STERIKING®

Steriking® Paper/Laminate pouches

Sterilization Compatibility

& Shelf life study

THE ULTIMATE PACKAGING
STERIKING®
CHOICE FOR STERILE SUPPLIES

1 INTRODUCTION

This test was designed to develop data about Steriking® Paper/Laminate packages compatibility with Pre-Vacuum Steam and Ethylene Oxide sterilization and data of shelf life after sterilization by Ethylene Oxide and Pre-Vacuum Steam. Compatibility with sterilization methods was performed in Feb-April, 2014 and shelf life studies were initiated in 2013 and accelerated aging finished in 2014. Compatibility testing was performed pre-sterilization, post sterilization and post five years accelerated aging.

2 TESTING FACILITY

Testing facility was LexaMed Ltd, USA. Test results presented in this report are based on the test reports of Lexamed protocols 13-L032 and 13-L071.

3 EQUIPMENT AND MATERIALS

3.1 Sterilant penetration study

Sterilant penetration study was performed both for single pouch and for double pouches. For sterilant penetration studies following pouches were provided: S24 (lot 0906), S30 (lot 1302), S5 (lot 1307), S14 (lot 1304), SS-T1 (lot 1209), SS-T5A (lot 1301), SS-T4 (1301), SS-T6 (lot 1301) and the sample quantities and distribution are presented in the Tables 1. and 2.

Table 1. Half Cycle Steam Sterilization Pouch Preparation

Pouch	Total	Used as a single pouch	Used for double pouching	Outer pouch
S24	80	40	40	S5
S30	80	40	40	S14
SS-T1	80	40	40	SS-T4
SS-T5A	80	40	40	SS-T6

Table 2. Half Cycle EO Sterilization Pouch Preparation

Pouch	Total	Used as a single pouch	Used for double pouching	Outer pouch
S24	30	15	15	S5
S30	30	15	15	S14
SS-T1	30	15	15	SS-T4
SS-T5A	30	15	15	SS-T6

A self-contained Biological Indicator (BI) and standard silicone tubing with various diameters were placed into each pouch prior to sterilization; the tubing was chosen to represent “typical” contents of a pouch. Each pouch was exposed to one of the three sterilization processes: 100 % EO sterilization at 55 °C, Moist heat sterilization with a pre-vacuum at both

132°C and 135°C. In order to provide information on sterilization conditions within the pouch for each sterilization load, temperature data loggers were placed inside representative pouches and loggers were geometrically distributed within the load (front, center, back). Five (5) data loggers were used in the steam cycles and three (3) were used in the EO cycles.

After each steam sterilization cycle it was demonstrated that a population of 10^6 spores of *Geobacillus stearothermophilus* was eliminated when packages were subjected to the Pre-Vacuum Steam sterilization cycle.

After Ethylene Oxide sterilization cycle it was demonstrated that a population of 10^6 spores of *Bacillus atrophaeus* was eliminated when packages were subjected to the EO sterilization cycle.

3.2 Shelf life Study

Wipak provided a total of eighty two (82) S24 (lot 0912) and eighty two (82) S32 (lot 1304) Steriking® pouches for shelf life studies. Standard silicone tubing of various diameters was placed into pouch S24 or S32 prior to sterilization and aging, the tubing was chosen to represent "typical" contents of a pouch. Pouches were closed with heat-sealer with sealing temperature of 170°C prior sterilization. Only the manufacturer's seals were tested for seal strength and seal integrity.

Two (2) S24 pouches and two (2) S32 pouches were not sterilized and retained for baseline package integrity testing.

Samples were sterilized in following conditions:

Ethylene Oxide (EO) Sterilization

Samples were exposed to a single 100% EO cycle with a concentration of 725-735 mg/L at 54-55°C and 40% - 80% relative humidity with a 60 minute exposure. Cycle was consistent with ANSI/AAMI ST41:1999 Ethylene oxide sterilization in health care facilities: Safety and effectiveness.

Pre-Vacuum Moist Heat Sterilization (PVS)

Samples were exposed to single pre-vacuum steam sterilization with the following parameters: 135°C, 4 minute sterilization, 3 vacuum pulses with a final pulse level of 27" Hg (91.4kPa), and a 20 minute dry time. Cycle was consistent with ANSI/AAMI ST 79, "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities."

4 TEST PERFORMANCE

4.1 Sterility testing

Prepared pouches were processed following the parameters described in the Table 3. Three (3) runs were conducted for each condition. Each cycle contained a BI that was not within a pouch to serve as a negative control.

Table 3. Sterilization Cycle Parameters

Sterilization Method	Cycle Parameters
Pre-Vacuum (Steam) Half Cycle (132°C)	Sterilization Temperature: 132±3°C Jacket Temperature: 133.0°C Purge Pressure: 10.0P Purge Time: 2.0 Minutes Pre-Vacuum Level: 27.0" Hg (91.4kPa) Pre-Vacuum Pulses: 4 Pre-Vacuum Hold: 1.0 Minutes Incremental Charge Time: 2.0 Minutes Final Charge Time: 2.0 Minutes Sterilization Time: 2.0 Minutes Dry Time: 30 Minutes
Pre-Vacuum (Steam) Half Cycle (135°C)	Sterilization Temperature: 135±3°C Jacket Temperature: 136.0°C Purge Pressure: 10.0P Purge Time: 2.0 Minutes Pre-Vacuum Level: 27.0" Hg (91.4kPa) Pre-Vacuum Pulses: 4 Pre-Vacuum Hold: 1.0 Minutes Incremental Charge Time: 2.0 Minutes Final Charge Time: 2.0 Minutes Sterilization Time: 1.5 Minutes Dry Time: 16 Minutes
100% EO – 55°C Half Cycle	EO concentration: 725-735mg/L Temperature: 55±5°C Exposure Time: 30 Minutes Minimum Aeration Time: 30 Minutes

4.2 Pre-Sterilization and Post Accelerated aging (5 years)

LexaMed performed following tests for the Baseline samples (pre-sterilization) and after Accelerated aging:

- Seal Peel Testing (ASTM F88)
- Dye penetration Test For Seal Integrity (ASTM F1929)

5 TEST RESULTS

5.1 Sterility Testing

Following sterilization the BIs located in each pouch and negative control BI processed in the run were tested for sterility. BIs were allowed to cool for a minimum ten (10) minutes prior to removal from test pouches.

To activate the media within the BI, the indicator was placed in an upright position and gently squeezed to break the glass ampule. The activated indicators were then incubated at the following conditions: a minimum 24 hours at 55-60°C for G. stearothermophilus and a minimum 48 hours at 37±2°C for B. atrophaeus.

Positive control BIs were tested and incubated in a similar manner as those exposed to half cycle sterilization. A minimum of one (1) BI of the same lot number and organism was used.

The incubation conditions for the BIs met specification for time and temperature. All positive control BIs exhibited growth indicative of the indicator organism and all negative control BIs were negative. All BIs within the single and double pouched test pouches exposed in the half-cycle sterilization runs exhibited no growth.

Following sterilization, data loggers located within representative pouches were removed and the data was downloaded and reviewed. All cycle parameters were met for each sterilization cycle.

5.2 Pre-Sterilization and Post Accelerated aging (1, 3 and 5 years)

Following sterilization, four (4) samples of each pouch type, from each sterilization condition, plus two (2) unsterilized pouches of each type were subjected to Dye Penetration and Seal Peel testing to provide Baseline data for shelf life studies.

Accelerated aging for sterilized sample pouches was performed at LexaMed according to ASTM F1980, “Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices”. The aim of this test was to simulate the aging of the packaging up to the expiry date, which is 5 years for the Steriking® paper/laminate packages with heat-seal. The packaging samples were placed in the thermo-regulated chamber at 55°C±2°C for 38 days to simulate 12 months, for 112 days to simulate 36 months and for 186 days to simulate 60 months. During the whole aging time, temperature of the chamber was monitored.

At each accelerated time point, six (6) pouches from each sterilization condition were removed for a total of twelve (12) pouch samples. Pouches were submitted for Seal Peel Testing and Dye Penetration Testing as outlined in the Table 4.

Table 4. Package Integrity Testing Sample Distribution

	Seal Peel Testing		Dye Penetration Testing	
	Method of Sterilization		Method of Sterilization	
	EO	PVS	EO	PVS
12 Month Accelerated	3	3	3	3
36 Month Accelerated	3	3	3	3
60 Month Accelerated	3	3	3	3

Seal Peel Testing (ASTM F88)

Seal Peel Testing (ASTM F88) was performed on zero (0) time baseline samples and on accelerated aged samples of each pouch type, stored under the 55±2°C accelerated aging conditions at the defined time points indicated in Table 4. The test was conducted by measuring the pounds of force necessary to open the seal of the package; test result was converted to N/15 mm. Only the manufacturer's seals were evaluated. The top seal of pouch was not tested, a sample was chosen from left or right side of pouch.

The following criteria were used to determine acceptable seal strength: The seal strength after sterilization must be no less than 1.5 N/15mm (EN 868-5:2009 requirement) and the results for the accelerated aged samples must demonstrate that the seals are not significantly weaker than the seals of the baseline samples (post-sterilization).

Dye Penetration Test for Seal Integrity (ASTM F1929)

Dye Penetration testing was performed on zero (0) time baseline samples and on accelerated aged samples of each pouch type stored under the 55±2°C accelerated aging conditions at the defined time points indicated in Table 4.

Only the manufacturer's seals were tested. The following criteria were used to determine the presence of a leak: a seal leak due to incomplete seals or channeling exhibiting dye penetration in approximately 5 seconds and travelling the full width of the seal was considered a failing result. Dye wicking after approximately 30 seconds was not considered evidence of the loss of seal integrity and was considered a passing result.

Visual inspection of all pouches upon receipt resulted in no observed damage.

All zero (0) time (baseline) and accelerated pouches demonstrated the absence of evidence of dye penetration across the seal area indicative of a channel or seal void.

All zero (0) time (baseline) pouches demonstrated a seal strength of no less than 1.5 N/15mm. All tested seals of the aged pouches met the seal strength specification. In addition the results of the seal peel testing on the aged samples demonstrated that the seals were not significantly weaker than the seals of the baseline samples (post-sterilization).

The samples for Real Time Storage are currently being stored at LexaMed under controlled ambient/real time storage conditions of 22±2°C. These samples will be removed from storage at the designated time-points and subjected to Dye Penetration and Seal Peel Testing to confirm the accelerated aging results.

6 CONCLUSION

This study demonstrated that the Steriking® self-seal and heat seal sterilization pouches produced by Wipak Oy were effective in allowing sterilant penetration into the pouches when processed in Ethylene Oxide (EO) and Pre-Vacuum steam sterilization processes. The ability of the sterilant to penetrate through the pouches and deliver a sterility assurance level (SAL) of 10^{-6} was tested successfully using a biological indicator (BI) overkill method.

The results of testing of accelerated aged samples representative of the Steriking® Heat Seal Family of Sterilization Pouches, produced by Wipak Oy, processed in Ethylene Oxide (EO) and Pre-Vacuum Steam (PVS) sterilization cycles and stored in accordance with the requirements of *ASTM F1980–07, Standard Guide for Accelerated Aging of Sterile Medical Device Packages, 2007* support a sixty (60) month or 5 year expiration date for the pouches. Testing of Real Time aged samples will be conducted to confirm this claim.