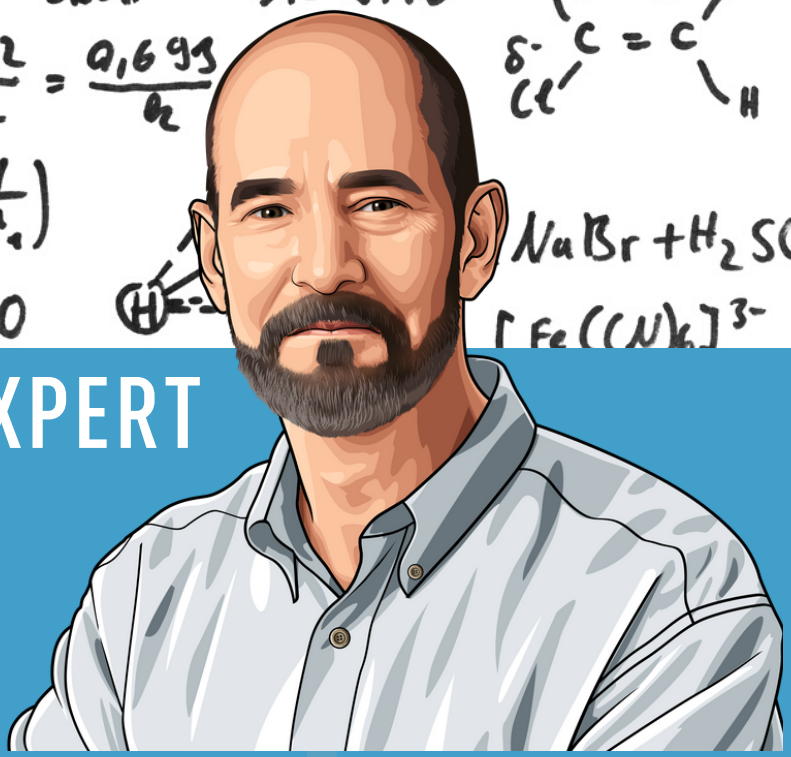
IS DISINFECTION GOOD ENOUGH?



GAS STERILIZATION EXPERT

BEYOND CLEAN

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

Beyond Clean Gas Sterilization Expert:

IS DISINFECTION GOOD ENOUGH?

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Over fifty years ago, microbiologist Dr. Earle H. Spaulding proposed a classification to determine when re-usable medical devices should be disinfected or sterilized. His system was straightforward; three categories based on how an instrument was to be used (what part of the body it enters) and the subsequent risk of an infection. The logic and simplicity of the system quickly brought it into widespread use.

Spaulding System Classifications

Instrument	Use	Risk	Method
Critical	sterile parts of the body, vascular system	High	Sterilization
Semi-Critical	mucous membranes, nonintact skin	Moderate	High-Level Disinfection (HLD)
Non-Critical	intact skin	Low	Disinfection

In the years since its introduction, the simplicity of Spaulding's system has been challenged. Biocide resistance, the role of biofilms and the increasing threat of multidrug-resistant organisms (MDRO) were not considerations in Spaulding's system. Modern medical instruments can be difficult to clean because of intricate device design, while delicate materials used in increasingly sophisticated instruments can be damaged by high temperatures and harsh chemicals.

The current debate over endoscope reprocessing is a good example of how Spaulding's recommendations have grown complicated. Spaulding himself recommended that semi-critical devices (such as endoscopes) be sterilized - but noted that HLD could be used if sterilization was not practical or possible. Because sterilization processes take more time, most healthcare facilities chose to reprocess their scopes with HLD. In recent years, the increasing prevalence of infections linked to endoscopes and the growing virulence of MDROs, has fostered a sometimes heated debated with the healthcare industry and regulators.

For example, the FDA recently opened an investigation into 450+ infection reports related to reprocessing urological endoscopes. It may very well turn out, as it did during the deadly 2015 carbapenem-resistant Enterobacteriaceae (CRE) outbreak, that the endoscopes were properly reprocessed according to IFUs.

It is time to pursue options that work. During the 2015 CRE outbreak, the FDA recommended four supplemental reprocessing measures. Subsequent field surveillance later confirmed ethylene oxide (EO) sterilization was the most effective of the supplemental measures, and validation studies showed that it was the only measure that assures the complete inactivation of highly resistant microorganisms. As you consider both patient safety and facility legal security - consider EO.

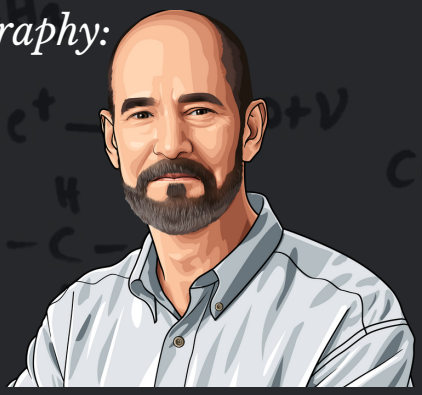
As one commentator put it, if an endoscope is going to be used on you or a family member, what would you prefer?

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

Beyond Clean Gas Sterilization Expert Biography:

A.E. TED MAY

ANDERSEN STERILIZERS
ANDERSEN PRODUCTS DIVISION
PRESIDENT & CEO



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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