To Mold, or Extrude, That is the Question

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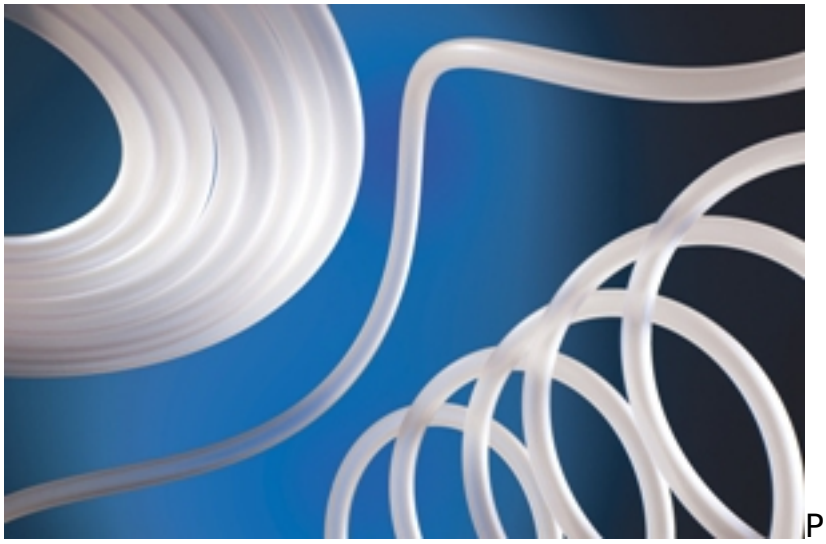
Selecting the right tubing may not be as straightforward as some medical device designers may think. This article will explore molded and extruded silicone tubing and address two areas that product development engineers should consider when seeking a solution—material differences and manufacturing advantages and limitations.



Pressure to drive down cost without sacrificing performance is not a new trend in the medical device industry, but as healthcare reform implementation continues, it is not likely to lessen. While medical device manufacturers have taken steps to decrease the development and manufacturing costs of their products, many are now turning to suppliers to continue cost-cutting measures for components and disposables. For both manufacturers and suppliers, though, a delicate balance must be achieved between price and performance.

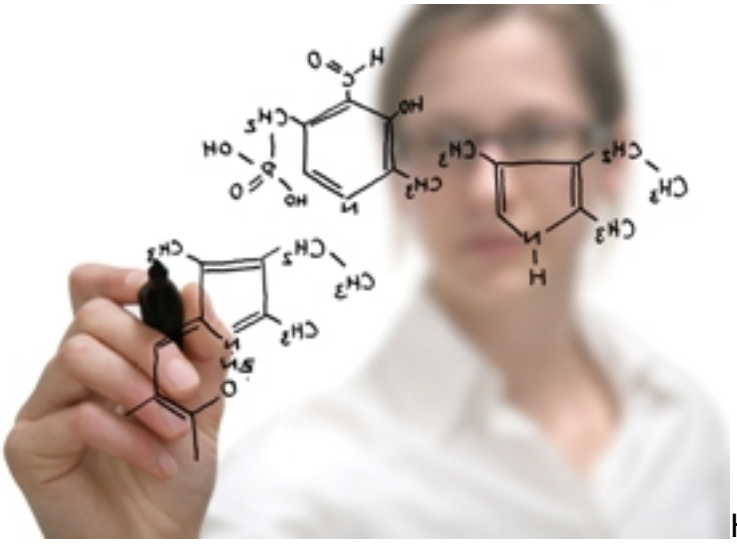
Silicone tubing is one area where suppliers are taking steps to decrease cost and maintain performance. There are two primary manufacturing processes used to produce silicone tubing: molding and extrusion. Traditionally, extruded tubes offer cost advantages but do not achieve the same level of accuracy as molded parts; however, as suppliers re-think their manufacturing processes to enhance performance, this dynamic is shifting. With new technologies emerging, it is becoming increasingly difficult for medical device manufacturers to identify which type of silicone tube is ideal for their product.

Material Differences

Due to its biocompatibility, low toxicity, and elastomeric properties, silicone is an

ideal material for medical device tubing. For manufacturing purposes, the material exists in two forms, liquid silicone rubber (LSR) and high consistency rubber (HCR) elastomers. While both LSR and HCR have similar physical properties, the main differences lie in how they are processed.

LSR is a two-part platinum catalyzed product that is primarily used for liquid injection molding because of its low viscosity, which allows it to flow easily into the molds. The process for LSR is highly automated. First, a pumping system mixes the two components—typically an "A" and a "B" component in a precision meter-mixer to a given ratio. Then, the mix is delivered to the mold in the injection machine to be cured into its final state. This manufacturing process and material is ideally suited for complex and intricate parts.



HCR is a high viscosity material with the consistency of putty and is the primary material for extruded tubing. HCR systems can utilize either platinum- or peroxide-cure packages. The process for manufacturing tubing with HCR begins by milling the silicone base and the catalyst system into a homogenous compound. It is then cut into preforms, or strips, that are fed into the extruder. The extruder forces the material past a pin and through a die head to create the shape, and then the tubing is heat cured by passing through an oven.

HCR does present an advantage over LSR silicone in that the raw material choices are more varied and property profiles are more easily custom formulated to fulfill a unique specification requirement. This custom compounding process, which is highly collaborative, starts with a silicone base that can be milled with additives to alter physical properties, such as tear strength, modulus, compression set, durometer, tensile strength, and elongation. Fine-tuning these physical properties enables a tubing manufacturer to deliver solutions that are specially formulated for unique end-use applications. Formulations can also be created to ensure materials meet requirements, such as high purity and low extractables.

Manufacturing Advantages and Limitations

For most tubing applications, extrusion is the preferred manufacturing method. There are many standard off-the-shelf solutions available that meet customer requirements and extruded solutions generally offer better value. However, for

applications where the tubing performs a critical function, the choice between extruded or molded tube segments is not as clear. As medical device manufacturers improve the sophistication of their products and enhance patient safety, they seek tubing to further enhance the accuracy and control of pumps. In peristaltic pumps, there has been a growing demand for greater precision and consistency in the components used in intravenous delivery devices and enteral feeding. Both molding and extrusion can be used to create silicone tubing solutions that deliver tight tolerances in material properties and product dimensions. However, both processes present challenges and opportunities.

The first advantage of the molding process is that tubing can be supplied with very tight manufacturing tolerances. Over the last 10 years, LSR formulations and molding techniques have improved to a point where millions of parts can be manufactured with minimal dimensional variation. Another advantage of the molding process is that parts can be manufactured with additional geometries. For example, a tube with a thinner wall in one section can be used to detect pressure build up in a delivery line. Molded components can also have molded collars or fixture elements to ensure proper placement of tube segments.

Molded silicone tubes also present limitations however. Inherently, molding is a more expensive process than extrusion due to the fact that molding is a discrete (versus continuous) process. Additionally, molding can be capital intensive, requiring investments for tooling and equipment. These costs can add up, particularly during the iterative design and development phase for new products. High precision tooling also requires working with a supplier that has the means and

the ability to maintain these special molds. A commitment to tool maintenance is required to ensure product consistency. Lastly, the nature of molding limits the overall length of tube that can be produced.

Silicone tubing manufactured by extrusion is also used for medical fluid delivery, and historically, has met the needs of the market. Though there is a sense that extruded products are limited in their consistency and precision. This has caused many medical device companies to pursue molded solutions. However, recent advancements in processing techniques are improving the dimensional consistency of extruded tubes, making them suitable for applications requiring high accuracy flow rates, like intravenous and enteral feeding pumps.

One of the most significant advances in extrusion processing for silicone tubing has been the increased use of closed-loop feedback systems. These systems require advanced measurement tools that can adjust extrusion processes on the fly, ensuring immediate correction to variations in dimensions. In the past, extrusion measurements related to inner diameter (ID) and wall thickness were made offline at regular intervals, which inherently increased the chance of variation within the process. This improved dimensional control of the extruded processes brings it into the same range of dimensional control as molded components.

The other factor affecting precision and consistency of the extruded process has been the consistency of the material. As mentioned earlier in the article, extruded processes only use HCR silicone. HCR offers a wider variety of solutions to the market and improved understanding of milling and compounding has added to this advantage for extruded materials. For example, the ability to custom formulate a silicone compound to meet a precise modulus requirement can ensure that the silicone tube will offer the same dynamic properties no matter what production run of material is used.

Lastly, because extrusion is a continuous process, it is capable of producing more parts per minute compared to liquid injection molding, often resulting in lower product costs.

Conclusion

Molded and extruded silicone tubes offer unique advantages and disadvantages, depending on the requirements of a device. For product development engineers, it is critical to consider the material choices and manufacturing processes to choose the most suitable silicone tubing solution. Identifying and collaborating with knowledgeable supply chain partners that have multi-disciplinary experience can also help streamline the process of finding the right solution. As the healthcare industry continues to evolve, such collaboration with suppliers will ensure medical device manufacturers are able to minimize costs while maximizing performance and safety.

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Links:
[1] http://www.medical.saint-gobain.com/