Medical-grade silicone lubricants for medical devices

Key factors for selecting an appropriate lubricious coating for your application

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WHITE PAPER

Medical device designers must account for the various types of friction encountered during device use. Different insertion, drag and break-loose forces are generated in medical devices such as needles, syringes, trocars, cannulae, guidewires, catheters and valves. Biocompatible silicone lubricants are commonly used to reduce friction within device components or against human tissue. Key factors—such as the lubricant's viscosity and surface interactions—must be considered when selecting the appropriate silicone formulation. What other key factors determine whether a given medical lubricant will be successful for a medical device manufacturer's process and for the end-use application? This white paper provides an overview of relevant considerations when selecting medical-grade silicone lubricants, first moving through lubricant properties and device substrates, then to criteria in purity and customization.

1. CONSIDERING GENERAL MEDICAL SILICONE LUBRICANT USES AND PROPERTIES

Before selecting a silicone lubricant, it's useful to understand how different formulations interact with a substrate in the manufacturing process as well as their overall performance benefits in an application.

Traditional lubricants

- **Silicone fluid / Silicone oil lubricant:** The most commonly used medical-grade lubricants are silicone fluids, or silicone oils, which have little interactivity with the device substrate or surface. They can also be easily removed or wiped from the substrate. Silicone fluids are available in a wide range of viscosities (from water-like low-viscosity silicone oil, to thicker than honey) and chemical makeup, offering lubrication options for a variety of substrates. This type of lubricant is compatible with most commonly used sterilization techniques.
- **Silicone grease:** Providing a less mobile, more stationary form of lubrication, silicone greases are nonflowing, thixotropic formulations that exhibit little to no migration. Consequently, silicone greases offer longer lasting lubrication at specific locations and provide a clean seal between parts under vacuum.
- **Silicone dispersion:** By blending the silicone lubricant with solvents, silicone dispersions provide a thinner, more uniform layer of lubrication that can evenly cover the whole device. Varying the silicone base properties and/or the viscosity of the final dispersion can accommodate the method of application, such as spraying, wiping or dipping, commonly used to siliconize needles, for example.

Integral lubrication technologies

- **Self-lubricating silicone elastomers:** Self-lubricating medical-grade liquid silicone rubbers (LSRs) enable manufacturers to avoid additional processing steps of applying a lubricant, lubricious coating or grease. The lubricity is built into the silicone elastomer system, which yields a lubricious surface on the molded component. The elastomer system is formulated with a proprietary additive that elutes out over time after vulcanization. The performance of many medical devices depends upon minimizing friction at the interfaces between various components, and self-lubricating LSRs provide the foundation for producing effective results.
- **Low coefficient of friction coatings:** There's another way to deal with the surface tack and blocking tendency inherent in silicone elastomers: Applying a silicone coating to the surface and then curing to chemically bond the coating to the substrate. Once cured, these coatings mimic the mechanical properties of the material, providing "dry" lubricity that reduces abrasive erosion and eliminates concerns about migration, leaking or rubbing off that are commonly associated with traditional lubricants.

2. CONSIDERING SPECIFIC SUBSTRATES

A main consideration is understanding the nature of the various substrates that need to be lubricated and identifying why the materials and surfaces require different types of silicone lubricants. Medical devices can incorporate a variety of substrates, including silicone, metal, glass and plastics. Each material has different characteristics that can pose unique silicone lubricant requirements.

Silicone Substrate

The surfaces of cured silicone elastomers often exhibit a high coefficient of friction. These surfaces can be tacky, causing problems when molded or extruded parts must move, or slide, in use during assembly. Silicone elastomers also tend to block, meaning they stick to each other due to chemical affinity. Blocking is particularly evident in slit valves, where the two sides of the silicone part touch each other and "heal," or close, the slit.

Considerations for silicone parts:

Surface interaction factors: Consider a lubricant with a low chemical affinity to the elastomer
For molded silicone parts, it's important to account for the difference in chemistries between the silicone part and the silicone lubricant itself. Otherwise, the lubricant may diffuse into a chemically similar material, and the molded component will swell. If this occurs, the fluid is depleted from the surface, which will reduce or eliminate the lubricating effect. Most silicone components are produced using a dimethyl silicone elastomer. Choosing a fluorosilicone lubricant, which has minimal chemical affinity to the dimethyl silicone, will result in minimal diffusion into the substrate and provide lubrication performance.

Dispersed silicone formulations minimally bond to the metal substrates they coat, making them ideal to lubricate needles, while hydrophobic lubricious coatings are available for syringe barrels to promote container drainability.

Viscosity factors: Consider a higher viscosity silicone for longer lubrication periods
Since diffusion, or the chance of migration, decreases as the silicone lubricant's viscosity increases, higher viscosity fluids or greases may lubricate a silicone elastomeric surface for a longer period of time than lower viscosity types.

Curable coatings: Consider alternative technologies in non-migrating coatings
Technological advances have resulted in some alternative options. One specific example is a curable, non-migrating coating that, when applied to a substrate's surface, reduces the coefficient of friction. Once cured, these coatings chemically bond to the underlying substrate and mimic its mechanical properties. The result is a durable, flexible coating that substantially reduces the coefficient of friction on moving, sliding and rubbing parts. Specific formulations are available for platinum-cured or tin-cured silicone substrates.

Reduced processing time: Consider self-lubricating silicone elastomers
Self-lubricating silicone elastomers may be chosen to reduce the number of processing steps required when compared to applying a lubricant after molding the part. This all-in-one solution incorporates the same medical-grade liquid silicone rubber used to mold the component or device, but the material is pre-loaded with the lubricant. The elastomer can be chosen with the physical properties and level of lubrication needed for the application.

Moisture-sensitivity factors: Consider ambient humidity When working with one-part dispersed silicone fluids that readily devolatilize, it's important to remember that they are moisture sensitive. Consequently, if adjustments are performed to optimize viscosity or solids content, they should take place in a moisture-free environment.

Other general factors
When planning the device-manufacturing process, consider either applying the lubricant directly as an oil or dispersed in solvent to provide the coverage needed for the required properties. To lower the coefficient of friction and enhance abrasion resistance, consider thin, wettable coatings. To minimize break-loose forces, consider thicker greases.

Metal

The metal surfaces and edges of hypodermic and suture needles, scalpels or other cutting tools have an inherently high surface friction. During incision or penetration in human tissue, friction damages the substrate surface and, of course, makes the patient uncomfortable as the metal pierces the tissue. To counteract penetration and drag forces, the design of a component can play a role. For example, hypodermic needles are tri-beveled with an elliptical opening followed by an elongated tube. This shape makes penetration easier and prevents coring effects, but the metal substrate still exhibits surface friction that prevents a smoother, more comfortable puncture. This friction can be addressed with a siliconization process to apply a medical lubricant on the substrate.

Considerations for metal:

For devices used multiple times, a dispersed high-molecular-weight polymer is more advantageous; as the solvent flashes off during the lubricant curing process, strong adhesion occurs with the metal to accommodate multiple punctures.

Surface interaction factors: Consider penetration frequency and lubricant longevity
To minimize the effects of surface friction, silicone lubricants can be applied to lower the coefficient of friction of the metal surface without compromising penetration or cutting efficacy. For applications involving repeated use, the lubricant must be robust. Taken together, factors that reduce friction include lowering puncture force, lowering drag force, reducing rub-off and providing consistency throughout multiple uses.

Formulation factors: Consider silicone dispersions and bonding behavior
Dispersed silicone formulations minimally bond to the metal substrates they coat, making them ideal to lubricate metal, for devices such as needles. Polydimethlysiloxane (PDMS) fluid is typically considered for this substrate. Inert PDMS fluid dispersions function as generic lubricants for various penetration and cutting surfaces. They improve lubricity but are more suitable for one-time use. For multiple usage, consider either applying a high viscosity fluid directly or dispersed in a solvent.

Other general factors
To reduce migration compared to silicone fluids, also consider using a silicone grease.

Glass

Silicone fluids have a silicon-oxygen chemical structure like glass, quartz and sand. Consequently, they tend to bond very well with glass. Cross-linking to enhance bonding over the glass substrate may be achieved by heating the silicone beyond its operating temperature.

Considerations for glass:

Formulation factors: Consider a hydrophobic lubricant To reduce drag forces in glass prefilled syringes, for example, the insides can be coated with a PDMS medical-grade silicone oil. For this siliconization process, hydrophobic coatings are available for syringe barrels to promote container drainability.

Curing factors: Consider high-temperature heating to activate cross-linking
Keep in mind that PDMS fluid by itself is nonfunctional and does not cure. However, this may be controlled by exposing the syringe to extremely high temperatures to activate polymer cross-linking, as previously described. The result is a functional interaction between the siliconized lubrication of the glass barrel and plunger stopper to make the system operate efficiently.

Other general factors
Consider either applying the lubricant directly or dispersed in solvent. To reduce migration compared to fluids, consider using a silicone grease. To enhance durability, consider heat treatment.

Plastic

A wide variety of plastics are used in medical products, such as valves and stopcocks. Friction points in these applications may benefit from silicone lubricants.

Considerations for plastics:

Formulation factors: Consider a very high viscosity grease
To enhance gliding with plastic and plunger stoppers, for example,

consider using a silicone grease to lubricate the device. In these applications, the grease provides a lubricant that is less likely to migrate when applied to a plastic surface.

Other general factors
Consider either applying the lubricant directly or dispersed in solvent. Consider a combination with a PDMS fluid for enhanced/customized lubricant properties. Consider compatibility of the silicone with the specific grade of plastic

3. OTHER IMPORTANT CONSIDERATIONS

Biocompatibility: Lubricious coatings and silicones used in medical applications should be biocompatible and in conformance with ISO 10993. As inorganic material, pure silicone lubricants are chemically inert and stable over extended periods of time. The molecular backbone of silicone fluids is much stronger than the carbon-to-carbon chain in hydrocarbon polymers. Consequently, silicone lubricants are more resistant to chemical attack, oxidation, shear stresses and extreme temperatures. Medical lubricants can be readily sterilized by ethylene oxide, dry heat or autoclaves, or other standard techniques without degradation. Device designers should be sure to consider high-purity, medical-grade silicone lubricant products supported by Master Files, which include biological tests conducted on each product, with the U.S. Food and Drug Administration (FDA) and international authorities.

Purity: The NuSil® brand of medical-grade silicones are designed, manufactured and purified to meet the strict requirements of the healthcare industry. Although there is no uniform definition of "purity," reputable premium silicone lubricant products are manufactured under applicable Current Good Manufacturing Practices (cGMP), such as cGMP 21 CFR §820 (Device), as well as ISO 9001 standards. In addition to the information mentioned earlier on biocompatibility tests, a pure silicone lubricant's Master File should also provide details about ingredients, manufacturing, processing, packaging and storage. Medical-grade silicones have extensive regulatory support, and reputable silicone manufacturers can provide the appropriate Device Master File (MAF) and GMP information on request. Some silicone manufacturers combine other standards, such as ISO 14001 and ISO 13485 standards, and implement proprietary quality systems as further assurance of quality and purity.

Manufacturability: Application and siliconization methods include dipping, spraying or wiping. If a very thin film is desired, silicone fluids may be further diluted as far as 1-5% silicone solids in a compatible solvent. Methyl polymers may be dispersed in nonpolar organic solvents, whereas fluoropolymers (and copolymers) may be dispersed in chlorinated hydrocarbons and ketones. Depending on your application, silicone dispersions can also be accomplished in aromatic hydrocarbons, mineral spirits and isopropyl alcohol. For convenience, some medical device manufacturers select polymers pre-dispersed to a specified percent of solids. Be sure the silicone material selected can work with these options and is compatible with end-use applications.

Customization: Given the possible variations in premium silicone lubricant formulations and different application demands, it's helpful to partner with a silicone manufacturer that offers a wide range of customization and product development to meet specific device and silicone manufacturing requirements. For example, as a premium silicone lubricant formulator, we can provide customization down to the molecular level through our state-of-the-art capabilities in R&D and molecular characterization. The chemistries of our silicones can be modified to accommodate lubricity, substrate compatibility, performance characteristics and cure chemistries. We can also adopt or develop custom test methods to accurately describe the application and help medical device manufacturers confirm that products meet specifications on a batch-to-batch level. For further customization, our advanced manufacturing processes and proprietary equipment enable production in small batches up to very large batches at mass scale to support complete product commercialization.

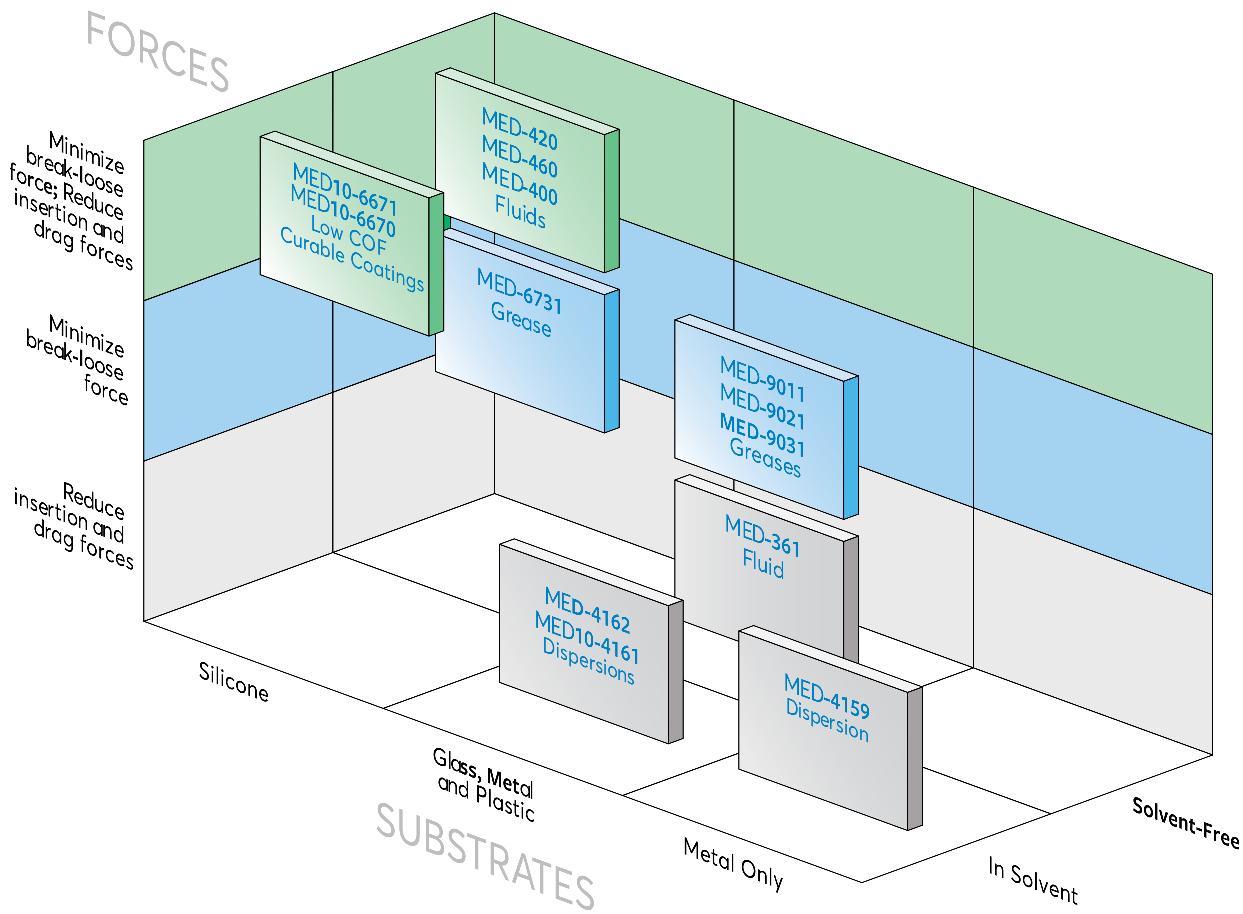
After nearly four decades of serving the most demanding industries, we have honed our silicone manufacturing processes and proprietary equipment to support unique products, product form factors and packaging. From start to finish, we offer direct access to a team of chemists, engineers, regulatory experts and technical specialists. This collaboration allows us to meet tight design and production parameters to give medical device manufacturers a competitive advantage when working with medical silicone lubricants for demanding applications.

Device designers should be sure to consider high-purity, medical-grade silicone lubricant products supported by Master Files, which include biological tests conducted on each product, with U.S. FDA and international authorities.

NuSil® LUBRICIOUS SILICONE SELECTION GUIDE

Use this tri-factor chart as a selection guide for specific NuSil® silicone lubricant products: Start with the type of substrate you're working with along the bottom X-axis. Then consider the type of frictional forces in the colored rows of the vertical Y-axis. The appropriate NuSil® product numbers can be found in the intersection of the Y and X rows. Products are further defined as in-solvent or solvent-free in the Z-axis rows.

Self-lubricating elastomers provide an alternative option to applying lubricant onto the substrate. Because the lubricity is formulated directly into the elastomer system, self-lubricating silicone material is not included in this selection guide. Datasheets for NuSil® lubricious silicone products are located at **www.avantorsciences.com/nusil/siliconelubricants**



It is the sole responsibility of each purchaser to ensure that any use of these materials is safe and complies with all applicable laws and regulations. It is the user's responsibility to adequately test and determine the safety and suitability for their applications, and NuSil Technology LLC makes no warranty concerning fitness for any use or purpose.

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