HEALTH

Proper Sterilization Methods for Medical Grade Thermoplastic Polyurethane (TPU)

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 structural integrity, produce harmful by products, and not fully sterilize the product itself.

It's also important to remember that all polymer products are not the same. A method that's perfect for one polymer might completely degrade another. When specifying sterilization methods for polymer-based medical devices, significant consideration of polymer properties and chemistry must be employed.

Common medical device sterilization methods and their impact on Lubrizol's medical grade TPU polymers are provided herein.

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 tolerance, 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 sterilize the product. Using radiative sterilization on aromatic TPUs can cause discoloration.

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 radiative sterilization on aromatic TPUs can cause discoloration.

Dry Heat

Sterilization utilizing hot air, conducting heat through the product. 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 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. The use of autoclave sterilization is not recommended for most TPU.

Please note that guidance in the table below is based on one cycle of the sterilization method. Several cycles may be required for complete sterilization depending on product/device design.

TPU	Type	EtO	Peroxide	E-Beam	Gamma 25 kGy	Gamma 50 kGy	Dry Heat	Autoclave
Carbothane™	Aliphatic	√	√	√	√	√	X	X
Carbothane™	Aromatic	√	√	O	O	O	O	X
Isoplast®	Aromatic	√	√	O	O	O	O	X
Pellethane®	Aromatic	√	√	O	O	O	O	X
Tecoflex™	Aliphatic	√	√	√	√	√	X	X
Tecophilic™	Aliphatic	√	√	√	√	√	X	X
Tecoplast™	Aromatic	√	√	O	O	O	O	X
Tecothane™	Aromatic	√	√	O	O	O	O	X

Key: √ = Recommend | O = May Cause Discoloration† | X = Do Not Recommend

Samples tested using a single cycle. Users should confirm results with their own tests. †Performance is not affected by discoloration.

LUBRIZOL LIFE SCIENCE
9911 Brecksville Road
Cleveland, OH 44141-3201 USA

Lubrizol.com/Health