Polymer Systems Technology Limited

UK & Ireland Distributor

NuSil SILICONE TECHNOLOGY®

Creative Partners in a Material World

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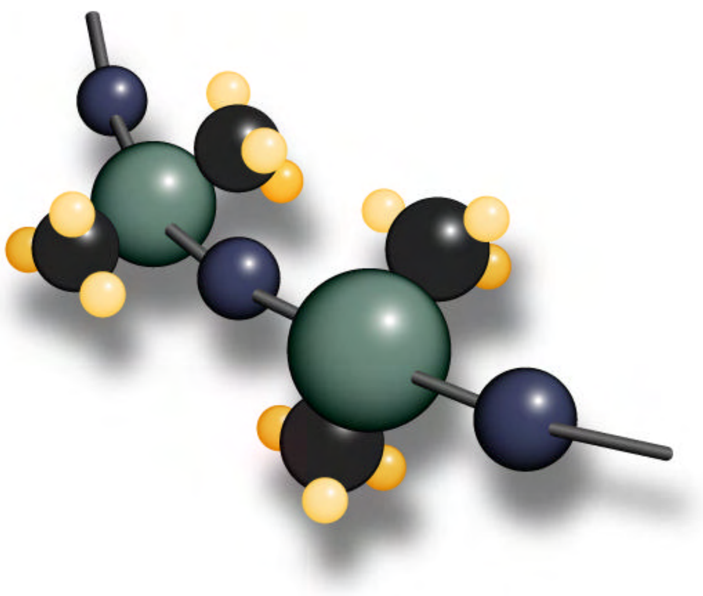

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Methods Used to Sterilize Silicone Based Medical Devices

The majority of sterile goods produced in the medical device and healthcare industries are terminally sterilized to remove unwanted microbial contamination. There are several sterilization methods commonly used for medical devices including: dry heat, steam autoclaving, ethylene oxide, gamma radiation and electron beam sterilization. Several concerns arise about the effects sterilization has on material properties including silicones. Device design, raw material selection, and processing are fundamental considerations that should be addressed before the product is sterilized and shipped to the device manufacurer. Silicone elastomers in general are temperature and moisture resistant and therefore are not adversely affected by most sterilization methods. Ultimately, it is the responsibility of the device manufacurer to determine the suitability of the materials for their applications and to comply with all applicable, statutory, regulatory and Healthcare industry requirements. Prior to determining the right method of sterilization, each user must identify and perform tests and analysis on several samples to ensure that its finished parts will be safe and suitable for end-use conditions.

Heat Sterilization

Dry Heat

Typical Conditions

- Heat conducted from exterior surface to interior
- 160°C/2 hrs or 170°C/1 hr, timing starts after desired temperature is achieved
- Commonly used for gels
- Allow for thermal expansion of silicone contents

Advantages

- Used for materials that cannot be safely sterilized with steam under pressure

Disadvantages

- Detrimental for heat sensitive components or packaging
- Cannot be used with temperature sensitive devices
- Decomposition temperatures of silicones at about 500° F

Steam Autoclave

Typical Conditions

- Process Temps: 126 °C/20 min
- Flash Autoclave: 134 °C/10 min
- Allow for heat expansion of silicone contents

Advantages

- Oldest and most common method for hospital sterilization
- Non-toxic, environmentally friendly & economical
- Has little effect on silicone elastomers

Disadvantages

- Cannot be used with heat sensitive devices
- Not well suited for most silicone adhesives
- Bulk fluid sterilization not recommended for silicone oils, can cause haziness

Chemical Sterilization

Ethylene Oxide (EtO)

Typical Conditions

- 2-12hrs exposure at 25ºC
- Requires aeration step to remove residual EtO for 24 hrs
- Requires porous packaging material

Advantages

- Long-established widely used method
- Compatible with heat sensitive devices
- Permeates & diffuses through polymer networks

Disadvantages

- Toxic, environmental threat from hydrofluorocarbons
- Need cycle development / validation process
- Slower processing time
- Bulk quantity sterilization not recommended for silicone fluids
- Critical to ensure full removal of EtO

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A major concern for many device manufactures is that radiation has been known to damage polymers including: unwanted crosslinking of the polymer network and chain scissioning (the random rupturing of bonds creating low molecular weight fragments, gas evolution and unsaturated bonds that will reduce the molecular weight of the polymer). The result is net loss of flexibility, tensile strength, and elongation. However, these losses may be within the application's specification and may not affect the device's ultimate function.

Radiation Sterilization

Gamma Radiation

Typical Conditions

- Typical dosages 2.5 - 3.0 Mrad
- Ambient temperatures

Advantages

- Good for heat sensitive products
- Good for products impermeable to air exchange
- Does not result in residues left from sterilization process (i.e. EtO)
- Short processing time
- Easily validated

Disadvantages

- Not recommended for gels, changes penetration
- May cause minor increase in durometer and modulus
- Higher doses and repeated exposure will cause further changes in properties
- In extreme cases discoloration and embrittlement as the silicone begins to decompose

Electron Beam

Typical Conditions

- Utilizes ionization energies
- High energy required to penetrate silicone: 2-3 Mrad and up
- Ambient temperatures

Advantages

- Good for heat sensitive products
- Short processing time
- Does not result in residues
- Good for products impermeable to air exchange

Disadvantages

- Required vacuum-like package to avoid inadvertent inflation
- Possible higher setup costs
- Minor increase in durometer and modulus
- Higher doses and repeated exposure will cause further changes in properties
- In extreme cases discoloration and embrittlement as the silicone begins to decompose

Customers seeking additional or specific information on sterilization methods mentioned in this document should contact NuSil Technology directly. Effectiveness and the impact on the materials incorporated into the device are specific to process, device configuration, and other factors. It is the responsibility of the customer to determine the safety and efficacy of sterilization methods and processes. The information contained in this document should not be used in the preparation of a specification.