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PROPPER'S **DUO-FLASH®** STERILIZATION INDICATOR

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About Flash Sterilization

From a historical perspective, flash sterilization, or steam sterilization by the un-wrapped method, has been regarded as an emergency procedure involving, at most, one or two urgently needed surgical instruments. The extension of this practice to complete sets of instruments, while not encouraged, is often necessary to keep pace with unplanned surgical activity amidst today's hectic operating room schedules.[1,2]

Flash sterilization is not recommended as a substitute for the more conventional wrapped sterilization procedure. However, both AAMI and AORN have recognized the need and, accordingly, have made provision for the use of flash sterilization when, and only when, the following conditions have been satisfied.[3,4]

1. There must be an urgent need.
2. Provision must be made for proper pre-sterilization cleansing, decontamination, inspection, etc.
3. Aseptic delivery of flash sterilized items to the point of use must be ensured.
4. Flash sterilizers must be subject to the same monitoring standards as other steam sterilizers in the facility.
5. Implantables should never be sterilized by the unwrapped (flash) method.

Flash sterilization is usually considered to be a 270°F gravity displacement process although pre-vacuum sterilizers (and cycles) are sometimes employed.' A small selection of surgical instruments in a single unwrapped mesh-bottom tray generally constitutes the load but, more porous items such as towels, rubber and plastic goods and instrument lumens are often included. For the most part, the tray and its contents are metallic in composition, non-porous in structure, and present considerable surface area to the saturated steam sterilant. Consequently, during the flash cycle, extensive condensation occurs at the tray and instrument surfaces and the load often emerges from the sterilizer in a "soaking wet" state. Even if a quick drying step is included, substantial load wetting occurs during the exposure segment of the flash cycle and residual moisture is apt to persist. It should be noted that this is generally not the case when the wrapped sterilization method is employed.

The profuse condensation, so characteristic of flash cycles, should immediately pose two major concerns ... one dealing with recontamination of the sterile load and the other with adulteration.

First, if the load is wet when it is retrieved from the sterilizer, maintaining sterility to the point of use is made much more difficult. This subject has received considerable attention by several authors and will not be discussed here at any length.[5, 8] It is sufficient to say that before flash sterilization is invoked, suitable provision must be made for handling wet sterile loads.

Second, to monitor the flash cycle, "A chemical indicator should be used in each tray or container being processed."[1, 3] Furthermore, "Indicators should be selected which do not bleed, flake or otherwise adulterate the devices being sterilized."[3] Therefore, the choice of indicator (presumably a direct-read chemical indicator) should be limited to one whose structural integrity is not impaired by the combined high temperature and severe wetting conditions encountered in flash cycles.

THE PROPPER DUO-FLASH® INDICATOR

Product Description

Propper's Duo-Flash® Indicator is a single-use dual-cycle steam sterilization monitor which satisfies all of the performance criteria designated by AAMI for flash sterilization chemical indicators.[3] Furthermore, its dual-cycle capability allows it to be used for monitoring both the 3-minute flash exposure of non-porous loads and the 10-minute flash exposure of porous/non-porous mixed loads at 270° F.

Duo-Flash® was specifically designed to integrate time, temperature and saturated steam into accurate, reproducible, Accept/Reject, color displays while withstanding the physical rigor of the flash sterilization process. Hence, it will monitor the exposure conditions necessary for sterilization without, in any way, adulterating the sterile load. Also, because Duo-Flash® is not degraded during the flash cycle, it can be retained as a convenient record of flash cycle validation.

Indicator Design

The Duo-Flash® Indicator consists of two specially formulated chemical inks imprinted on a paperboard strip which, in turn, is completely enveloped by a polymeric laminating film. The paperboard, inks and polymeric film are all critical elements in defining the performance characteristics of the indicator.

The paperboard serves as the structural "backbone" of the indicator and the substrate or carrier for the chemical inks. In addition, its permeability to steam must be optimal to help regulate the speed at which the indicator changes color. Thus, careful scrutiny is required in the selection of the paperboard for its essential performance characteristics.

The indicator inks are unique formulations that are supersensitive in their response to the critical sterilization parameters: time, temperature and saturated steam. This super sensitivity or high-speed reactivity is necessary to offset the slow rate of steam vapor penetration through the paperboard and polymeric film. Prior to autoclaving, the color of each ink is light green but during the flash cycle the colors progress, in a stepwise manner, through increasingly darker shades of green culminating in black endpoints. These endpoints occur after three-minute and ten-minute exposures to saturated steam at 270°F ... precisely the minimum exposure requirements for the flash sterilization of non-pours and porous/non-porous mixed loads, respectively.

Finally, the polymeric film completely insulates the chemical inks and paperboard strip from the instrument tray and its contents. It also plays the primary role in regulating the rate at which saturated steam vapor penetrates the indicator. Because the film itself is not degraded during the flash cycle, the indicator remains intact. No ink or paper residues can adulterate the load. Furthermore, the processed Duo-Flash® Indicator represents a cleaner, more permanent record of flash cycle validation then would be possible from the unprotected paper indicator strip.

Performance Characteristics

Propper's Duo-Flash® Indicator has been thoroughly tested in accordance with the AAMI recommended minimum process conditions for unwrapped (flash) sterilization. Literally hundreds of Duo-Flash® Indicators were evaluated for color change after exposure to saturated steam at 270 °F. Exposure times ranged from one to three minutes for the 3-minute ink and one to ten minutes for the 10-minute ink. (Heat-up times ranged from 20 to 75 seconds.)

In each test sequence there were clear color distinctions from one exposure time to the next for both the 3 and 10-minute inks.' Although some shade variations occurred for both inks, the results did indicate a high degree of color reproducibility with virtually no color overlap for adjacent exposure times.

Exposing the Duo-Flash® Indicator to a three or ten-minute dry heat cycle at 270°F produced only minor shifts in the corresponding indicator colors (reject indications). This illustrates the indicator's dependency on saturated steam as well as time and temperature to trigger the color change.

In summary, the test results showed that a black Accept color can be anticipated only after simultaneously satisfying all three minimum process variables, i.e., three or ten minutes exposure to saturated steam at 270 °F. In every case the integrity of the Duo-Flash® Indicator was completely preserved. No ink bleed, paper residues or any form of indicator degradation was ever observed during the test period.

References:

(1) "Flash Sterilization": Journal of Hospital Supply, Processing And Distribution, 59-69, May/June 1985.

(2) "Fogg, Dorothy, M. "Criteria For Flash Sterilization"; AORN Journal, 50(4), 888-892, Oct. 1989.

(3) "Good Hospital Practice: Steam Sterilization Using The Unwrapped Method (Flash Sterilization)"; AAMI Recommended Practice (AAMI SSUM-9/85); Association For The Advancement of Medi cal Instrumentation, Arlington, VA; 1986.

(4) "Recommended Practices Sterilization and Disinfection"; AORN Journal, 45 (2), 450-452, Feb. 1987.

(5) Perkins, John J. "Principles And Methods of Sterilization In Health Sciences"; 218, 2nd ed.; Charles C. Thomas, Springfield, IL 1983.

(6) Probst, H.D. "The Effect of Bactericidal Agents On The Sterility of Surgical Linen"; Amer. J. Surg., 86, 301-308, 1953.

(7) Beck, W.C. and Collette, T.S. "False Faith In The Surgeon's Gown And Surgical Drape"; Amer. J. Surg., 83, 125, 1952.

(8) Karlson, K.E., Riley, W. and Dennis, C. "A Quantitative Evaluation Of The Permeability Of Wet Surgical Drapes To Staphylococcus Aureus"; Surg. Forum, 9, 568-571, 1959.

(9) Propper Manufacturing Co., Inc. - Research data on file.