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WHY A STERILE PACKAGE ALLOWS AIR THROUGH ITS MEMBRANE

Sterilization is a procedure intended to make objects free of live bacteria and any other microorganisms. While there are several sterilization processes used in the medical field, DeRoyal mainly uses an Ethylene Oxide sterilization process to sterilize its devices.

METHOD

Ethylene Oxide (EtO or EO) is by far the most effective and most popular method in the medical device industry. EtO is a complex process during which destruction of pathogens is achieved by diffusing effective concentrations of EtO gas into the innermost sections of the product in question. When this process is applied correctly, all bacteria and microorganisms are not only eliminated from the product, but regeneration is prevented. The success of the EtO sterilization process depends primarily on the precise combination of variables, which are:

Chamber Temperature (50˚C - 60˚C)	**Relative Humidity** (50%)	**Time of Exposure** *(based on individual product specifications)*	**Gas Concentration** *(based on individual product specifications)*	**Physical and Chemical Nature of the Product**

PACKAGING SELECTION

Close attention is given to the design and selection of the product packaging, which is typically constructed of a medical grade gas permeable paper or breathable non-woven material on one side and a plastic film on the other. The packaging used to house the sterile products is designed to accommodate the method outlined above. Specifically, the packaging must meet the following three (3) requirements, known as Permeable Packaging Configuration *(Primary Sterile Barrier)*, for successful sterilization:

1. Permeability to EtO gas, water vapor (moisture), and air
2. Impermeability to bacteria and other contaminants
3. Resistance to pressure and temperature fluctuations

This packaging configuration is not only important for the sterilization process, it is also crucial in the post-sterilization process because this type of sterilization generates two types of minimally toxic residues in the product. These are:

- Ethylene oxide (the main product)
- Ethylene chlorohydrin

Due to these residues, aeration must occur to release the residual gases from the product. This is the main reason EtO gases and moisture are injected into packages and air comes out of a sterilized product. However, the exchange of air is not synonymous with non-sterility; the package itself acts as a barrier (filter) that blocks any harmful microorganisms from entering the product.

EXPLANATION

The following table compares scientific data on the sizes of the elements in play; notably microorganisms, the oxygen molecule (O_2), nitrogen molecule (N_2), ethylene oxide molecule (C_2H_4O) and the package (filter):

	VIRUS	BACTERIA	DEROYAL'S PACKAGE	OXYGEN (O_2) MOLECULE	NITROGEN (N_2) MOLECULE	ETO $[CH_2]_2O$ MOLECULE
Size (Nanometer)	30-450nm	1250nm	1.03nm (LRV)	.28nm	.30nm	.94nm
Size (Inches)	964-14464 x 10^{-6}	40179 x 10^{-6}	33.09 x 10^{-6}	9 x 10^{-6}	9.6 x 10^{-6}	30.2 x 10^{-6}

The first row of measurements is in nanometers (one billionth of a meter) and the second row contains the same data shown in inches. Viruses and bacteria are very small (30nm to 450nm and 1250nm, respectively) and are invisible to the naked eye. However, they are much larger than a molecule of oxygen (.28nm), nitrogen (.30nm), and EtO (.94nm). The table demonstrates how the pores of the package, which function as a filter, are smaller (1.03nm) than the size of "bad" particles such as bacteria or viruses, but bigger than that of "good" particles, such as oxygen, nitrogen, and EtO molecules. Therefore, the smaller "good" particles can go through, but the bigger "bad" particles cannot pass through, resulting in a sterile product.