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Biological indicators for vaporized hydrogen peroxide (VH_2O_2) sterilization in healthcare facilities: a comparison study

Background

Sterilization is a process that cannot be inspected or tested in a practical manner to assure that all microorganisms have been inactivated on medical devices. Sterilization processes in healthcare facilities must therefore be monitored on a per-cycle basis. According to the Centers for Disease Control (CDC), biological indicators (BIs) measure the sterilization process directly by using the most resistant microorganisms (i.e., Bacillus spores), and not by merely testing the physical and chemical conditions necessary for sterilization. Thus, biological indicators are the only process indicators that directly monitor the lethality of a given sterilization process.[1]

Method

The 3M™ Attest™ Rapid Readout Biological Indicator 1295 for vaporized hydrogen peroxide has been cleared for use in vaporized hydrogen peroxide (VH_2O_2) sterilization cycles in healthcare. The objective of this study was to compare the performance of the 3M™ Attest™ 1295 BI to the ASP® STERRAD® CYCLESURE® 24 BI and the STERIS® VERIFY® V24 BI. All three BIs are self-contained biological indicators currently available for use in VH_2O_2 sterilization. The 3M™ Attest™ 1295 BI provides a final fluorescence readout result after four hours of incubation, whereas the other two BIs evaluated provide a final readout result after 24 hours of incubation.

The BIs were compared in the ASP® STERRAD® 100S sterilizer and the ASP® STERRAD® 100NX® sterilizer, both of which are installed and routinely operating in a healthcare facility. All test cycles in the STERRAD® 100S were performed with a loaded chamber using both fractional exposure times (reduced exposures that would be considered inadequate cycles) and full exposure times (full cycles). The fractional exposure test times included a single injection and exposure times of 15, 30 and 90 seconds. The times chosen represent an extreme sterilization cycle failure. For comparison, a full STERRAD® 100S cycle includes two injections of sterilant (VH_2O_2). Each sterilant injection has an approximate exposure time of eight minutes for a total estimated cycle exposure time of 16 minutes; therefore 15 to 90 seconds of sterilant exposure is a mere fraction of the cycle exposure time (approximately 1.5 percent to 9.3 percent of a full cycle exposure).

All test cycles performed in the STERRAD® 100NX® involved loaded chambers and full sterilant exposure cycles only (no fractional test cycles).

All fractional test cycles included three lots of each BI type, with two BIs per lot, for a total of 18 BIs in each fractional test cycle. All full sterilization test cycles included three lots of each BI type, with one BI per lot, for a total of nine BIs in each full test cycle. The BIs were placed in VH_2O_2 compatible sterilization pouches and then inside the chamber with the load.

All test cycles contained a product load of devices. The product load was assembled following manufacturer instructions for use, including compatible packaging and device materials. The sterilizer chambers were loaded using good loading practices per the sterilizer manufacturer's operator's manual, and the STERRAD® 100NX® cycles were loaded meeting the strict weight limits for each cycle type.

There were statistical differences in the performance of the 3M™ Attest™ 1295 BI compared to the ASP® STERRAD® CYCLESURE® 24 BI and the STERIS® VERIFY® V24 BI.

Results

There were statistical differences in the performance of the 3M™ Attest™ 1295 BI compared to the ASP® STERRAD® CYCLESURE® 24 BI and the STERIS® VERIFY® V24 BI. Figure 1 illustrates the side-by-side comparison of the percentage of positive results for the combined lots of each BI type in the fractional sterilant exposure times performed in the loaded STERRAD® 100S. In this study, the 3M™ Attest™ 1295 BIs achieved 100 percent positive results at each of the shortened exposure times of single injections of 15, 30 and 90 seconds. Only a fraction of the STERRAD® CYCLESURE® 24 BIs and VERIFY® V24 BIs tested were able to detect the shortened exposures in any of the tests. At 90 seconds of exposure, 94.4 percent of the STERRAD® CYCLESURE® 24 BIs tested and 88.9 percent of the STERIS® VERIFY® V24 BIs tested failed to provide a positive result, as illustrated in Figure 1.

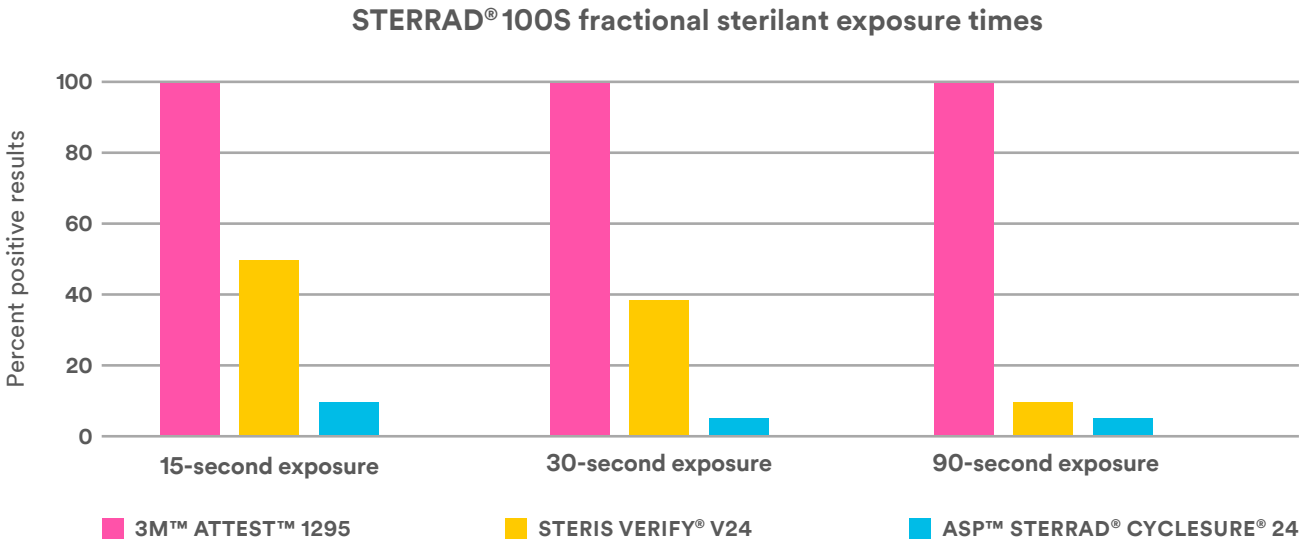

Figure 1. Side-by-side comparison of the percentage of positive results for the combined lots of each BI type tested in fractional sterilant VH_2O_2 exposure times in the STERRAD® 100S

As expected, the full sterilization test cycles for both the STERRAD® 100S and the STERRAD® 100NX® cycles resulted in complete inactivation of all biological indicators from all lots from all three manufacturers. Table 1 contains the results of the full sterilization test cycles for both the STERRAD® 100S and the STERRAD® 100NX® cycles for all three BI types.

Sterilizer	Full sterilization cycles with loaded chambers	Cycle #	Combined lots (# negative/# tested)		
			3M™ Attest™ 1295 BI	ASP® STERRAD® CYCLESURE® 24 BI	STERIS® VERIFY® V24 BI
STERRAD® 100S	100S cycle	1	3/3 negative	3/3 negative	3/3 negative
		2	3/3 negative	3/3 negative	3/3 negative
		3	3/3 negative	3/3 negative	3/3 negative
STERRAD® 100NX®	STANDARD cycle	1	3/3 negative	3/3 negative	3/3 negative
		2	3/3 negative	3/3 negative	3/3 negative
		3	3/3 negative	3/3 negative	3/3 negative
STERRAD® 100NX®	FLEX cycle	1	3/3 negative	3/3 negative	3/3 negative
		2	3/3 negative	3/3 negative	3/3 negative
		3	3/3 negative	3/3 negative	3/3 negative
STERRAD® 100NX®	EXPRESS cycle	1	3/3 negative	3/3 negative	3/3 negative
		2	3/3 negative	3/3 negative	3/3 negative
		3	3/3 negative	3/3 negative	3/3 negative

Table 1. BI results for full sterilization test cycles, loaded chambers, for both the STERRAD® 100S and STERRAD® 100NX® cycles for all three BI types

Discussion

The purpose of sterilization monitors is to detect situations when sterilization process conditions are not achieved. Sterilant exposure time is a critical cycle parameter for all sterilization processes. Biological indicators provide a direct measure of sterilization process lethality and would be expected to detect major reductions in the sterilant exposure time. They would also be expected to provide a pass result if all sterilization parameters and loading requirements are met. The fractional exposure testing indicated substantial differences in the performance of the 3M™ Attest™ 1295 BI versus the STERRAD® CYCLESURE® 24 BI and VERIFY® V24 BI. These differences were statistically significant. The data in Figure 1 indicates that the STERRAD® CYCLESURE® 24 BIs and the VERIFY® V24 BIs were not able to consistently detect a significant process failure (reduced exposure time). In this test, the 3M™ Attest™ 1295 BI did reliably detect 100 percent of the sterilization failures designed in this study.

As expected, all BIs tested in the full sterilization cycles in loaded chambers were inactivated in both the STERRAD® 100S and STERRAD® 100NX®.

Conclusion

The ASP® STERRAD® CYCLESURE® 24 BIs and the STERIS® VERIFY® V24 BIs tested in this study were not able to consistently detect a major sterilization process failure created by a significant reduction in sterilant exposure time. The 3M™ Attest™ 1295 BIs tested in this study were able to consistently detect this same sterilization process failure. All BIs tested gave pass results in properly loaded complete sterilization cycles.

References

1. *CDC Guideline for Disinfection and Sterilization in Healthcare Facilities*, 2008 William A. Rutala, Ph.D., M.P.H.1,2, David J. Weber, M.D., M.P.H.1,2, and the Healthcare Infection Control Practices Advisory Committee (HICPAC).

3M Infection Prevention Division
3M Health Care
2510 Conway Avenue
St. Paul, MN 55144-1000 USA

Phone **800-228-3957**
Web **3M.com/infectionprevention**