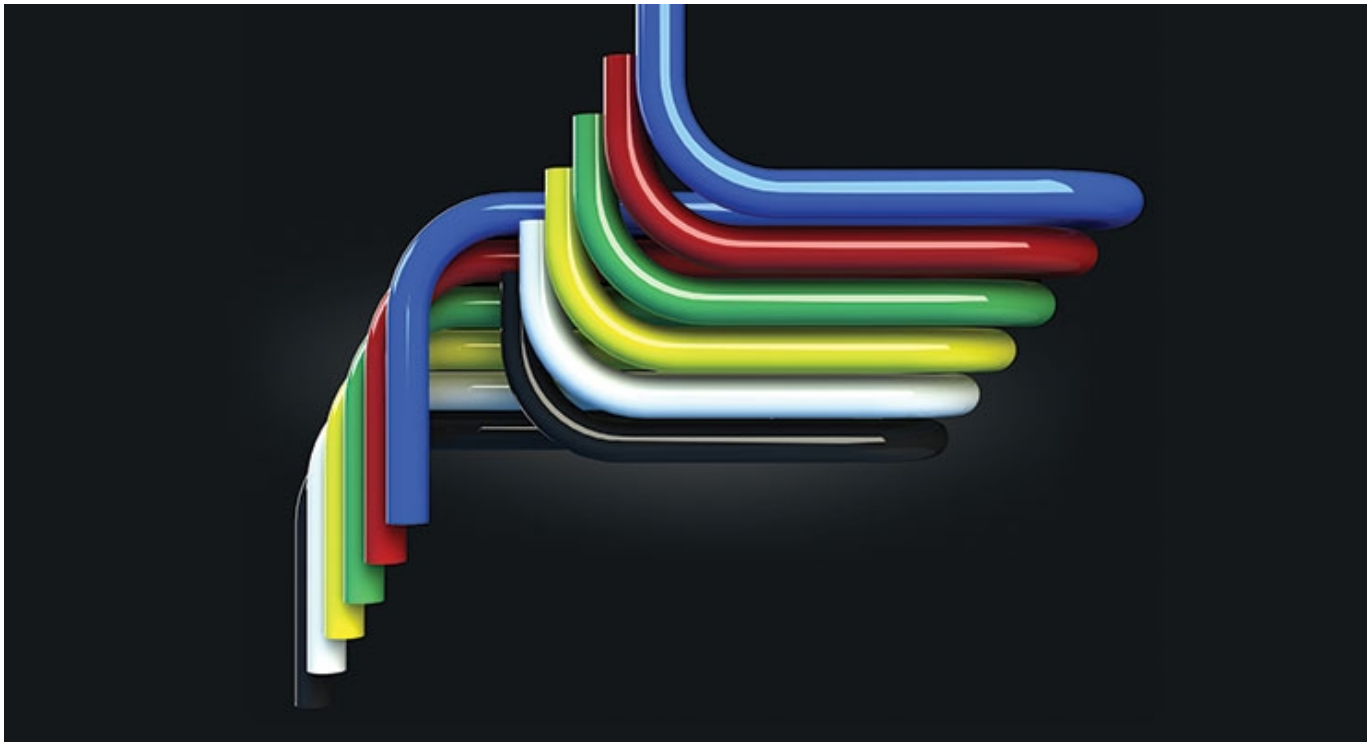
MPO
MEDICAL PRODUCT OUTSOURCING

Switch on the Tube, Let's See What's On

"Medical Tubing's" season premier episode features tight tolerances, multi-lumens, antimicrobials, and much more.



Thermoformed tubing minimizes space and eliminates tubing kinks. Image courtesy of Eldon James Corp.

Sam Brusco, Associate Editor | 10.12.16

Some might say tubing manufacturers are the unsung heroes of the medical device industry. Certain devices and instrumentation can't perform their functions correctly without the ability to transport air or fluid (go on, think of a way to place an IV without a tube connected to the patient), but at the end of the day, it's not a device's tubing technology thrust into the spotlight.

OEMs certainly should be singing about medical tubing's often Herculean labors, and taking into account the impressive array of options tubing suppliers can offer for a device. As medical equipment continues to become smaller, more complex, and reliant on novel materials and manufacturing methods, medical tubing manufacturers are challenged with specifications like remarkably tight tolerances, smaller inner and outer diameters, multiple lumens, co-extruded materials, lubricity, and antimicrobial properties—just to name a few. In order to provide insight into just how complicated manufacturing a seemingly simple tube can be, a half-dozen participants spoke with *MPO* about current trends and challenges impacting medical tubing.

Marcia Coulson, president of Denver, Colo.-based Eldon James Corporation.
Ronelle Decker, marketing manager of Rancho Dominguez, Calif.-based Avalon Laboratories LLC, a division of Nordson Corporation.
Christian Herrild, director of sales and marketing of Baraboo, Wis.-based Teel Plastics Inc.
Robert LaDuca, CEO of Santa-Cruz, Calif.-based Duke Empirical Inc.
Apur Lathiya, senior business development manager of Franklin, Wis.-based Vesta, a Lubrizol LifeSciences company.
Drew Rogers, vice president of sales and marketing of Tustin, Calif.-based Specialty Silicone Fabricators, part of Trelleborg Group.

Sam Brusco: What are some of the most popular service requests you receive and what are the healthcare trends driving this?

Marcia Coulson: Here are some trends we've been noticing:

- *Made in the U.S.:* Re-shoring initiatives as other countries' political and economic status may challenge on-time delivery of product.
- *Sub-assemblies:* Manufacturers are looking to reduce time and expense by ordering cut tubing to length with fittings and clamps assembled.
- *Tubing additives:* We are being asked to add antimicrobials, hydrophobic, and hydrophilic additives to enhance surface properties, such as reduced friction.
- *Microbore tubing:* Smaller tubing and components are needed for less invasive procedures. Smaller tubing is demanded as wearable, mobile, and disposable devices grow in popularity.
- *Pre-formed tubing:* We use secondary processes to pre-form color-coded tubing to minimize the space required and eliminate potential kinking to route around components in complex medical devices.

Ronelle Decker: Avalon's processing technology allows for thin wall thicknesses or coatings on reinforced materials. In many instances, working through inner and outer dimensions to achieve ideal specifications requires the thinnest walls available, while still offering strength and flexibility on the tubing. Many of these thin wall products are in neuro-interventional or peripheral vascular applications, where there are new research and development activities.

Chistian Herrild: One of the most popular requests we are seeing is full IQ [Installation Qualification], OQ [Operational Qualification], and PQ [Performance Qualification] data and reporting for products in development. We had done some of this work historically, but we are seeing it become part of development for more parts and more companies. Generally, this becomes a full packet of information generated during the development work. We work with customers to tailor what we provide to their needs, but this development service was not as frequently requested in the past. The increased focus on identifying and addressing risk throughout the supply chain is driving this.

Robert LaDuca: The most popular service requests we receive are for tubing with tight tolerances, high concentricity, and thin walls—the most commonly requested materials being Pebax, nylon, and polyurethane—in a range of durometers from hard to soft. These are used to manufacture PTFE- [polytetrafluoroethylene] lined, coil, or braid-reinforced catheters with variable stiffness. Requests for certifications commonly include dimensions, material composition, water purity, maximum defect size, and physical and mechanical properties. Drivers for these requests for material composition are the new "DEHP-free" and other regulatory requirements. Other drivers include the device manufacturer's product optimization efforts—Lean and Six Sigma initiatives lead to an understanding of the opportunities to control processing conditions, which directly affect product performance and secondary processing yields. The key is to utilize a process with an appropriate level of control to ensure the product meets all requirements, including cost.
Apur Lathiya: It varies depending on application, but in general we are seeing more requests for tri-layer tubing and multi-

lumen tubing with more than seven lumens.
Drew Rogers: SSF has a reputation for developing and manufacturing the "tough stuff"—parts the customer is unable to procure elsewhere. One example is multi-lumen tubing—in particular, tubing that facilitates transitional geometry through moveable die and mandrels. This capability has grown in demand as healthcare companies demand smaller and more complex ID/OD [inside/outside diameter] tubing, with pacemakers serving as a prime example.

Brusco: Which materials do you use to manufacture medical tubing, and what benefits do they offer end-use products?

Rogers: As our name suggests, Specialty Silicone Fabricators works primarily with silicone. The benefits of silicone in medical implants and devices are well documented. Silicone is used in a wide variety of applications because it can be designed to achieve specific performance, aesthetic, or therapeutic properties. Key silicone attributes include biologically inert; availability in a wide range of durometer (hardness); can be sterilized in any method; once cured, holds its shape; and permeability and elution characteristics.

LaDuca: One of the more interesting materials is a thermoplastic, melt process-able flouroelastomer, which exhibits clarity, high operating temperature, elastic elongation, and chemical resistance. These can be compounded with agents to improve resistance to infection. Flouroelastomers may be used to replace higher cost and silicone materials, and may also benefit development of reusable devices, which require repetitive and sometimes high temperature re-sterilization cycles. The combination of distinct polymer groups is co-extruded to provide added benefit for specific applications—specifically, the combination of an inner layer of high-strength material with an outer layer provides toughness and puncture resistance for balloons.

Herrild: We use a large variety of different materials to make medical device products. They vary from commercial grade PP [polypropylene] and PE [polyethylene] materials to custom compounded specialty urethanes and PEBAs [polyether block amides]. The benefit for any material depends on the end use application. There is a kind of cost/benefit analysis that needs to be done in material selection, in order to use the right material for the right application, but it still needs to be cost-effective for the customer.

Coulson: As the medical market moves away from PVC products, we have embraced alternative materials allowing us to introduce several clean and green options to our customers. We offer a wide range of TPEs [thermoplastic elastomers] and polyethylene-based materials to meet sterilization, regulatory, and shore hardness requirements.

Brusco: Are there new materials that offer increased value to customers over more traditional options? If so, what are they?

Herrild: We have recently done some development work using bonding grades of PEBA and EFEP [a terpolymer of ethylene, tetrafluoropropylene, and hexafluoropropylene] that are formulated to adhere well together with co-extrusion and no need for a tie layer or later chemical treatment. This can eliminate a step from later assembly processes in certain catheters. Any time a step is eliminated, one can both save money and eliminate another point to have an issue in the process. Of course, there are still some tricks to getting the materials to adhere well during the co-extrusion process, but it can be a real time saver.

Lathiya: None I am aware of, other than materials with different additives such as Propell or Siloxane for added lubricity. We are starting to see more on the antimicrobial additives as well.

Rogers: New recipes for silicone composition continue to evolve. Recent advances have been made in silicone material designed for drug/device combination products where the application requires specific qualities for drug absorption, drug elution, and zone of inhibition. SSF is at the forefront of development and manufacture of combination products.

Coulson: Many of our customers are able to replace silicone with TPEs that meet temperature, flexibility, and regulatory requirements at a cost savings. We offer tubes that can be autoclaved at 121 C and 135 C. Through our co-extrusion capabilities, we can offer antimicrobial and highly chemical-resistant tubing at a fraction of the price by extruding a thin layer of expensive resin on the exposed inner or outer surface of the tubing.

LaDuca:
One company produces softer urethanes with durometers as low as 40A. These materials allow for cost savings when designing highly compliant balloon catheters, where elastic recovery over 1,000 percent is required. Previously, balloon materials that met challenging elongation requirements were not likely to be compatible with the preferred materials for the catheter shaft. As a result of material innovation, the product can now be produced using less expensive processes with compatible polyurethanes for the balloon and shaft. We're currently working on an low-cost, kink-resistant, thin-wall tubing material suitable for replacing higher-cost products (i.e., traditional braid- or coil-reinforced tubing), while offering additional advantages for processing value-added secondary operations.

Brusco: What are some of the more challenging requests you receive from OEMs, and what's the driving force behind these requests?

Coulson: Clean and green materials such as TPEs can be "sticky." We are working to innovate materials that reduce friction to allow slick/lubricious surfaces to tubing. Elimination of adhesives has been our offering to this market. We have found that medical companies have been slow to migrate to alternatives to PVC because of the challenge with bonding fittings to the tubing. Our single barb line of fittings allows our customers to eliminate adhesives and solvents, thus lengthening shelf life of products.

LaDuca: The more challenging requests we receive require the development of new tooling and processes, often with new material compounds. These may require design and fabrication of custom cross heads, tips, and dies for configurations of multiple materials in very specific geometries, and require producing within tight tolerances as contained in the part specification for the tubing or profile.

Some challenging requests result from trying new processes, like projects that characterize driving factors for the primary dependencies among a particular product's processing variables. This may involve the development of a new measurement method, test method validation, data collection, and statistical analysis. For example, we may produce a co-extrusion of two materials with similar natural color or where the thickness of a layer is so thin that it may be impossible to measure the thickness of each independent layer using standard techniques. Likewise, there are new surface defect and gel detection systems that allow for continuous monitoring and sorting of product, should gels be detected that fail the programmed inspection criteria.

Herrild: We have recently seen more requests for parts with materials other than plastic either inserted into the tube in-line or co-extruded into a wall. Both can be challenging because the process needs to be managed differently than standard extrusion processes. We have seen these both in existing products where the OEM is looking to take some cost or complexity out of their process, or for new products where this gives the engineer more design freedom.

Brusco: Does your approach to a project change with these more challenging requests?

Decker: With more challenging requests, we work from a team approach with development, manufacturing, and quality engineering staff up front to identify areas of concern and best practice manufacturing options. Avalon may also provide an early-on feasibility sample of capabilities closely aligned with the customer's specifications—from that, decisions can be made on direction and development moving forward.

Herrild: We take the same approach for all medical products, and don't take anything for granted. We don't assume it is an "easy" part or it may not be critical to device function. To the customer, it doesn't matter; they want all their parts to be top quality, and we want to provide that service. We work with them to do a risk assessment and understand the customer's needs and concerns. We try to provide feedback to help the process along when we can, and try to do this work face-to-face whenever possible.

Lathiya: Yes, it does change; we need to spend more engineering time and have a game plan of what we are going to do next if we are unsuccessful at the first attempt. It may be different tooling sets, processing parameter, or something else, but we need to think through options prior to extruding.

Rogers: We're set up to handle the challenging requests, and it's the simpler projects that vary. A large and diverse engineering staff provides customers design assistance as well as process development. This group has expertise in material selection and design-for-manufacture and they work closely with the customer to ensure quality and manufacturability, even for the most complex parts. The exceptions to our standard processes are the simpler parts where our manufacturing engineers can more simply convert specs and drawings into manufacturing runs.

LaDuca: Each experience builds accumulated learning, which is applied to future activities. Our approach is based on fundamentals; critical thinking and methodical problem-solving techniques using empirical methods are the keys to efficiently meeting challenging projects. Having a well-established history of innovative projects builds confidence in new endeavors and having ready access to the key resources necessary within an integrated facility also is a difference maker when it comes to reaching results that have not been previously obtained anywhere.

Brusco: How has the trend toward miniaturization of medical devices impacted tubing development and/or customer demands?

Coulson: We specialize in miniature tubing and fittings to include microbore tubing and stainless steel fittings. We have incorporated the use of lasers to monitor tubing ID and OD during the manufacturing process to ensure tight tolerances are met.

Herrild: Obviously, everything in medical is getting smaller. We see requests for tubes that are smaller than in the past, and I think everyone sees this. However, we are also seeing tolerances become smaller even on larger parts so they can interface with the smaller components. We've seen the tolerances even on existing parts shrink and customers are continuing to push the envelope on these parts.

Decker: Thinner wall thicknesses to achieve both inner and outer dimensions for miniaturized tubing with multi-functionality on the length of the tubing shaft. Avalon is also working on very small-length tubes that require complexity in design with little room and thin wall thicknesses.

LaDuca: There are certain products that are composed of so little polymer material that smaller equipment is needed to control the output for stringent requirements. The very small multiple material layered tubing—with or without tapers—is an example of a product which has led processors to select equipment that is fully integrated for such purposes, rather than discrete components as found on most medical tubing lines. I think the continued miniaturization of medical products, along with the specialization of equipment providing unique capabilities, enables new opportunities such as the emergence of new companies that are addressing these market needs for miniaturization. Companies with specialized capabilities in miniaturization are able to differentiate their product offerings from the many choices in the market and provide real, innovative value. This trend also represents the opportunity existing suppliers have to broaden their capabilities and enter new product markets.

Brusco: Where in the development process do OEMs usually seek tubing? Where should they seek them?

Rogers: Most OEMs do a good job of reaching out to SSF in the design stage in order to avail themselves of our material and process knowledge. We joke that we often take a scribbled drawing on a napkin and eventually convert that to manufactured, regulatory-approved parts. This is where they should seek our assistance; during design and development, where we can offer the greatest technical assistance and better ensure more efficient, low-cost manufacturability.

Decker: Many OEMs will present Avalon with a complex idea and work with our engineers to determine our capability to accommodate the necessary product function in the early stages of development—or, they've tried other material processing technologies and are looking for a better option. We also receive drawings that are not flexible in design and the OEM will inquire whether we can meet their specifications, usually for next-generation devices. It's always best to work with a contract manufacturer in early-on development or brainstorming to best understand material benefits, cost consequences of design elements, and manufacturability.

Herrild: It really depends on the customer. We see some customers come in for tubing when they are still designing the overall device, and sometimes this lets things like fitments or materials change. This is when customers really should come in to talk about the tubing. Unfortunately, we see more customers come in very late in the process, when all the details are supposedly worked out. The problem is those details can sometimes make the part very difficult to manufacture. The earlier the customer comes in, the better. Minor changes in the details can have major impacts on the ease of manufacturing and we like to try to work on those details with customers.

Lathiya: OEMs usually seek tubing right at the beginning of the development process. Since catheters are tube-based products, the tubing is one of the most crucial components of the device. OEMs should seek tubing from well-established companies with robust quality systems. The universe of tubing manufacturers is quite large, but choosing the wrong one could have adverse implications to the whole development process.

LaDuca: OEMs are actively seeking tubing products at all phases of product development. It's great when the supplier is introduced to the project at an early enough point where input is desired. Often, it is the collaborative process that results in more optimized outcomes, and where all relevant factors for goal achievement are input. Only in this way can the supplier's deep processing expertise maximally contribute to the end result.

Brusco: What benefits can OEMs reap if the tubing supplier is consulted with early enough in the process?

Lathiya: A knowledgeable extruder will be able to understand and communicate the pitfalls of the tubing design and make suggestions up front to make any design changes that will make the tubing more manufacturable, thus saving time and money.

LaDuca: One benefit is cost; design costs for a more expensive process or more expensive material specification often result from a lack of awareness. This is a consequence of device developers' unfamiliarity with the extrusion process. Much like machinists prefer to receive dimensioned drawings in a format that takes manufacturing method into account, the extrusion process leads suppliers to have dimensioning preferences that designers should use as guidelines to optimally specify the aspects of the design important to be controlled. Material processors, fabricators, and quality inspectors generally less prefer absolute coordinate systems for extrusion drawings and tooling to dimensioning schemes that facilitate the creation of tooling and part inspections by taking into account how those activities are performed. Another benefit is to assist with design optimization. Tubing suppliers know the processing particularities of given polymers, and can recommend customizable materials or compounds to solve particular product requirements. By consulting with suppliers at an early enough stage in the development process to allow design input to be considered, OEMs can realize the benefits of better design optimization with higher efficiencies in primary and secondary manufacturing operations, and improve the likelihood of selecting the most cost-effective materials.

Coulson: Elimination of adhesives and solvents can be achieved by starting earlier in the process to test clean and green tubing options with single barb fittings. Shelf life can be lengthened with this combination.

Brusco: Though extrusion is a primary tubing fabrication method, what other services might OEMs find more beneficial for their tubing needs? What advantages do they offer over extruded options?

Decker: Polymer solution casting is a versatile technology and lends itself well to many catheter designs, since it offers the flexibility of varying material stiffness along the length of the catheter, as well as creating as a single-piece design. By using conventional extrusions to create a complex catheter design, the manufacturing process will require several different extrusions to be bonded together to achieve transitions in stiffness. Polymer solution casting can achieve this by modifying the layering order and location of different types of polymers, allowing for designs with varying wall thicknesses along the length with seamless and naturally occurring tapered transitions, which cannot be easily achieved with conventional extrusions. This technology has been used primarily in cardiovascular applications, but has recently been evaluated for more innovative and smaller dimensional tubing from concept to manufacturing.

Lathiya: The other methods are dip casting and reflow. Dip casting offers the ability to manufacture thin walls, but the process can be slow and more costly for high volumes. However, dip casting may not offer the same mechanical properties as traditional extrusion. With reflow, multilayer tubing can be manufactured with different durometers on the outside. This is a more manual, "pseudo assembly" type of fabrication. Also, the outer layers will require extrusion prior to the actual reflow.

Rogers: In addition to extrusion, silicone is a great material for molded parts, sheeting, and dipping. SSF has applied its innovation to challenges such as a part that we were given to produce a balloon catheter. That part had previously involved mating a molded balloon to an extruded tube and SSF was able to vary the material durometer during the extrusion run to vary the wall thickness of the tube sufficient to make portions inflatable and, thus, eliminate the molding portion entirely. This saved the OEM considerable money and production time.

LaDuca: Polyimide tubing is produced in a continuous dip coating process, so it is possible to braid, coil, and top coat with other materials in subsequent dipping steps to build up a composite multi-layer tubing, where the outer surface may be a thermoplastic such as polyurethane. The advantage of producing high-performance thin-wall tubing in this manner is the extremely thin walls that are possible are not as achievable using the extrusion process. Polyimide doesn't melt when heated to temperatures hot enough to melt most thermoplastics; it is an ideal choice for constructing catheters with extremely thin walls, where the polyimide-lined lumens are fused into the braided, multi-durometer, catheter jacket materials.

Brusco: How will tubing manufacturing change over the next five years? Do you foresee a significant shift from extrusion in favor of another method for any reason?

LaDuca: I believe tubing manufacturers will continue to develop specialized capabilities using advancements in equipment, and the leading companies will gain experience with novel materials. Overall, this trend will provide continued business growth opportunities for many companies. Those companies that do not participate in the acquisition of new product opportunities early in the development phases—and yet look for growth in manufacturing and wish to continue being a valued partner within the OEMs shrinking supply chain—will still find opportunities for growth through the continued consolidations that are prevalent in the tubing sector. Along with those changes I expect we'll see continued and increased reliance by OEMs on the deep expertise possessed by tubing fabricators.

Coulson: We are watching the evolution of 3D printing and how we might be able to use that as an advantage to our manufacturing and product development for our customers.

Lathiya: Tubing manufacturers will continue to evolve their capabilities and offer more secondary operations to service the customer movement of supply chain rationalization.

Rogers: We don't see any significant shifts away from extrusion. Rather, we see greater innovation to extrusion processes such as the geo-trans previously mentioned. Certainly, other fabrication methods will continue to improve and/or arise, and SSF plans to continue leadership in those areas.

Herrild: I don't see a significant change from the current trends in the next five years. I think tubing will still be an extrusion-focused business. I do see more new materials coming into the market to allow better customization, and this will require extruders supplying the medical market to be more versed in different materials to help customers understand what is possible.