



## Updated FDA Guidance for Liquid Chemical Sterilant Processing: What You Need to Know

The U.S. Food and Drug Administration (FDA) updated the “General Hospital Devices and Supplies” web site with new guidance and recommendations for liquid chemical sterilant processing to include the following:

- “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.”
- “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 Indicators are not appropriate or required for monitoring liquid chemical sterilization process.** They are generally used for monitoring traditional sterilization processes where an SAL  $10^{-6}$  is achieved. FDA has not cleared any biological indicators for monitoring liquid chemical sterilization process.”

**The full FDA guidance can also be viewed here:**

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/ucm208018.htm>

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