

The Growth of Biocompatible Silicone in Implantable Medical Devices

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After more than 50 years of using silicone rubber in medical implants, the number of applications for the material's use in both short- and long-term implantable medical devices just keeps growing. With its long track record of biocompatibility, medical-grade silicone is being used in a range of implantable devices with critical functions, such as defibrillators, heart pumps and surgical reconstructive components.

Transparency Market Research estimates that sales by U.S. manufacturers in the global implantable medical devices market will reach \$73.9 billion by 2018, for a compound annual growth rate of 8% from 2012 to 2019.

The firm studied U.S. manufacturers of implantable devices in the following categories.

- Orthopedic implants
 - Reconstructive joint replacement
 - Spinal implants
- Cardiovascular implants
- Dental implants
- Intraocular lens
- Breast implants
- Other implants

"Amongst these, on the basis of market value and growth opportunity, orthopedic implants will lead the market in the forecast horizon." Transparency Market Research reports.

Silicone's history of biocompatibility in implants

Silicone's biocompatibility and stability when implanted within the human body for short-term or long-term applications have made it a highly popular material for implantable medical devices.

Seventy years of silicone implants

The first use of silicone as a material implanted in the human body for medical treatment is said to date back to 1946, when surgeon Dr. Frank Lahey used silicone for bile duct repair. Since the early success with experiments with such uses as tubing for urethra replacements and hydrocephalus shunts, silicone has been employed in a wide variety of medical applications and implantable devices, such as orthopedic joint implants, pacemakers and neurostimulators.

Controversy over breast implants

In the 1990s, silicone breast implants were blamed for causing medical issues and lawsuits were filed against silicone suppliers, which led the United States Food and Drug Administration (FDA) to halt the use of silicone
silicone's pioneers, Dow Corning. However, after numerous clinical studies failed to detect a causal link between silicone and secondary health issues, the use of implantable silicone quickly made a comeback.

Demand for silicone growing

According to market researchers The Freedonia Group, "U.S. demand for biocompatible materials is forecast
and cost advantages in a broad range of applications, synthetic polymers will remain the dominant-selling product group." In its report, Biocompatible Materials, Freedonia forecasts, "Engineered resins – especially thermoplastic elastomer, silicone, sulfone, and polyketone materials – will command the fastest revenue and volume growth based on quality and safety advantages in high value-added catheters and implants."

Biocompatibility testing for materials and the end device

For long-term implantable devices, the U.S. Food and Drug Administration requires that the silicone
be tested
the human body for more than 29 days. In practice, implantable silicone may last inside the human body for a lifetime.

Only a handful of suppliers offer long-term implantable silicone. Medical grade silicones are manufactured under strict quality standards that follow ISO 9001 and are either directly or indirectly regulated by the FDA. What differentiates medical-grade silicone for long-term implants, short-term implants or skin contact applications are the differences in the level of testing and support.

In using silicone in implantable devices, sourcing the silicone is only the first step in ensuring its purity. Medical device manufacturers need to understand how the silicone is handled and processed in the production of molded parts to ensure its quality.

Changes to FDA standards:

In 2013, the FDA issued draft guidance on changes to testing standards in 'Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.'

According to an article in *MDDI Medical Device and Diagnostic Industry News*, author Thor Rollins states, "The new draft guidance document is the most expansive presentation of standards affecting the medical device industry in 18 years." He highlights the guidance that the FDA does not approve individual materials but only final devices. "Often, medical device manufacturers test raw materials for biocompatibility, assuming that they can apply the results directly to the final device. While this approach can be successful, manufacturers must also evaluate the impact of the production process on the materials. For example, how do mold-release agents or sterilization methods such as gamma radiation affect the biocompatibility of the final device? Just because a raw material is biocompatible does not necessarily mean that the device itself will also be biocompatible."

In short, medical device manufacturers are still required to test the device as a whole to ensure biocompatibility.

Focusing on patient safety

The attention given to the science and technology of implantable silicone stems from the imperative of the safety of the patient when in short- or long-term contact with an implantable device.

In a forum between representatives of the FDA and industry members of the Association for the Advancement of Medical Instrumentation, panelists addressed the issues of biocompatibility, risk management and sterility. Their report stated, "Edward Reverdy, director of corporate toxicology and biocompatibility services at Boston Scientific Corporation, began with the key question that biocompatibility evaluations must answer: 'Are the device materials interacting with a patient going to work safely, as intended and as designed, without causing risk or hazard?' Patient safety must be the overarching consideration that drives biocompatibility evaluations."

In "Medical Applications of Silicones" from the book *Biomaterials Science*, the authors, who are Dow Corning researchers, write, "Silicone's chemical stability and elastic nature are beneficial for many applications involving long-term implantation." Their report concludes, "A variety of silicone materials have been prepared, many possessing excellent properties including chemical and thermal stability, low surface tension, hydrophobicity, and gas permeability. These characteristics were the origin of silicone's use in the medical field and are key to the materials' reported biocompatibility and bi durability. Since the 1960s silicones have enjoyed expanded medical application and today are one of the most thoroughly tested and important biomaterials."