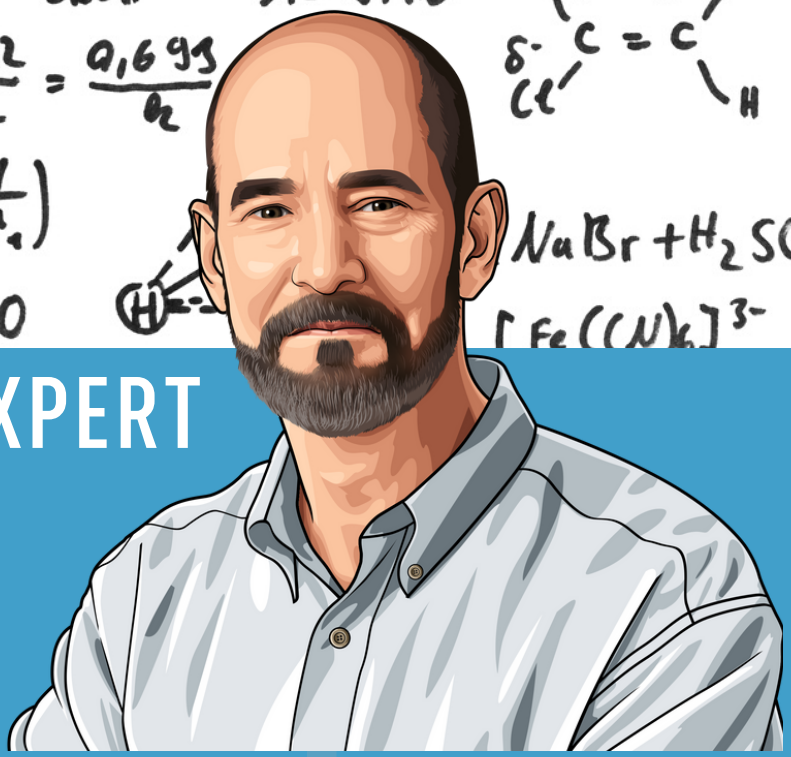
WHEN TO USE A PCD OR TEST PACK



GAS STERILIZATION EXPERT

BEYOND CLEAN

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

Beyond Clean Gas Sterilization Expert:

WHEN TO USE A PCD OR TEST PACK

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Do you know the difference between a biological indicator (BI) and a test pack (also called a process challenge device or PCD) and the proper use of each in a sterile processing program?

Biological indicator: A successful sterilization process is verified with a biological indicator. BIs contain active bacterial spores, which provide a defined resistance to a sterilization process. The complete destruction of all the BI's spores, often over one million of them, provides assurance that sterilization was achieved. Medical equipment that has been properly cleaned is typically never contaminated with organisms more resistant to sterilization and harder to destroy than a BI's spores.

The problem is, a BI's "negative" result does not, by itself, confirm that the processed item, particularly a complex device, is sterile. Why? A negative BI result only indicates that all resistant spores were destroyed at the site where the BI was placed.

When processing a complex instrument, the challenge is to confirm that every microorganism deep within the load itself – for example, within the long and narrow internal channels of a flexible endoscope – was destroyed. How do you place a standard BI in the middle of an endoscope's longest and narrowest channel?

Process challenge device: This confirmation is resolved using a unique accessory called a process challenge device, or PCD. Also referred to as a "BI test pack," the PCD is validated to be more difficult to sterilize than the "worst-case" location of a given load.

Moreover, the PCD standardizes practice by eliminating the requirement that staff consistently place the BI at the same, proper site within the sterilizer prior to each cycle, a technique that can vary and cause misinterpretation of the BI's result.

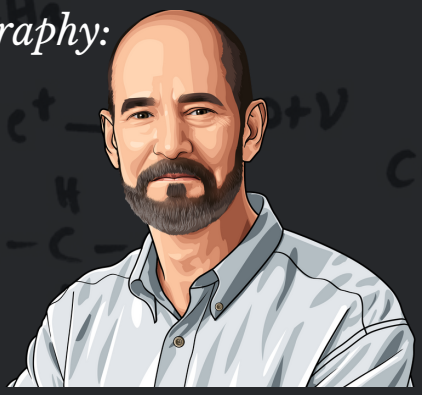
How does your department utilize PCDs or test packs? Do you have a PCD that is validated for especially complex devices such as duodenoscopes or are you assuming that a BI placed in the load is "good enough?"

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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