



PROFESSIONAL INFORMATION REPORT **00-02**

PERFORMANCE TESTING OF FLASH STERILIZATION CYCLES
Comparison of **Duo-Flash®** Versus Biologicals

Gianina Aronovici DVM
John D. Dyckman Ph.D.
Propper Manufacturing Company
Long Island City, New York, 11101, USA

Product Description and Purpose:

Propper's DUO-FLASH® indicator is a dual cycle chemical indicator for use in steam flash sterilization cycles. It consists of 2 specially formulated chemical inks imprinted on a paper strip which is enveloped in a polymer laminating film. It is designed to monitor both the 3-minute exposure of unwrapped non-porous loads and the 10-minute exposure of wrapped or porous loads at 270°F(1). DUO-FLASH® was designed to integrate the exposure conditions of time and temperature of saturated steam necessary for successful flash sterilization. It was also designed to monitor the sterilization cycles beyond the conditions needed to kill the most resistant bacterial spores. Cycles which meet these sterilizing conditions are indicated by the change of the appropriate indicator ink from green to black.

The purpose of this study was to verify that the DUO-FLASH® indicator inks would monitor complete sterilization conditions for unwrapped or wrapped instruments in the three-minute and ten-minute flash sterilization cycles. It was also designed to compare the exposure time necessary to kill biological indicator preparations of highly resistant bacterial spores, that are routinely used to monitor sterilization cycles, with the time necessary for DUO-FLASH® to indicate an acceptable cycle.

Materials and Methods:

A series of flash sterilization cycles was performed for various exposure times at 270° ± 1°F in a 26 x 16 inch diameter manually operated autoclave. Chamber temperature was monitored by use of a thermocouple located in the center of the chamber. Three different lots of DUO-FLASH®, and three lots of Duo-Spore® biological indicators were used in this study. Ten indicators (Duo-Spore® and/or DUO-FLASH®) were placed along with six stainless steel instruments in a 9 x 15 inch metal tray with a perforated bottom for each sterilizer run. Heat-up times ranged from 38-65 seconds. For wrapped loads, the tray was covered by a single sheet of Steri-Wrap® I disposable wrap.

Following the cycles, the DUO-FLASH® indicators were examined and interpreted based upon the change of color from green to black. The Duo-Spore® strips were aseptically removed from their glassine envelopes, transferred to a modified Trypticase Soy Broth, incubated at 56°C for 48 hours and examined for growth.

Results:

In unwrapped loads, the biological indicators began to show a low level of acceptable results (kill) in cycles with only 15-second exposure. All biological indicators were killed after 30 seconds exposure. The DUO FLASH® indicators demonstrated no accept results at the end of 1 minute, 33% accept results at the end of two minute exposures, and 100% accept results at the end of the standard 3-minute unwrapped cycle (see Table below).

In wrapped loads, the biologicals showed complete survival at the end of a one-minute exposure, and no growth in all test strips after only 2.5 minutes of exposure. The DUO-FLASH® indicators demonstrated no acceptable color change to black at 5 minutes, an acceptable color change in 33% of the indicators at 7.5 minutes, and 100% acceptable results at the end of a standard 10 minute wrapped cycle.



Time (min)	Unwrapped Cycles		Wrapped Cycles	
	Duo-Spore (Kill/Total)	DUO-FLASH (Accept/ Total)	Duo-Spore (Kill/Total)	DUO-FLASH (Accept/ Total)
Heat-Up	0/30			
0.25	7/30			
0.5	30/30			
1.0		0/30	0/30	
2.0		10/30		
2.5			30/30	
3.0		30/30		
5.0			30/30	0/30
7.5				10/30
10.0				30/30

Conclusions and Discussion:

The proper use of flash sterilization cycles by personnel in the operating room has been a topic of debate for several years. The reasons for these concerns and the steps taken to assure a complete quality system have been presented thoroughly in a recent article(2). The main issue is that the operating room setting is a fast paced environment in which the reprocessing of surgical supplies was not given as much care and attention as in the more controlled environment of the Sterile Processing Department. Decontamination, inspection, and sterilization of surgical instruments were found to be poorly controlled and documented. This led to a thorough education and monitoring program which took several years to implement.

The use of chemical indicators in flash sterilization cycles is a universally recommended practice(3). This can be especially important for the acceptance of articles which have undergone flash sterilization and are needed in the operating room STAT. Personnel are not available to document the printed record of the sterilizer run, and there is no time to wait for the results of biological indicators.

It is evident from this study that both unwrapped and wrapped flash sterilization cycles are capable of killing large numbers of highly resistant bacterial spores at an early time in the sterilization cycle. Both cycles also provide adequate "overkill" or safety factor to provide for a very high probability that sterilization has been achieved. The DUO-FLASH® indicators for the three minute unwrapped and ten minute wrapped cycles did not reach the correct color endpoint until long after complete kill of the spore preparations had been achieved.

In this study, the Proper DUO-FLASH® indicator consistently demonstrated performance beyond that of biological indicators in monitoring the sterilization cycle. The DUO-FLASH® three and ten .minute indicator inks did not change to the full endpoint until after the conditions for spore death had occurred. Since the results of these chemical integrators are available immediately to personnel responsible for releasing flashed goods for use, DUO-FLASH® should be employed as a vital part of the flash sterilization quality control program.



References:

1. Propper Professional Information Report 91-1. Propper's DUO-FLASH Sterilization Indicator. Propper Mfg. Co. Inc. 1991.
2. Donaldson, Jack and Donaldson, Kathy, "Flash Sterilization/ The Fundamental Issues." Infection Control Today, pp22-26, October, 2000.
3. "Flash Sterilization- Steam sterilization of patient care items for immediate use." AAMVANSI ST37-33 I June 1996.

