avantor™ | NuSil™

New possibilities for medical devices

Enabling next generation medical implants through in situ cure technology

Medical grade silicone is used for a broad range of medical devices, including cardiovascular, neurological, urological, ophthalmic and aesthetic applications.

Now from the NuSil™ brand, the market leader in long-term implantable silicones, comes a new technology: an innovative silicone dispensing system that makes it possible for medical device manufacturers to create devices that can be in situ cured in the body rather than cured into a part outside the body, then implanted. The prefilled cartridge allows the silicone to be sterilized in the uncured form, opening new possibilities for silicone-based medical devices.

This patented[1] dual-barrel dispensing system may now enable:

- Customized fit of implanted devices
- Less invasive implantation procedures
- Customized silicone formulations to support desired performance characteristics

NEW PACKAGING ENABLES STERILIZATION

Implanted medical devices fabricated from silicone must be sterilized—so an efficient and fully verifiable sterilization solution is necessary. Ethylene Oxide (EtO) exposure is a widely used sterilization method for medical devices. The design of this new cartridge lends itself to EtO sterilization, thereby maintaining the integrity of both the uncured silicone and its packaging. Now, medical device manufacturers can offer novel solutions using a unique package that enables sterilization in the uncured form.

In Situ Cure Makes Innovative Therapies Possible

Potential applications: In long-term medical implants, design options are limited to preformed materials that may require invasive implantation procedures.

New dispensing technology serves as a means to provide an alternate method of surgical implantation, where uncured, pre-sterilized silicone can be provided as a part of the surgical kit and formed within the body during the surgical procedure, resulting in a custom-fit device.

STERILIZABLE PATENTED TWO-PART DISPENSING SOLUTION

The packaging solution for in situ curable silicones features a dual-cartridge prefilled dispensing system. Each barrel has a gas-permeable plunger seal that allows EtO sterilant gas to permeate through the plunger seal to sterilize the contents of the cartridge.

Sterilization verification demonstrated:

- Effective sterilization
- No residual ethylene oxide post-sterilization
- Minimal change to key silicone physical properties such as rheology, durometer, modulus, work time and cure rate

Please note: Sterilization validation of final formula, packaging configuration and lot size is the responsibility of the customer.

Key features of the packaging system include:

- Disposable syringes available in a variety of sizes—5, 10, 50 and 75 ml
- One-step sterilization of silicone components and packaging
- Adaptable to a variety of injection technologies
- Engineered for use in complete surgical kits

THE INDUSTRY LEADER IN SILICONE FOR MEDICAL DEVICES

Our signature NuSil™ Medical Implant line offers a complete range of silicones designed specifically for long-term implants in the body. This line comes fully supported with Master Files. It demonstrates our continued commitment to the medical device market, providing award-winning customer care and quality support that has made us the premier choice of the world's leading healthcare companies.

Contact NuSil™ to Get Started

The NuSil™ team is ready to collaborate with you to provide custom medical grade silicone formulations to satisfy your unique requirements. We look forward to working with you to advance applications of in situ cured silicone for new therapeutic solutions.

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

1 Gas Sterilizable Two-Part Polymer Delivery System, US Patent No. 8,435,217 B2, May 7, 2013.