Objet Geometries

Medical Applications
Sterilization of PolyJet™ Models

Overview

The process known as sterilization refers to the process in which all living cells, spores, and viruses are completely destroyed or removed from an object or environment. Once something is sterilized, it will remain sterile if properly sealed. Sterilization is performed on surgical equipment, needles, and certain lab equipment in order to prevent the spread of microorganisms.

Methods used to sterilize objects involve the use of heat, radiation, filtration, and/or chemical means. Autoclaves are devices which use hot steam under high pressure to sterilze objects.

Sterilization is an extreme level of cleanliness that is usually not required outside of a medical, industrial, or laboratory environment. The sterilization of PolyJet™ models may be conducted directly while using different types of sterilization considered as 'cold' process. The main common sterilization processes are listed hereafter.

Glutaraldehyde and Formaldehyde Solutions (also used as fixatives) – are additional accepted liquid sterilizing agents, provided that the immersion time is long enough – it can take up to 12 hours for glutaraldehyde to kill all spores, and even longer for formaldehyde. (This assumes that a liquid not containing large solid particles is being sterilized. Sterilization of large blocks of tissue can take much longer, due to the time required for the fixative to penetrate.) Glutaraldehyde and formaldehyde are volatile, and toxic by both skin contact and inhalation. Glutaraldehyde has quite a short shelf life (<2 weeks), and is expensive. Formaldehyde is less expensive and has a much longer shelf life if some methanol is added to inhibit polymerization to paraformaldehyde, but is much more volatile. Formaldehyde is also used as a gaseous sterilizing agent; in this case, it is prepared on-site by depolymerization of solid paraformaldehyde.

Ethylene Oxide (EO) – gas is commonly used to sterilize objects that cannot survive temperatures greater than 60°C such as plastics, optics and electrics. Ethylene oxide treatment is generally carried out between 30°C and 60°C with relative humidity above 30% and a gas concentration between 200mg/l and 800mg/l for at least 3 hours. Ethylene oxide penetrates very well, moving through paper, cloth, and some plastic films and is highly effective. Ethylene oxide however is highly flammable, and requires a longer time to sterilize than any heat treatment. The process also requires time for aeration post sterilization to remove toxic residues. Ethylene oxide is widely used and sterilizes around 50% of all disposable medical devices.

Plasma Sterilization – When a modulated electric field is applied to a pair of electrodes, a plasma is formed, which makes the Oxygen molecules of the air passing near the electrodes break down into reactive oxygen species (ROS). Organic substrates such as bacteria, viruses and mold spores that

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Sterilization Method	Advantages
Ethylene oxide	• Economical for high and low volume operations • Can sterilize plastics whose physical properties may degrade with irradiation • Accelerated preconditioning decreases processing time • Will not degrade packaging materials
Gamma radiation	• Economical for high and low-volume operations. • Fast • Does not require a quarantine or post-sterilization treatment • Is easily validated • No residuals • Can be quantitatively monitored • Used in many single-use medical supplies such as syringes, catheters, IV sets, gloves, and face masks

become exposed to these ROS are destroyed or rendered harmless on contact, and the same reaction convert the ROS back into oxygen. In fact, any amount of air that is exposed to the ROS becomes substrates-free.

Gamma Radiation – is radiation of photons in the gamma part of the spectrum. The radiation is obtained through the use of radioisotopes, generally cobalt 60 or in very few cases caesium 137 It is the most cost-effective technology and is preferred by many processors because the good penetration enables administering treatment to entire industrial pallets or totes, greatly reducing the need for material handling. A pallet or tote is typically exposed for several minutes depending on dose. The environment is protected by a large concrete shield. With most designs the radioisotope can be lowered into a water storage pool in order to allow maintenance personnel to enter the radiation shield. In this mode the water in the pool absorbs practically all radiation providing a safe working environment for plant personnel. Other not commonly used designs feature dry storage by providing movable shields that eliminate radiation levels in areas of the irradiation chamber.

One variant of gamma irradiators keeps the cobalt 60 under water at all times and lowers the product to be irradiated under water in hermetic bells. No shielding is required for such designs.

Electron Beam Irradiation – Electron beam irradiation uses electrons accelerated in an electric field to a velocity close to the speed of light. International and national regulations limit the energy of the beam to guarantee that no induced radioactivity occurs. Electrons have cross sections many times larger than photons, so that they do not penetrate the product beyond a few inches, making it necessary to treat each individually; on the other hand, treatment times are only a few seconds. Electron facilities rely on substantial concrete shields to protect workers and the environment from radiation exposure.

Disclaimer

Objet Geometries Ltd. is not responsible for misuse of our products or their use in conjunction with unsafe or improperly maintained equipment or for uses other than intended as specified in this application note.

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