An engineer’s perspective on medical tubing design

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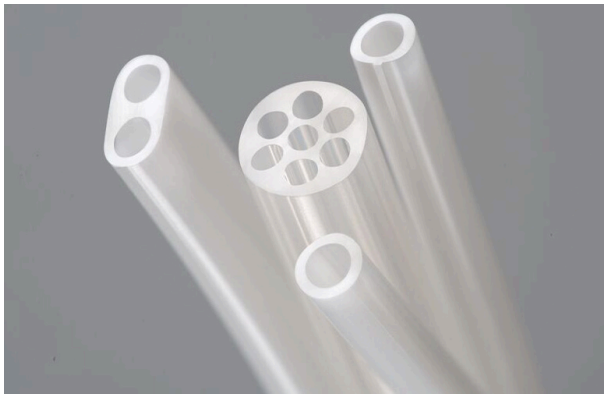
By Dan Sanchez, Trelleborg Medical Solutions

As an engineer at Trelleborg Medical Solutions for more than two decades, I’ve seen firsthand how a seemingly simple component like tubing can make or break a device’s success. Today, the industry is creating complex, multilumen extrusions with features that were once thought impossible, all while making devices smaller, safer and more effective for patients.



Multilumen tubing for medical device applications [Photo courtesy of Trelleborg Medical Solutions]

During the early stages of design, you need to navigate the complexities of material selection and manufacturing to get your product to market quickly. Let’s walk through some of the critical considerations and innovations I’ve encountered when it comes to specifying tubing and hoses for medical applications.

Key factors in tubing specification

Before thinking about materials, you need to nail down the “must-haves” of your tubing. These factors are interconnected, and a change in one can easily affect another.

Size: The push toward minimally invasive procedures means we’re constantly shrinking geometries and tightening tolerances. This is a huge driver in device design, but it also presents challenges in process control, testing and assembly down the line.

Kink-resistant tubing for medical device applications [Photo courtesy of Trelleborg Medical Solutions]

Hardness (durometer): As durometer increases, tensile strength often decreases. This matters for applications like wound drains, which are under significant tension when removed from the body.

Tear strength: This determines how easily a nick in the tube can propagate. It's a key consideration if the tube might be exposed to sharp edges or features small internal radii. Lower durometer silicones generally have lower tear strength.

Elongation: For devices like balloons, the elasticity of the tubing is paramount. Lower durometer silicones typically offer higher elongation, allowing for greater expansion.

Surface friction: Silicone has an inherent "stickiness" or friction. To minimize this, biocompatible coatings can be applied. This is useful for deploying stents or balloons, or to make it easier to assemble components with tight fits, like in the assembly of pacing leads.

Transparency and visibility: For many devices, it's necessary to see the fluid moving through the tube to verify flow. Silicone is naturally translucent, but additives can change that. By adding radiopaque stripes (often using barium sulfate), tubing becomes visible under X-ray or fluoroscopy, helping a surgeon guide a device through the body.

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Why silicone shines as a medical tubing material

While materials like polyvinyl chloride (PVC) and thermoplastic elastomers have their place, silicone is often the gold standard in medical tubing, especially for implants. Its unique properties make it incredibly versatile.

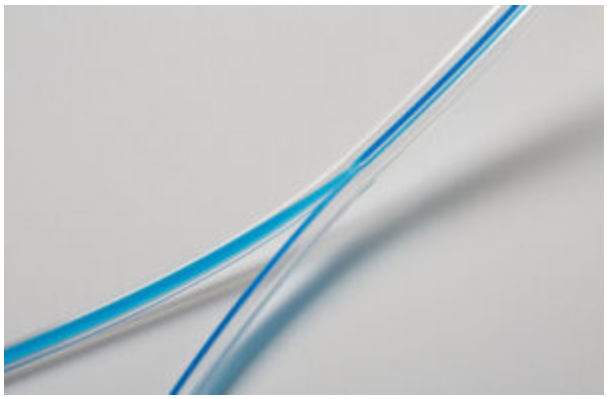
Silicone is inert, biostable and biocompatible. It can be platinum-cured for the highest purity, with low levels of extractables. It doesn't use leaching plasticizers, resists temperature extremes, and can be sterilized using various methods like radiation, ethylene oxide sterilization (EtO) or steam.

Innovations in tubing technology

This is where real engineering creativity comes into play. Modern extrusion technologies allow us to build incredible functionality directly into the tubing itself, often eliminating the need for secondary bonding or assembly steps.

Multilumen extrusion: We can create a single tube with multiple lumens, or channels. This is common in catheters for fluid transfer, drug delivery and housing electronics. The challenge is controlling and measuring the numerous dimensions, including inner diameters and the thin walls between them.

Geometric transitioning (GeoTrans): We can change the cross-section of the silicone tube during the extrusion process. Imagine a dual-lumen extrusion that smoothly bifurcates into two single-lumen tubes. This eliminates bonding joints, creating a more hygienic and robust design.



Trelleborg Medical Solutions says its GeoTrans process allows for silicone tubing to change cross section during extrusion to eliminate molding and secondary bonding steps, allowing for a strong, hygienic design with a lower overall device cost for custom applications requiring precision tolerances. [Photo courtesy of Trelleborg Medical Solutions]

Reinforced and kink-resistant tubing: To keep fluid paths open under pressure, we can reinforce silicone tubes. Polyester braids add burst resistance, while a spiral reinforcement with nylon monofilament prevents kinking and crushing.

Bump tubing: By stretching a tube at a varying rate during processing, we can create a component with different diameters at each end. This is often used to accommodate connectors without extra parts.

Twisted extrusions: For applications that undergo repeated flexing, we can continuously twist a multi-lumen tube during extrusion. This spirals the outer lumens around a central one, distributing stress on the internal wires and dramatically reducing the risk of dynamic flex failures.

Medical device tubing application examples

Theory is great, but let's look at how these technologies solve real-world problems.

In one case, we worked on an implantable neurostimulator. The leads had to be tiny but maintain perfect insulation to deliver signals to precise locations in the brain. We used microextrusion to produce tubing with diameters under 0.030 in./0.08 cm, holding tolerances of just 0.001 in./0.003 cm on the inner diameter, outer diameter and wall thickness.

For a pacemaker lead, the challenge was mitigating the risk of conductors breaking from dynamic loading. We used a continuously twisted multilumen extrusion. This design involved more than 30 dimensions with tolerances of 0.002 in./0.005 cm or less, requiring custom tooling and measurement fixtures to ensure quality.

By understanding the interplay of material properties and manufacturing technologies, you can design tubing components that are not only functional and reliable but also enhance patient outcomes. The key is to start the conversation early and collaborate with experts who can help turn your complex vision into a manufacturable reality.

Dan Sanchez is a product manager at Trelleborg Medical Solutions and has worked in silicone manufacturing for the healthcare and medical industry since 1998. Drawing from his extensive knowledge in silicone tubing and engineered extrusions, he helps medical device designers realize product concepts through manufacturing solutions and design for manufacturability support.
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Dan Sanchez is a product manager at Trelleborg Medical Solutions. [Photo courtesy of Trelleborg Medical Solutions]

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