
Andersen EOGas Series 4 Lumen Study

PR0811-01

November 18, 2008

Purpose

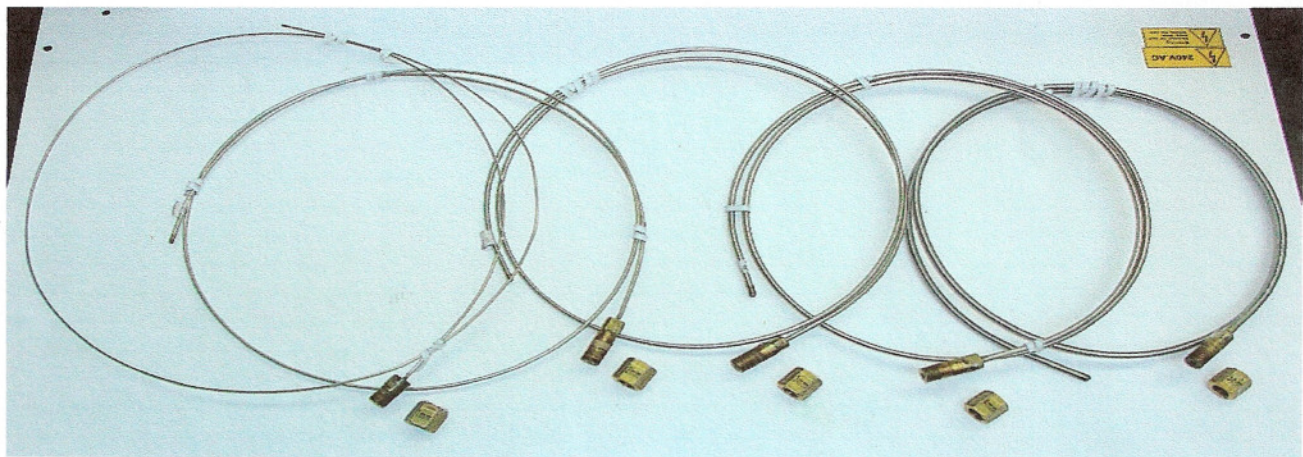
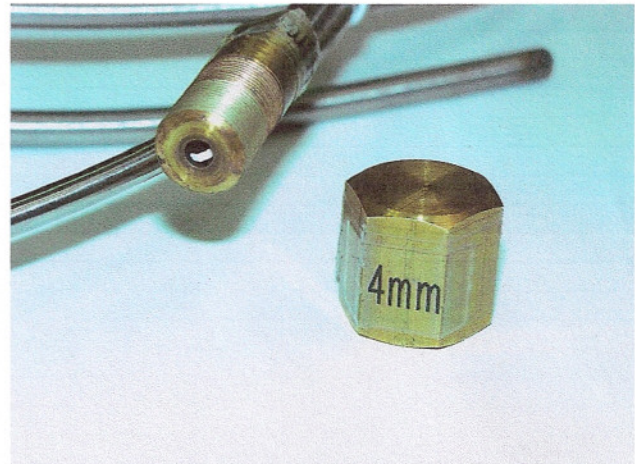
The sterilization of long, narrow lumens is a traditional challenge to a sterilization system. This test was designed to determine the maximum length of varying diameter lumens that can be confidently sterilized using an Andersen EOGas Series 4 sterilizer. All lumens tested were closed at one end.

Summary

Five, sixty-inch stainless steel lumens varying in diameter from 1 to 5 mm (id) were seeded with Biological spore strips and run through an Andersen EOGas Series 4 Sterilization cycle. At the end of the study the ends of the lumens were soldered closed to illustrate that the BI chambers were impervious to ethylene oxide (gas did not leak past the threaded seal on the BI chamber).

Materials and Equipment

1. Andersen EOGas Series 4 Sterilizer
2. 1mm x 25mm spore strip
3. Calibrated Incubator and related BI Culture Equipment
4. AN-1004 EOGas Cartridge and AN-1004 EOGas Sterilization Bag
5. 5 Stainless steel metal helices, with lumens ranging from 1mm to 5mm in diameter and 60 inches lengths
6. AN-1071 Humidichip
7. AN-1087 Dosimeter

**Procedure**

1. Record the length and diameter of the 5 lumens.
2. Seed the lumens with a BI
3. Run through an EOGas Series 4 cycle

- a. Bag- EOGas #4
- b. Humidichip
- c. EOGas 1004 Cartridge
- 4. At the conclusion of the cycle transfer the BIs in the sterile transfer room and incubate for 7 days in a 37°C incubator.
- 5. If the BI result is positive cut the length of the lumen by 10% of the lumen length.
- 6. Repeat the process until the BI result for each lumen is negative
- 7. Repeat final test until three successful cycles (with no failures) have been obtained for each of the five lumens at its maximum length.
- 8. When three successful cycles have been completed solder and seal the ends of the lumens.
- 9. Seed the sealed lumens and run through a sterilization cycle to ensure there is no leaking.

Data

Table 1. Length of Lumens.

Diameter of Lumen (mm)	Length (inches)
1	60.0
2	60.0
3	60.0
4	60.0
5	60.0

Table 2. Sterilization Cycle Results of Lumens.

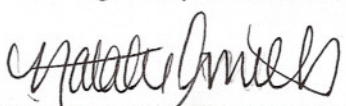
Lumen Diameter (mm)	Biological Indicator Results per Cycle		
	1	2	3
1	Negative	Negative	Negative
2	Negative	Negative	Negative
3	Negative	Negative	Negative
4	Negative	Negative	Negative
5	Negative	Negative	Negative

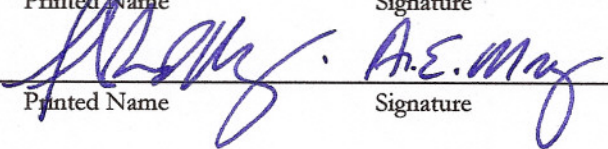
Table 3. Sterilization Cycle Results of Sealed Lumens.

Lumen Diameter (mm)	Biological Indicator Results
1	Positive
2	Positive
3	Positive
4	Positive
5	Positive

Conclusion

This study indicates that the EOGas Series 4 Sterilization System can be used effectively to sterilize sixty-inch stainless steel lumens varying in diameters from 1mm to 5mm. Please note that for lumens that are open at both ends, the effective lumen length may be doubled (120 inches).

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