



PROFESSIONAL INFORMATION REPORT **85-1**

EVALUATION OF THE **BIO-CHALLENGE TEST PAK®**
COMPARED TO THE STANDARD LINEN
BIOLOGICAL TEST PACK



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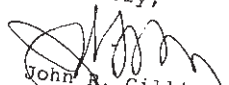
Dear Dr. Augurt:

Enclosed is the report from the study conducted at Skyland under the direction of Dr. Carl Bruch, comparing the Propper Bio-Challenge Test-Pak® to the standard linen pack. Test exposures were made in both 250 F gravity and 270 F pulsing vacuum cycles. Both types of test packs were used with biological indicators to test the efficacy of steam sterilization cycles.

The data indicate that under the test conditions used, evaluation of cycle adequacy was equivalent for both packs. The standard linen pack and Bio-Challenge Test-Pak® are essentially equivalent in relative resistance to steam penetration and in the time needed to completely kill the biological indicator spores.

It is important to note that the method of preparation of the standard linen pack generates the likelihood of pack-to-pack variation. Therefore, it is probable that greater reproducibility in test results can be obtained with the Bio-Challenge Test-Pak® than with the manually-assembled standard linen packs.

Sincerely,


John R. Gillis, Ph.D.
Executive Vice President
Marketing and Business Development

JRG:ac
Enclosure

Report

The standard linen pack is currently recommended for use with biological indicators to test the efficacy of steam sterilization cycles.^{1,2} Any alternative pack should give equivalent results in terms of determining cycle adequacy. The purpose of this study was to compare the results from Proper's Bio-Challenge Test-Pak® to those obtained with the standard linen pack.

Materials and Methods:

Standard linen packs were prepared using freshly laundered linens, and consisted of 1 drape, 3 surgical gowns, 5 laparotomy sponges, 12 towels, and 30 gauze sponges double wrapped in double thickness muslin wraps. Linen packs had maximum dimensions of 12x12x20 inches and weighed 12 +/- .8 pounds. Two biological indicators (Proof™, Amsco) were placed in the center of the stack of towels. Two biological indicators from the same lot used in the standard linen pack were placed in the central cavity of the Bio-Challenge Test-Paks®.

Standard linen packs and Bio-Challenge Test-Paks® were subjected to 250° -252° F gravity displacement cycles for either 18 or 22 minutes. The pre-vacuum cycle parameters were: 1) steam to 2 PSIG; 2) vacuum to 2 PSIA; 3) steam to 2 PSIG; 4) vacuum to 2 PSIA; 5) steam to 270° -272° F. Exposure times for the pre-vacuum cycles were 2.5 and 4.0 minutes.

After exposure cycles, biological indicators were removed from the test packs, allowed to cool, and then activated. Biological indicators were incubated at 55 -60°C and examined at 72 hours.

Results:

Data from the 270°F pre-vacuum cycles are listed in Table I. In the 2.5 minute exposures, all cycles were judged to be inadequate. The standard linen pack yielded 6/6 indicators positive while the Bio-Challenge Test-Pak® had 5/6 positive. Both types of packs indicated adequate cycles in the 4 minute exposures with all biological indicators showing no growth.

Table 1
270°F Pre-Vacuum Cycles

Standard Linen Pack				Bio-Challenge Test-Pak®	
Exposure Time	Run Number	Biological Indicators Results	Cycle Interpretation	Biological Indicators Results	Cycle Interpretation
2.5 Min.	1	2/2	Inadequate	2/2	Inadequate
	2	2/2	Inadequate	2/2	Inadequate
	3	2/2	Inadequate	1/2	Inadequate
4.0 Min.	1	0/2	Adequate	0/2	Adequate
	2	0/2	Adequate	0/2	Adequate
	3	0/2	Adequate	0/2	Adequate



Data from the 250°F gravity displacement exposures are shown in Table II. Both types of packs detected inadequate cycles at the 19-minute exposures with all biological indicators positive. Both packs had complete negatives after 22-minute exposures.

Table 2
270°F Pre-Vacuum Cycles

Standard Linen Pack				Bio-Challenge Test-Pak®	
Exposure Time	Run Number	Biological Indicators Results	Cycle Interpretation	Biological Indicators Results	Cycle Interpretation
18 Min.	1	2/2	Inadequate	2/2	Inadequate
	2	2/2	Inadequate	2/2	Inadequate
	3	2/2	Inadequate	2/2	Inadequate
22 Min.	1	0/2	Adequate	0/2	Adequate
	2	0/2	Adequate	0/2	Adequate
	3	0/2	Adequate	0/2	Adequate

Discussions and Conclusions:

The data indicate that under the test conditions and specific vessel operating parameters used, the Bio-Challenge Test-Pak® and the standard linen pack show virtual equivalence in relative resistance to penetration by saturated steam. Determination of cycle adequacy (complete kills of the biological indicators) or inadequacy (complete or partial survival) was identical for both types of test packs.

The standard linen pack is difficult to prepare correctly and is subject to variation in preparation, and possible resultant resistance to steam penetration. The folding, compression, and taping of the standard linen pack are subjective variables which are eliminated by use of the Proper Pack. Use of the Bio-Challenge Test-Pak® is more convenient than use of the standard linen pack.

References:

1. AAMI Recommended Practice, Good Hospital Practice: Steam Sterilization and Sterility Assurance, pg. 8; AAMI, Arlington, VA., 1980.
2. AORN Recommended Practices for Inhospital Sterilization, AORN Journal, vol 32 pp 222-246, 1980.

