Case study: Customizing self-lubricating silicone elastomers to move medical device fabrication forward

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INTRODUCTION

Due to its biocompatibility, processability and wide range of physical properties, liquid silicone rubber (LSR) is ideal for injection-molded valves, O-rings and other precision medical-device parts. At the same time, the inherent tackiness, blocking tendency (sticking to itself) and the high coefficient of friction (COF) of silicone elastomers pose challenges to device design and fabrication. These properties may cause self-healing of one surface against another or prevent the desirable sliding and gliding action between surfaces in many devices. The traditional solution to these challenges requires medical device manufacturers to apply a silicone lubricant onto the molded part as a separate manufacturing step. During regular discussions with a customer over how to boost productivity, a medical device manufacturer asked the question, "Can you make a silicone elastomer that lubricates itself?", Their thinking was that if a silicone elastomer can be customized with the silicone lubricant already in the material, then the manufacturing step of applying the lubricant on the surface could be eliminated.

To answer that question, NuSil® experts drew on their years of experience and turned to their "toolbox" of resources that facilitated the customization of a successful self-lubricating silicone elastomer for this customer's specific needs.

According to Dr. Jim Lambert, NuSil® Director of Technology and Innovation for Biomaterials, "When we're collaborating with a customer to identify a solution, we explore a lot of options in our formulation database. Our goal is to characterize the requirements for an elastomer that contains a silicone oil and demonstrates the required modulus, strength and CoF".

Successful customization through collaboration and iteration

When developing custom silicone elastomers, the NuSil® team initiates a process of collaboration with customers who are open to iterative design methods. The optimum solution is identified through several prototyping iterations, testing and analysis.

The goal of the initial discovery phase is to get a thorough understanding of customer objectives, bottlenecks and limitations. The inquiry covers constraints, needs and preferences with a range of questions on critical topics that include:

What properties are needed from the base material?
How flexible or elastic does it need to be? What is the required hardness?

What are the lubrication requirements?
Does migration need to be minimized? Will there be repeated gliding and sliding action? Is there a need for a better seal?

What is the end application?
The compatibility of the silicone with other materials used in the construction of the device needs to be determined. What is the useful life of the device? How long does the device need to be lubricated for a single-use or for multiple uses?

Where in the manufacturing process can we create efficiencies?
Can manufacturing steps be eliminated? Can process time periods (e.g., curing times) be shortened? Can maintenance be simplified?

What testing and regulatory support would be helpful?
What biocompatibility testing, Master File (MAF) and Current Good Manufacturing Practices (cGMP) documentation or support are needed?

Working with a full toolbox of resources

From the start, NuSil® chemists, engineers, regulatory experts and technical specialists focus on the factors the customer faces to meet competitive market demands.

"We know that standard solutions don't always fit," explains Dr. Lambert. "That's why we create customized silicones with a toolbox of resources that can meet our customers' unique applications."

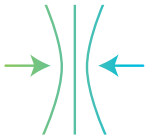
The first set of resources in the NuSil® toolbox is a formulation database used to evaluate our wide range of materials in terms of:

RHEOLOGY

We have a variety of pumpable silicones for use in standard liquid injection molding equipment.

CURE

We can design the cure rate for long work time and fast cure at high temperature during the molding process.



ELASTOMERIC PROPER AND MATERIAL HARDNESS

We can apply self-lubricating technology to a wide range of durometers or moduli of elasticity. For this application, a mid- to highfirmness material was selected, so the device component would flex easily and recover quickly.

LUBRICITY

We identify the appropriate lubricant that will remain in solution in uncured state and accommodate the desired bleed rate in the cured, finished part.

Another set of toolbox resources is a line of pigmenting options for adding color to silicone LSR. Color masterbatches can be formulated for applications requiring colored silicones to ensure the color doesn't bleed out when the lubricant weeps to the surface.

According to Dr. Lambert, "What differentiates NuSil® color masterbatches from other color options in the medical device market is the level of biological testing performed on these materials. Our color masterbatches are supported by extensive biological test data and comprehensive Master Files (MAF) submitted to the FDA."

Varying levels of regulatory support can also be provided depending on the needs of the customer and the application. 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 elastomer formulations and different application demands, the NuSil® brand's customization capabilities allow us to meet specific device and manufacturing requirements.

As a silicone formulator, we develop self-lubricating silicone elastomers 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 ability to develop customized silicone elastomers with consistent quality is particularly valuable where large-scale quantities are produced. It is especially important in the case of our self-lubricating elastomers for such applications as valves, O-rings, stoppers, plungers, seals and other fluid management systems.

"Based on years of experience with iterative collaboration and supplying self-lubricating elastomers, we delivered a solution that not only eliminated the need to apply lubricant onto the finished part, but also met both the physical properties and lubricating performance requirements of the customer," says Dr. Lambert.

"For them and other medical device manufacturers, a custom self-lubricating silicone elastomer can yield faster throughputs, boost productivity by cutting process steps and reducing costs — all of which put you a step ahead of competitive market demands."

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

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