Micro-Sized Components for Medical Extrusion

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Miniature-sized components are critical for medical devices being developed today. One important component fabrication option that enables tight component tolerances is extrusion. Whether for tubing or components, this process offers a number of benefits to engineers. This article reviews several distinct advantages of using this process that every engineer should know.

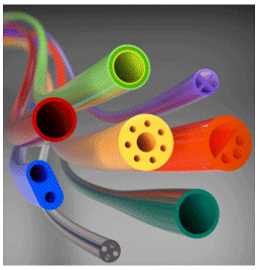
According to BCC Research, the global market for minimally invasive surgical devices and instruments is expected to grow from $14.4 billion in 2011 to $21.1 billion by 2016, a compound annual growth rate of almost 8%.

Minimally invasive procedures result in smaller incisions, faster procedures, reduced complications, shorter hospital stays, and lower healthcare costs. These techniques are especially beneficial for cardiovascular and neurovascular procedures, gastrointestinal endoscopies, advanced drug delivery, IV therapy, and microanalysis.

Creating miniaturized components for medical device companies and their end users can be very challenging. Micro-parts and micro-tubing cannot be efficiently or reliably produced using standard extrusion machines. They can, however, be produced using microextrusion technology—an evolving science that requires state-of-the-art equipment, deep understanding of material chemistry and behavior, very high precision and process control, and a very clean production environment. When all of these requirements are met, combined with the product knowledge and operational skills of experienced technicians, a wide range of micro-components and micro-tubing with extremely tight tolerances can be produced, such as complex parts as small as 0.001 grams or tubing with walls as thin as 0.001 inches.

A microextrusion system consists of the extruder, die head, sizing unit, puller, and control unit. With the sharp increase in demand by medical device companies for thinner walls and even tighter tolerances on tubing, in-line ultrasonic wall measurement gauges are absolutely essential for quality control; several loops of control should be in place to monitor every aspect of the process. A precisely designed and controlled system will produce a perfect melt, free of contaminants, gels, and bubbles, that will not degrade at flow rates as slow as 1.0 ml/hr.

Materials and Tubing Design



Extrusion: single lumen, multi-lumen, tri-layer and striping co-extrusion, and bump tubing

The first step in manufacturing any micro-component or micro-tubing is selecting the raw material. Microtubing can be made from polyurethane, nylons, and high-temperature thermoplastics such as PEEK, PEI, and FEP. Tubing can also be coextruded with multiple materials, or embedded with radiopaque stripes, using microextrusion technology.
Polyamides are a preferred material because of their strength and optimal draw-down characteristics. Medical device manufacturers are also requesting more PEEK because of its ability to withstand heat; the trade off is that it is a costly material and requires more clean-up time than other polymers.

Multi-lumen tubing is a favorite in the healthcare setting for introducing guide wires, tools, optical equipment, drugs, or other fluids into the body. Multi-lumen tubing is often used as a corridor for electro-active fibers or steering wires. Bump tubing (also known as taper tubing) is becoming increasingly popular for inserting catheters and other devices. Bump tubing is characterized by a smaller-diameter distal (insertion) end and a larger-diameter proximal outside the body that is sized to enhance easy connection to monitoring devices or bedside equipment. Multi-lumen bump tubing can be microextruded with as many as ten lumens or more for drug delivery and other multiple applications.

Operational Considerations

Just having the latest microextrusion equipment isn’t enough; companies must also possess a highly accurate, in-depth understanding of how each material responds to specific combinations of parameters during the microextrusion process. This database and depth of knowledge is crucial to designing and extruding high quality components and tubing in a quick and efficient manner. Experienced balloon and tubing companies, for example, maintain extensive, proprietary databases of scientific and process information on raw materials and finished balloon materials, sizes, and dimensions, as well as complete sets of process parameters and finished balloon test results for nearly every balloon type/material type available. An important characteristic for any material is its melt strength, or ability to be drawn out and maintain its viscosity; this too is dependent on the variables of heat and pressure and is not typically published or readily available information, meaning it must be part of the experienced extruder’s database. Even with this depth of information, it may take several design attempts to find the best combination of material and parameters for the proposed medical application. An example design requirement for microcatheter materials needs to consider exceptional pushability and trackability through small vessels (2 Fr access) along with providing shaft support, tip flexibility and smooth transitions. Creating extrusion to meet these demanding clinical applications is crucial.

Microextrusion of multi-lumen tubing typically requires special extrusion machinery and tooling, including extrusion crossheads, dies, and tips. Lower material outputs are often the case, with screw diameters as small as 0.5 inches. Because longer residence times in the barrel result in degradation of molten polymers, microextruders are designed to pump the melt through the extruder at a speed that is fast enough to avoid degradation, but slow enough to allow minimal shear. Maintaining this delicate balance requires extensive experience of how resins behave as melts under specific pressure and temperature parameters.

Extrusion can offer dimensions smaller than the tip of a ballpoint pen

Since each polymer in its molten state is characterized by slightly different physical and chemical properties, it is impossible for a single die head to process every polymer to the required tolerances. For multi-lumen and co-extruded micro-tubing, the biggest manufacturing challenge is often designing extrusion dies and tips that are project specific; several versions of these tools may have to be tested before the extrusion process is ready to manufacture.

Draw down ratios can be 10:1 or higher, depending on the complexity of the product design and the chosen material. Even though draw down ratios this high would be considered to be stretching the limits for many thermoplastics in most cases, these ratios can be achieved with smaller dies and tips that are specially designed to withstand the stresses of extrusion.

The pulling unit also has a major impact on draw down because the pulling speed controls the draw-down rate. Even the slightest variations in pulling speed can result in imperfections, such as irregular surfaces or flawed geometry of the tubing—at worst, creating expensive scrap to be discarded. Also, vigilance does not stop once the micro-tubing is extruded and cooled; because softer elastomers are more difficult to cut and measure compared to more rigid materials, special care and special cutting fixtures are required to obtain a clean cut to properly measure the tubing. Specialized, high-definition video microscopes must also be used for dimensional inspection of these tiny profiles with outside diameters as small as 0.01 inch.

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