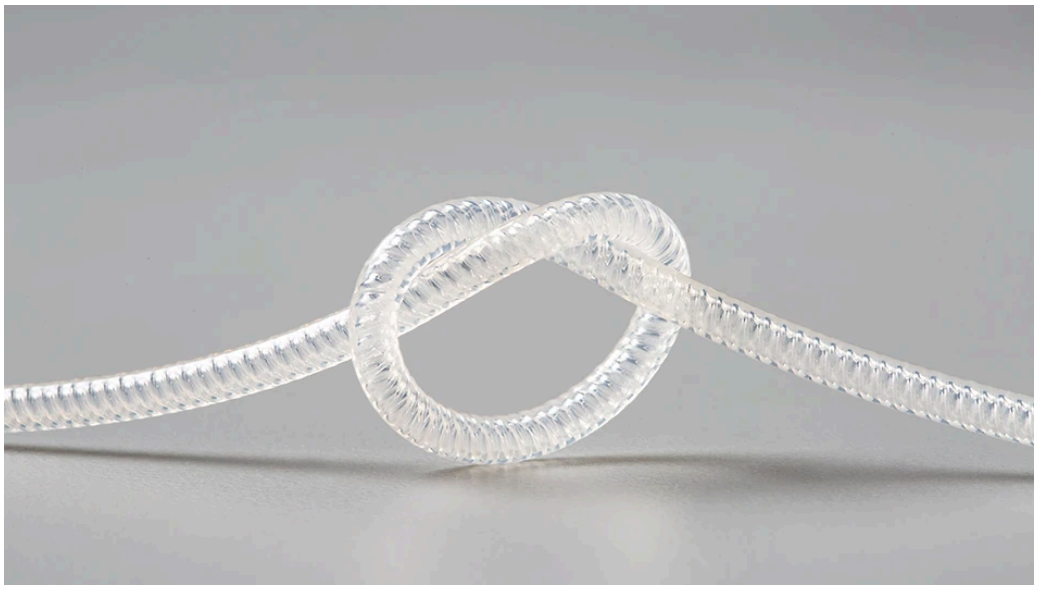
Precision under pressure

How advanced extrusion is meeting the demands of modern medical devices



Kink-resistant tubing from Trelleborg Medical Solutions
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Silicone extrusion has been a critical capability of medical device manufacturing for decades. From early-stage catheter development to long-term implantable leads, the ability to produce consistent, biocompatible tubing at tight tolerances has helped

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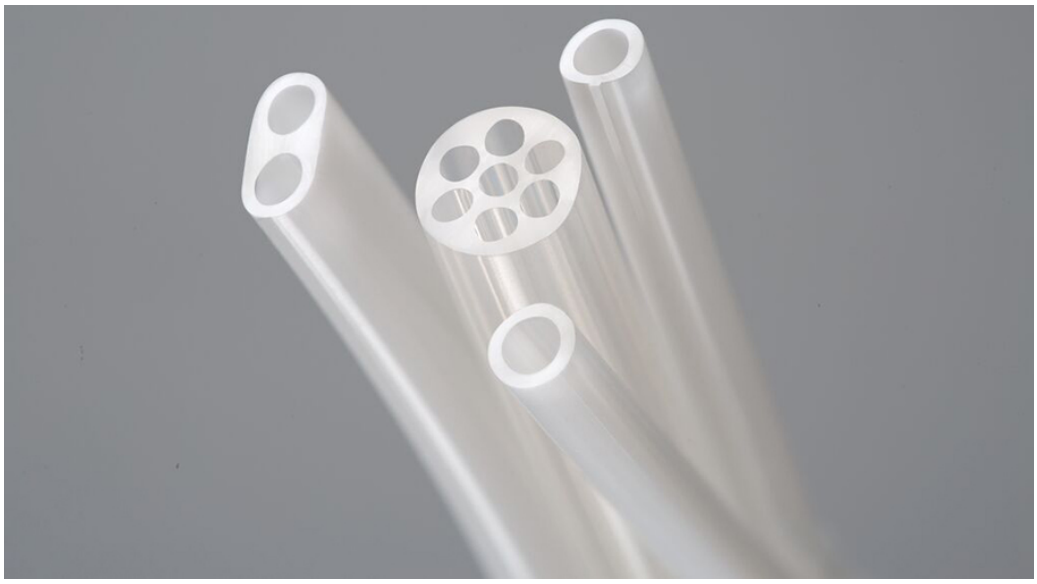
immense. Understanding how the field has evolved and where challenges lie is essential for any medical device company navigating product development.

From commodity process to precision discipline

The early days of medical-grade silicone extrusion borrowed heavily from thermoplastic processing. Extruders were adapted rather than purpose-built and the focus was largely on achieving basic dimensional consistency. As device designs grew more complex and implant classifications became more stringent, it became clear that off-the-shelf equipment and generalist processing knowledge were no longer sufficient.

Leading manufacturers began building extrusion equipment specifically optimized for silicone, a material that behaves very differently from thermoplastics in terms of viscosity, heat sensitivity, and processability. Screw designs, drive systems, head configurations, and downstream forming equipment were all reconsidered from the ground up. Quality control evolved from post-process inspection into a discipline embedded within process design itself.

The result is a manufacturing environment where extrusion is no longer treated as a commodity step but as an engineered solution – one that begins with material selection, encompasses tooling and equipment design, and extends through secondary operations such as forming, overmolding, drilling, and printing.



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GeoTrans multi-lumen tubing

The challenges device companies face today

Despite these advances, medical device companies continue to encounter a consistent set of challenges when it comes to extruded components. Understanding these pressure points matters because they directly affect time to market, regulatory outcomes, and device performance.

Tolerance demands are increasing. Neurological implants, pacemaker leads, and micro-scale catheter components routinely require extruded tubing with 30 or more critical dimensions, many held to tolerances of ±0.001" to 0.002"/0.025mm to 0.051mm. For a multi-lumen extrusion at micro scale, achieving this level of consistency demands not only capable equipment but a deep understanding of how silicone behaves under varying heat loads and line speeds. Many contract manufacturers find themselves unable to meet these requirements because their equipment was not designed for it. Companies such as **Trelleborg Medical Solutions** design and use purpose-built extrusion equipment in-house, enabling rapid tooling iteration and precise simultaneous control of line speed and thermal load.

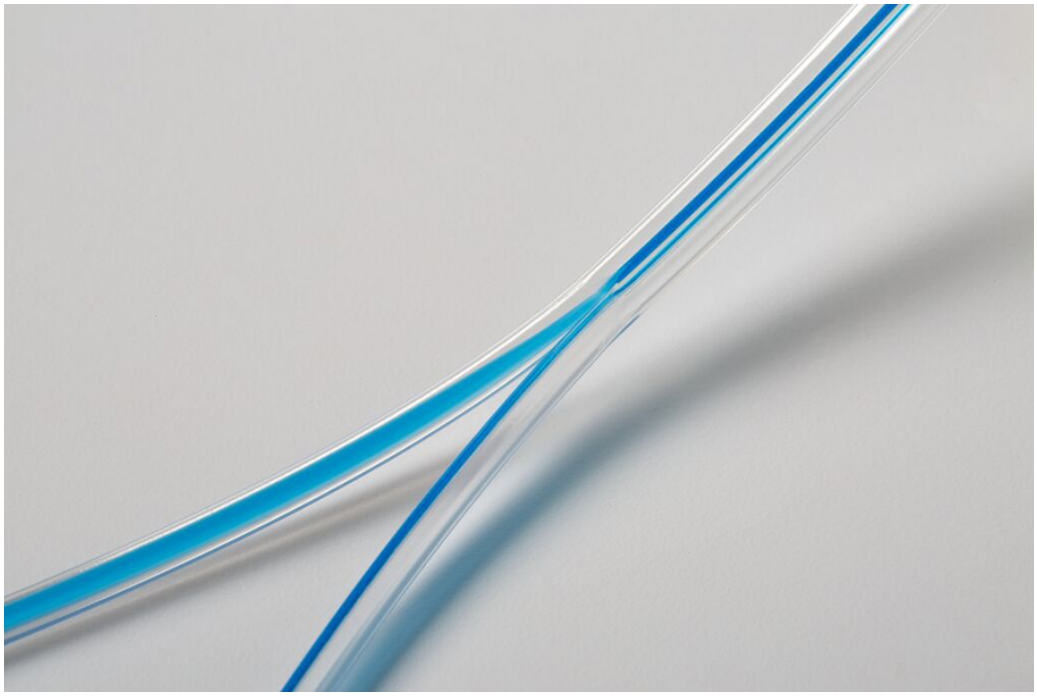
regulatory risks. Customers in neurology and cardiology are increasingly demanding 100% inspection protocols, often at high magnification, as a condition of supply. Trelleborg operates highly accurate inline charge-coupled device (CCD) micrometer systems with high scan rates for continuous dimensional measuring and combines this with rigorous in-process inspection and final sampling making 100% inspection commercially viable at production scale.

Material selection matters. Silicone is not a monolithic material. Different high-consistency rubber formulations process very differently, and some widely qualified legacy materials carry a higher risk of gel formation during extrusion. Device companies, particularly those with long-standing material qualifications, sometimes continue specifying materials that are inherently problematic to process, unaware that newer alternatives exist which could reduce defect rates, simplify processing, and accelerate qualification timelines.

Speed to market creates tension with risk mitigation. Every week lost at the start of a project's development cycle is revenue that cannot be recovered. Yet implant-critical components require structured validation, appropriate certifications, and robust design-of-experiments approaches before commercial production can begin. Device companies that bring their project to an extrusion partner late in the development process often lose the opportunity to optimize geometry, material selection, and tooling, compressing timelines that could have been managed more efficiently.

Complex geometries require more than straight tubes. Modern device designs increasingly call for multi-lumen extrusions, variable cross-section tubing, reinforced structures, and downstream formed components. Kink-resistant tubing, twisted multi-lumen leads designed for strain relief, and encapsulated radiopaque stripes for neurology applications all require processing capabilities that go well beyond what most extrusion suppliers offer as standard. For example, Trelleborg's proprietary **GeoTrans** technology enables the

steps, reducing supply chain complexity and supporting hygienic design.



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GeoTrans dual-lumen tubing

Where advanced capabilities make the difference

Device companies experience the most success when they partner with a contract manufacturer that treats extrusion as a problem-solving system rather than a build-to-print service.

This begins with equipment. Manufacturers who design and build their own extrusion equipment in-house can iterate tooling rapidly and optimize control systems to maintain stable line speed and heat load simultaneously. This is a meaningful distinction. Many extrusion operations compensate for process variation by adjusting line speed, which introduces its own thermal inconsistencies. Purpose-built systems that hold both parameters steady are better equipped to achieve and sustain tight dimensional tolerances.

Equally important is material expertise. An experienced extrusion partner can guide customers away from legacy materials that are prone to defects, prototype multiple material options quickly to evaluate performance in application, and recommend custom

monofilaments within the extrusion itself opens design possibilities that catalog-focused suppliers cannot offer.

Perhaps most importantly, the value of early engagement cannot be overstated. When extrusion partners are brought in at the concept stage, they can contribute to design for manufacturability, structure development testing efficiently, and help customers understand which tolerances are functionally critical and which carry flexibility. This kind of collaboration consistently reduces development time and lowers the total cost of qualification.

A more demanding future

As devices become smaller, smarter, and more targeted in therapy delivery, more will be demanded of their components. Long-term implantable leads, neurostimulation devices, and drug-delivery systems require extrusion capabilities combining material science, process engineering, and quality discipline in ways that weren't required of the field a generation ago.

Meeting those demands will require the accumulated knowledge of how silicone processes, how tolerances behave at micro scale, how defects form, and how to prevent them. This strategic knowledge often takes years to build and cannot be replicated by purchasing a turnkey system. It requires the problem solving that commodity suppliers cannot address.

About the author: Dan Sanchez is product manager, extrusion manufacturing at Trelleborg Medical Solutions.

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