Compromised Sterilization Bag Does Not Pose EO Exposure Risk

This study shows that if a sterilization bag placed inside the sterilizer is accidentally compromised by a one-inch cut, operator exposure (in the area around the sterilizer) would be less than 1.0ppm. Ethylene Oxide (EO) levels deemed unsafe by OSHA are considered no more than 5.0ppm over a 15-minute period. Therefore, if the manufacturer's installation and operation instructions are otherwise followed, a tear in the sterilization bag should not cause risk to the operator.

CONDITIONS:

The sterilization bag environment reached a maximum air temperature of 26.1°C and a low of 24.5°C. The relative humidity ranged from 45.0 to 64.5 percent.

The test room itself had no air changes. Performing the test in an unventilated room increases the risks associated with a malfunction of this kind. Andersen Products, Inc. recommends that the sterilizer be installed in a room with at least 10 air changes per hour. Operation of the sterilizer in a room with no air changes constitutes a gross misuse of the system.

MATERIALS:

AN74i Sterilizer
PAN-TY cable ties and Thomas & Betts cable tie tool
Andersen Sniffer™ with nylon gas sampling bags
Gas sampling pump and collection bag
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/PolySurlyn 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®
  Cox Recorder
- 1 AN79 (17.6ml) Anprolene® Ampoule

METHOD:

After the one-inch slit was made in the sterilization bag, the gas sampling pump was started and the operator's breathing zone was monitored. (Samples were taken within 4 feet of the door of the sterilizer.) During this sampling period, the ampoule was activated, and the sterilizer door was closed. After 15 minutes of air collection, a 1.0 ml sample was drawn from the air collection bag and injected into the Gas Chromatograph (GC). The GC calculated the concentration of Ethylene Oxide in the sample, and therefore, the air.

RESULTS:

15 minute OSHA STEL levels

	OSHA allowable limit	Detected level
Operating breathing zone air sample	5 ppm	<1.0 ppm[2]

CONCLUSION:

This test shows that when the sterilization bag is compromised, the operator is still not at risk for EO exposure, if proper manufacturer protocols are followed. Actual EO levels were <1.0ppm, well below OSHA's short-term exposure (STEL) of less than 5.0ppm.

[1] The study, AN74i Single Fault Failure Testing for Bag Break, based on Standard Load 1, was conducted by Andersen Scientific, Inc. For more information on this test, e-mail: ansci@mindspring.com.
[2] The lowest GC calibration standard is 1.0ppm, so the test can only reflect the lowest standard.