Fast-curing silicone adhesive reduces medical device assembly time from hours to minutes

INTRODUCTION

In medical device assembly, manufacturers value silicone adhesives for their biocompatibility, versatility and elasticity. As with any bonding agent, the curing process for silicone adhesives must be considered to accommodate production needs. Conventional, one-part room-temperature-vulcanizing (RTV) silicone adhesives are a popular choice due to their proven history of use and convenient, ready-to-use formulation. Despite these advantages, one medical device OEM came to NuSil™ experts with the question: "Is there a silicone adhesive formulation that cures much faster than RTVs, because we need greater throughput to maximize efficiencies?"

In order to find a solution, NuSil™ experts opened their "silicone toolbox" and designed a custom accelerated cure silicone adhesive that reduced the manufacturer's cure time from hours to minutes using slightly elevated temperatures.

According to Dr. Jim Lambert, NuSil™ Director of Technology and Innovation for Biomaterials, "One of the main drivers prompting our development of heat-cure silicone adhesives was to create an option that enables medical device manufacturers to reduce bottlenecks in production and increase throughput. One-part RTV adhesives—although a popular solution for many manufacturers—depend on humidity and other factors to cure. They may take hours—even days, depending on conditions—to reach complete cure. With a heat-curable formulation, however, complete cure can be reached in a matter of minutes. When there were no biocompatible, heat-cure silicone adhesives for implantable devices on the market, we were able to meet the manufacturer's requirements by formulating a custom solution."

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NuSil™ Director of Technology and Innovation for Biomaterials

A COLLABORATIVE PROCESS

To tackle the customer's demanding challenge for a custom formulation, the NuSil™ team, including chemists, engineers, regulatory experts and technical specialists, kicked off a highly collaborative process to determine the most important properties for the customer.

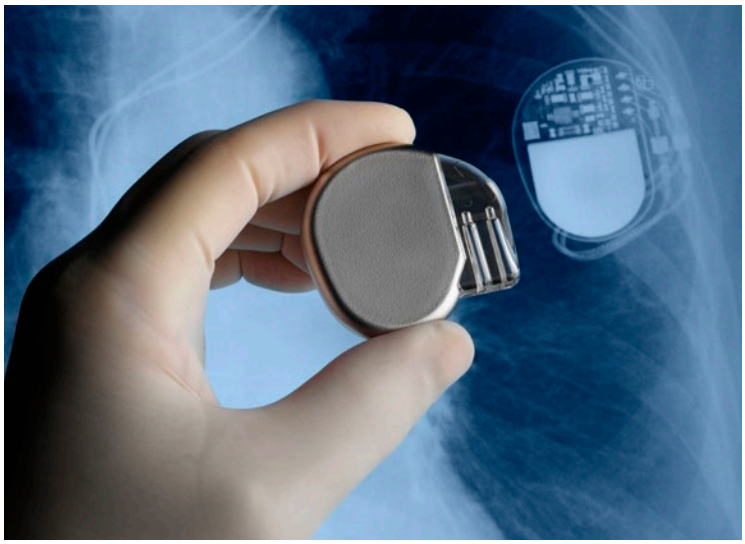
The main considerations included:

- **What substrates are you adhering?**
  We can tailor the adhesive to increase the bond strength to the specific substrates.

- **Can heat be applied to cure the adhesive?**
  If the process allows for higher temperatures (80˚C and above), our high temperature vulcanizing (HTV) adhesives offer the convenience of rapid cure and long work times. If not, our RTV two component systems will cure at room temperature in less than a few hours, but even the slightest increase in temperature can significantly reduce the time required to cure.

- **Other relevant factors to consider?**
  The NuSil™ team worked with the customer to evaluate any additional considerations including specific material properties and compatibility of the adhesive with other components of the device, manufacturing environment or equipment.

The formulation advanced from initial assessment through development and finally to several iterations of prototyping, testing and analysis.



OPENING THE TOOLBOX OF RESOURCES

The initial step was to identify the critical-to-quality factors (CTQs) that will help the customer meet competitive market demands.

"The primary focus was designing a formulation that met all their CTQs," explains Dr. Lambert. "And we were bound to using ingredients we knew would pass a list of biological tests."

The team identified materials that would meet the specified criteria and collaborated with the customer to evaluate any additional specifications that might influence the selection of formulary ingredients.

RHEOLOGY

For optimal performance in the manufacturing environment, the NuSil™ experts addressed the requirements for viscosity, extrusion rate, and degree of thixotropy for the new adhesive.

CURE SPEED

The curing conditions were optimized to balance the need for a faster cure, in minutes instead of hours, while maintaining a suitable work time for the customer's assembly process. The solution required a minimal increase in cure temperature relative to ambient temperatures.

FUNCTIONAL PERFORMANCE

Another important aspect is the material's ability to be dispensed during assembly. A dual barrel cartridge with an integrated static mix dispensing tip enables the material to be dispensed directly, similar to a traditional one part RTV adhesive.

The NuSil™ toolbox also includes pigmenting options for adding color to silicone adhesives. Color masterbatches can be formulated for applications requiring color matching for aesthetics or a visual marker of the deposit area. These color masterbatches are differentiated from other color options in the medical device market by the level of regulatory support. NuSil™ color masterbatches are supported by extensive biological screening (ISO and USP testing protocols) and comprehensive Master Files (MAF) submitted to the U.S. Food and Drug Administration (FDA).

In addition, varying levels of regulatory support can be provided depending on the needs of the customer and the application. The NuSil™ brand medical-grade silicones are designed and manufactured to meet strict purity standards with the lowest volatility levels.

> "It was a truly collaborative development process. Many ingredients go into one of these formulations, so it was a matter of using a consultative approach to find the right combination that met their goals."

Drawing upon this portfolio of materials, the NuSil™ team created initial prototypes for customer trials.

BRINGING CUSTOMIZATION CAPABILITIES TO SCALE

Given the possible variations in silicone adhesive formulations and different application demands, the NuSil™ team's product customization capabilities allow us to meet specific device and manufacturing requirements.

As a silicone formulator, we develop medical grade silicone adhesives through molecular characterization and our state-of-the-art R&D capabilities. Existing test methods can also be adopted or new test methods can be developed to confirm that formulations meet specifications on a batch-to-batch level. Furthermore, advanced manufacturing processes and proprietary equipment enable production from small batches to mass production, supporting our customer's complete product commercialization.

The NuSil™ team collaborated to meet the customer's distinct needs and ensure success through an iterative process. The end result: medical device manufacturers and contract manufacturers can gain competitive advantages from using medical grade heat-cure silicone adhesive solutions to achieve faster throughputs, reduced costs and improved productivity.

"It was a truly collaborative development process," Dr. Lambert says. "Many ingredients go into one of these formulations, so it was a matter of using a consultative approach to find the right combination that met their goals. The customer gave us several criteria, and we ranked them to understand the relevance of different factors. The main driver was to increase throughput for their assembly process, while maintaining all other performance aspects."

"Collaboration is something we pride ourselves on, and we have a very strong Technology & Innovation department," continued Dr. Lambert. "Companies often call us for unique solutions because they want something they can't get elsewhere. And they know that we will customize and formulate to their needs."

To learn more, visit **www.nusil.com/siliconeadhesives** or contact NuSil™ experts today at **silicone@nusil.com** or **+1 (805) 684-8780**.