

One of the challenges of ethylene oxide (EO) sterilization is the removal of any residual gas after the sterilization cycle, so as to ensure the safety of the operator when unloading the sterilizer.

Ongoing research and development of the Andersen Anprolene® sterilizer has led to our evaluation of various purge technologies. Our studies indicated that the use of a purge/aeration probe that extends into the sterilization liner bag proves to be most effective.

This study was conducted to document the effectiveness of the extended purge probe in aeration of the contents of the liner bag at the end of the sterilization cycle. Within 45 minutes of the inception of the 2-hour purge cycle, the EO samples taken decreased in measure from a pre-purge concentration of approximately 40,000 ppm to 4 ppm - a reduction of 99.999%, and a measurement below the OSHA short-term exposure limit of 5.0 ppm.

### MATERIALS:

AN74i Sterilizer  
PAN-TY cable ties and Thomas & Betts cable tie tool,  
Shimadzu gas chromatograph and analyzer,  
1.0 ml gas-tight syringes for gas injection into GC  
Standard Load:

- 10 AN10 Andersen tubes sealed in 4.5" PolyEthylene/PolySurllyn pouch
- 2 Patient Gowns wrapped in CSR wrap
- 1 AN42 Sump Pump wrapped in CSR wrap
- 6 Pairs of Latex Gloves sealed in Seal and Peel®
- 10 Cotton-Tipped Applicators sealed in Seal and Peel®
- 30 PPE Sutures inserted in aluminum pouches, sealed in a self-seal 7"x13" paper plastic pouch
- 4 Hemostats sealed in Seal and Peel
- 12 Syringes (3 large, 3 medium and 6 small) sealed in a self-seal 7"x13" paper plastic pouch
- 10 Glass Vials (amber with rubber stoppers) sealed in a self-seal 7"x13" paper plastic pouch
- 1 Humidichip® placed in a Humiditube®
- 1 AN79 (17.6 ml) Anprolene® Ampoule

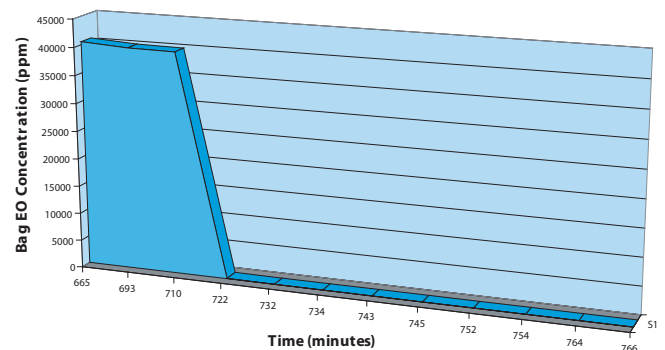
### METHODOLOGY AND EQUIPMENT:

Air samples were collected from the sterilization bag during the 12-hour sterilization cycle, as well as during the 2-hour post sterilization purge cycle using a 1.0 ml gas-tight syringe.

A gas chromatograph (GC) was used to test the concentration of the ethylene oxide in the air samples. At 11 hours and 50 minutes into the 12-hour sterilization cycle, EO concentration averaged/measured 39,942 ppm. Twelve minutes later (two minutes into the purge cycle) air samples taken showed a concentration of 56ppm; 46-minutes into the purge cycle, the EO concentration in the air sample taken showed 4 ppm. The air sample collection ended here. It can be extrapolated that by the conclusion of the 2-hour purge cycle, the EO levels will be well below 4 ppm.

### RESULTS:

#### Efficacy of the AN74i Evacuation Probe



### CONCLUSION:

The Anprolene® sterilization system has always put operator safety first, by allowing the products being sterilized to remain inside the sterilizer while evacuating the residual/excess EO. Manufacturers of other EO systems depend upon the operator moving the product to a separate "purge" area. The addition of the new probe with ¼-inch NPT checkvalve purges both the EO and introduces fresh air that is circulated through the bag as a safety measure, which shows that the AN74i is a unique device and process in the marketplace.

This study confirms the efficacy of the evacuation purge probe with the ¼-inch NPT checkvalve. The measurement of 4ppm at 46-minutes into the 2-hour purge cycle show that at the conclusion of the cycle there will be operator-safe levels of exposure based upon the OSHA limit for short term exposure.