Full or Extended Sterilization Cycles Shelf Life Study for Steriking® Heat Seal Sterilization Pouches

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Aim:

Conduct testing to establish a 60-month expiration date for Ethylene Oxide (EO), Pre-Vacuum Steam (PVS) and Gravity Steam (GS) sterilized Steriking Heat Seal Sterilization Pouches produced by Wipak Oy.

This study was initiated on Aug. 15, 2013 and completed on September 18, 2018.

Materials and Methods:

40 pouches of each of the two pouche sizes- representing the smallest (pouch item # S24) and largest sizes (pouch item # S32) available were used for each of the three sterilization modalities tested.

Following visual inspection upon receipt, the pouches were filled with a sufficient amount of standard silicone tubing with varying diameters to represent the weight of a filled pouch. Pouches were then sealed at 160-180°C.

Pouch sterilization parameters**:**

Ethylene oxide (EO):

40 prepared pouches of each type were exposed to a single 100% EO cycle with a concentration of 725-735 mg/L at 54-55°C (129-131°F) and 40% - 80% relative humidity with a 60-minute exposure. Cycle was consistent with ANSI/AAMI ST41:2008, *Ethylene oxide sterilization in health care facilities: Safety and effectiveness.*

Pre-Vacuum Moist Heat Sterilization (PVS):

40 prepared pouches of each type were exposed to a single pre-vacuum steam sterilization cycle with the following parameter set points as defined in ANSI/AAMI ST 79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities:*

- Sterilization Temperature: 135°C (275°F)
- Sterilization Time: 4 minutes
- Number of Pre-Vacuum Pulses: 3 (final pulse level of 27" Hg (91.4kPa))
- Dry Time: 20 minutes

Gravity Displacement Moist Heat Sterilization (GS):

40 prepared pouches of each type were exposed to a single gravity displacement steam sterilization cycle with the following parameter set points as defined in ANSI/AAMI ST 79, *Comprehensive Guide to* Steam *Sterilization and Sterility Assurance in Health Care Facilities:*

- Sterilization Temperature: 135°C (275°F)
- Sterilization Time: 15 minutes
- Dry Time: 30 minutes
- 2 prepared pouches of each type were not sterilized for use as common negative control samples.

Following sterilization, pouches were distributed for aging and package integrity testing.

Accelerated Ageing:

Following sterilization accelerated aging of 6 pouches from each sterilization modality was conducted at 55±2°C to 12, 36 and 60 months of warehouse storage.
The accelerated aging time at 55±2°C equivalent to each time point was calculated as described in ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

Ambient /Real Time Storage:

A second set of pouches of each size was stored for 12, 36 and 60 months under controlled ambient conditions at 20-25°C. Humidity conditions were not monitored during this study.

Package Integrity Testing:

The Expiration date was verified by demonstrating package seal integrity with Dye Penetration testing (ASTM F88/ F88M-15) and package strength with Seal Peel testing (ASTM F1929-15).

Seal Peel Testing was performed on 6 baseline samples, 1 negative control and 9 samples of each pouch type, that were stored under the 55±2°C accelerated aging or ambient real-time aging conditions. Only the manufacturer's seals were evaluated.

Dye penetration testing was performed on 6 baseline samples, 1 negative control and 9 samples of each pouch type, that were stored under the 55±2°C accelerated aging or ambient real-time aging conditions. Only the manufacturer's seals were evaluated.

Observations:

The pouches passed the acceptance criteria after sterilization with Ethylene Oxide, Pre-Vacuum Steam and Gravity Steam.

Seals of all negative control, baseline, accelerated, and real-time aged pouches demonstrated the absence of dye penetration across the seal area indicative of a channel or seal void.

Pouches also demonstrated a seal strength of the manufacturer supplied acceptance criteria of 2: 1.5N/15mm (0.571b/in).

Results:

A 60 month (5 years) shelf life is qualified for the Steriking Heat Seal Sterilization Pouches.