Developing the Vasculature of Medical Devices

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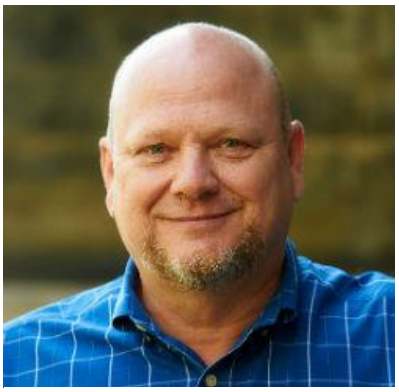
Tubing represents the veins and arteries of many different types of medical technologies. It carries critical elements wherever they need to be — within a device, throughout the human body, or as a bridge between the two. It must provide passage for gas, fluid, electronics, and even small devices to travel seamlessly, sometimes with several of those components within the same single tube (just through different lumens). Given its importance in medical technology, it's critical for design engineers to stay abreast of the latest advances in tubing development and how it's impacting medtech. As such, this component was the topic of discussion in this issue's Roundtable.

Advancements

While tubing appears to have remained unchanged throughout the history of medical devices (that is, a tube produced today looks quite similar to a tube produced 50 years ago), it's actually a sophisticated solution that has gone through an array of revisions and improvements. Since it is often such an integral part of a medical technology, the designers continue to demand that the limits be pushed in the development of tubing solutions. This is no different with some of the latest advancements realized recently.



Tom Harrington

"The extrusion of thermoplastic elastomer (TPE) tubing has improved processing and biocompatibility," says Tom Harrington, Technical Director at Kent Elastomer Products. "Extrusion offers synthetic materials with low extractible content. This improves biocompatibility when used in the body or in contact with pharmaceutical products."

Diego Sosa

Diego Sosa, Extrusion Manufacturing Engineer at Helix Medical shares his own thoughts on tubing advancements, "Tighter tolerances allow for smaller, micro extrusions, and more precision applications. With micro extrusions, we are now able to go inside the body for ophthalmic, neurology, and cardiology applications. Advancements are enabling thin-wall, multi-lumen, and striped tubing configurations for complex tubing applications."

"Every day, we work with engineers where science is paired with supplier innovation to advance the performance of medical procedures and there, in turn, improve clinical outcomes," offers Emily Barnes, product development manager for medical sales at Zeus. "We see this most dramatically with bioabsorbable tubing, which is designed with tailored degradation profiles that allow the material to

perform in the body for a finite period of time. Another biomaterial advancement impacting medical devices is electrospun non-woven polymers for stent encapsulation. This novel technology has proven to reduce process time and improve stent performance."

Materials


Emily Barnes

While Harrington and Barnes mention several very interesting advances that material innovations are enabling for medical technology through tubing, there are more worth noting.

"Ongoing advancements in materials offers improved functionality in radiopacity, anticoagulation properties, lubricity, and biostability, explains Andres Rodriguez, materials engineer at Avalon. "Specifically, polymer solution casting can easily provide seamless material transitions that can offer varied property profiles along the shaft of a medical device."

"Custom formulations can deliver unique project applications. UV cured silicone material, for example, cures more completely and at a much higher rate than traditional platinum-cured silicone and allows delivery of more product at a cost effective price," says Sosa. "Additionally, material properties can help to prevent infections when antimicrobial modifications are incorporated into the material."


Andres Rodriguez

Harrington offers a number of ways in which materials have impacted tubing. "Engineered TPEs have improved the life of a tube in peristaltic pumps. Material innovations have addressed compliance requirements. The global economy has increased the need for tubes to be free from animal byproduct, phthalates, oils, BPAs, and other issues. Advances in materials have also brought alternatives to PVC replacements and alternatives to the high cost of silicone tubing. Material improvements have aided manufacturers in the ability to eliminate connectors by welding tubes with the use of heat."

Multi-Lumen Challenges

As devices become more sophisticated and offer greater functionality, more "stuff" has to travel through tubing. While single lumen tubing is needed for a wide range of applications within medical technology, designers are looking at multi-lumen solutions in order to cut down on the number of tubes required within an often already constrained space. With that, however, comes a number of challenges.

"With the request for tighter tolerances and the lot to lot variability of silicone material it can be difficult to maintain multiple lumens. Profiles may need to be modified slightly to ensure a robust and efficient production process. Multiple iterations of tooling may be required to hone in on the tighter tolerances. Having the proper fixtures for measurement and inspection technique is also helpful," says Sosa.

"Multi-lumen tubing has become more complex as medical devices are requiring or increasing the intended clinical application with newer technology," explains Ihab Khayal, product engineer at Avalon. "Multi-lumens now have various lumen sizes within the single shaft, making concentricity of each lumen more difficult to achieve along with obtaining the right wall thickness for each lumen's intended application. It is still ideal to have the smallest OD even with multiple lumens that include pull-wires, inflation lines, sensors, flush ports and/or electrical wiring.


Ihab Khayal

Barnes adds, "The challenge comes with being presented with an idea for a design that may not be sustainable in full-scale production. There are times where multi-lumen profiles can be overdesigned with dimensions that are difficult — if not impossible — to measure."

What's Ahead?

Since it's unlikely tubing will eliminated from medical technologies any time soon, the Roundtable participants share their thoughts on what medical device designers can expect of this component in the years to come.

Harrington offers, "Physical properties will continue to improve to mirror that of silicone, natural rubber latex, and other non-TPE materials."

"Five years from now we will see more precision applications and better material options," says Sosa.

Returning to a previous point, Barnes says, "Bioabsorbables represent the greatest stride in medical device innovation and patient care. This novel technology has far reaching platforms from orthopedics to brachytherapy to vascular scaffolding. Coupled with advancements in material science and healthcare, these novel materials will propel medtech into the next decade and beyond."

Closing out the discussion, Khayal explains, "The need to reach distal and tortuous anatomy and deliver multiple therapies requires tubing to become smaller and more complex. Extrusion and inspection equipment is expected to advance to meet designers' needs, which include multi-lumen designs with thinner and more controlled walls. Additionally, new material blends are expected to allow for varying mechanical properties, without compromising lubricity. Extrusion technologies such as multi-layer extrusion, multi lumen extrusion, and tapered extrusion are expected to advance and become integrated to allow for in line processing of complex and economically viable medical tubing.

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