Understanding Silicone Molding for Implantable Medical Devices

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Medical device manufacturers rely on the biocompatibility of silicone for a wide range of devices that come in contact with the body, ranging from long-term orthopedic surgical implants and cardiovascular devices to one-time-use devices.

This article provides guidance to medical device manufacturers on the types of silicone required for different classes of medical devices, the molding processes employed, and quality considerations.

Silicone in Class II and III Medical Devices

Although market growth in the U.S. has been slowing, demand for implantable and other medical devices is growing worldwide. According to The Global Market for Medical Devices, 7th Edition, from Kalorama Information, the world market for medical devices reached $381 billion in 2015. The market research firm cited the impact of an aging population in the U.S. and abroad on growing demand for devices and particular strength in revenues from cardiovascular, respiratory, patient monitoring, wound care imaging and orthopedics, many of which incorporate silicone molded parts.

We estimate that implantable silicone represents only a fraction of the total amount of medical-grade silicone used in medical devices. Due to the amount of testing and the level of purity required, implantable silicone can cost 10 to 15 times as much as standard medical-grade silicone, but implantable silicone is critical for certain devices, especially those categorized as Class III.

Medical Device Classes

Class III – Long-Term Implantable Devices

Devices that save lives or prevent death, such as defibrillators, heart pumps, and surgical reconstructive components

- 30 days to indefinite use
- Implantable silicone required

Class II - Short-Term Implantable Devices

Temporary implants and surgical instruments that come in contact with skin, bodily fluids, bone and tissue, such as over-molded surgical blades, electrosurgical devices, catheters, and diagnostic guide wires

- 29 days or less
- Medical-grade silicone required

Class II – Disposables
Devices designed for single use but which come in contact with skin or body tissues, such as suture sleeves, disposable components for medical devices, optically clear ophthalmic lenses for use during eye surgery, and orthopedic devices

- One-time use
- Medical-grade silicone required

**Advantages of Silicone**

**Due to its unique properties, silicone is frequently used in medical devices to:**

- Provide insulation from electrical current
- Protect sensitive components of an implantable device, such as pacemaker leads, from corrosive bodily fluids
- Offer flexibility and long-term durability for implantable devices that must conform to the body, such as catheters and shunts

Also key to silicone’s functionality is its ability to operate in temperatures ranging from -55 °C to +230 °C, which also allows it to stand up to steam sterilization (autoclaving).

**Implantable Silicone Molding Processes**

Silicone molding is used to produce precision components for both implantable and disposable medical devices.

Silicone may be used to:

- mold a complete implantable part
- mold a component of an implantable device, or
- overmold a part of the device or the exterior of the device

Molding engineers will work with the OEM’s engineers to determine the optimal molding process, tool design, and manufacturing controls for the application, in keeping with the OEM’s material preferences and plans for manufacturing and assembly, as well as expected production volume.

The main molding processes are:

- Liquid injection molding
- Transfer molding
- Compression molding
Types of Silicone Materials and Additives in Implantable Devices

Silicone rubber is formulated in liquid or gum stock and may be combined with additives specific to the function of the implantable device. The molding firm’s engineers and chemists will advise on the specific formulation of silicone and any additives that may be required.

Types of Silicone

The type of silicone used depends on the type of component being manufactured and the best molding process for the part.

The primary types of silicone used in implantable devices are:

- **Liquid silicone rubber (LSR):** Liquid silicone rubber is used in liquid injection molding to create parts of high strength and flexibility. The cure time is considerably less than gum stock silicone, which reduces production costs.

- **High Consistency Silicone Rubber (HCR or gum stock):** HCR or gum stock silicone is used in transfer molding to achieve specifications such as complex shapes or thin walls.

Additives

Additives may be mixed in by either silicone suppliers or by silicone molding firms, including:

- Pigments, including custom Pantone colors
- Desiccants to address issues with moisture
- Antimicrobial agents
- Radiopaque tracers such as barium sulfate for detection by x-rays

Transparent silicone is also available, which is fabricated for high-refractive index and optically clear applications such as implantable lenses.

Quality Considerations

**Batch Consistency**

In evaluating the additives to silicone used in implantable components, OEMs will want to ensure that the additive is properly measured and weighed as it is added to ensure uniform mixing. Molding firms should employ advanced technology in their silicone mixing and molding operations, including computer-operated and controlled production, custom automated assembly, and automated measuring machinery to ensure homogeneity, quality, and batch-to-batch consistency and tracing.
Because of the proven quality of silicone manufactured in the U.S., medical device OEMs and their suppliers will often specify U.S. medical-grade silicone, even for overseas production.

**Cleanroom Manufacturing of Silicone Molded Parts to ISO Standards**

Manufacturing silicone-molded components to meet cleanliness standards is a critical process that begins with the materials themselves and ends with the packaging. In production and handling, cleanrooms are essential to avoiding contamination.

Silicone molding cleanrooms are designed and operated to meet ISO standard 14644, which classifies cleanrooms according to measurements of particulates of different sizes, from 0.1 micron to 5 microns, per cubic foot of air. Class III implant-grade and Class II short-term implantable and disposable medical devices typically require at least a Class 7 (10,000) cleanroom and some as stringent as Class 5 (100).

Keeping a cleanroom manufacturing environment to ISO standards requires both good design and technology and good operating practices. Cleanrooms are designed to control contaminants, which require the right room configuration and a combination of airflow and HEPA filtration to capture airborne particulates.

For more details on the importance of cleanroom manufacturing for implantable devices, please refer to our blog article, "How Silicone Molding Cleanrooms Factor into Patient Safety."

**Raw Material Handling**

In cleanroom production, one of the most important steps is to avoid contaminants in the raw materials themselves. Although medical-grade silicone is a proven material in medical device manufacturing, the handling and preparation of silicone and other materials prior to molding must be done in the cleanest section of the cleanroom.

**Cleaning and Molding**

Manufacturing processes, by their very nature, generate particulates. Therefore, each component must be cleaned after the molding process is complete, which also is conducted in a high-level cleanroom environment.

It should be noted that cleaning is not the same as sterilization. Silicone molders will wash the component before packaging and shipping. OEMs typically sterilize the component themselves and then test whether the component meets their specified contamination levels. The cleaner the silicone molded part shipped from the molder, the more likely that sterilization will be effective and the device will meet FDA and international standards.

**OEMs can benefit by consulting with engineers at silicone molding firms early on in the product development process for implantable devices to get their recommendations on the best silicone material and molding process for the application.**