Andersen EOGas™ Series 4® Sterilization Efficacy in a 914mm x 1mm Stainless Steel Lumen

INTRODUCTION:

Hospitals and small doctors offices have faced a difficult decision when it comes to cleaning, disinfecting and / or sterilizing flexible and rigid scopes. While Ethylene Oxide offers the most effective sterilizing agent without damage to the instrument, the lengthy turnaround times have caused facilities to move to shorter less effective cycles that can and often do reduce the life expectancy of the scope. With the introduction of the new Andersen Series 4 sterilizer, hospitals and doctors offices know have the best of both worlds—a cycle that not only sterilizes (rather than disinfects) but does so in only three-hours.

MATERIALS & EQUIPMENT:

Andersen EOGas Series 4 sterilizer
Calibrated incubator
3x914.4mm length stainless steel tubes with a 1mm lumen
Self-contained biological indicators (min. pop. $1x10^6$)
Standard load (items sterilized in the Series 4 sterilizer):
- 10 AN10 tubes sealed in polyethylene/polysurlyn pouches
- 2 patient gowns wrapped in CSR wrap
- 1 AN42 Sump Pump wrapped in CSR wrap
- 6 pairs of latex gloves sealed in Seal & Peel packaging
- 10 cotton-tipped applicators sealed in Seal & Peel packaging
- 30 PPE Sutures inserted into aluminum pouches, then sealed in self-sealing paper / plastic pouches
- 4 hemostats sealed in Seal & Peel packaging
- 12 syringes sealed in self-sealing paper / plastic pouches
- 10 glass vials sealed in self-sealing paper / plastic pouches
- 1 AN2018 Andersen EOGas™ cartridge
- 2 Humidichips placed in a Humiditube

Items were placed in a 22inch x 36inch 5mil Series 4 PE/Nylon/PE sterilization bag.

ABSTRACT:

Three sections of flexible stainless steel tubing (914.4mm in length x 1mm lumen) were seeded with a specialty biological indicator ($2.23x10^6$)—mimicking a contaminated rigid / flexible scope. The microbial death kinetics of these biological indicators was then established through a series of partial exposure cycles where all sterilization parameters remained constant except time. The resulting survivor curve was then used to determine the absolute sterilization time. This sterilization or exposure time was then tested in triplicate to demonstrate the Series 4 efficacy is sterilizing small and lengthy lumens.

METHOD:

Survivor Curve:

Using Andersen Scientific protocol 110804.1S4[1], the stainless steel lumens were seeded with $2.23x10^6$ *Bacillus atrophaeus* spores and processed in four independent exposure cycles. Exposure times of 0, 60, 90 and 120 minutes were employed to create the survivor curve. At the conclusion of each exposure phase, the biological indicators were removed and immediately processed by Andersen Products, Inc. laboratory to enumerate the surviving populations. A survivor curve was created by graphing the surviving population against time. From this graph, the absolute kill time was established.

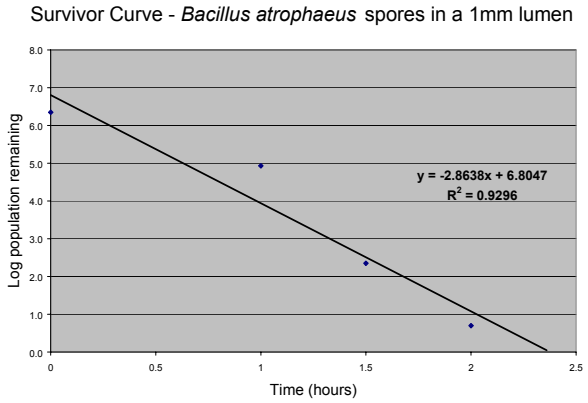
Sterility Testing:

Three independent cycles were performed to verify that the established absolute kill time was sufficient to sterilize $2.23x10^6$ *Bacillus atrophaeus* spores placed in the center of the lumen.

RESULTS:

Survivor Curve:

The survivor curve indicates that the absolute kill time is less than 2.5 hours.



Sterility Testing:

The verification sterility studies indicate that the Series 4 sterilizer can sterilize the specialty biological indicators—greater than a 6-log reduction in three hours.

Cycle Number	Lumen 1	Lumen 2	Lumen 3
3 hour #1	Pass	Pass	Pass
3 hour #2	Pass	Pass	Pass
3 hour #3	Pass	Pass	Pass

CONCLUSION:

The results from this study indicate that the Series 4 sterilizer can be used effectively to sterilize long lumens even with diameters as small as 1mm.

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Andersen Scientific, Inc., March 20, 2005

[1]Andersen Scientific Protocol No.: 110804.1S4, Title: Evaluation of the Andersen EOGas Series 4 Sterilizer: Lumen Challenge.