Sterilizing Silicone

Sterilization is a standard process for many medical devices. As such, careful consideration has to be given to the materials used in a device that will require a specific type of sterilization method as some materials will not react well to certain processes. This article reviews the most common sterilization methods and specifically notes how they will affect silicone in a medical device.

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A typical steam autoclave

Sterilization of medical devices is inevitable and always raises questions of whether a selected method has an adverse effect on the device and/or the materials used within it. If silicones are part of the device, it is critical to understand the physical effects sterilization imparts on the material properties. Because silicones, in general, are temperature and moisture resistant, they are typically not affected by most sterilization methods. The most common sterilization methods used for medical devices that contain silicone include: dry heat, steam autoclaving, ethylene oxide (EtO), gamma radiation, and electron beam (e-beam) radiation. In general, the effects of sterilization on silicones can be useful in determining the optimal method, but other factors such as device design, throughput, and sterilization efficacy are factors that must be considered when making a decision regarding the sterilization technique.

Dry heat or steam autoclaving will most likely have little effect on silicone's physical properties because of its moisture and heat resistance. Dry heat sterilization is typically used for sterilizing lightly to moderately crosslinked unfilled silicones known as silicone gels. Steam autoclave is commonly used to sterilize reusable medical devices. This method is typically not recommended for use on medical grade adhesives since many substrates and adhesives do not survive well under the high-pressure steam environment.[1] The drawback to heat sterilization of silicone

materials is that the high heat may cause the silicone to expand which must be taken into consideration in how the device is configured and packaged.

EtO is a chemical steriliant small enough to penetrate the microbial cells destroying nuclear cell components.[2] Silicones generally have a high permeability to gases compared to most elastomeric materials,[3] permitting the small EtO molecules to diffuse through the polymer network, inducing sterilization throughout the polymer matrix. The only precaution is to ensure that all of the EtO has been removed from the silicone device before it is used, which usually takes 24 hours.[4]

Gamma radiation and e-beam are alternative sterilization methods for heat sensitive devices and devices that are not permeable to gasses used in chemical sterilization. A major concern for many device manufacturers is that radiation may damage or degrade polymeric materials. Unwanted crosslinking of the polymer network or chain scissioning are the two major mechanisms of change observed by radiation sterilization. The result can be net loss of flexibility, tensile strength, elongation, and/or an increase in durometer. Chain scissioning-the random rupturing of bonds-creates low molecular weight fragments that may lead to gas evolution and unsaturated bonds that will reduce the molecular weight of the polymer.[5] Since these losses may be within the application's specification limits, the minor loss in physical properties may not adversely affect the device's ultimate function. Polymers containing aromatic groups, such as phenyls, tend to have greater resistance to radiation effects.[5,6]

Device design, selecting the proper materials, and material processing are fundamental considerations when developing a medical device, but understanding how the device is packaged and sterilized is also useful. The brief summary of each method presented here can provide an initial screening for selection of a sterilization method. Prior to deciding on a method of sterilization, each user must identify the proper sterilization technique by performing tests and analysis on several samples to ensure that its finished parts will be safe and suitable for end-use conditions. Sterilization service providers are in an excellent position to recommend the most effective sterilization methods through either empirical or experience based knowledge.

References

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