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PARTNERSHIP**

Choosing a Partner for Micro-Molded, High-Precision, Silicone Implantable Parts

By Dennis Rector, Flexan



Silicone micro molding is a specialized silicone molding process utilized for parts and components requiring tight tolerances and high precision. While thermoplastic elastomer (TPE) and rubber also are utilized in micro molding, silicone typically is used for medical products — particularly implantable devices — due to its biocompatibility.

Micro molding is used for products that require tolerances within the micron range (i.e., $\sim 1/1,000$ inch), including components in minimally invasive surgical tools, valves, seals, and over-molding, as well as microsensory and microfluidics products. Additional medical applications include parts for pacemakers and pain management devices, as well as suture leads and anchors.

On top of part geometry tolerances, micro molding is used to work within tight flash requirements (i.e., less than $4/1,000$ -inch extension). Flash, a common defect in liquid injection molding (LIM), comprises the thin layer of material where any two dissimilar surfaces from the mold meet.

Flexan operates exclusively in the medical device space and has extensive experience manufacturing parts and components to these demanding parameters. We serve organizations working to refine existing products as well as companies devising new iterations of a product or introducing novel devices to market. Flexan's capability in this realm stems from a combination of optimal instrumentation, technical acumen, and experience.

In terms of equipment and technical acumen, Flexan understands that large machinery is ill-suited to producing small parts; manufacture cannot be precisely controlled. Accordingly, we partner with numerous tooling shops across the United States to ensure we have the means to achieve high-precision, specialty parts guided by more explicit parameters than more general molded components. Working with diverse tooling partners also gives us insight into multiple experts' points of view if we encounter tooling or production challenges.

Consider that precise tooling with edge, fan, and/or micro-gates allows meticulous control when molding even the most challenging geometries. Different types of gates, or combinations of gates, may be required, depending on the product. For example, fan gates enable a thinner witness mark/imprint on the

part because the gating is spread out more along the length of the part, rather than in a pinpoint location.

Additionally, and more critically, experience specific to the medical industry informs Flexan's part design guidance, operational and manufacturing processes, and even our interactions with customers. Industrial molders, despite boasting technical acumen and offering general micro-molding expertise, cannot match the insight and experience of our silicone and thermoplastic divisions, which operate 100 percent in the medical space.

Understanding the regulatory and timeline-related pressures faced by our clients, Flexan utilizes a phase-gated new product introduction (NPI) process that has been refined to quickly and accurately home in on critical product attributes or features, as well as quickly translate those requirements into specifications that can be tightly controlled in our facility. Aligning with customers in terms of product dimensions is only half the recipe to success; critical attributes are just as important relevant to implantable devices. Critical attributes can comprise several elements, such as ensuring the part contains no embedded metal particulates, fibers, or air bubbles, in addition to meeting rigid tolerances and maximum flash requirements.

Typically, the clients we serve have generated a 3D model and are seeking a prototype part for design verification and/or proof of concept, or they approach us with a detailed rendering, seeking a secondary supplier. Often, clients for whom Flexan has provided engineering samples (i.e., prototypes) will work with us to narrow down an optimal design and progress with us on to production tooling. From start to finish, this process — beginning with initial engagement, progressing through our NPI process, and concluding with production at the client's required volume — generally spans 12 to 18 months.

Additionally, Flexan has served clients who have encountered difficulty throughout design and/or manufacturing while working with other partners. For example, a recent client approached Flexan after components provided by their previous micro-molded silicone parts supplier — intended to seal the area surrounding a needle on a pharmaceutical device — were plagued by leaks. Flexan was able to partner with that client, creating tooling and a process that corrected the issue, putting development of the device back on track.

Final Thoughts

While numerous molders offer micro-molding services, Flexan is differentiated by its medical industry specific experience and expertise; specialized equipment to produce silicone, rubber, and TPE components within demanding tolerances; and technical competency to help clients through the design and production of existing, redesigned, and novel parts.

Moreover, our processes emphasize transparency and open communication, so clients always know where a project stands. Our engineers work with each client to determine the optimal molding process, tool design, tolerancing, inspection, and manufacturing controls for their application while also considering all material preferences and plans for manufacturing.

To learn more, visit flexan.com.

About The Author

Dennis Rector is Director of Engineering at Flexan, Lincolnshire, IL, and has over 20 years of experience in medical contract manufacturing. His expertise includes molded, extruded, and purchased components, as well as assemblies and sterile intent packaged devices. At Flexan, Dennis is responsible for quoting, plus process, project, and design engineering roles supporting process improvement initiatives and new product introduction (NPI). He is Six Sigma Black Belt trained and holds a B.S. in mechanical engineering and an MBA.

About Flexan

Founded in 1946 and based in Chicago, Flexan has been delivering custom contract manufacturing solutions for over 70 years. Today we stand out as medtech custom manufacturing leaders, solidified by a leadership team with more than 120 years of combined medical device industry experience. With four locations across the globe and over 2,000 SKUs, as well as the capability to provide products from molded components to final packaged full assemblies, Flexan has the pedigree medical device companies are looking for in a custom contract manufacturer.

