Extrusion: Beyond Simple Tubing

Sean Fenske

Medical device manufacturers have traditionally relied on their extrusion supply partners for affordable medical tubing for a variety of application areas. However, more and more, these OEMs are seeking greater capabilities and more design solutions from these same supply parterners. This article looks at how medical extrusion is impacting device development today.

Tubing, tubing, and more tubing. That’s the traditional view of what an extruder offers to medical device manufacturers. Parts, like tubing, that have a continuous profile and are to be produced in long lengths are ideal candidates for extrusion. Unfortunately, when compared to injection molding, extrusion can suffer from a limitation in the tolerances able to be achieved. Due to the manufacturing process of an extruded part, a number of factors can impact the end product and thereby influence the tolerances achieved. However, extrusion also offers an array of benefits to medical device manufacturers for emerging technologies in areas including minimally invasive surgical devices, diagnostics, neuroradiology, electrostimulation, and more.

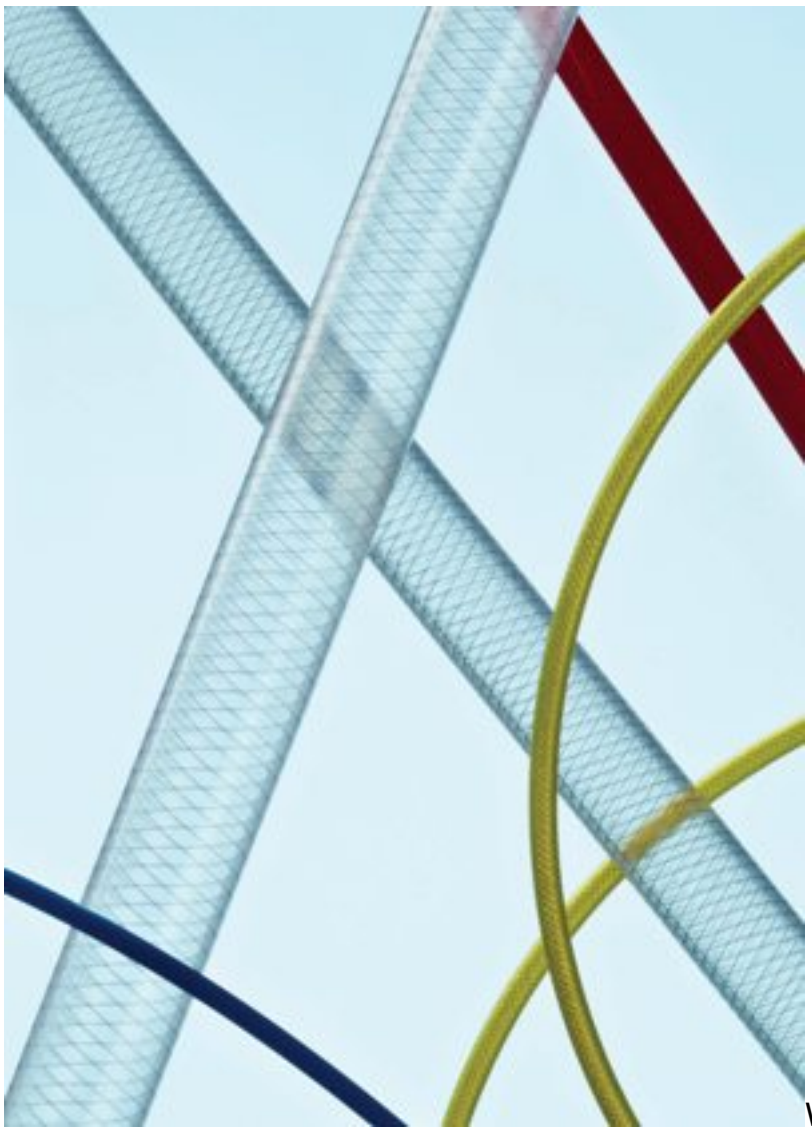
“As the designers of extrusion tooling continue to refine their craft, more and more complex shapes become capable for extrusion production. Specifically, the area of catheters has advanced medical procedures to new levels as surgeons enter the human body through smaller and smaller incisions. Extrusion-made probe tubes can bristle with all sorts of complex medical instruments that fit inside custom shaped cavities,” explains Paul Frechette, engineering manager at Pexco [1], a leader in the design and fabrication of extruded plastics products.

It is this sort of advanced capabilities that are being incorporated into more and more medical device technology. Catheters that enable doctors to access remote regions of a patient’s body without making large incisions are just one benefit. Extrusion makes it possible to deliver a host of devices to those same locations, enabling a variety of treatments to be carried out.

Claudia Aurand, global market manager with Teleflex Medical OEM [2]—a single source provider of design, development, and production services—speaks more to this point. “The trend toward minimally invasive surgery techniques is the driving force behind smaller, more complex devices that require innovative design and manufacturing. A good example would be microcatheters, which are used for diagnostic and delicate therapeutic neuroradiology or occlusive therapies for the treatment of stroke and aneurisms. They require extrusion companies to possess a thorough understanding of catheter construction, and the deep expertise in advanced levels of precision manufacturing.”

With the continuous emergence of these minimally evasive technologies that are traveling through the canals fabricated from extrusion processes, designers are seeking more functionality and features in their catheters and other tubing products. Bill Woinowski, Vesta's Silicone Division [3]R&D manager—a leading medical device contract manufacturer—explains that customers are "seeking innovative extrusion solutions such as multi-durometer extrusions, increased radiopacity, higher pressure capabilities, and greater kink resistance." He adds, "we are seeing an increase in the number of lumens and complexity of lumen configurations as our customers add functionality delivered through a single channel."

Fortunately, along with the increased complexity designers are tasking their extrusion supply partners with, at the same time, they seem to be realizing the benefits of getting that partner on board earlier in the development process. "More of our customers are engaging us at the development stage and looking for innovative solutions to design challenges. There seems to be a movement in the medical device industry in this direction to utilize the capabilities and experience of suppliers earlier in the development process," explains Mark Erson, QA director at Sil-Pro [4], a company that specializes in LEAN silicone molding and silicone extruding for a vast array of medical products.



While not likely to surpass molding in terms of the volume of product produced for medical devices, extrusion has certainly come a long way from simply being the process used for making a basic tube. “I think that medical device companies are looking to extrusion for complex profile shapes, multiple layer tubing, and fabrication to supplement their equipment,” agrees Frechette.

As extrusion continues to move toward offering more complex solutions for sophisticated, minimally invasive medical devices, design engineers will become more familiar (and comfortable) with the array of benefits, as well as the limitations, of the process. Getting the extrusion supplier on board early in the design process is certainly an ideal scenario for achieving the best results. However, at minimum, medical device designers need to at least explore the options with a reliable partner to determine if the process is even the right option for a product, Frechette explains, “There is no shortage of examples where medical device programs have failed or struggled because the designers learned too late in the process that their parts could not be produced in extrusion, whether by shape or tolerance level. Going back through the lengthy approval process for a device with design revisions is a daunting task for any medical project manager.

Sean Fenske is the editor-in-chief of MDT.

Source URL (retrieved on *07/25/2014 - 8:51am*):
http://www.mdtmag.com/articles/2012/10/extrusion-beyond-simple-tubing

Links:
[1] http://www.pexco.com
[2] http://www.teleflexmedicaloem.com
[3] http://www.vestainc.com
[4] http://www.sil-pro.com