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MEDICAL DESIGN

# A Mighty, Small Idea

Liquid Silicone Rubber provides flexibility for miniature medical device design.

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Today's medical device manufacturers operate in a challenging landscape. Stricter regulations and the need for biocompatibility are making development and manufacturing more demanding. Add to that user requirements for devices that suit their lifestyle choices, such as wearable products and home monitoring solutions, and you can understand why

engineers are looking for novel component options.

One solution is Liquid Silicone Rubber (LSR) molding and multicomponent manufacturing. LSR is a stable and adaptable material that's accelerating innovations in medical device design, making devices more robust, efficient and adaptable to patients' needs.

Silicone is ideal for medical devices and equipment, not only because it's inert, biostable and biocompatible, but also because it can be processed in many ways. It can be molded on its own, but the real magic happens when it is combined during the molding process with engineered plastics and other substrates in what is termed multicomponent manufacturing.

Examples of molded components with LSR.

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This technology produces a single component instead of separate parts that need to be assembled, and it has several advantages for the medical device manufacturer. It reduces production costs and supply chain costs associated with stocking and handling multiple parts. The single, integrated device has greater integrity and removes undesirable spaces where bacteria can grow, eliminating the risk of contamination.

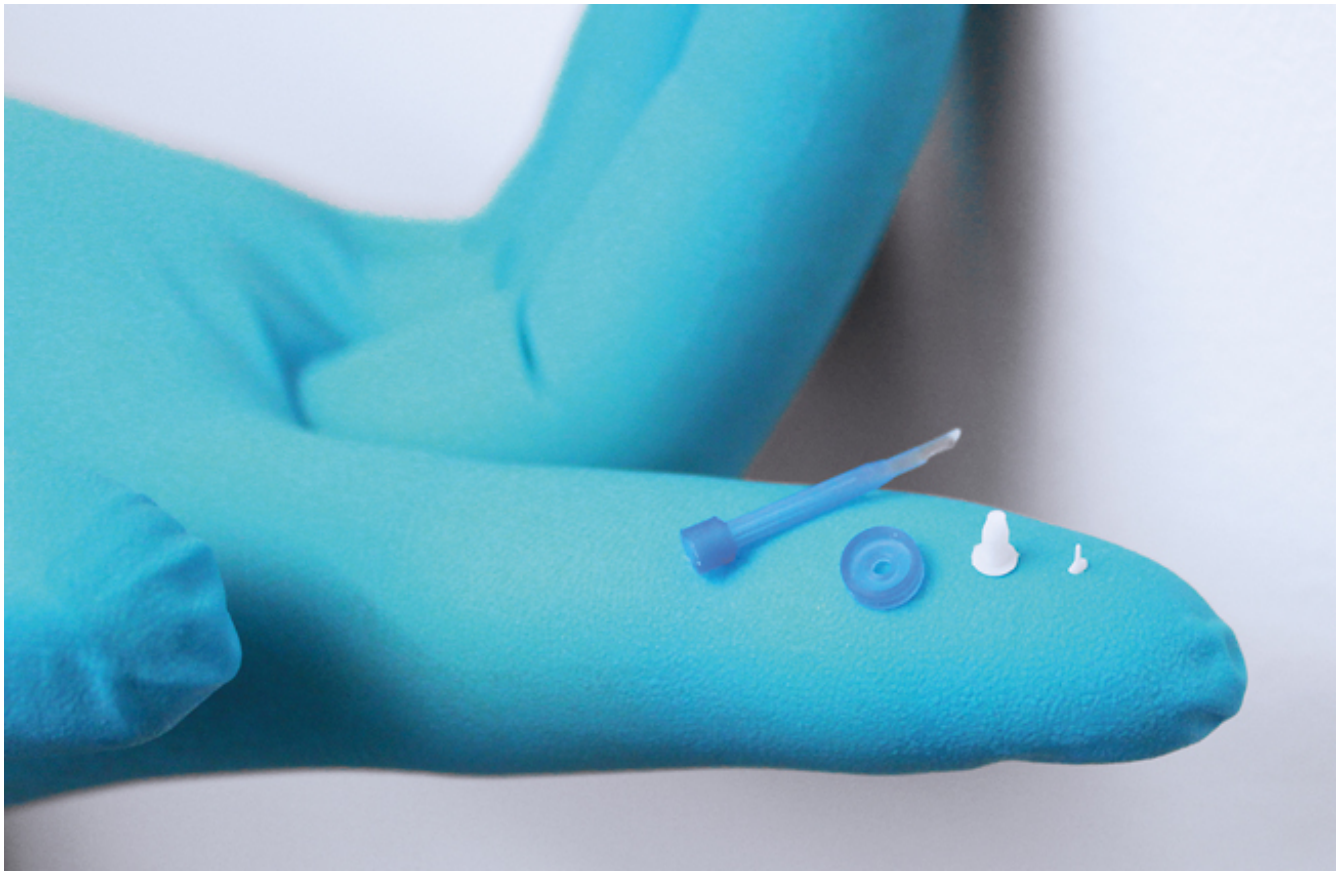
For new multicomponent LSR applications, it is important to involve the component manufacturer as early as possible in the development process, ideally from the concept stage. Some molders, including Trelleborg, take a black box approach in which the designer specifies the component's function and performance requirements, along with the available design window. The molder then develops a proposal that includes the benefits of LSR processing.

The LSR molding process is well-suited for miniature parts. It can produce micro- and nano-sized components below 10 milligrams in weight through needle-point injection technology. One of the smallest pieces manufactured by LSR molding is a septum, the membrane in the cap of a medicine bottle through which a syringe is inserted and withdrawn. This typically weighs just 0.003 grams. At that size, you can hardly pick the part up, and the standard molding burrs are larger than the part itself.

Manufacturing a micro-component such as this requires extreme accuracy in tool construction, control of shot weight and the molding process. After molding, automatic handling of the product is performed by a specially

developed robot gripper arm. The process ensures reliability and accuracy for millions of shots.

The example of the septum shows that automation is critical for medical device component manufacturing. This makes the high-volume production of extremely complex multicomponent LSR geometries possible. Automation can also help ensure cleanliness requirements are met by reducing the risk of contamination during the production process.



These micro-molded silicone components are smaller than a fingertip but vital to medical applications.

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## Quality and Flexibility

Quality is paramount for medical devices. The “holy grail” here is to ensure quality in process rather than to conduct post-production quality checks. Thus, certified quality systems and process controls are built into the production process.

The ability to segregate suspect products effectively with minimal disruption is crucial to minimizing downtime in a high-volume, rapid production process. Ideally, in-line quality checks should be electronically recorded to allow full traceability. Any issue can therefore be isolated to just a small number of components.

Though standards vary, cleanliness in medical device manufacturing is always vital. For some medical devices, production in an “uncontrolled environment” is clean enough. However, due to the nature and positioning of LSR moldings within a medical device, they may need to be manufactured and packed in a fully “controlled” cleanroom of class 100,000, ISO 8 or class 10,000, ISO 7.

Though they’re not generally a sterile environment, cleanrooms control a specified number of particles per cubic meter, at a maximum specified particle size. This includes environmental pollutants, such as dust, airborne microbes, aerosol particles and chemical vapors.

The ambient air in a typical urban environment contains 35 million particles per cubic meter of a diameter of 0.5 micrometers or larger. This in comparison to an ISO Class 7 cleanroom in operation, where only 352,000 particles of size 0.5 micrometers and larger are permissible per cubic meter of space.

In an ISO Class 7 cleanroom, only 352,000 particles of 0.5 micrometers or larger are permitted per 3 square meters of space.

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Current applications for LSR technologies range from drug delivery, such as primary drug packaging or wearable smart drug pump systems, to fluid management, diagnostics and biotechnology.

With so many advantages, it's no surprise that LSR technology is seeing exponential growth. And in this emerging niche market, Trelleborg has been a notable exponent of precision LSR molding and multicomponent technology for medical devices. To wit:

## Case Story: Patient Benefits

When a customer's medical valve was leaking and generating too much friction, a multicomponent LSR solution was the answer.

The control valve was made up of three separate parts: a piston sealed with two silicone O-Rings. Finite Element Analysis (FEA) simulations

found that the plastic piston was misaligned, causing the leak. High friction between mating surfaces and assembled O-Rings was a second concern.

A new valve was developed using multicomponent technology, consisting of a single component with a compressive inner seal that was pressurized on both sides. It also had a deflective outer seal to reduce friction, creating a pressure-energized seal. The new design was subjected to FEA simulations and a Design for Manufacturing (DfM) analysis, including material flow simulation, both to ensure manufacturing feasibility and to prove the intended tool concept.

The new LSR part was a reliable solution to leakage and friction issues. The integration of three individual components into one streamlined the manufacturer's supply chain and production process, increasing the company's product quality and reliability, while also reducing production risk and overall costs.

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