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Medical Devices

Liquid Chemical Sterilization

Although the terms are similar, "liquid chemical sterilization" is different from thermal and gas/vapor/plasma low temperature "sterilization." As explained on this webpage, FDA believes that sterilization with liquid chemical sterilants does not convey the same sterility assurance as sterilization using thermal or gas/vapor/plasma low temperature sterilization methods.

Traditional Sterilization

"Sterilization," as defined in FDA's [Liquid Chemical Sterilants/High Level Disinfectants](#)¹ guidance document, is a validated process used to render a product free of all forms of viable microorganisms. In many cases, thermal methods, such as steam, are used to achieve sterilization. Thermal sterilization methods have been studied and characterized extensively. In addition, the survival kinetics for gas/vapor/plasma low temperature sterilization methods have also been well characterized.

Liquid Chemical Sterilization

Liquid chemical sterilization involves a two-part process:

1. Devices are treated with a liquid chemical germicide (LCG).
2. The processed devices are rinsed with water to remove the chemical residues.

There are several limitations with liquid chemical sterilization. Although the rinse water is treated to minimize any bioburden, it is not sterile. Because the rinse water is not sterile, devices rinsed with this water cannot be assured to be sterile. Furthermore, devices cannot be wrapped or adequately contained during processing in a liquid chemical sterilant. This means that there is no way to maintain sterility once devices have been processed.

Recommendations

For the reasons stated above, FDA recommends that the use of liquid chemical sterilants be limited to reprocessing only critical devices that are heat-sensitive and incompatible with sterilization methods such as steam and gas/vapor/plasma low temperature processes.

Biological and Chemical Indicators for Liquid Chemical Sterilization

Biological Indicators are not appropriate or required for monitoring liquid chemical sterilization process. They are generally used for monitoring traditional sterilization processes where a SAL 10⁻⁶ is achieved. FDA has not cleared any biological indicators for monitoring liquid chemical sterilization process.

Chemical indicators are appropriate and are required for monitoring the minimum required concentration of most liquid chemical sterilants. FDA has cleared many Chemical Indicators for monitoring the concentration of liquid chemical sterilant. Refer to the manufacturer's instructions for a compatible Chemical Indicator that is cleared by the FDA for use with the liquid chemical sterilant.

Links on this page:

1. </MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073773.htm>