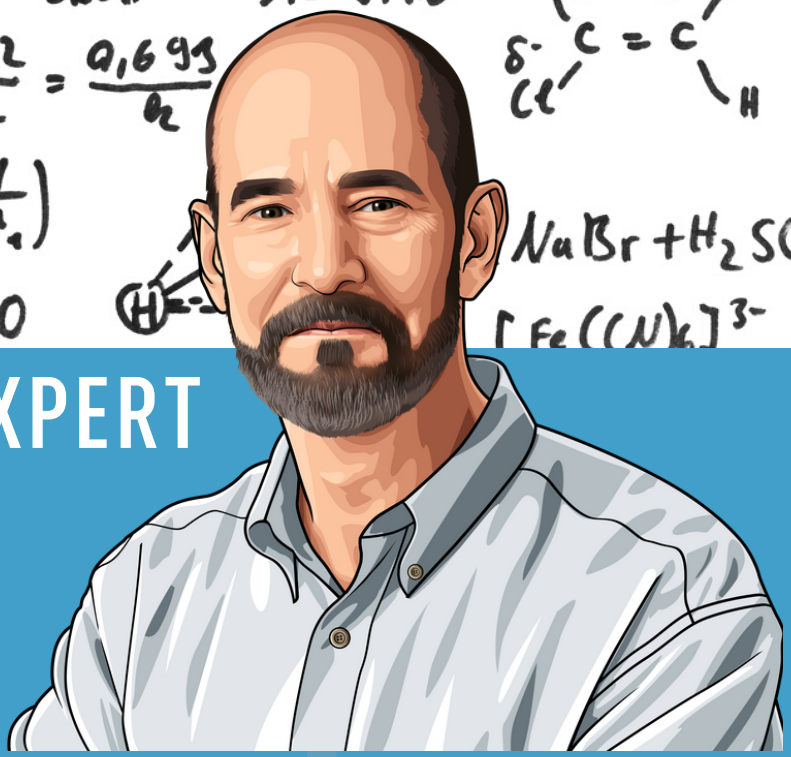
IS LIQUID CHEMICAL STERILIZATION EFFICACY THE SAME AS ETHYLENE OXIDE STERILIZATION?



GAS STERILIZATION EXPERT

BEYOND CLEAN

A.E. Ted May | Andersen Sterilizers
President & CEO | Andersen Products Division

Beyond Clean Gas Sterilization Expert:

IS LIQUID CHEMICAL STERILIZATION EFFICACY THE SAME AS ETHYLENE OXIDE STERILIZATION?

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Ethylene oxide (EO) and liquid chemical sterilization (LCS) are typically used for devices that would be sensitive to high heat used in steam sterilization, as well as rubber and plastic devices that can be damaged by irradiation.

Does that mean EO and LCS efficacy are one in the same?

LCS: FDA describes LCS as a 2-part process: 1) Immerse the device in a liquid chemical germicide. 2) Terminally rinse the device with water to remove chemical residues. [1] Displayed in Table 1, LCS has several limitations.

EO sterilization: In contrast, EO achieves "traditional sterilization," which FDA defines as a "validated process used to render a product free of all forms of viable microorganisms." According to FDA, for many medical devices, "sterilization with (EO) may be the only method that effectively sterilizes and does not damage the device during the sterilization process."

Characteristics	Ethylene oxide gas sterilization	Liquid chemical sterilization
A "traditional" sterilization process	✓	×
SAL: 10^{-6}	✓	×
Process monitored using a BI	✓	×
Sterilized device is dry	✓	×
Device is wrapped, packaged providing a sterile shelf life	✓	×
Survival kinetics are well characterized.	✓	×

LCS sterility assurance level: FDA states, although "the rinse water is treated to minimize any bioburden, it is not sterile" and therefore 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,"[2] rendering the devices prone to re-contamination.

EO Sterility assurance level: EO gas sterilization processes are designed by manufacturers with an associated sterility assurance level (SAL) of 10-6—a level, according to the CDC, liquid chemical sterilants may not convey.[3]

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Have more gas sterilization questions? Contact Ted at: ted.may@sterility.com

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Biological Indicator use with LCS vs. EO: Another salient limitation, FDA states that biological indicators (BIs) are "not appropriate" for monitoring a LCS process (Table 1).[4] FDA notes further that BIs "are generally used for monitoring traditional sterilization processes, like EO sterilization, where a SAL 10-6 is achieved. FDA has not cleared any (Bis) for monitoring (LCS) process." [5]

A comparative study: Rutala et al. (1998) compared the sporicidal activity of four different low-temperature instrument processing technologies including two using EO with hydrochloro-fluorocarbons and a liquid chemical sterilant, respectively.[6] These researchers reported that the former was "highly effective" in killing approximately 106 resistant Bacillus stearothermophilus spores present in the center of narrow-lumen stainless steel tubes." This study found, however, that the liquid chemical sterilant process "was not effective in completely eliminating the 106 inoculum under test conditions."

Unlike LCS, EO sterilization is a traditional sterilization technology that is associated with a SAL of 10-6, can be routinely monitored biologically, yields a dry, wrapped processed instrument that can be stored sterile with a shelf life.

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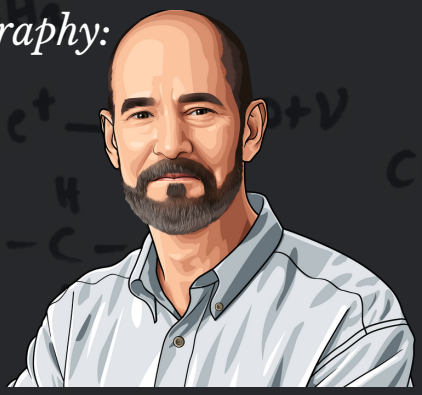

A.E. Ted May is President & CEO of the Andersen Products Division of Andersen Sterilizers, a North Carolina-based medical device manufacturer specializing in low temperature sterilization equipment and hospital consumables. Ted has over twenty years of experience in the field of infection control. He is an expert on ethylene oxide sterilization, with a particular expertise in EO flexible chamber systems. He is a cleared advisor to the US Federal International Trade Advisory Committee on medical devices (ITAC3), where he is Co-chair of the Life Sciences Sub-committee. Ted serves on a number of AAMI committees and has been a subject matter expert for the US delegation to the international ISO Ethylene Oxide Working Group (ISO TC198 WG1). He is a frequent speaker and writer on the subject of sterilization and infection control.

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