



## Your Link To: Proper Sterilization Methods for Lubrizon's Pathway TPU Excipients

Sterilization is the treatment process that rids materials of possible contaminants, including microbial life, bacteria, fungi and viruses. In order to limit transmission of these contaminants, the medical industry requires certain levels of sterilization for all equipment. Common glass and steel medical products are often suited for a variety of sterilization processes, while polymer-based products may require specific sterilization methods. Using the incorrect method for a polymer-based material can damage its overall quality, degrade the polymer's structural integrity, cause the polymer to produce harmful byproducts, and not fully sterilize the product itself.

It's also important to remember that all polymer products are not the same, meaning polymers composed of differing molecules don't behave the same way during sterilization. A method that's perfect for one polymer might completely degrade another. Understanding polymer molecules and their properties is essential. A polymer molecule might be blended and processed in different ways to produce end products with varied material characteristics, such as tensile strength, elongation and color. Sterilization methods can directly affect blend properties. When making sterilization method recommendations for polymer products – like Lubrizon's Pathway™, pharmaceutical-grade thermoplastic polyurethanes (TPUs) – significant consideration must be taken.



# Common Types of Sterilization\*

## Ethylene Oxide (EtO)

Sterilization via immersing the product in ethylene oxide gas in a chamber, then aerating it. This method enables sterilization for products with a low heat capacity, making it suitable for many plastics. EtO also works in conditions where radiation may be damaging. EtO is generally the preferred method for sterilizing TPUs, as there are no significant side effects recorded.

## Hydrogen Peroxide

A type of chemical sterilization used primarily for temperature-sensitive material. The product is put in a sterilization chamber that is vacuumed and filled with hydrogen peroxide vapor and then aerated. It operates at low temperatures, although it can damage electronics. At high concentrations, hydrogen peroxide is a strong oxidizer, allowing it to eliminate contaminants within the material. One advantage of hydrogen peroxide over other chemical sterilization processes is the short cycle time required, due to high vapor concentrations.

## E-Beam Radiation

Sterilization involving ionizing energy that has low penetration and uses a high dose rate to eliminate contaminants. An accelerator produces a beam of electrons that are focused on the product to be sterilized. As the beam passes through the product, energy from the electrons is absorbed. This extra energy in the product helps break down chemical and molecular bonds of the contaminants to fully sterilize the product.

## Gamma Radiation

Sterilization using an isotope source, usually Cobalt-60, to produce ionizing energy that flows through the product. This energy causes cellular damage to the organisms, ridding the product of them. Capable of sterilizing high densities of materials, it produces strong rays with high penetrating power and low dose rate. Using radiation on aromatic TPUs can cause discoloration, which may fade over time but never disappear.

## Dry Heat

Sterilization utilizing hot air, conducting heat through the equipment. Objects are heated to a steady temperature and held for a certain length of time, depending on the material. Dry heat sterilization is very effective, as it can reach all surfaces of an assembled product. However, some types of plastics cannot withstand the temperatures required, and some plastic discoloration may occur.

## Autoclave

A type of steam sterilization common for equipment that can handle high temperatures. An autoclave is a device that subjects equipment to high-pressure saturated steam. Sterilization is achieved by denaturing the proteins and enzymes in the bacteria.

\*Please note that the specific measurements in the descriptions above portray one cycle of the method, and several cycles may be required for complete sterilization.

TPU	Type	EtO	Peroxide	E-Beam	Gamma 25 kGy	Gamma 50 kGy	Dry Heat	Autoclave
Pathway™ Hydrophobic	Aliphatic	√	√	√	√	√	X	X
Pathway™ Hydrophilic	Aliphatic	√	√	√	√	√	X	X

Key: √ Recommend | X Do Not Recommend

Samples tested using only a single cycle. Users should confirm results with their own tests.

<sup>1</sup>Performance is not affected by discoloration.



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