

Ethylene Oxide Sterilization, The Latest Method for Sterilization of Medical Devices - Literated Market Research

Products that cannot support conventional high temperature steam sterilization are the primary medical devices that make use of ethylene oxide sterilization.

BANGALORE, INDIA, November 16, 2015 /EINPresswire.com/ -- Exposure to Ethylene Oxide gas (EtO) is one of the most popular methods of sterilization of medical devices. Medical and pharmaceutical products that cannot support conventional high temperature steam sterilization are the primary medical devices that make use of ethylene oxide sterilization process. Such devices include ones that incorporate electronic components, plastic packaging or plastic containers.

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Examples of medical devices where this gas is used include plastic products and packaging that get discolored with irradiation, devices that incorporate electronic components, materials that get damaged at higher temperatures, custom kits and materials that are not compatible with other methods such as Gamma and Steam sterilization.

Packaged medical devices are infiltrated by the gas which is an alkaline agent and helps to kill microorganisms and thus achieve sterilization. Ethylene oxide is used on products that could get damaged or cannot withstand high temperature processes as the gas is toxic and flammable.

The gas is explosive as it is mixed with air at a ratio of at least 3% EtO gas. The exact boiling point of pure EtO gas boiling point is 10.73 °C at atmospheric pressure. Most of the time, it is mixed with Nitrogen or CO₂. For security of people as well as security of the process itself, the explosive condition requires the use of Intrinsic Safe material (ATEX) zoning.

The actual EtO process must occur within enclosed chambers to prevent leaks and exposure to the ethylene oxide gas due to its reactive nature. Sterilization by the EtO process is longer compared to other sterilization methods such as Gamma. There are three main stages of the sterilization process. The first stage is preconditioning and conditioning of the device through temperature and humidity variations, followed by the Gas Dwell Phase or the Sterilizing Cycle where the device is exposed to the EtO gas and ends with the Aeration of exposed device for removal of gas from the product.

Due to the harmful effect of EtO on humans, the safety of personnel is an important issue. Polluted

areas need to be alarmed using gas detectors set up at different locations to monitor any leak. Visual and audio alarm systems need to be provided.

After the removal of the toxic gas from the room, thermal burners, scrubbers or oxidation needs to be used for treatment for environmental protection or be transported to an alternate facility for treatment.

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