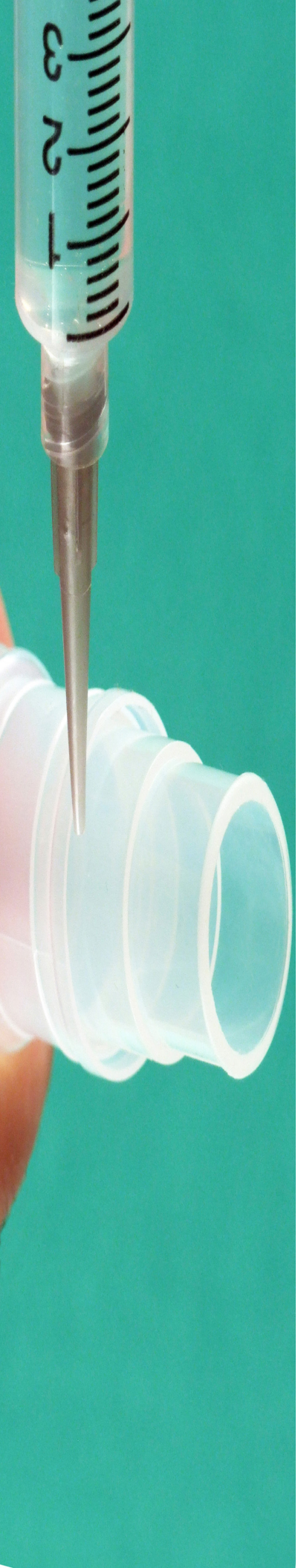

MASTERBOND®
CASE STUDY

MasterSil 151Med Used in an Implantable Device for Electrical Nerve Stimulation

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CASE STUDY

MasterSil 151Med: Used in an Implantable Device for Electrical Nerve Stimulation

Overview of MasterSil 151Med

MasterSil 151Med is a two-component, low-viscosity silicone compound suitable for high-performance potting and encapsulation applications. The formulation is non-solvent based and does not require exposure to air to ensure complete crosslinking. It is highly flexible, can withstand thermal cycling, and resists vibrations, shock, as well as water intrusion. These properties, especially the fact that it meets USP Class VI biocompatibility and ISO 10993-5 non-cytotoxicity specifications, make it suitable for various medical device applications. In this study, MasterSil 151Med was used for the encapsulation of an implanted device for electrical vagus nerve stimulation.

Application

Vagus nerve stimulation (VNS) sends electrical signals to the vagus nerve to treat various medical conditions such as epilepsy and obesity. Animal model research is a critical precursor to human clinical research for VNS devices, but most VNS devices are indicated for use in humans but not small animals. To develop a smaller device more suitable for small animal models, researchers at the Norwegian University of Science and Technology used commercially available components to construct an implantable VNS device. After its construction, it was encapsulated in MasterSil 151Med to form a waterproof, biocompatible coating after curing, which made it suitable for implantation in animals.

Key Parameters and Requirements

The authors needed to encapsulate their entire device with a biocompatible silicone to allow the power source to be changed. The authors chose MasterSil 151Med because it meets the USP Class VI biocompatibility requirements and adhered to the device components. The electrode pin and battery were connected to the device upon molding with MasterSil 151Med, followed by curing.

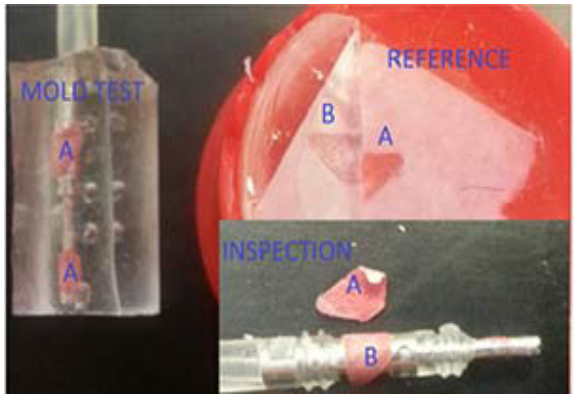

Figure 1. Test of the water intrusion resistance by encapsulating a 304 electrode pin in MasterSil 151Med and then submerging it in saline solution for 3 months (image taken from Moen, L. 2014).

Results

As shown in Figure 1, the authors tested the water intrusion resistance of MasterSil 151Med by attaching moisture indicator paper to the electrode pin conductors, which was then inserted into a mold with the silicone. After soaking the cured sample for 3 months in the saline solution, the authors found no evidence of water intrusion, showing that MasterSil 151Med created a complete seal. According to the authors, this provided "a simple and effective method for encapsulation" of the electrode pin, while also allowing it to be easily removed to change the power source. Ultimately, the authors developed an implantable vagus nerve stimulation (VNS) device that was four times smaller than other VNS devices for use in humans, which may make this device suitable for use in small animal models.

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References

Moen, Lars Lyse. Norwegian University of Science and Technology, Department of Engineering Cybernetics. "An Implantable Device for Electrical Nerve Stimulation." July 2014.