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WHY A STERILE PACKAGE ALLOWS AIR THROUGH ITS MEMBRANE

Sterilization is a procedure that serves the purpose of making objects free of live bacteria and any other microorganisms. There are several sterilization processes used in the medical field however, DeRoyal uses mainly a procedure known as 100% EtO (Ethylene Oxide).

METHOD

100% EtO or EO (Ethylene Oxide): By far the most effective and most popular method in the Healthcare Industry, EtO is a very complex procedure. Destruction of pathogens is achieved by diffusing effective concentrations of Ethylene gas into the innermost sections of the product in question. If this process is applied correctly, all bacteria and microorganisms are not only eliminated from the product, but regeneration is prevented. The success of EtO sterilization process depends mainly on the precise combination of several variables, which are:

1. Chamber temperature (50_oC-60_oC)
2. Relative humidity (50%)
3. Time of Exposure (Depends on the product)
4. Gas concentration (Depends on the product)
5. Physical and chemical nature of the product

PACKAGING SELECTION

A great deal of attention has been given to the design of the package, which is a Medical Grade Gas Permeable Paper on one side and a plastic film on the other. The package used to house the sterile product is therefore designed to accommodate the above procedure. Known as a Permeable Packaging Configuration (Primary Sterile Barrier), the package must meet these three requirements:

- Permeability to Ethylene Oxide gas, water vapor (moisture), and air
- Impermeability to bacteria and other contaminants
- Packaging material must withstand pressure and temperature fluctuations

This is very important not only in the sterilization process, but crucial in the post-process. Why? Because the sterilization process generates minimal toxic residues in the product in the form of three toxic gases, which are:

- Ethylene Oxide (the main product)
- Ethylene Chlorohydrin
- Ethylene Glycol

Therefore, aeration must happen if the above gases are to be released from the product. This is the main reason why Ethylene Oxide gases and moisture are injected in and air comes out of a sterilized product. However, the exchange of air is not synonym of non-sterility because the package itself acts as a barrier (filter) that blocks any harmful microorganisms from entering the product. To fully understand this concept, let's take a closer look at the following table:

	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}

EXPLANATION

This 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 ($[CH_2]_2O$), and the package (filter). The second row of the table contains the measurements in Nanometer (one billionth of a meter) and the third row contains the same data in inches (for matters of practicality and simplicity, we will use the second row data). Viruses and bacteria are very small (30 to 450nm and 1250nm respectively) and are invisible to the naked eye, however, they are mammoth when compared to the molecule of oxygen (.28nm), nitrogen (.30nm), and ethylene oxide (.94nm). As we can see, the pores of the package (filter) are smaller (1.03nm) than the size of bacteria or viruses but bigger than that of an oxygen, nitrogen, and ethylene oxide molecules. Therefore, the smaller particles (oxygen, nitrogen, & ethylene oxide) can go through but the bigger ones (bacteria and viruses) cannot pass through. Hence its name STERILE PACKAGE!!!