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Introduction to the Andersen EOGas® Gas Diffusion Sterilization Method

OVERVIEW

Unlike traditional Ethylene oxide(EtO) sterilizers which involve rigid metal chambers and large external tanks of gas, the Andersen EOGas® system uses flexible plastic sterilization bags and unit dose 100% EtO cartridges. Packaged items to be sterilized are placed inside a sterilization liner bag along with an EtO cartridge and a Humidichip®. The Sterilization liner bag is heat sealed and loaded into the sterilization cabinet. Once inside the cabinet, the EtO cartridge is manually activated through the wall of the sealed sterilization bag.

The sterilization cabinet acts as a heated aeration chamber, maintaining a constant temperature (typically 50°C) and drawing off the EtO as it diffuses through the plastic walls of the sterilization bag over the course of the 16 hour sterilization/aeration cycle. Validated cycles may be shorter or longer depending upon the product type.

Standard EOGas sterilization bags are available in two sizes; 35-Liter or 7 liter. EOGas cartridge range in size from 4 gram to 17.5 gram, and will be selected as part of the validation process. This unique technology allows you to match each sterilization load to the appropriate bag/cartridge combination, and to adjust cycle length and temperature as needed.

EOGas sterilization cabinets vary in capacity from six to thirty three cubic feet, and are designed to process from three to twenty individual sterilization bags. EOGas cycles are validated using the applicable portions of AAMI/ISO 11135.

THE GAS-DIFFUSION PROCESS

Gas diffusion is our name for how Ethylene Oxide (EtO) passes through a barrier (the sterilization liner bag) at a controlled rate. The EtO, which is released from the cartridge, dissolves in the interior surface of the liner bag, migrates across the thickness of the liner bag material and, then, evaporates from the exterior surface of the liner bag. The EtO released from the outside of the liner bag is mechanically exhausted from the sterilization chamber. So long as the concentration of EtO inside of the liner bag is greater that the concentration in the air surrounding the liner bag, EtO will continue to move (diffuse) from inside of the liner bag to its outside.

The transmission of EtO across the permeable membrane of the sterilization bag is predictable and depends upon several factors including the following:

- The temperature of the gas and of the barrier.
- The type, thickness, composition, and crystallinity of the barrier.
- The area exposed to the transmission.
- The concentration gradient that exists across the barrier.

Temperature is controlled by the EOGas sterilization cabinet. EOGas sterilization bag material is chosen to satisfy specific diffusion rate criteria. The exact composition of EOGas sterilization liner bags is an Andersen trade secret . Individual lots of bag material are inspected against a range of physical requirements and undergo gas transmission testing before use in EOGas refill kits.

THE EOGas STERILIZATION PROCESS

When the EOGas cartridge is activated, EtO gas is released in the sterilization liner bag and outside of the porous packaging containing the product. The EtO gradually diffuses through the porous packaging membrane and contacts all accessible surfaces of the product. It is driven by its inherent kinetic energy. EtO diffuses both inwards, into the packaged products and, simultaneously, outwards, through the sterilization bag walls while the concentration in the sterilization bag is greater that the concentration of EtO either inside the packaged products or outside of the sterilization bag. As the cycle progresses, there comes a time when the concentration of EtO in the packaged products becomes greater that the concentration of EtO in the sterilization bag. This marks the point at which aeration begins and EtO moves from the product packaging back into the sterilization bag and then through the walls of the sterilization bag and into the atmosphere surrounding the sterilization bag.

During the aeration phase of the EOGas cycle, the concentration of EtO in the sterilization bag falls below the concentration of EtO in the product packaging, and the primary direction of gas diffusion reverses. The concentration gradient now favors diffusion out of the product packaging and out of the sterilization bag into the sterilization cabinet. The heat of the sterilization cabinet, first responsible for aiding the inward diffusion of the gas and promoting the chemical inactivation of product bioburden, now enhances outward diffusion. Due to mechanical ventilation, the EtO concentration in the sterilization cabinet is near zero, thus aiding diffusion of the gas from the product and through the walls of the sterilization bag. This is analogous to the heat supplied by the wall jackets of an industrial vacuum/pressure vessel. Initially the heat serves to increase gas diffusion across the multiple layers of packaging and to promote uniform chemical reaction on the products. Later it helps drive the gas back out of all layers of packaging, where it can be evacuated to the emission control system.

GAS PERMEATION CONSIDERATIONS

Those who have had the chance to follow an entire EtO process validation for an industrial vessel will have noticed that as the size of the product load increases, the sterilization process becomes less efficient. To compensate, the following cycle parameters must be boosted:

- Load heat-up time.
- Humidity addition.
- Humidity penetration time.
- EtO addition.
- EtO penetration time.
- Sterilant dwell time.

The gas sterilization process loses efficiency as product lot size increases not because the vessel hardware is insufficient, but as a result of the progressive increase in package interference and load density.

The gas-diffusion method largely circumvents the problem of permeation obstruction by delivering precisely metered doses of both moisture and EtO right to the primary packaging--mere centimeters from the microbial site. In a sterilization bag, the permeation time of EtO depends on only one layer of porous packaging; consequently, the gas absorption and depletion by multiple layers of packaging is avoided. In designing a gas diffusion validation, the user must consider only two sources of resistance to the process: product bioburden and one layer of porous packaging. The permeation time is much more efficient.

By avoiding dead space and the dramatic overgassing that takes place inside an industrial chamber, gas-diffusion technology cuts the time and energy required to aerate the final product to FDA-mandated EtO residual levels and reduces the demand on the facility's emission control system. We estimate that devices sterilized with the system use 30 to 80% less EtO than industrial vacuum/pressure vessels achieving the same SAL.

CONCLUSION

Gas-diffusion technology is a safety-conscious, effective, and efficient way for device manufacturers to routinely perform terminal EtO sterilization of medical devices. It is based on the well-known chemical and physical laws of gas diffusion across permeable barriers.

This information was taken from "*An Introduction to Gas-Diffusion Sterilization: Gas-diffusion technology offers device manufacturers a cost-effective and environmentally safe alternative to traditional in-house EtO sterilization";* By Lauren Andersen, Marcus Delvers, and Edna Hu; **MD&DI,** May, 1997.

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