

Challenges and Rewards of Molding Silicone

Mats Håkanson

Silicone is a significant material in medical device design. As such, finding an expert partner who understands all of its benefits and challenges is key for manufacturers who wish to implement the material into a product. This article highlights several advantages of using silicone for component fabrication as well as some of the obstacles to success.



Injection molding liquid silicone components for use in medical technology applications is an area that requires a high degree of expertise and know how.

Silicone rubber has a perfect balance of mechanical and chemical properties, making it ideal for use in medical applications. The material is fully accepted by human tissue, is resistant to UV light, can cope with large differences in temperatures, returns to its original form after being stretched out or pressed together, and can be injection molded using complex molds and very thin walls. These properties make silicone rubber highly suitable for medical technology products within areas such as anesthesia, cardiology, dialysis, orthopedics, and urology.

The Challenges of Measuring Silicone Components

Silicone components are soft and their shape can, therefore, be affected by handling. As a result, it is

vital that these components are handled properly and that they are correctly oriented before measuring.

Arrangements involving fixtures, vacuums, etc. are often needed to ensure that the component is positioned correctly before measuring begins. It is also important to ensure that the shape of the component is not affected by it being under pressure.

Choice of Measuring Method

The measuring method chosen depends on factors such as the accuracy required.

Today, scanning is one measuring method that offers excellent opportunities. A number of different scanning methods are available. Nolato Medical uses CT, optical, and white light interferometers. The most suitable method depends on size, complexity, and the degree of accuracy required.

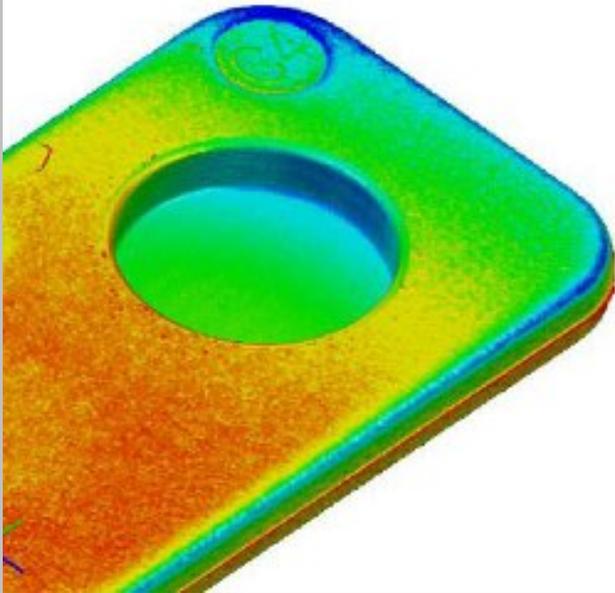
Measuring Hundredths of a Millimeter

With a white light interferometer, it is possible to measure to within 0.001 mm in small areas.

The measurement analysis involves comparing the scanned outcome with the CAD model. In this way, deviations can be seen clearly.

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During scanning, green indicates the correct measurement, while yellow/red indicates +0.01 to +0.04 mm and blue indicates -0.01 to -0.04 mm.

“Here at Nolato, we have more than thirty years of advanced experience of working with silicone rubber,” says Magnus Björk, a mold specialist at Nolato MediTech in Sweden. “Right from the start, we have helped to develop the processes together with the machinery manufacturers, and this has given us a particularly firm footing.”

After all, silicone injection molding isn’t something that everyone can do well. Although the basic principle is the same, the process is very different from injection molding plastic.

“Not least because it places much higher demands on the molds in which the product is made,” explains Björk. “When manufacturing plastic components, the raw material is melted down into a viscous mass, whereas silicone has a particularly low viscosity when processed, which makes things more complicated. The silicone mustn’t leak out between the halves of the mold or be marked by the edges of the mold when it vulcanizes.”

Freer Forms Bring New Opportunities

Silicone’s unique properties also bring great advantages and make it possible to manufacture products that couldn’t have been produced using other materials.

“Since silicone returns to its original form after being deformed, we can manufacture projects with geometric forms that would be impossible to remove from the mold with a harder material,” says Jörgen Nilsson, a product developer at [Nolato Medical](#) [1].

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In plastic manufacturing, the product needs to be knocked out of the mold, since the piece of plastic is relatively rigid in its final form. But when making silicone products, it is easier to pull almost any shape of component out of the mold.

“For example, the product can be thicker further into the mold than at the mold joint; it really doesn’t matter. We pull the product out and it returns to its original shape as soon as it’s out of the mold,” explains Nilsson.

In practice, however, this isn’t as simple as it sounds. Designing the right method to get the product out of the mold requires both a high degree of expertise and a great deal of experience.

Verification Requires Special Expertise

Once a product has been approved for production, the supplier must be able to demonstrate and document that it also meets the customer’s requirements in mass production. This is done through visual checks, precise measurements, and other studies of what has been produced. This verification can be a little tricky for a silicone product, since it is not rigid.

“It’s important to validate a measuring method so that it always gives the same results,” explains Anders Roth, who deals with quality assurance at Nolato MediTech.

Measuring a cross section is relatively straightforward, whereas measuring the diameter of an O ring that is just a couple of millimeters thick, for example, can be considerably more problematic.



These seals for pacemakers have been injection molded in liquid silicone.

“Over the years, we’ve worked hard to develop practically applicable methods for

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verifying the most complex and hard to measure products, even with minimal tolerances,” says Roth. This often involves measuring to an accuracy of hundredths of a millimeter, and, in certain extreme cases, even thousandths.

Importance of Early Involvement

Achieving the best production efficiency and economy is largely about being able to influence the producibility and the functionality of the individual component together with other parts of the product from an early stage of the customer’s product development.

“The earlier we can get involved, the more likely we are able to help customers to achieve their goals,” says Jim Håkansson, a project manager at Nolato MediTech. “Being able to consider the components’ manufacture and assembly early on in terms of design for production and design for assembly is extremely important if we are to be able to optimize the cost of the overall production process.”

Nolato Medical Transfers Silicone Technology to U.S. Company

Nolato Medical is excited to announce the addition of liquid silicone injection molding to its U.S. facility in Baldwin, WI—Nolato Contour.

Nolato Contour has added its third cleanroom, a Class 7 cleanroom that accommodates the new liquid silicone injection molding machines.

The new liquid silicone injection molding service is built on transfer of technology and know how from Nolato Medical in Sweden. Nolato boasts over 30 plus years of liquid silicone and thermoplastic injection molding experience for complex implantable and non-implantable medical products. The company has also established a strong reputation in its ability to over-mold silicone to thermoplastic components.

Coating Metal with Silicone

This isn’t just about adapting individual components; it also involves seeing possibilities that might not be obvious. For example, coating metal with silicone rubber can avoid the need for a difficult and costly stage when the product is subsequently assembled. Similarly, two-component injection molding of hard plastic and soft silicone can be a simple and cost-effective way of helping to give the product the desired properties.

“Today, we can even print directly onto the silicone,” says Håkansson. “This is normally difficult, as the ink doesn’t adhere to the surface of the silicone easily.”

Conclusion

As silicone is a critical element of so many medical devices, securing the right

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molding partner is of paramount importance for success. Look for a service provider who is an expert with these opportunities silicone offers.

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[1] <http://www.nolato.com/medical/>