

STERIKING®

See-Through Pouches and Rolls - Double packing -

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Test Objective: To test the sterilization capabilities of the **STERIKING®** See-Through packages when double packed

Test Samples: **STERIKING®** See-Through Pouches S2 – lot 0606 as inner package and Pouches S8 – lot 0608 as outer package

1. INTRODUCTION

Testing demonstrated that steam sterilization process was capable of eliminating a population of 10^6 *Bacillus stearothermophilus* spores when double packed packages were subjected to the steam sterilization cycles $134^{\circ}\text{C} - 3\text{ min}$ and $123^{\circ}\text{C} - 30\text{ min}$. Acceptance was based on negative BI's.

2. SCOPE

A steam sterilization cycles - $134^{\circ}\text{C} - 3\text{ min}$ and $123^{\circ}\text{C} - 30\text{ min}$ were performed on the test sample Steriking® See-Through packages. Cycles included double package with Biological Indicator (BI) placed into the inner package. Testing demonstrated that a population of 10^6 spores of *Bacillus stearothermophilus* could be eliminated during the steam sterilization process $134^{\circ}\text{C} - 3\text{ min}$ and $123^{\circ}\text{C} - 30\text{ min}$.

3. EQUIPMENT and MATERIALS

- 3.1 Steam autoclave ref. No. 00 (program 2 - $134^{\circ}\text{C} - 3\text{ min}$) and Steam autoclave ref. No. 00 (program 11 - $123^{\circ}\text{C} - 30\text{ min}$) at Sterico Oy, Kivihaantie 7, FIN-00310 Helsinki
- 3.2 Biological Indicators: Attest™ 1292E - 10^6 *Bacillus stearothermophilus* spores (Lot 2007-12 AJ) Exp. 2007-12).
- 3.3 **STERIKING®** See-Through packages # S2 – lot 0606 , S8 – lot 0608
- 3.4 Incubator 193 (230V) 193G (230V)

4. PROCESS DESCRIPTION

- 4.1 Steam sterilization process in 134°C , 3 min and $123^{\circ}\text{C} - 30\text{ min}$

5. PRODUCT DESCRIPTION

- 5.1 The packages used in this study were **STERIKING®** heat seal See-Through packages S2 – lot 0606 as inner package and See-Through packages S8 – lot 0608 as outer package

6. TESTING METHODS

- 6.1 A steam sterilization cycles 134° C, 3 min and 123° C – 30 min were performed. Each cycle included the double package.
- 6.2
- 6.2.1 The inner package contained the biological indicator. The BI contained a minimum of 10⁶ *Bacillus stearothermophilus* spores.
- 6.2.2 The inner and outer packages were heat sealed.
- 6.2.3 A steam sterilization cycles 134° C, 3 min and 123° C – 30 min were then run.
- 6.3 The packages were removed from the sterilizer.
- 6.4 BI's were incubated and monitored at 60° C (+/- 2 ° C) for three (3) hours.

7. RESULTS

- 7.1 BI's from the cycles were negative following the incubation period and instructions.

8. CONCLUSION

- 8.1 Based on the results of this study, the STERIKING® See-Through packages used in double package are capable of eliminating a 10⁶ population of *Bacillus stearothermophilus* spores when exposed to a steam sterilization. The STERIKING® See-Through package used in double package has shown compatibility for use when exposed to steam sterilization process.

Attachment 1

Cycle Parameters

Biological Indicator Test Results

Cycle	
134° C, 3 min	No Growth
123° C – 30 min	No Growth