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**Andersen Anprolene Lumen Study**

PR0812-19

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**Purpose**

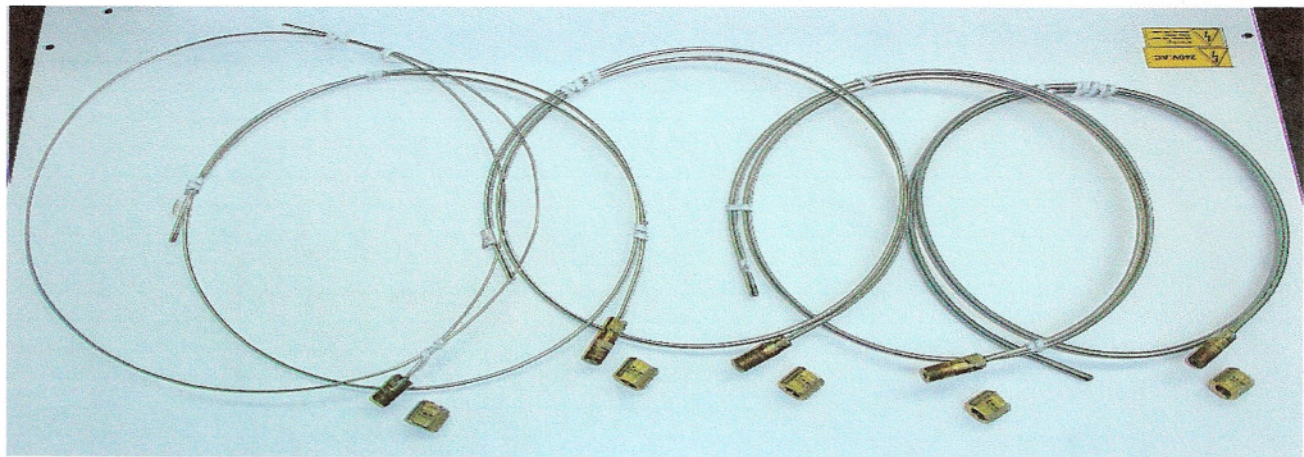
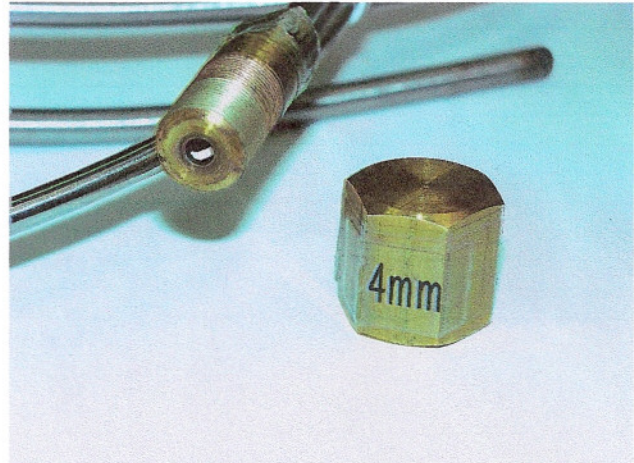
The sterilization of long, narrow lumens is a traditional challenge to a sterilization system. This test was designed to determine the maximum length of varying diameter lumens that can be confidently sterilized using an Andersen Anprolene sterilizer. All lumens tested were closed at one end.

**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 Anprolene 24 hour 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 Anprolene Sterilizer
2. 1mm x 25mm spore strip
3. Calibrated Incubator and related BI Culture Equipment
4. AN-79 Ampoule and AN-79 Anprolene Sterilization Bag
5. 5 Stainless steel metal helixes, with lumens ranging from 1mm to 5mm in diameter and 60 inches lengths
6. AN-1071 Humidichip
7. AN-87 Dosimeter

**Procedure**

1. Record the length and diameter of the 5 lumens.
2. Seed the lumens with a BI
3. Run through an Anprolene 24 hour cycle

- a. Bag- AN79 Anprolene Bag
- b. Humidichip
- c. AN79 Ampoule
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 Anprolene 24 hour 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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