

PLATINUM-CURED SILICONES OPEN MEDICAL MARKETS TO GASKET FABRICATORS

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Many gasket fabricators want to enter the medical marketplace, or increase their sales of silicone gaskets to makers of medical devices and equipment. Market research can be challenging, however, and many companies don't have cleanroom equipment or in-depth regulatory expertise. Yet by focusing on the right silicone elastomers, gasket fabricators can uncover new business opportunities.

Platinum-cured silicones are ultra-clean elastomers that can meet FDA CFR 177.2600, USP Class VI, and RoHS requirements. They come in a range of durometers and custom colors to match medical device and equipment designs. Importantly, platinum-cured silicones support cost-effective gasket fabrication through die cutting, water jet cutting, molding, extrusion, and other gasket fabrication methods.

Advantages of Platinum Curing

Silicones are formed into solids by curing or cross-linking. In medical applications, the most common curing systems use either peroxide or platinum. The peroxide system requires post-curing to remove by-products such as volatile organic acids. The platinum curing system does not. That's not where the differences end, however.

With peroxide curing, any by-products that remain after curing represent potential extractables – chemicals that can be extracted by heat, pressure, surface exposure, or multiple sterilization cycles. To maintain biocompatibility and avoid contamination, extractables cannot exceed limits established by regulatory agencies like the U.S. Food and Drug Administration (FDA) under FDA CFR 177.2600.

Non-government organizations such as the United States Pharmacopeia (USP) also define allowable levels of extractables. In order for a silicone to meet USP Class VI standards, specimens must exhibit a very low level of toxicity. The European Union's Restriction of Hazardous Substances (RoHS) directive also establishes limits for extractables in products such as medical gaskets.

Compared to peroxide systems, platinum-cured silicones have very low levels of extractables. Platinum curing also offers greater control over cure rates for medical silicones with a more consistent appearance. Additional advantages of platinum-curing include low shrinkage and high tear strength. Platinum-cured silicones also support the use of adhesives and resist water, high-temperatures, and sterilization.

Platinum-Cured Silicones for Gasket Fabrication

Platinum-cured silicones are ideal for prosthetic and orthotic devices, skin-safe appliances, and medical tubing. They're also used in silicone parts such as the pads that attach to medical monitoring and patient care devices. Flat platinum-cured gaskets support the cutting of slits that hold tubes or valves in medical equipment. Washer-like gaskets are used in the handles of medical devices in ambulances.

Platinum-cured silicones are available in various form factors and durometers. For example, SSP-2390 Series silicones from Specialty Silicone Products (SSP) are available as continuous rolls from .005 to .125 inches thick. These ultra-clean silicones are also supplied as compression-molded sheets and ready-to-mold compounds. Available durometers include 10, 20, 30, 40, 50, 60, 70, and 80 (Shore A).

SSP's platinum-cured silicones have low levels of extractables and meet FDA CFR 177.2600, USP Class VI, and RoHS requirements. These ultra-clean elastomers are normally translucent, but support custom color matching to meet your requirements. For more information about platinum-cured silicones for gasket fabrication, contact Specialty Silicone Products (SSP).