict extrusion requirements.

The best way for MDMs to manufacture challenging tubing products is to align themselves with preferred vendors who can share their expertise and advise them during the design process. This is especially true for the often-complicated process of designing tubing components for laparoscopic procedures.

"Smaller tubes that provide greater maneuverability are in great demand for devices used for minimally invasive surgeries," said Santoro. "Contract manufacturing organizations need to work with even greater attention to detail to keep production effective, efficient, and on time."

For example, laser-cutting of steel tubing, which gives instruments the ability to articulate, also results in slugs which can be as small as a human hair. Removing these unwanted pieces of metal is a critical, challenging process. CMs should partner with their OEM customers during the design stage to ensure this process is properly controlled to prevent problems—for both the cutting machine and the final product itself.

The medical device industry continues to move rapidly toward customized work as devices become smaller and more complex. For example, MDMs have rapidly advanced from trying to make stock tubing work to regarding tubing as a design advantage. "A decade ago, most of our tubing sales were from our catalog," said Crane, "but today, 90 percent of what K-Tube manufactures is custom tubing."

In turn, K-Tube Technologies is expanding its capabilities to keep up with increasing technical demands. In the past year, it has developed ways to produce tubing with thinner walls (<0.0013 inches) without the use of centerless grinding and processed parts with a bright/mirror interior-diameter surface finish at smaller sizes than previously possible.

Duke Empirical is also advancing its own in-house technologies to enable new clinical applications and offer device developers new tools to access the human body for the diagnosis and treatment of diseases. "By taking advantage of new tubing materials, tubing product design, and processes, innovative companies will usher in a new class of tubing for devices that have specialized properties and specific uses, such as optimized fluid management," said LaDuca.

When it comes to overcoming tubing challenges, the experience of the processor is critical to solving the problem in a cost-effective way. The processor with relevant experience can use a methodological approach to problem solving such investigating the raw material, the process, or the specification. Often times processors are asked to do something new or to push the known limits and try a different approach to overcoming past obstacles.

For example, Duke Empirical recently ran a very soft elastic material with a 5A durometer. "This material elastically stretches over 2,700 percent and is tacky and creates processing challenges including wrapping around the puller belts with wall thicknesses as small as 0.003 inches," said LaDuca. "Fortunately we could draw on our experience of running other less extreme materials to optimize our equipment set up to produce a capable process. Working with the fundamental principles helps guide the iterative solution process by trying the simplest and most applicable ideas first while moving up in complexity as required until a solution is obtained. Of course, there may be more than one solution and not every problem is worth solving so the need and desire to obtain a solution should justify the economic investment required to solve the problem."

"Value is often misunderstood," reflected Santoro. "It isn't always about the lowest price; instead it is about producing the most cost-effective and efficient product that will be profitable. OEMs and their CM partners need to work together, early in the development cycle to ensure a product can be manufactured in a way that meets OEM goals. Design for manufacturability can help realize the optimal cost to repeatably produce a functional, compliant product. OEMs need to involve the CM early in the design phase to leverage the CM's expertise and minimize the risk of having to undergo multiple design iterations, which are costly and time-consuming. A successful partnership is essential for ensuring quality and value in product development and production." ❖

Reference

[1] *http://bit.ly/mpo190460*

Mark Crawford is a full-time freelance business and marketing/communications writer based in Madison, Wis. His clients range from startups to global manufacturing leaders. He also writes a variety of feature articles for regional and national publications and is the author of five books.

The Science of Multi-Layer Extruded Tubing and Medical Devices Incorporating Such Tubing

Multi-layer extrusion technology is a process in which two or more polymers are extruded and simultaneously joined in a co-extrusion die head to form tubing with multiple layers. Running two or three extruders into a co-extrusion die head produces a single, multi-layered, extruded tube from a combination of materials with different physical properties, friction coefficients and bonding characteristics. In this article we will discuss multi-layer coextrusion of dissimilar and similar polymers.

Co-Extruding Dissimilar Polymers

Multilayer coextrusion poses some challenges, particularly in creating uniform wall thicknesses. Differences in the viscosities, melt temperatures and velocities of dissimilar polymers may cause problems, including delamination.

Dissimilar polymers have different chemistries with low levels of interlayer adhesion and are subject to wave like instabilities at the layer interfaces. This is compounded when polymers with low surface energies are used in the multi-layer structures. As a result of the chemical incompatibility, these different grades of polymers do not form strong bonds with each other during coextrusion, and thus, tubing comprising layers of dissimilar materials tend to be subject to delamination.

Medical Device and Co-Extrusion Polymer Selection

For example, multi-layer tubing suitable for percutaneous transluminal catheters (Figure 1) used to deliver an angioplasty balloon or stent to a calcified lesion in an artery may require a lubricious polymer on the inner layer such as high density polyethylene (HDPE) to facilitate advancement of the catheter over the guidewire. The adhesive middle layer could be made of a modified linear low density polyethene (LLDPE) and the outside may be a soft "bondable" layer such as polyether block amide (PEBA) for bonding a polyamide (PA12) or polyester (PET) non-compliant balloon to the catheter shaft. Percutaneous transluminal catheter tubing contains ultra-thin individual wall thickness down to 25 microns with internal diameters designed to support 0.014", 0.018" and 0.035" guidewire delivery platforms.

From an extrusion standpoint, viscosity is the most important flow property in multi-layer polymer selection. Typically, the inner layer has the highest viscosity and the outer layer has the lowest viscosity as the low viscosity melt can encapsulate the high viscosity melt while flowing through the die head and tooling channels.

Polymers with compatible glass transition temperatures (T_g) and melt temperatures (T_m) should also be chosen for consistent layer distribution.

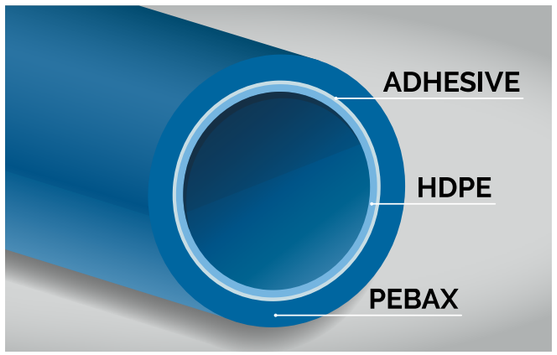


Figure 1: Tri-layer percutaneous transluminal catheter tubing

The die head used for this type of multi-layer extrusion is commonly referred to as an ABC design, because the inner layer (A), middle layer (B) and outer layer (C) are made of different polymers. The die flow channels (deflectors) are designed based on the rheology of the individual polymer layers and analyzed by using computational fluid dynamics (CFD) flow analysis software to ensure uniform flow velocities of each polymer melt stream at the die exit. When a higher velocity polymer layer merges with a lower velocity layer, the high velocity layer decelerates, causing wave like flow instabilities at the interface as shown on Figure 2. These instabilities result in intermixing of the layers, decreased mechanical performance and poor aesthetics in catheter tubing. Coextrusion process conditions can be optimized to avoid the occurrence of interlayer flow instabilities by controlling the melt temperatures of each extrudate and thereby the velocity ratios of each melt stream.

Adhesive (Tie) Layers Used in Multi-Layer Co-Extrusion of Dissimilar Polymers

In addition to interlayer instability concerns, the lack of adhesion between the polymer layer interfaces must be considered when selecting polymers to be used in a multilayer structure. This is done in order to provide strong bonding between the adjacent polymer layers such that the layers resist delamination especially under rigorous conditions such as super high balloon inflation pressures of up to 40 atmospheres (588 psi). Hard to bond polymers are polymers with low surface energies that will delaminate when co-extruded together and therefore an adhesive layer is used to hold the layers together.

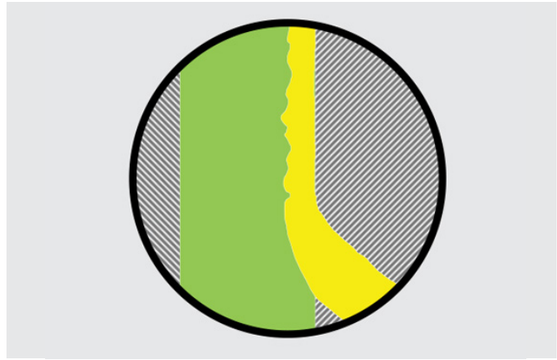


Figure 2: Wave like flow instabilities caused by velocity mismatch at the layer merge point

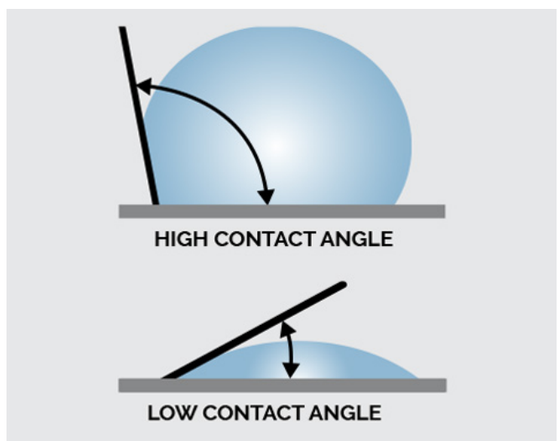


Figure 3. Contact angle of a low surface energy polymer on the top and a high surface energy polymer on the bottom

The surface energy of a plastic is measured by evaluating the contact angle of the polymer as shown on Figure 3 below. A liquid droplet will bead up on the low energy polymer surface and the same liquid droplet will spread or "wet out" on a high energy polymer surface. For reference, HDPE has very low surface energy and a contact angle of approx. 100 degrees and PA12 has high surface energy with a contact angle of approx. 72 degrees.

A co-extruded adhesive bonding layer, commonly referred to as a "Tie" layer, acts as a stress reliever at the interface so that the layers show good uniformity and are held together to resist delamination. Table 1 lists a few common medical grade polymers in their order of bonding strength.

Low Surface Energy Polymers	Higher Surface Energy Polymers
PTFE	PA12
Silicone	TPU
HDPE	PEBA
Acetal	PET

Table 1: Relative surface energies of common polymers used in medical device applications

Co-Extruding Similar Polymers

Super high-pressure balloon tubing may have a wall with at least three coextruded layers of similar polymers such PA12, with varying durometer ranges for each layer. After the multi-layer tubing (preform) is reheated and formed via a stretch blow molding process into a biaxially oriented balloon, the burst performance of the multi-layer balloon is much greater than that of a traditional single-layer non-compliant dilatation or stent delivery balloon. The super high-pressure multi-layer balloons are considered, in addition to cutting balloons and rotablation, for procedures where coronary lesions are difficult to dilate due to significant calcification.

When designing a multi-layer balloon tubing extrusion of similar polymers, it is important to understand the durometers of each layer. Lower durometer polymers have an increased elongation (lower flex modulus) therefore the combined elongation should not be greater than that of the harder durometer material. The blow ratios i.e. Radial Ratio and Stretch Ratio should be designed closer to the harder durometer polymer as excessive stretch during the forming process will create delamination between the layers. Each layer is designed separately taking into consideration its position Outer/Intermediate/Inner.

Conclusion

When designing a co-extruded multi-layer tube for an intravascular application, the final physical properties of the polymers used are not the only factor. For optimal extrusion and device performance, it is also important to consider the effects of the viscosity, the polymers' melt temperatures and durometers, and their placement in the structure. ❖