

Protecting Implantable Medical Devices from Moisture with Desiccant-Infused Silicone

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Anyone who has ever opened a bottle of aspirin has witnessed the use of desiccants in the medical field, in the form of a little desiccant-filled canister enclosed to keep the pills from absorbing moisture. In implantable medical devices, however, desiccants (added to silicone during production) are practically invisible, yet the drying function they perform is extremely critical.

The Use of Desiccant-Infused Silicone in Implantable Medical Devices

For implantable medical devices that operate with electronics, such as pacemakers, moisture is the enemy. Excess moisture can cause oxidation and dendritic growth in metal parts and wires. The worst-case scenario is that a device corroded by the effects of moisture could short out, sending a shock through the body, which could be potentially fatal. Of equal concern is the potential for device failure, which could result in severe harm to the patient.

To address moisture issues and to protect the body from electrical currents, silicone is often mixed with desiccants and molded as a protective layer near batteries, electronic circuits and chips, leads, and power cords.

According to UOP, which manufactures molecular sieve adsorbent powders, these powders are effective even at low water concentrations, will dry at high or low temperatures, do not alter formulations, and can remove other contaminants as well as water.

Silicone itself is a biocompatible barrier to moisture and electrical current. Desiccants, although not necessarily biocompatible, can be incorporated into silicone to manufacture a part that will be sealed within the device.

Because the component will not come in direct contact with the body, the desiccants do not have to meet the same FDA materials requirements as does medical grade silicone. In these applications, the desiccant-infused silicone part will not be exposed to bodily fluids. Instead, any moisture will come from the environment in which the part was assembled, including natural humidity. Medical

device OEMs will typically cook off the part in a high-temperature oven to eliminate as much moisture as possible before assembly.

Preparation and Mixing of Desiccants

In designing a medical device, OEMs must conduct extensive evaluation through volume studies of how much moisture the part is likely to encounter once assembled and implanted. From those findings, the OEM will specify the maximum amount of moisture the desiccant will need to absorb in the silicone molded part, once in operation.

The silicone molder then will calculate the amount of desiccant powder and the particle size that should be infused in the silicone.

Desiccants act like a sponge and are only able to hold a certain amount of moisture, so the calculations must be exact. The silicone molder must be experienced in mixing desiccants with silicone, balancing saturation and humidification in the preparation stage to achieve optimal performance. If mixed improperly, the desiccants can damage the silicone. As with parts for any implantable device, all material preparation must be done in a cleanroom environment.

The silicone molder and the OEM will each conduct a range of tests to ensure that the finished parts are clean, such as ionic contamination testing and weight testing of the part when dry and moist. Finally, the OEM will conduct tests on the finished device.

Although desiccants have become ubiquitous in packaging, these tiny particles can play a big role in the ultimate function of an implantable medical device and patient safety.