



THE SILICONE... MAKES ALL THE DIFFERENCE

MEDICAL AND PHARMACEUTICAL APPLICATIONS BENEFIT FROM
PLATINUM-CURED SILICONE COMBINED WITH ADVANCED PROCESSING EXPERTISE

Due to its beneficial attributes, silicone is utilized today in countless medical and pharmaceutical applications. It is the preferred material for sealing complex systems as well as for peristaltic and pharmaceutical tubing. Silicone is available in a wide range of durometers, from super soft (000) to relatively hard (90 Shore A), and can withstand a range of temperatures. A number of silicones are also biocompatible – meaning they are safe to use in healthcare products, and specific formulations can be implanted in the human body. As a result, implantable silicones can be used in applications such as port systems, cochlear implants, and gastric bands.

The silicones readily available in today's market differ not only in their level of approval for medical and pharmaceutical applications, but also in their cross-linking mechanism. There is a clear distinction between platinum-cured and peroxide-cured silicones. Materials

that use a peroxide cross-linking system utilize free radicals in the reaction. As a result peroxide-cured silicones dissociate with heat in order to start the cross-link reaction. However, the decomposition by-product does not completely dissolve but remains permanently within the manufacturing equipment (extruder or molding machine) and within the final product. An equation illustrating this point is: $A+B = C+D$, where C is the cross-linked silicone rubber and D is the by-product. This results in a significant odor and the possibility of leaching of the peroxide by-product from the material. This risk of peroxide migrating to the product surface is specifically of concern in medical and pharmaceutical applications.

“Our experience with clients in the pharmaceutical industry indicates that peroxide by-products can reach the drug during processing or filling of liquid preparations,” notes Sven Rosenbeiger, General Manager, Freudenberg

Medical Europe. “When analyzing peroxide in silicone products, on behalf of clients, through the detection of 2,4-Di-chlorobenzoic acid (DCBA) and their derivatives, measurable concentrations are found at the control limits.” Mr. Rosenbeiger further adds that quantifying peroxide and oligo-siloxanes (an indication of correct processing) is done via thermal desorption and subsequent analysis by gas chromatography and mass spectroscopy. The analysis methodology is tailored to each customer’s individual project needs and further developed based on the customer’s specifications and allowable limits.

In the early days of silicone development, there was no alternative available on the market. However, throughout the last decade, a different set of silicones have been developed — platinum-cured silicones. Modern silicones use platinum as a catalyst with a polyaddition reaction of silanes. The silanes are fully integrated into the silicone, without decomposition or by-product. This results in platinum-cured silicone tubing, commonly used for medical and pharmaceutical applications, that is non-hazardous. Platinum-cured silicones do not release any odor nor are there instances where a by-product could be released. In short: A+B = C. From the material properties perspective, platinum-cured silicones and peroxide-cured silicones are equal. They both provide the same superior properties in terms of strength, processability, and media resistance with regard to fluids.

Another difference, no less significant, between these two types of silicones is their mechanical properties after radiant exposure. Silicone products, especially tubing used in the pharmaceutical industry, are often subject to intense radiation via gamma or E-Beam as repeated sterilization is required to make products ready for use. “Studies indicate that gamma or E-Beam sterilization treatments will affect the mechanical properties of peroxide cross-linked silicone, attributes such as hardness, elasticity or tensile strength result in significant deterioration,” explains Lars Gerding, Technology Director at Freudenberg Medical. “However, for platinum-cured silicone, this deterioration of mechanical properties is not distinctive.”

Success with silicone is not just a matter of material knowledge, but also of advanced processing expertise. The behavior of the material cannot be compared with the processing behavior of thermoplastics for example. This limits the choice of manufacturers for high-precision silicone components to those processors specialized in medical applications. Freudenberg Medical has been exclusively processing platinum-cured silicones for medical and pharmaceutical applications for over 10 years. “Cross contamination is not an issue with our products, only products free of decomposition and other by-products are processed within our cleanrooms, explains Dr. Mark Ostwald, VP and General Manager Global Business Unit Silicones at Freudenberg Medical. “At Freudenberg Medical operations in the United States, Europe, and Asia we process platinum-cured silicone tubing and precision molded components made exclusively with medical, implantable, or pharmaceutical-grade silicone.”

In addition to silicones, Freudenberg Medical offers medical-grade thermoplastics and implantable PEEK as well as a wide range of supplemental services such as coating technology and treatments for precision molded parts and combination products. Our services cover the entire value chain, from processing of platinum-cured silicones to customer-specific value-added solutions for medical, pharmaceutical, and biotechnology applications.

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