STERIKING®

Steriking® LT-Blueline pouches

Low Temperature Sterilization Compatibility

& Shelf life study 2013

THE ULTIMATE PACKAGING
STERIKING®
CHOICE FOR STERILE SUPPLIES

1 INTRODUCTION

This test was designed to develop data about Steriking® LT-Blueline packaging, made with DuPont™ Tyvek® compatibility with low temperature oxidative sterilization. Steriking® LT-Blueline pouch made with DuPont™ Tyvek® pouch testing was performed during 2013 and sheet testing of Tyvek® Transition Protocol Material 1073B in 2013 and beginning of 2014. Compatibility testing was performed pre-sterilization, post-low temperature oxidative sterilization and post five years accelerated aging.

DuPont provided Wipak with Tyvek® 1073B Transition Protocol Material and Wipak produced Tyvek® pouch samples for testing in external test laboratories.

2 TESTING FACILITIES

Testing facilities were ISEGA Forschungs- und Untersuchungsgesellschaft GmbH, Germany and Nelson Laboratories, USA. Test results presented in this report are based on the test reports of ISEGA (order nos.: 3394/7-1 and 3394/7-2) and Nelson Laboratories – data presented by DuPont on their website (www.areyouready.tyvek.com).

3 EQUIPMENT AND MATERIALS

Wipak manufactured totally seven hundred ten (710) unprinted pouches from three different Tyvek® 1073B lots and Wipak's 12µ BOPET/ 50µ PE Film. Both heat-seal pouches, 250 x 500 mm (LTS2550), and self-seal pouches, 190 x 330 mm (LTSS5A), from Tyvek® were manufactured.

Five hundred forty four (544) unsealed, empty pouches were sterilized in Steris Amsco® V-Pro® 1 Plus, at Hämeenlinna hospital and Sterrad® 100NX®, at Kokkola hospital. Details of low temperature oxidative sterilization of test pouches are as follows:

Steris Amsco® V-Pro® 1 Plus, Hämeenlinna hospital:

- Total sterilization time: standard cycle 56 min; varying ± few minutes according to the manufacturer
- Sterilant (H_2O_2) concentration: 59 %
- Maximum temperature: 51 °C

Three Steris VERIFY™ Biological Indicator Challenge Packs for VH_2O_2 Sterilization was used per cycle; the Biological Indicators were placed internally within the packages. After each sterilization cycle it was demonstrated that a population of 10^6 spores of *Geobacillus stearothermophilus* was eliminated when packages were subjected to the Steris Amsco® V-Pro® 1 Plus sterilization cycle.

Sterrad® 100NX®, Kokkola hospital:

- Total sterilization time: 47 min; varying ± few minutes according to the manufacturer (standard cycle)
- Sterilant (H_2O_2) concentration: 58 %
- Maximum temperature: 52 °C

Three STERRAD® CYCLESURE® 24 Biological Indicators was used per cycle; the Biological Indicators were placed internally within the packages. After each sterilization cycle it was demonstrated that a population of 10^6 spores of *Geobacillus stearothermophilus* was eliminated when packages were subjected to the Sterrad® 100NX® sterilization cycle.

4 TEST PERFORMANCE

4.1 Pre- and post-sterilization

Following tests were performed by ISEGA and DuPont for pouches pre- and post-sterilization:

- Pouch fiber tear testing (DuPont internal test method)
- Visual inspection (ASTM F1886)
- Seal strength (EN 868-5)
- Dye penetration (ASTM F1929)

4.2 Post Accelerated aging (5 years)

After Accelerated aging, the following tests were performed for packages by ISEGA:

- Visual inspection (ASTM F1886)
- Seal strength (EN 868-5)
- Dye penetration (ASTM F1929)

4.3 Tyvek® 1073B sheet testing

Physical property testing of Tyvek® 1073B was covered in the DuPont Phantom Protocol sheet testing. The following tests were performed on Tyvek® 1073B sheets pre- and post-sterilization by Nelson Laboratories:

- Tensile strength MD/CD (ASTM D5034)
- Microbial Barrier (ASTM F2638)
- Puncture resistance (ASTM F1342)
- Biocompatibility/Cytotoxicity (ISO 10993-5)

(Please see DuPont website www.areyouready.tyvek.com)

5 TEST RESULTS

5.1 Pre- and post-sterilization

Fiber tear of LTS2550 pouches was evaluated pre- and post-sterilization by DuPont internal test method and the fiber tear was reported to be 0%, which means that all the tested pouches passed, see Table 1.

Table 1. Fiber tear testing - DuPont

LTS2550 Pouches	Samples	% Fiber tear	Severity
non sterilized	100	0	0
Steris® Amsco® V-Pro® 1 sterilized	88	0	0
Sterrad® 100NX® sterilized	100	0	0

Visual inspection of the heat seals was performed according to ASTM F1886, "Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection". This test method covers the determination of channels in the package seal down to a width of 75 µm with a 60 - 100 % probability.

The entire seal area of each pouch was visually controlled under daylight conditions for unsealed areas, channels, under- and over sealed areas, wrinkles, fold overs, cracks etc. No channels or other defects of the sealed area were detected on pre- or post-sterilized LTS2550 or LTSS5A pouches.

Seal Strength tests were performed according to the EN 868-5, annex D, "Method for determination of the strength of the heat seal joint for pouches and reel material." Strengths of the heat seals were measured from 72 (total 144) pre- and post-sterilized LTS2550 and LTSS5A pouches.

The seal of each pouch was tested on ten different locations, see Figure 1. The results of ten measurements were statistically evaluated. Test parameters of seal strength testing were:

- tail unsupported,
- test speed 200 mm/min,
- specimen width 15 mm

Figure 1. Seal strength sampling scheme at Isega.

Minimum seal strength value of all the measured values was 3.62 N/15 mm, which is above the minimum requirement of 1.2 N/15mm for EN 868-5, and Wipak's Steriking® LT-Blueline product specification of 1.5 N/15mm.

Determination of integrity of the heat seals / packaging integrity was performed according to ASTM F1929-12, "Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration", method A (injection method). This test method will detect and locate a leak equal to or greater than a channel formed by a 50 µm wire in package edge seals formed between a transparent film and a porous sheet material.

The complete sealing of unsterilized, Sterrad® 100NX® sterilized and Steris Amsco® V-Pro® sterilized LTS2550 and LTSS5A pouches, nine each, was examined. A dye penetrant solution was applied locally to the seal edge to be tested for leaks. After contact with the dye penetrant for a specified time, the packages were visually inspected for dye penetration. All examined heat seal joints showed no dye penetration and no seal leaks could be detected.

5.2 Post Accelerated aging (5 years)

Accelerated aging for Sterrad® 100NX® and Steris Amsco® V-Pro® 1 Plus sterilized sample pouches was performed at ISEGA 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® Tyvek® packages. The packaging samples were placed in the thermo-regulated chamber at 55°C±2°C; RH 10% ±5% for 162 days, which simulates 5 years at 20°C. During the whole aging time, temperature and relative humidity of the chamber was monitored.

The determination of visual inspection of the heat seal joint was performed according to ASTM F1886. The entire seal area of each pouch was visually inspected under daylight conditions for unsealed areas, channels, under- and over sealed areas, wrinkles, fold overs, cracks etc. No channels or other defects of the sealed area were detected post accelerated aging of LTS2550 or LTSS5A pouches.

Seal Strength tests were performed according to the EN 868-5, annex D. Strength of the heat seal were measured from 48 (total 96) sterilized LTS2550 and LTSS5A pouches after accelerated aging.

The seal of each pouch was tested on ten different locations; see Figure 1. The results of ten measurements were statistically evaluated.
Test parameters:

- tail unsupported,
- test speed 200 mm/min
- specimen width 15 mm

Minimum seal strength value of all the measurements was 2.97 N/15 mm, which is above the minimum requirement of 1.2 N/15mm for EN 868-5 and Wipak's Steriking® LT-Blueline product specification of 1.5 N/15mm.

Determination of integrity of the heat seals / packaging integrity was performed according to ASTM F1929-12. The complete sealing of Sterrad® 100NX® sterilized and Steris Amsco® V-Pro® sterilized LTS2550 and LTSS5A pouches, nine each, were examined after accelerated aging. All examined heat seal joints showed no dye penetration and no seal leaks could be detected.

5.3 Tyvek® Sheet testing

Tyvek® 1073B sheet testing was included in the Phantom Protocol of the DuPont™ Tyvek® Medical Packaging Transition Project (MPTP). Aging is still in progress.

Table 2. Physical properties pre- and post-sterilization – 1073B Transition Protocol Material and Current Material.

Property	Test Method	Unit	Pre-Sterilization		Post-Sterilization STERRAD® 100S		Post-Sterilization Vapor hydrogen peroxide	
			Current 1073B	Transition Protocol	Current 1073B	Transition Protocol	Current 1073B	Transition Protocol
MD Tensile Strength	ASTM D5034	lbf	92	104	91	100	92	104
MD Elognation		%	21	23	19	20	21	22
CD Tensile Strength		lbf	112	125	105	121	118	122
CD Elognation		%	26	28	23	26	26	27
Puncture Strength	ASTM F1342	lbf	3	3	2	3	3	3
Microbial Barrier	ASTM F2638	% penetration	<0,1%	<0,1%	<0,1%	<0,1%	<0,1%	<0,1%

Biocompatibility, Food Contact and Pharmacopeia Testing as well as more data is presented by DuPont on their website (www.areyouready.tyvek.com).

6 CONCLUSION

Based on the results of this study the Steriking® LT-Blueline packages made with DuPont™ Tyvek® have shown compatibility for use when exposed to Sterrad® 100NX® and Steris® Amsco® V-Pro® 1 Plus processes. Tests after 5 years accelerated aging have shown that the integrity of the Steriking® LT-Blueline packages can be maintained for at least 5 years.