# Designing silicones for medical device applications: an overview

Brian Reilly, Marketing and Sales Director, Medical Implants
Danielle Peak, Technical Writer, NuSil Technology LLC

Since the 1950s, silicone's chemical stability, physical strengths, and biocompatibility have proven it a valuable candidate for medical device applications. Silicone can be found in cochlear implants, joint orthopedics, birth control devices, and pacemakers—to name a few common uses.

WHITE PAPER

Since the 1950s, silicone's chemical stability, physical strengths, and biocompatibility have proven it a valuable candidate for medical device applications. Silicone can be found in cochlear implants, joint orthopedics, birth control devices, and pacemakers—to name a few common uses. Considering the expansiveness of the healthcare field, perhaps the most advantageous feature of silicone is that it can be formulated to achieve specific performance, aesthetic, or therapeutic properties not inherently offered. Silicone is so versatile that its properties can vary greatly and even contradict each other, from one silicone to the next. For instance, basic polydimethylsiloxane (PDMS) silicone is inherently insulative at approximately 1015 Ω·cm, but with the addition of certain fillers a silicone can be made to conduct heat, electricity, or both.

In general, silicone is known to possess temperature stability potentially ranging from -115°C to 260°C and to exhibit low shrinkage, low outgassing, and low shear stress. Many properties of silicone can be enhanced or diminished via careful and deliberate design and processing steps. Depending on an application's requirements, a silicone might be tailored for specific needs from polymer alterations and/or filler incorporation. Formulating silicones often involves trial and error because imparting characteristics to a silicone can affect other properties of the system. A thorough understanding of the requirements of a particular application becomes paramount in order to develop the optimal silicone to meet these needs.

## SILICONE CHEMISTRY

Comprising the siloxane polymer backbone of a silicone are repeating helical silicon-oxygen bonds (Si-O), with substituent, or R′, groups attached to the open valences of the silicon atom. Compared to epoxies and other organic-based rubbers with Carbon-Carbon (C-C) bonds, the Si-O bonds of silicones provide larger bond angles1. These bond angles yield large amounts of free volume, leaving space for design or, more specifically, for managing the amount and type of substituent group and filler that go into a silicone system. This ability for formulation flexibility is largely what enables silicone to be so versatile. More specifically, varying the substituent groups on the polymer chain can help optimize silicones for very specific needs. These components interact with the Si-O-Si units to cause the resulting silicone material to exhibit certain properties. In this way, silicone is available in a variety of forms for an even more expansive variety of uses.

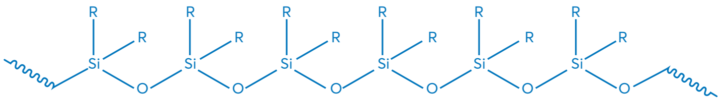

**FIGURE 1:** Basic structure of polysiloxane chain.

Typical substituent groups include methyl, phenyl and trifluoropropyl. The most common type of silicone is comprised of polydimethylsiloxane polymers (PDMS) from dimethyl groups, which facilitate strong physical properties such as tensile, tear strength, and elongation. Chemically, these are the most accommodating to incorporation of fillers into the silicone formulation. Trifluoropropyl (fluoro) or phenyl groups are often added in varying degrees to form trifluoropropyl methyl polymers or diphenyldimethylpolysiloxane polymers, respectively. Phenyl groups can manipulate the refractive index (RI) of a silicone system, as well as its glass transition temperature (Tg) and permeability to moisture and gases. Fluoro-containing silicone products, also known as fluorosilicones, are often used for applications that require hydrocarbon resistance. Compared to dimethyl silicones, fluorosilicones generally exhibit lower elastomeric properties—a tradeoff for their resistance to fuel and organic solids.

| R′ Group | Chemical and/or physical effects |
|---|---|
| Methyl | Standard Refractive Index = 1.40 - Standard<br>polymer Used industrially since 1950's |
| Trifluoropropyl | Refractive Index < 1.40 Hydrocarbon solvent resistance |
| Phenyl | "Refractive Index > 1.40<br>Increased temperature stability, reduces moisture permeability" |

**TABLE I:** Common substituent (R′) groups and contributions.

### Silicone Material Types

Based on composition, uncured silicone systems can possess different characteristics. From fluids and greases to clay-like rubbers, the broad range of material compositions makes silicone a viable option for an endless number of applications. Gels and elastomers are among the most common silicone types in the healthcare field.

Silicone gels are made of reactive silicone polymers and reactive silicone cross-linkers in a two-part system that yields little to no elastomeric strength. When cured, these low-viscosity materials are designed to have a soft, compliant feel which, combined with silicone's low modulus, allows them to mimic human tissue. They range from very soft for prosthetic applications, to very tacky (sticky) for topical and transdermal wound care applications. Encapsulation of electronics such as LEDs and sensors is also a common application for using silicone gels.

Silicone elastomers are similar in composition to gels but exhibit increased physical and mechanical properties due to high levels of reinforcing fillers and longer polymer chains. For instance, elastomers have higher viscosities than gels and fluids. High consistency rubbers (HCRs) are ideal for extruded tubing because their silica-reinforced, high molecular weight polymers enable them to maintain a shape when uncured; low consistency elastomers (LCEs), by contrast, are flowable and more ideal for coatings, encapsulants, and molded parts requiring optical clarity. Compared to HCRs and liquid silicone rubbers (LSRs), the high clarity and low viscosity associated with LCEs are primarily attributed to their unique base formulations, which may incorporate phenyl. Of intermediate viscosity, LSRs are used to mold high precision parts such as gaskets, valves, O-rings, and seals. HCRs, LCEs, and LSRs are moldable materials that can be cast orinjected into molds of various configurations.

Low-viscosity elastomer systems that incorporate silicone-based adhesion promoters are used as adhesives. These are often dispersed in solvent systems for use in spraying or dipping applications which call for a thin protective barrier against the surrounding environment. For example, silicone acts as a protective barrier in the case of wound care dressings, external prosthetic devices, and contact lenses. Often in these applications, the silicone simultaneously needs to be permeable in order to act as a membrane through which water can be transmitted to surrounding tissue. On the other hand, devices such as pacemakers, cochlear implants or other devices that rely on electronics or battery require silicone with significantly decreased permeability to moisture in order to avoid corrosion and delamination.

Requirements for processing and end use determine the polymeric design of the silicone system to yield the desired physical and mechanical properties. Additionally, the combination of these needs will dictate what filler should be added and how much of it is suitable to produce the desired silicone profile.

## Filled Silicone Materials

Beyond alteration of substituent groups on the polymer chain, fillers are common additions to silicone formulations for the properties they impart, such as conductivity and radio opacity. Generally speaking, fillers are distinguished between functional and reinforcing. Reinforcing fillers are the most common fillers added to a silicone elastomeric system. Silica is a frequently used reinforcing filler used to improve mechanical properties related to strength and toughness such as lap shear, elongation, modulus, and tear2. Primarily, reinforcement fillers are used to improve the mechanical properties of silicone and to increase their ability to survive in harsh environments. Functional fillers are those which, rather than enhance existing properties, actually impart new ones to the silicone. Various fillers and the properties they impart are listed in Table II.

| Fillers | Properties |
|---|---|
| Boron Nitride, Aluminum Oxide, Silver | Thermally Conductive |
| Silver, Gold, Carbon Black | Electrically Conductive |
| Iron Oxide, ZnO, TiO2 | Thermal Stability |
| Microballoons | Reduce Density |
| Barium Sulfate (BaSO4) | Radio Opacity, Blocks X-Rays |
| Pigments, Dyes | Coloration |
| Ground Quartz, Diatomaceous Earth, Calcium Carbonate | Increase Viscosity and Hardness |
| Precipitated Silica, Fumed Silica | Enhance Mechanical and Rheological Properties |

**TABLE II:** Silicone filler type and effects.

Although the incorporation of fillers adds desired benefits, it should also be understood that the physical and mechanical properties of the silicone material can be compromised if the filler is not added properly or in the right amount. As a general rule, the changes presented in Figure 2 can often be expected in the physical properties of any given material with the addition of filler. For example, as the filler loading level increases, so does the silicone material's viscosity. An inverse relationship is often seen, however, between increased loading levels of functional fillers and the silicone's mechanical properties. However, the changes shown in Figure 2 are merely typical and do not describe all cases of filler incorporation, the effects of which are dependent upon filler loading level and the interaction between the polymer and filler.

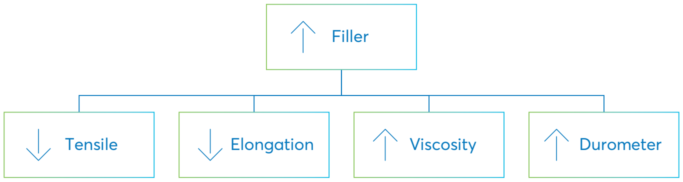

**FIGURE 2:** Typical filler effects on tensile, elongation, viscosity and durometer.

With any filler, functional or reinforcing, proper mixing is vital to ensure a homogeneous distribution. Uniform mixing is dependent on the shearing capacity of the mixing equipment, the length of the shearing time, the viscosity of the polymer, and the added filler's particle size and density. Inadequate mixing causes clumping which can lead to accelerated filler settling and inconsistent, unreliable performance. Even the shape and size of the filler particles can make a difference for better or worse, because point-to-point contact of filler particles to each other and the polymer is necessary to maintain effect3. At ambient conditions, achieving point-to-point contact is more dependent on the concentration of the filler than anything else.

## BARIUM SULFATE STUDY

A recent study by NuSil Technology evaluated the effects of barium sulfate (BaSO4) on the durometer and tensile strength of an implant-grade silicone elastomer, NuSil's MED-4765. MED-4765 is a firm, non-tacky silicone elastomer with high tear strength used for molding or extruding silicone parts such as feeding tubes and prosthetics. Barium sulfate, used to obstruct X-rays to maintain the performance and mechanical integrity of silicone parts and devices, was incorporated into the formulated silicone as a masterbatch. A masterbatch is a highly filled or concentrated component that is typically compounded into a functional polymer to ensure compatibility with the silicone system to be utilized. In this study, a 75% BaSO4 masterbatch was added to MED-4765 to total 25% of the silicone product.

The same lot of MED-4765 was used for all testing. For durometer assessment, values for each percent loading of masterbatch are a mean of 5 replicates. For tensile strength assessment, values are a mean of 3 replicates per percent loading.

Figure 3 Results. From 0-25% loading of BaSO4, the durometer of MED-4765 decreased by a value of 7. This is a reduction of approximately 10%, which may or not be of negative significance depending on application requirements.

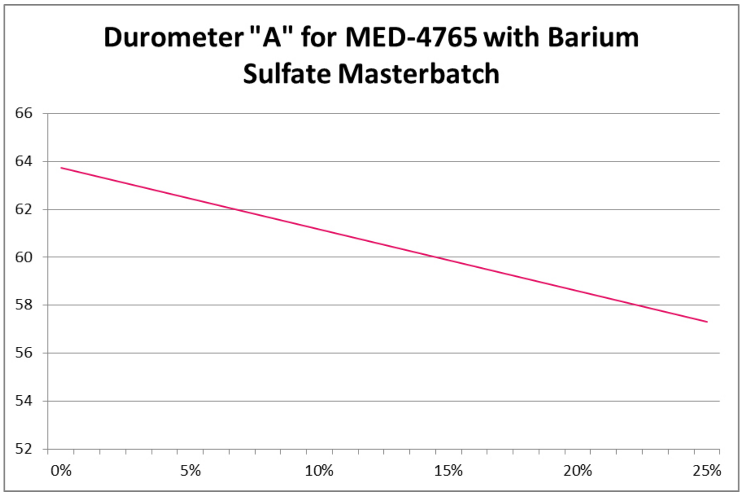

**FIGURE 3:** Type A durometer values for MED-4765 at 0-25% loading levels of BaSO4 masterbatch.

Figure 4 Results. From approximately 1300 psi with no barium sulfate masterbatch to about 1150 psi at 25% loading level BaSO4, the tensile strength underwent a slight decrease that is not likely to be of any consequence to the silicone's performance in an application requiring the pre-filler tensile strength

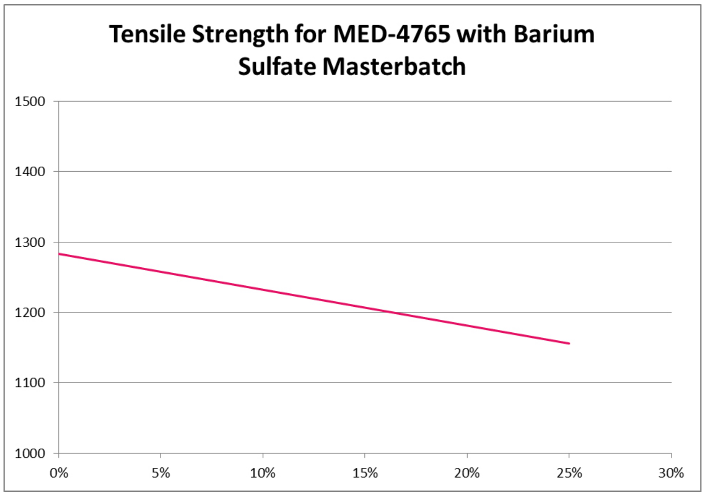

**FIGURE 4:** Tensile strength values (in psi) for MED-4765 at 0-25% loading levels of BaSO4 masterbatch.

## CONCLUSIONS

Based on the results of this study, projection for changes in durometer and tensile strength at loading levels of BaSO4 greater than 25% suggests that this filler could significantly alter these and other properties of the silicone into which it is incorporated.

Whether the effects are adverse or positive would depend upon the requirements of the application at hand. Like achieving the needed level of radio opacity, retention or attainment of the needed physical and mechanical integrity of the silicone is also essential to performance success.

It should be noted that pairing BaSO4 with a different silicone formulation than Med-4765 may impose very different changes to the durometer and tensile strength than what is seen here. Different effects may also be induced with the introduction of a second filler to MED-4765, or with other fillers in the absence of barium sulfate. Although some assay and analysis may be required to find the best silicone formulation for a given use, the versatility of silicone allows for both inherent and fabricated properties to coexist at ideal levels for a prodigious number of medical applications.

## References

1. Mark, James E, “Some Interesting Things about Polysiloxanes”, Accounts of Chemical Research, Volume 37 No. 12, 946-953, 2004.
2. Taikum, Orawan. Friehmelt, Rainer. Scholz, Mario. Degussa, Evonik, “The Last 100 Years of Fumed Silica in Rubber Reinforcement”, Rubber World, 2010.
3. Velderrain, Michelle. “Modifiable Silicones for Harsh Environments”, Presented at International Microelectronics Assembly and Packaging Society (IMAPS) in Long Beach, California, 2011.