Among Medical Materials, Liquid Silicone Rubber Shines

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The medical material's properties make it a good fit for use in disposables and home-health devices.

Silicon, the basic constituent of silicone, is one of the most common and easily accessible elements on Earth. This availability, combined with the favorable properties of liquid silicone rubber (LSR)—including its ability to be molded into complex shapes and its inert chemical nature—have made it well suited for use in medical devices from the material's earliest development.

A top housing features a silicone vibration dampener.

Recognition of the unique specific properties of LSR is leading to its expanding use as the medical device industry recognizes the value this medical material adds to products. As these qualities are more widely recognized, even wider use of LSR in medical devices is likely, driven by new applications and expanding markets.

Unique LSR Properties

For medical applications, silicone must be tested for biocompatibility and meet the necessary FDA requirements. Medical silicone applications are divided into two classes: restricted and unrestricted. Normally, restricted is referred to as short-term implantable and unrestricted is referred to as long-term implantable. The LSR referred to in this article is medical grade.

LSR is biocompatible and hypoallergenic, resulting in minimal risk of allergic reaction during its use. It's also hygienic, giving bacteria and fungi little chance to grow and spread. These properties make it ideal for use in both short-term and long-term implantable devices.

LSR is flexible, durable, transparent, and ultraviolet- and stain-resistant. Unlike conventional rubber, LSR can withstand extreme temperatures, from –55°C to 200 °C, without changing its properties. Such durability allows for autoclave sterilization of instruments that use LSR to facilitate secure handling.

LSR also offers exceptional compression set properties and can be molded to varying wall thicknesses within the same part. These characteristics, together with the material's durability and flexibility, have led to LSR becoming a critical component of medical devices.

Due primarily to its inert chemistry and virtual immunity to heat damage, LSR has a long shelf and use life. Silicone suppliers recommend that the raw material be used within six months of manufacture, but molded parts incorporating LSR have a virtually unlimited shelf life, though molders generally recommend a maximum of three years. This medical material's durability can extend the life of medical devices that incorporate it, benefitting both manufacturers and end users.

The medical device industry is also showing a preference for LSR over alternative medical materials. Unlike latex rubber, which produces sensitivity in some end users, LSR is hypoallergenic. Unlike polyvinyl chloride (PVC), it does not contain phthalates, which have been found to disrupt the endocrine system and have caused reproductive and neurological damage in laboratory animal tests, used as plasticizers.

One limitation of LSR, however, is cost. Silicone can cost three to five times as much as other raw materials such as TPEs and TPUs, and it can cost twice as much to process due to longer cycle times.

In some applications where cost is a concern, less expensive medical materials such as thermoplastic elastomers (TPEs) or thermoplastic polyurethanes (TPUs) can be used in its place if the properties of LSR (resistance to temperature extremes, compression set, chemical resistance, and inertness) are not required.

Applications for this Medical Material

LSR has been used in a range of medical devices, including seals, plungers, and gaskets in implanted and nonimplanted devices, and as part of medical electronic devices. Specific applications in which manufacturers used LSR include:

- Buffering for lung catheters, where the catheter's leading edge is bonded with soft LSR to prevent tearing of delicate lung tissue as the catheter is inserted.
- Pigtail catheter sealing component.
- Top housing cover with silicone vibration dampener.
- Polycarbonate ablation tube with bondable silicone sealing fins.
- Silicone tubing coupler.
- Silicone sealing cap used for medical device.

Wider applications of LSR are only limited by designers' depth of experience, education, and creativity, and manufacturers' experience and willingness to explore new innovative use of this medical material.

LSR Manufacturability

During manufacturing, LSR can be injection-molded with both bondable and nonbondable properties. Parts fabricated from LSR can be bonded to metal, plastics, glass, ceramics, silicone-glass laminates, or to silicone rubber itself.

A manufacturing advantage of this property is that LSR can be used to eliminate separate components of a device. Using insert molding, LSR O-rings and gaskets, for example, can be molded directly onto the metal or plastic part they will protect, reducing both inventory and assembly costs.

Manufacturers are also demanding the ability to mold LSR directly onto hard plastic substrates to create single components rather than combine separate parts made from the two materials using adhesives in a separate operation. This eliminates the manual process required to join the separate parts and, by creating a single component, reduces the chance of leakage due to a failed seal. It also often offers manufacturers the opportunity to design a more visually appealing and functional device. LSR can employ color for visual appeal and can also be molded with different durometers (hardness).

Given LSR's versatility as a manufacturing material, molding tooling can be quickly adapted to each project to control manufacturing costs. Standardized off-the-shelf cold decks and tooling components are available from a number of suppliers.

Industry Trends and Future Outlook

LSR can be molded using both horizontal and vertical press applications, ideally within a Class 100,000 clean room. Thanks to the the advantages LSR offers in both manufacturing and end use, consistent growth is anticipated in years to come. U.S. demand for silicones is forecast to climb 5.6 percent annually, to $4.1 billion in 2016, according to the Fredonia Group.

One trend that has already surfaced is closer collaboration between product design and development teams, and LSR injection molders. Manufacturers that have learned about the benefits of LSR recognize that taking full advantage of its capabilities requires working closely with molders during the design phase of a new device. A close manufacturer/molder relationship will help ensure products are designed for optimal manufacturability, thus minimizing rework and helping speed time to market.

The growing demand for LSR from manufacturers means injection molders must be capable of the extremely precise LSR molding that many medical device projects require. For molders with minimal experience with LSR, that may require adding equipment and a cleanroom in which to produce precision molding, as well as ensuring operators are thoroughly trained. Manufacturers must perform their due diligence in evaluating a molder, as they would in evaluating any supplier. It is important to evaluate the molder's previous experience, expertise, and facility, including conducting a plant tour to evaluate technology and capacity.

The Future of LSR as a Medical Material

As demand for home health and disposable devices grows, the demand for LSR's use in these products will also increase. The aging U.S. population, for example, will require urological devices such as catheters, and demand for personal self-diagnostic devices is also on the rise.

These and other outpatient healthcare settings can benefit from LSR’s hygienic and hypoallergenic qualities, and ease of cleaning and sterilization.

LSR is being increasingly used as the seal on polycarbonate CPAP masks used to treat sleep apnea. The material creates a tight seal, is comfortable on the user’s face, can be easily cleaned and even sterilized, and resists the growth of microorganisms. Because LSR is biocompatible, it does not react with skin tissue. The end product can also be made clear, so care providers can see the user’s face to check for signs of anxiety or discomfort.

LSR is also playing an increasing role in the development of needle-free valves to help reduce the number of needles required in treatment settings. An LSR check valve in a polycarbonate housing placed in an IV line, for example, allows the administration of medications directly, without the use of a hypodermic needle, while still enabling uncontaminated administration.

The growing trend toward miniaturization of devices will require extremely precise micromolding from injection molders, but it will also create greater demand for LSR because its properties are not affected by the size of the molded part. Another growing area of development is the use of LSR in combination products, which combine silicone rubber and active ingredients.

Conclusion

The combination of increasing demand, refinement in molding techniques to apply LSR in a wider range of devices, and an increasing number of molders skilled in working with LSR will lead to an expanded use of LSR in medical devices intended for use in both clinical and home settings. This medical material’s availability, plus the expanding interest in and development of new applications, promises a bright future for LSR.

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