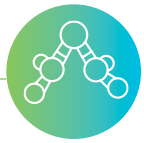
Methods to sterilize silicones for medical devices

Understanding the right sterilization method for your application.

Sterilization removes unwanted microbial contamination from silicones used on and in a device, reducing the risk of infection or irritation for the patient. Choosing which method to sterilize the silicones and understanding the advantages and disadvantages of these methods can be difficult. Use the following information to help you make the right choice for your application.

ETHYLENE OXIDE (ETO)



Advantages
- Long-established, widely used chemical method
- Compatible with heat-sensitive devices and packaging
- Permeates and diffuses through polymer networks
- Acceptable for single-use or reusable devices and/or repeated sterilization
- Minimal impact to silicone properties

Disadvantages
- Requires aeration step to remove chemical residue of EtO and its byproducts
- Requires porous packaging material
- Personal Protective Equipment (PPE) and handling considerations due to toxicity and flammability of EtO
- Longer overall processing time compared to other sterilization methods

STEAM AUTOCLAVE

Advantages
- Most common method for hospital sterilization
- Repeated sterilization possible for reusable devices
- Has little effect on silicone elastomer properties
- Lower cost compared to other sterilization methods
- Minimal impact to silicone properties

Disadvantages
- Cannot be used with heat-sensitive and moisture-sensitive devices
- Not well suited for many 1-part silicone adhesives
- Device design needs to consider allowance for thermal expansion of the silicone
- Silicone may experience discoloration with extended use

DRY HEAT

Advantages
- Long-established, widely used method
- Used for materials that cannot be safely sterilized with steam under pressure

Disadvantages
- Detrimental for heat-sensitive devices and/or packaging
- Silicone may experience discoloration with extended use
- Device design needs to consider allowance for thermal expansion of the silicone
- May impact silicone properties including increased durometer and decreased elongation

ELECTRON BEAM (E-BEAM)

Advantages
- Good option for heat-sensitive products
- Short processing time compared to Gamma radiation
- Good option for products impermeable to air exchange

Disadvantages
- Minor changes in properties compared to Gamma radiation
- Higher doses and repeated exposure may impact silicone properties including increased durometer, and/or decreased tensile strength, tear strength and elongation

GAMMA RADIATION

Advantages
- Good option for heat-sensitive products
- Good option for products impermeable to air exchange
- No chemical residue when compared to EtO sterilization

Disadvantages
- Longer processing time compared to E-Beam sterilization
- Has more significant effect on silicone elastomer properties than any other sterilization method
- Higher doses and repeated exposure may impact silicone properties including increased durometer, and/or decreased tensile strength, tear strength and elongation
- In extreme cases, discoloration and embrittlement can occur as the silicone begins to decompose
- May be limited to single-use devices due to change in properties after repeated exposure

To learn more about the different silicone sterilization methods, visit: **avantorsciences.com/nusil** or contact a NuSil expert at **silicone@avantorsciencesgcc.com** or **+ 1 805 684 8780**

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