How to select silicone adhesives for medical device manufacturing

Understanding key factors, such as cure characteristics, temperature, rheology, surface prep and inhibition, can help simplify the specification process while saving time in device manufacturing.

WHITE PAPER

Medical device manufacturers choose various types of silicone adhesives to bond different substrates together when assembling devices such as catheters, pacemakers, cochlear implants, aesthetic implants, gastric balloons and other medical equipment because of their biocompatibility, hydrophobicity and versatility. When selecting a silicone adhesive, many factors need to be considered, including the substrates, their surface energy and available bond sites, the relevant aspects of the manufacturing process and the end-use application. This paper reviews key considerations in choosing and using silicone adhesives for medical devices.

1. CONSIDERING ADHESIVE OPTIONS

Room Temperature Vulcanizing (RTV) Silicone Adhesives

Traditional RTV silicone adhesives cure at room temperature upon exposure to atmospheric moisture. Without relying on moisture to cure, newer, more versatile formulations can cure faster with heat or at room temperature. RTV adhesives are available in one- or two-part formulations and may be dispersed in a solvent carrier for ease of application.

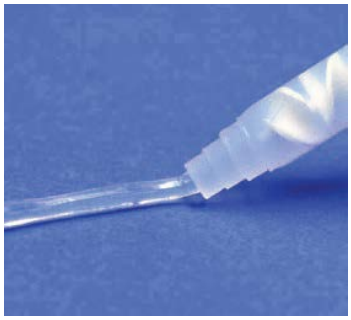
One-part RTV Silicone Adhesives

Due to their long history and wide availability, one-part moisture-cure RTV adhesives are the most common silicone adhesives used in medical devices. They can be applied directly and do not require premixing. Heat is not required to cure, making them ideal for temperature-sensitive components, such as electronics and thermoplastics. They are also well-suited for creating a seal and for bonding silicone to other silicones, metals, some plastics and glass.

- **Cure characteristics:** Cure rates of one-part moisture-cure RTV adhesives are influenced by several factors, including humidity levels (20-60% relative humidity recommended), cure temperature (25-50°C recommended), thickness of adhesive applied and surface area exposed to air. Because the material cures from the outside in, with thinner sections curing more quickly than thicker ones, moisture-laden airflow needs access to the adhesive in order to cure thoroughly, and "leaving groups" (byproducts of the curing process, such as mild acids, alcohols or other volatile substances that evaporate from the material) need to be evacuated from the silicone.
- **Rheology:** These adhesives are available in self-leveling formulations that flatten or spread out over time, as well as thixotropic, or non-slump, formulations that hold shape over time.
- **Application considerations:** One-part RTV adhesives tend to have slower cure rates compared to two-part RTV adhesives. Due to leaving groups, the adhesive may shrink during cure, typically between 3-6% of its original volume. This type of adhesive is easily dispensed with no mixing required, and the product is packaged in convenient resealable containers.
- **Customization:** One-part RTV adhesives have customizable attributes to enhance process and performance characteristics. The adhesion properties can be tuned to specific substrates. Viscosity can be adjusted to desired flow characteristics. Fillers can be added to match color or enhance properties such as radiopacity.

Device designers should be sure to consider high-purity, medical-grade silicone adhesives with extensive regulatory support and Master Files submitted to the U.S. Food and Drug Administration (FDA) and international authorities.

A two-part thixotropic, or non-slump, adhesive that holds its shape over time.



Two-part RTV Silicone Adhesives

Two-part RTV silicone adhesives are among the most versatile silicone polymer compounds. In general, the cure time for two-part RTV adhesives is much faster compared to one-part RTV adhesives. Because two-part RTV adhesives do not require moisture to cure, they can meet unique assembly requirements such as forming bonds at interfaces that have little or no access to air. Two-part RTV adhesives are also ideal for temperature-sensitive components and assembly processes where a relatively low temperature must be maintained. They adhere well to a variety of substrates and can also be used for sealing, potting or encapsulating.

- **Cure characteristics:** The two-part RTV curing process is initiated by mixing two components together in a 1:1 mix ratio and is not dependent on atmospheric moisture. The cure rate is influenced by heat, rather than exposure to air, and is not limited by the thickness of the adhesive because it cures uniformly. Practically no byproducts or leaving groups are released during the curing process.
- **Rheology:** Two-part RTV adhesives are available in non-slump formulations with moderate to high extrusion rates, enabling the adhesive to be easily dispensed.
- **Application considerations:** Cure rate can be accelerated by increasing temperature and shrinkage is minimal. Typical work times range from 15 minutes to two hours depending on temperature. As an option, the product can be supplied in ready-to-use cartridges (where the material is dispensed through a static mix tip and air is not introduced).
- **Customization:** Similar to one-part RTV adhesives, two-part RTV adhesives can also be customized to adjust viscosity, add fillers or additives, apply pigmentation, enhance physical properties or modify adhesion to meet specific end-application requirements.

High Temperature Vulcanizing (HTV) Silicone Adhesives

HTV silicone adhesives differ from RTV adhesives in that they are formulated specifically to cure with the application of heat and are only available in two-part formulations. HTV adhesives are ideal for bonding parts that are not heat-sensitive or when a quick cure is desired to save time in device assembly.

All the features and advantages of two-part RTV adhesives apply to HTV adhesive formulations, and the cure characteristics of HTV adhesives offer several additional advantages: They cure rapidly when applying heat and have a work time ranging from 15 minutes to greater than 24 hours depending on the formulation.

Dispersed RTV and HTV Silicone Adhesives

For ease of use, adhesives can be supplied dispersed in a compatible solvent to help facilitate a specific process or application of the adhesive. Its rheology is ideal for thin sections or small intricate areas where the adhesive needs to reach a location that might otherwise be hard to access. This is especially useful as today's medical devices continue to get smaller in size, and the application of adhesives requires more precision. Dispersed adhesives are available in one- or two-part formulations using both RTV or HTV chemistries.

- **Cure characteristics:** All the features and advantages of one- and two-part RTV and HTV adhesives apply to dispersed adhesive formulations.
- **Rheology:** The dispersed silicone adhesive easily spreads out in a thin, uniform layer that conforms to the underlying shape.
- **Customization:** Dispersed adhesives have customizable attributes that include viscosity; the ability to adjust solids content or add fillers or other additives, e.g., pigmentation for translucent adhesives or color matching; and modification of physical properties or adhesion properties to enhance process and performance characteristics.
- **Application considerations:** In a solvent system, a low-viscosity dispersion can be easily applied by spraying, wiping, dipping or screen printing. Work times can be extended when the adhesive is solvated. The rate of solvent evaporation can be optimized with a combination of airflow, time and heat. Cure can take place once the solvent has evaporated.

2. CONSIDERING SUBSTRATES AND PROPER SURFACE PREPARATION

Proper preparation of the substrate surface is essential to forming a long-lasting bond. Surface treatment prior to adhesive bonding offers the best adhesion results. Cleaning, activating and/or priming the surface can maximize the surface area's available bond sites and wettability to improve long-term adhesion.

When developing a surface preparation procedure, there are several variables to consider:

- Substrate cleaning: Proper cleaning methods remove contaminants, such as finger oils, dust particles, mold release agents and machine oils on metal parts – all of which can directly impact the level of adhesion. Surface cleaning is the most important part of surface preparation and is conducted by mechanically or manually wiping the surface with an appropriate solvent (e.g., isopropyl alcohol or heptanes) using swabs or lint-free cloths.

- Substrate surface finish: Preparation methods must be appropriate to the surface finish, which can vary from highly polished to matte and corrugated textures. Surface finish can influence surface contact and wettability of the adhesive, thus affecting adhesion.

- Contact angle: The contact angle of the substrate surface helps quantify the wettability of the surface (i.e., the substrate's acceptance of a coating). In general, a contact angle below 90° has high surface energy and provides good surface wettability, while a contact angle greater than 90° has low surface energy and leads to poor surface wettability and more likelihood of poor adhesion.

- Surface treatments: To help increase the substrate's surface energy for better adhesion, several methods can be considered. Plasma treatment bombards the substrate surface with ions of a gas such as argon. Corona discharge technique is another treatment method that uses increasing voltage cyclically to generate a plasma known as "corona discharge."

Poor surface wettability
Low surface energy
Contact angle > 90°

Good surface wettability
High surface energy
Contact angle < 90°

3. CONSIDERING INHIBITION FACTORS

When working with silicone adhesives, it's important to consider the solvents, chemicals or substrates they may contact in their uncured state. Certain chemical elements and compounds can retard or inhibit the adhesive's curing process during the device handling, storing or assembly process. The introduction of these cure "poisons" can lead to unacceptable variations in the manufacturing process and in the finished product. The presence of inhibitors may cause the silicone to appear "wet" or tacky at the substrate interface. Modest cure inhibition can result in lower physical properties, while severe cure inhibition can lead to a complete failure to cure. For platinum-catalyzed silicone systems, most poisons typically have a sulfur-containing material (e.g., natural rubber, latex and neoprene), a nitrogen-containing material (e.g., amines) or an organotin-containing material (e.g., condensation-cured silicones). For RTV or tin-catalyzed silicone systems, the most common inhibitor is the presence of an alcohol, such as isopropyl alcohol.

Preventing inhibition requires proper surface preparation that ensures the surface is free of contaminates. To determine whether substrate surfaces have been properly prepared, we recommend testing a small amount of silicone on the surface as a trial to evaluate potential inhibition effects.

4. OTHER IMPORTANT CONSIDERATIONS

Measuring Adhesion

Many different physical, mechanical and chemical forces act against a bond. Consequently, determining the acceptable failure point will differ from device to device and manufacturer to manufacturer. Tests can be done in different conditions to simulate real-world use of the device to confirm that adhesion is suitable for the given application. It's important to work with an adhesives manufacturer equipped to perform different tests to qualify adhesion, depending on the application. For example, adhesion tests for NuSil™ brand adhesives can include several methods, such as lap shear, peel strength and peel strength of cured bilayers from silicone dispersions.

Biocompatibility

NuSil™ medical grade silicones used in medical adhesive applications are biocompatible and in conformance with applicable ISO and USP testing protocols. As an inorganic

material, medical-grade silicone is chemically inert and stable over extended periods of time. Consequently, silicone adhesives are resistant to chemical attack, oxidation and shear stresses. They 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 adhesives with extensive regulatory support and Master Files submitted to the U.S. Food and Drug Administration (FDA) and international authorities. Master File (MAF) and GMP information on silicone adhesives support medical device manufacturers in their regulatory filings with details about ingredients, manufacturing, processing, packaging and storage.

Purity

NuSil™ brand medical-grade silicones are designed and manufactured to strict purity standards. We start with carefully selected raw materials and utilize proprietary purification technology to produce the most refined intermediates and purest finished products with some of the lowest volatility levels.

Custom Adhesives

Given the possible variations in premium silicone adhesive formulations and different application demands, it's helpful to collaborate with a silicone adhesive manufacturer that offers a wide range of customization and product development services to meet specific device and silicone manufacturing requirements. For example, as an experienced silicone adhesive formulator, the NuSil™ team can provide customization from the molecular level through formulation and packaging. Using state-of-the-art capabilities in R&D and molecular characterization, the chemistries of our silicones can be modified to accommodate adhesion, substrate compatibility, performance characteristics and cure profiles. Custom test methods can be adopted or developed to help translate the application needs and 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.

CONCLUSION

After nearly four decades of serving the most demanding industries, the NuSil™ team has honed its silicone adhesive development and manufacturing processes to support unique products and packaging. From start to finish, we offer access to experienced 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 adhesives for demanding applications.

For additional guidance during your selection process, see our support resources at **www.nusil.com/siliconeadhesives** or please contact us at **silicone@nusil.com** or **+1 (805) 684-8780**.

HOW TO OPTIMIZE YOUR PRODUCTION WITH THE RIGHT SILICONE ADHESIVE

Whether creating innovative designs or optimizing processes, medical device manufacturers are regularly seeking adhesive solutions. Use the chart below to assess your application's specific adhesive requirements.

1

What is the **application?**

The right NuSil™ brand silicone adhesives can help you increase adhesion and improve productivity.

- **Long-term Implant** (> 29 days)
- **Short-term Implant** (≤ 29 days) or **Non-implant**

2

What are the **substrates?**

A wide variety of substrates may be used in device assembly. It is important to understand the substrate compatibility with the selected adhesive.

- **Plastic**
- **Silicone**
- **Metal**

3

Are there temperature limitations with the substrates you are adhering to?

Can you apply heat to increase **rate of cure?**

- **Yes** (> 60° C) → **Two-part** Adhesive
- **No** (< 60° C) → **One-part** Adhesive

Other **considerations**

Rheology: Flowable vs. non-flowable

Viscosity: High vs. low

Work time: Long (hours) vs. short (minutes)

Extrusion rate: High vs. low

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