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Why having a skilled injection molding partner matters

A holistic approach enables a molder to guide medical device manufacturers from prototype to production.

Justin Strike
Trelleborg
Sealing
Solutions

The road to full-scale production for a medical device can be arduous. The challenge becomes even greater when the device requires custom-molded components. Collaborating with a molder experienced in medical device development can help device manufacturers navigate the process from concept to launch quicker, while avoiding common medtech manufacturing pitfalls.

Experienced molders have expertise in details such as complex geometries, material selection, tight tolerances, applied stresses, scale-up and more. They will also consider the finished device, including all other components, to ensure the best fit, production quality, repeatability, ease of assembly and cost.

The silicone-molded part is often just part of a device and the right molding partner should consider how other parts within the device integrate with the silicone part, address tolerance stack and potentially find more robust ways of making the device using advanced capabilities, such as 2K molding, overmolding and automated assembly. This holistic approach to the engineering of the component enables a molder to guide device manufacturers from prototype to production.

Prototyping for successful manufacturing

A prototype shop may be able to provide what a device manufacturer is looking for but might not consider opportunities to enhance the product or the ability to scale-up effectively. Creating a prototype without considering how it will translate to full-scale production can lead to increased costs, an extended time to production, and possibly the inability to ramp up to the multi-million-piece volumes often required by the medical industry.

An experienced molder will think beyond prototyping to the process that can enable large-scale production — designing tooling, locking in tolerance ranges and identifying potential flaws early in the process. A skilled injection molding partner can also reduce design complexities.



Image courtesy of Trelleborg Sealing Solutions.

Liquid silicone rubber for custom injection molding

Experienced molders can also recommend the optimal material for the application. Liquid silicone rubber (LSR) is highly viscous, fast-curing and biocompatible and offers easily altered durometers, varying textures, resistance to different types of sterilization, the inclusion of additives and more.

Precise injection molding processes using LSR result in flash-free, waste-free parts that with consistency in product dimension, precision and quality.

Silicone's reliability, tensile strength and compression-resistance make it ideal for custom injection molded medical parts, especially those used in long-term implantable devices.

Additives and silicone

Because additives and fillers can alter the physical capabilities, appearance and performance of LSR, the proper balance must be determined. Additives such as different colors are mostly used to change the appearance of the final product to act as a visual aid and increase the ease of use.

Radio-opaque fillers can also be added to ensure that the components are visible during surgery. When used with in-process X-ray, the surgeon can see exactly where the component is within the body. This



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is particularly useful to ensure proper device placement. Conductive fillers, used to provide electrical connections within the molded form, are particularly important for some implantable devices, such as pacemakers.

Experimentation with silicone additives — including active pharmaceutical ingredients (APIs) — continues to lead to innovations that improve device performance. Common applications include the addition of antibiotics to prevent infections, steroids to reduce inflammation surrounding implanted devices, and therapeutic drug doses that elute at a controlled rate over time in targeted applications within the body.

By relying on the expertise of a molding partner, medical device manufacturers should expect the product to be designed for manufacturability. When approached correctly, this partnership can increase the performance of the product while reducing its time to market and the device manufacturer's total cost of ownership. ☺

Justin Strike is product manager for Trelleborg Sealing Solutions. A mechanical engineer with a background in polymers and coatings, Strike has 20 years of experience in the industry.