Sterilization Resistance (Repeated)

Plastics are widely used in medical applications (both single-use and reusable) as well as industrial food equipment & packaging. Plastics used in these applications must be capable of being sterilized to guarantee an absence of contaminant species without loss of performance.

Sterilization is indeed a standard procedure used to prevent the spread of pathogens by destroying or removing living organisms. Hence, **Plastics Sterilization Resistance** characterizes the ability of polymers to endure repeated sterilization cycles (chemical, steam or gamma radiation sterilization…) without significant damage.

Sterilization deactivates cell processes involved in metabolism or genetic transcription, inducing cell death or stopping the replication ability of contaminant species.

This is particularly useful in applications such as medical and dentistry devices or industrial food equipment as stated above. Some of the common sterilization methods include:

− **Chemicals** (EtO, plasma, oxidizing agents such as hydrogen peroxide, chlorine dioxide… or liquid sterilants like glutaraldehyde, etc.)
− **Radiation** (Gamma irradiation and electron beam)
− **Heat** (Steam, dry heat)

» Select the Suitable Plastic with 'Good Sterilizability' Meeting your Requirement!

Compatibility to sterilization processes is a critical generic requirement in some industries. It is important for polymer producers as well as device manufacturers to demonstrate that their products are free from microbial contamination to a specified statistical level. Manufacturers must be aware of how material interact with various sterilizing processes.

Check out more on Sterilization Resistance:

» Sterilization Resistance of Several Plastics

» Types of Sterilization Techniques Used for Plastics
» Selecting the Most Suitable Sterilization Technique

Types of Sterilization Techniques Used for Plastics

Heat Sterilization (Steam, Dry Heat)

Water saturated steam at high temperature (121-134°C) and pressure (1.1-2.1 bar) is the most common sterilization technique used. Steam is non-toxic, inexpensive, and has a high sporicidal effect with short application time (4-15 min). ***Steam is highly recommended for sterilizing heat-resistant materials***, however, inapplicable to heat sensitive materials. Plastics that have higher softening temperature than the sterilization temperature must be used when considering steam sterilization.

Hence, stream sterilization plays a major role in hospital sterilization procedure for reusable and procedure trays.

Dry heat sterilization (150-170°C for 60-150min) is obtained in an over (Pasteur stove) by hot air that destroys pathogens by oxidation, volatilization of light components, and deep dehydration of microorganisms. Different from saturated steams, it does not induce superficial corrosion and deposits and allows the effective sterilization of complex designs.

Ethylene Oxide

Ethylene oxide (EtO) sterilization is a commonly used sterilization technique used to sterilize items that are **heat or moisture sensitive**. Used in the gaseous state, EO gas must have direct contact with microorganisms on or in items to be sterilized.

- The sterilization process includes a vacuum phase in autoclave and a subsequent injection of EtO gas in concentrations ranging from 600 to 1200 mg/L.
- The chamber is kept between 30 and 501°C with a relative humidity of 40% - 50%.
- The cycle lasts for 2–8 h according to the specific sterilization protocol and sterilizer load.

EO gas sterilization is dependent upon four parameters:

1. EO gas concentration
2. Temperature
3. Humidity, and

4. Exposure Time

The main advantage of EtO sterilization is related to the low-temperature process and the wide range of material compatibility.

The sterilization cycle should include a post process **aeration for detoxification of gas residual**.

Plasma Techniques

Cold plasma techniques are currently the most effective alternative to EO for low-temperature sterilization of **thermosensitive materials**. Cold plasma is a partly ionized gas including ions, electrons, ultraviolet photons, and neutral reactive species such as radicals and excited molecules. They can be generated through the action of either a strong electric or magnetic field, somewhat like a neon light.

Materials and devices that cannot tolerate high temperatures and humidity are often sterilized by hydrogen peroxide gas plasma. This Method is compatible with most the materials and applications.

Radiation

Sterilization by exposure to ionizing radiation is widely used as a room temperature treatment and end-point process of chain production. Ionizing radiation produces ions by knocking electrons out of atoms.

- **Gamma radiation sterilization** is the most popular form of radiation sterilization. Co-60 and, to a lesser extent, Cs-137 serve as radiation sources and undergo decomposition to release high energy gamma rays.
- Sterilization can alternatively be accomplished using electron beam irradiation. High energy electrons capable of inducing biological damage are generated by electron beam accelerators.

Gamma rays can deeply penetrate low-density materials, such as polymers, whereas high-energy electrons usually interact with the superficial layer of materials.

Chemical Sterilization

Chemical sterilants such as formaldehyde, glutaraldehyde, and chlorine dioxide are excellent at sterilizing many heat sensitive polymers and materials, but they will leave residuals or by-products, and will not penetrate all designs, configurations, plastics, packaging etc.

Ethylene oxide gas sterilization and radiation sterilization methods represent the majority of the sterilization market for devices containing polymeric materials

Check out this overview of common sterilization methods used for polymeric materials:

Steam	Applicable only to heat resistant materials: Corrosive effect need to be considered with metals Not compatible with most biologicals (medical devices incorporating material of animal origin) **» Check Out Polymeric Grades Suitable for Sterilization with Superheated Steam!**
EO	Compatible with most polymeric materials: Some materials are sensitive to the humidity of the ETO process, for example certain hydrophilic coatings Certain extremely temperature sensitive materials are not compatible Residues may be toxic; requires degassing process **» Find All Polymeric Grades Suitable for Sterilization with Ethylene Oxide!**
Radiation	Compatible with many polymeric materials at sterilization dose range upto 50KGy Some materials (e.g, acatal unstabilized polypropylene and polytetrafluoroethylene, PTFE) need to be carefully evaluated Not compatible with active electronics **» Discover Polymeric Grades Suitable for Sterilization with Radiation!**
Plasma	Materials effect are typically small Broadly applicable for surface sterilization Ability of plasma to penetrate interior of devices is challenging

	» Check Out All Polymeric Grades Suitable for Sterilization with Plasma!
Other Gases	Dependent of the nature of the gas; many are strong oxidizing agents and the material impact needs to be evaluated carefully.

Selecting the Most Suitable Sterilization Technique

In researching and selecting the most suitable sterilization technique for a specific device, it is important to perform in-depth polymer compatibility analyses with process used.

A variety of factors must be carefully considered in selecting a sterilization process without affecting the properties of plastics (physio-chemical, biocompatibility, stability etc.).

- Steam or dry heat sterilization will melt and degrade some plastics
- EO has toxic residuals, and it has limited penetration, but it can sterilize almost every plastic
- Radiation may discolor or degrade some plastics, but it has excellent penetration and no residuals but can damage many plastics on repeated sterilization. It has a larger impact on materials than EO, in particular on PTFE, **polyacetal** and unstabilized **PP**.

Overall, sterilization compatibility, material type, bio-compatibility, qualification time, turnaround time and cost are the key drivers in the selection of sterilization process.

There are several requirements and guidance that exists to validate the level of sterility and to maintain the routine controls to deliver such a process on a repeated basis.

- **ISO 14937** – It has been developed for generic guidance for any sterilization method
- **ISO 11135 -** describes requirements that, if met, will provide an ethylene oxide sterilization process intended to sterilize medical devices
- Moist Sterilization – **ISO 1134**, **13683**, **554**

Sterilization Resistance of Several Plastics

Polymer Name	Value
ABS - Acrylonitrile Butadiene Styrene	Poor
ABS Flame Retardant	Poor
ABS High Heat	Poor
ABS High Impact	Poor
ABS/PC Blend - Acrylonitrile Butadiene Styrene/Polycarbonate Blend	Poor
ABS/PC Blend 20% Glass Fiber	Poor
ABS/PC Flame Retardant	Poor
ASA/PC Blend - Acrylonitrile Styrene Acrylate/Polycarbonate Blend Flame Retardant	Poor
COC - Cyclic Olefin Copolymer	Fair
EVA - Ethylene Vinyl Acetate	Poor
HDPE - High Density Polyethylene	Poor
HIPS - High Impact Polystyrene	Poor
HIPS Flame Retardant V0	Poor
LCP - Liquid Crystal Polymer	Excellent
LCP Carbon Fiber-reinforced	Excellent
LCP Glass Fiber-reinforced	Excellent
MABS - Transparent Acrylonitrile Butadiene Styrene	Good
PA 46 - Polyamide 46 30% Glass Fiber	Poor
PA 6 - Polyamide 6	Poor
PA 66 - Polyamide 6-6	Poor
PA 66, 30% Glass Fiber	Poor

PA 66, 30% Mineral filled	Poor
PA 66, Impact Modified, 15-30% Glass Fiber	Poor
PA 66, Impact Modified	Poor
PC (Polycarbonate)	Fair
PC (Polycarbonate) 20-40% Glass Fiber	Fair
PC (Polycarbonate) 20-40% Glass Fiber Flame Retardant	Poor
PC - Polycarbonate, high heat	Fair
PC/PBT Blend - Polycarbonate/Polybutylene Terephthalate Blend	Poor
PC/PBT blend, Glass Filled	Poor
PE - Polyethylene	Poor
PE - Polyethylene30% Glass Fiber	Poor
PEEK - Polyetheretherketone	Good
PEEK 30% Carbon Fiber-reinforced	Good
PEEK 30% Glass Fiber-reinforced	Good
PEI - Polyetherimide	Good
PEI, 30% Glass Fiber-reinforced	Good
PEI, Mineral Filled	Good
PESU - Polyethersulfone	Fair
PESU 10-30% glass fiber	Fair
PET - Polyethylene Terephthalate	Poor
PET, 30% Glass Fiber-reinforced	Poor
PET, 30/35% Glass Fiber-reinforced, Impact Modified	Poor
PETG - Polyethylene Terephthalate Glycol	Poor
PFA - Perfluoroalkoxy	Excellent

PI - Polyimide	Excellent
PMMA - Polymethylmethacrylate/Acrylic	Poor
PMMA (Acrylic) High Heat	Poor
PMMA (Acrylic) Impact Modified	Poor
POM - Polyoxymethylene (Acetal)	Poor
POM (Acetal) Impact Modified	Poor
POM (Acetal) Low Friction	Poor
POM (Acetal) Mineral Filled	Poor
PP - Polypropylene	Poor
PP - Polypropylene 10-20% Glass Fiber	Poor
PP, 10-40% Mineral Filled	Poor
PP, 10-40% Talc Filled	Poor
PP, 30-40% Glass Fiber-reinforced	Poor
PP (Polypropylene) Copolymer	Poor
PP (Polypropylene) Homopolymer	Poor
PP, Impact Modified	Poor
PPA - Polyphthalamide	Good
PPE - Polyphenylene Ether, Flame Retardant	Poor
PPE, Impact Modified	Poor
PPS - Polyphenylene Sulfide	Good
PPS, 20-30% Glass Fiber-reinforced	Good
PPS, 40% Glass Fiber-reinforced	Good
PPSU - Polyphenylene Sulfone	Excellent
PS (Polystyrene)	Poor
PS (Polystyrene) 30% glass fiber	Poor

PS (Polystyrene) Crystal	Poor
PS, High Heat	Poor
PSU - Polysulfone	Good
PSU, 30% Glass finer-reinforced	Good
PSU Mineral Filled	Good
PVC (Polyvinyl Chloride)	Poor
PVC, Plasticized	Poor
PVC, Plasticized Filled	Poor
PVDF - Polyvinylidene Fluoride	Excellent
SAN - Styrene Acrylonitrile	Fair
SAN, 20% Glass Fiber-reinforced	Poor
SMA - Styrene Maleic Anhydride	Poor
SMA, 20% Glass Fiber-reinforced	Poor
SMA, Flame Retardant V0	Poor
SMMA - Styrene Methyl Methacrylate	Fair
SRP - Self-reinforced Polyphenylene	Good