High-Tech Extrusions

Medical extrusions are meeting higher standards, becoming more responsive to customer demands, and providing increasingly sophisticated product. If material costs can be kept in line, there is no telling how far technological advancements will go.

AT A GLANCE

&#149 Demand for smaller tubing

&#149 Wall thickness issues

&#149 Braided catheters

&#149 Marking, bonding, fitting

&#149 Prices and planning

&#149 Resin advancements

&#149 DEHP-free materials

By Peter Cleaveland, West Coast Editor
Demand for more performance in less space, the rising cost of raw materials, and technological advancements are causing extruders to update processes and products. As a result, the world of medical extrusion is facing forces that are causing changes in multiple areas. Customers want tighter tolerances, they want smaller tubing, they want multilumen tubing, and they want more and fancier coextrusions. Raw material prices and availability are changing, too. Extruders are responding with improvements in both products and manufacturing processes. This article, based on interviews with experts in the field, will explore how these changes are affecting manufacturers and users.

Tighter Tolerances

Extruders and their tooling suppliers are faced with ever-increasing demand for smaller tubing with the same properties as larger tubing. As Michael Badera, president of Precision Extrusion, puts it, "what used to work as a 6 French catheter is 5 French today; people want it to be a 3 French tomorrow. It has to have all the same properties, has to carry all the same amounts of fluid through it, or other accessory components have to fit with it, even though it's only half the size." This

means that tolerances must be tighter.

"Typically customers were happy with a thousandth before," says Bill Conley, sales manager of Guill Tool. "More recently it was half a thousandth. Now they want to get tighter than that." How tight? "Two to three tenths on concentricity," says Jim Prue, technical director at Guill Tool. In terms of percentage of wall, says Conley, the old goal was 90 percent, but "we don't usually blink at 95 percent. I have customers that are running 99 to 99.5 on their walls."

Multilumen and Multilayer

As medical devices become more complex, extruders are being asked to produce tubing with multiple layers and multiple lumens&#151anywhere up to eight lumens, some with wire inside, some with braids, some with different lining materials&#151and there seems to be no end in sight for the complexities that users demand. "I guess the sky's the limit there," says Conley. "If you look at sheet manufacturing, they go up to 10 layers." As a percentage of the business, says Badera, "roughly 50 percent of the requests we get now are multilumen, where maybe 25 percent of the requests a year ago were multilumen."

As wall thicknesses decrease, it becomes difficult to retain all the desired properties, and increasingly the answer is coextrusion. By combining two materials, it's possible for a thin-wall tube to maintain the feel of a thicker-wall tube.

There's also a growing demand for tubing with stiffness that varies with length, which makes tooling more complex. "You're basically oscillating the extruder," says Prue. "You're going from one durometer to the other and back. Within that one tube, they actually have two durometers, and it's changing in the length of the tube, so they can guide it up through the body with a harder durometer and have it go around areas in the body with the soft durometer."

Changing durometer with length is just the beginning, says Badera. "We do braided catheter work," he explains, "and they're looking to change the braid along with changing the hardness of the material over the braid. They're looking to change the braid&#151the hardness and the ID or the OD at the same time. It's not just as simple as saying I want a stiff shaft and a transitional area to a soft tip."

Outsourcing Secondary Operations

Manufacturers in many industries are trying to reduce costs by outsourcing as much as they can, and medical equipment manufactures are no exception. Instead of developing in-house expertise in everything, companies are asking extruders to perform more and more secondary operations.

"For example," says Mike Bailey, general manager of Upchurch Medical, "instead of just machining PEEK, we'll also get the raw material for markers and cut the markers, and incorporate markers. We'll laser mark as well. Another example:

instead of just extruding tubing, we'll neck the tubing down; we'll form the tubing. Instead of just extruding one material, we'll extrude multiple materials and assemble these together to make more of an entire shaft or catheter assembly. We'll provide marking. We'll bond multiple parts, fitting tubing. So instead of just providing a single tube, we'll provide tubing that's been necked, bonded together, bonded to a fitting, labels on that tubing, markers on the tubing, forming of the tubing."

Coated Materials

The benefits of bioactive coatings&#151to add lubricity, to prevent blood clotting, or to resist the formation of biofilms, for example&#151are becoming better known (see "An Evolution in Coatings" in the March issue of *Medical Design Technology*), and while extruding companies don't generally apply these coating to their products, they are aware of it and are helping customers. "We get more and more requests for that," says Bailey, "and we do provide courses and recommendations."

Sometimes customers ask for some fairly complicated things, continues Badera: "Can I get this coextruded with this on the outside and something else on the inside, and I want the something else to be filled with something that's going to make it lubricious or with something that's going to be an anticoagulant. Or vice versa, they want a material on the inside that gives them, say, the burst strength or the flexibility they want. And then the material on the outside, they want to know if there's some additive that can go in it, that could be an anticoagulant."

Increases in Raw Material Prices

One challenge facing the industry is the constantly rising price of raw materials. "In the last year, it's gone up probably 20 percent," says Ray Ramos, district sales manager of Saint-Gobain Performance Plastics, "and we've heard it will be 20 percent again this year." Costs have not gone up across the board, however, Badera points out. While increases of 15 to 20 percent have been the norm, he says, some materials have gone up 35 percent and others just a little.

Changes in price can make things difficult to plan. "Sometimes we get a month's notice and sometimes a week's notice," says Ramos. And, says one of the people we interviewed, distributors can make things difficult even without raising prices. Instead, they increase minimum order size. "We've run into some more distributors who've said no, we're not doing 50-lb bags or 100-lb orders or 300-lb drums. If you want to buy this material, you have to buy 1,300 lbs at a time. They can sell more material that costs them less because they're not putting anything extra into bagging and handling. The price stays the same, but I have to buy 1,300 lbs instead of 600 lbs, and then I sit on it for six months or a year."

Extruders and molders aren't the only ones feeling the pinch of increased raw material prices. Tooling manufacturers are seeing increases in both prices and lead times for their raw materials&#151high-quality steel and other alloys. "When you're

working with fluoropolymers, you have to have Inconels and Hastelloy materials; we've been quoted on some sizes one-year delivery. Needless to say, the customers aren't going to wait a year to get a tool," says Conley. Part of that can be ascribed to greater demand (Conley reports a 50 percent increase in demand over last year), but most of it is probably due to increased demand from overseas, especially China.

Changes in Materials

While medical polymers tend to change slowly, there are some interesting things taking place. Bailey points out that resin manufacturers are beginning to embrace the medical device market more than before and are making available materials that they previously did not. In the polyetherketone family, he says, "there are resins that are actually championed by the resin manufacturers for use with short- and long-term implantables, USP Class VI, and providing FDA master files."

Also of note, Bailey adds, is an increasing demand for bio-absorbing materials, as well as some increase in the use of materials that promote bone regeneration, and proprietary compounds and mixtures for orthopedic applications that "promote bone growth and then will absorb as that growth occurs."

Phthalates and Other Plasticizers

In recent years, there has been increasing concern about the possible dangers of phthalate plasticizers such as DEHP used in PVC tubing. Richard Brooks, vice president of sales and marketing, and Richard LaFreniere, vice president of operations, at Bunzl Extrusion Massachusetts LLC pointed out in "Tubing and Extrusion Trends Yield More Material Options" in the February issue of *Medical Design Technology* that users are looking at alternatives. While many long-time users of PVC seem content to stay with what they have, says Badera, others, particularly those planning new products for sale in Japan or Europe, have begun to request DEHP-free materials. Saint-Gobain, for example, sells its TYGON MPF line as a replacement for PVC, and polymers such as EVA, polyolefins, polyesters, and polybutadiene have been investigated.

For some manufacturers, of course, phthalates are not a concern because either they don't use PVC very much or their products are used more in medical offices than in surgical units. "A surgical unit," says Ramos, "has a different set of standards completely."

CHANGES TO MEDICAL MOLDING

Many of the factors affecting extruders are being felt by molders as well. Tolerances are getting tighter, materials are evolving, and customers are demanding more secondary operations&#151all of which require molders to keep their processes and their people up to date.

Demand for Tighter Tolerances

Meeting tighter tolerances means having a repeatable process. "And in order to have a repeatable documented process, your press has to do the same thing from shot to shot," says Phil Cashen, business development manager at Vaupell Inc. "You have to have a capable press, and if the press isn't capable, you don't have a prayer of meeting the customer's expectations." For this reason, and to reach compliance with ISO 13485:2003 and ISO 14644, Vaupell has adopted scientific injection molding, with cavity pressure transducers, on electric presses.

Process Control

Many of the changes we've seen in injection molding technology have been in the area of control. "Over the last several years," says Mike Bailey, general manager of Upchurch Medical, "we've been able to incorporate additional process control in the molding process with pressure transducers and thermocouples, which are tied directly to mold cavities to obtain more precise feedback."

Modern computerized control has affected other types of molding as well, adds Ray Ramos, district sales manager of Saint-Gobain Performance Plastics. "Years ago we used to use all pin routers and hand routers and hand jigs and fixtures, but now it's all CNC, very accurate," he says. "All the drawings come on IGES files."

Better Training

Advancements in technology mean little without the people to use them, and these people must have up-to-date skills. "The days of having a press operator just run a press for 15 years and mold product is behind us," says Cashen. "The skill sets of the people on the production floor need to be improved as the technology of the product that we're molding becomes more challenging."

And employee training goes beyond just running the machines. Molders must understand the validation process, says Cashen, "to be able to conduct and manage and document validations, IQ/OQ/PQ. Protocols need to be established. It's another layer of documentation and process management that requires your staff to be trained and capable in all those areas."

Changes in Materials

Changes in materials affect molders as much as they do extruders, with perhaps a few additions. Molders may be manufacturing housings for devices that contain electrical and electronic components, and thus fall under the European requirements RoHS and WEEE. These ban toxics such as cadmium, hexavalent chromium, lead, mercury, asbestos, and others, but they also ban or severely restrict the use of PVCs because they cannot be incinerated safely and because they may give off plasticizers-especially phthalates-when put into landfills. While it may be feasible in some cases to go to ABS or polycarbonate, says Ramos, things may not be all that simple. "With the RoHS standard, people are still figuring out what we have to do to comply," he says. "In that part, those inserts are not RoHS compliant. The plastic is, but the fasteners are not."

Secondary Operations

Cashen reports that his company, like others, has seen increased demand for secondary operations including machining, painting, surface finishes, and even packaging. What customers want, says Ramos, is to "basically get a turnkey part." And if the molder won't do all the secondary operations, the customer will find someone else who will. Increasingly, he says, "we are not shipping to the company who's designed and ordered it; we're shipping to contract manufacturers" who add latches, screens, assemblies, other sheet metal parts."

ONLINE

For additional information on the technologies discussed in this article, see *Medical Design Technology* online at www.mdtmag.com or the following websites.

&#149 www.precisionextrusion.com [1]

&#149 www.guilltool.com [2]

&#149 www.upchurchmedical.com [3]

&#149 www.plastics.saint-gobain.com [4]

&#149 www.vaupell.com [5]

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