Factors in selecting medical-grade silicones

Applied Silicone explains the different levels of testing required for implantable silicones, and offers advice for device manufacturers on the lookout for a long-term-implantable silicone supplier.

Pure silicones have gained widespread medical acceptance because of their low toxicity and low risk of unfavourable biological reactions. The present healthcare market supports a small group of silicone raw materials manufacturers, such as Applied Silicone, Dow Corning, Wacker, Momentive, Bluestar, Shin-Etsu and NuSil Technology. Concerns over liability have deterred most large silicone manufacturers from providing long-term-implantable silicones – those intended to be used in the human body for more than 30 days. Applied Silicone is one of two companies willing to serve this market.

Material grades and testing protocols

Silcones designed for medical application are subjected to specific safety evaluations by ISO 10993, a multipart standard used to evaluate the bio-safety of materials that contact the body. Silicones meeting ISO 10993 are deemed appropriate for use in medical applications. Although food-grade status afforded a level of security in the past, it is no longer used in assessing silicones for medical applications. Applications for medical-grade silicones subject to ISO 10993 evaluation are grouped into three categories: limited exposure, prolonged exposure and permanent contact.

Limited exposure

Limited exposure devices may have a brief service life of up to 24 hours in contact with skin, mucosal membrane, or compromised or breached surfaces. Testing of silicones for limited exposure is characterised by cytotoxicity, sensitisation and intracutaneous reactivity.

Prolonged exposure

Prolonged exposure is defined by surface or implanted contact of more than 24 hours and up to 30 days. Silicones qualified for prolonged exposure are commonly referred to as healthcare grade, based on tests such as genotoxicity, subchronic toxicity, haemolysis and intramuscular implantation with histopathology.

Permanent contact

Silicones used in medical devices intended to be implanted for more than 30 days are classified as permanent contact or long-term implantable, and must undergo physiochemical and biological testing beyond that for prolonged exposure. Additional testing includes carcenogenicity, chronic toxicity and developmental toxicity. Test methods and results are assembled into master access files (MAFs) by the raw materials manufacturers and filed with the US Food and Drug Administration (FDA). Class 3 medical device approvals now require exhaustive data only available from world-class silicone manufacturers that specialise in implantable silicones. Leading suppliers, such as Applied Silicone, offer materials compendia organising MAF data into tabulated electronic directories, providing quick and easy navigation to the detailed information.

Choosing a supplier

When evaluating what level of materials testing is needed, a manufacturer of a device incorporating silicone should consider a number of factors:

1. Will it reside in the human body for more than 30 days?
2. What US FDA or other regulations apply?
3. What qualifications testing must be submitted to the US FDA or other regulatory agency?
4. What testing is available from the raw materials supplier?
5. What is the qualification cost and how long will it take?

A second list of questions must then be posed when choosing a silicone supplier. Is the supplier willing and able to:

1. serve the market application?
2. provide the required staff and facilities?
3. follow good manufacturing procedures (GMP) as defined by 21 CFR 820 or ISO 13485?
4. have a certified quality system, such as ISO 9001?
5. formulate a product to meet the manufacturer's physical and processing requirements?
6. provide the information required to perform the qualification testing and evaluation?

If the answers to any of the above questions are not clear, companies should find a consultant with direct experience in qualifying materials for medical devices.

Conclusion

Despite ongoing discussions regarding the testing of medical and implant-grade silicones, there is no evidence of safety issues in their use, and their efficacy is proven repeatedly. Reports from the *New England Journal of Medicine*, the American College of Rheumatology and the British Institute of Health confirm that properly formulated silicones are among the most biocompatible materials available. ■

Further information
Applied Silicone
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