

Gamma Sterilization for Medical Devices and its Effect on Epoxies

WHAT

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WHY

Irradiation can cause some changes to epoxies.

What is Sterilization?

Sterilization is a process that effectively kills any transmissible agents (such as bacteria, viruses, fungi, spore forms, etc.) on a surface. The selection of a specific sterilization method is dependent on the product's resistance to heat and chemicals.

There are three basic sterilization processes: Radiation, in the form of either gamma sterilization or E-Beam, High Heat & High Pressure, (Wet/Steam or Dry Heat), or Chemically, using either Ethylene Oxide (EtO) gas, Vaporized Hydrogen Peroxide plasma (VHP), or various liquid reagents.

What is Gamma Sterilization?

Gamma sterilization, also known as irradiation, is a very common method of sterilization. It is performed by exposing a product to continuous gamma rays; commonly used is Cobalt-60.

It is most often performed on disposable medical devices, such as: syringes, catheters, electro- surgical tools, & thermoplastic fittings, parts, and connector accessories; anything which comes in contact with bodily fluids, tissue or skin.

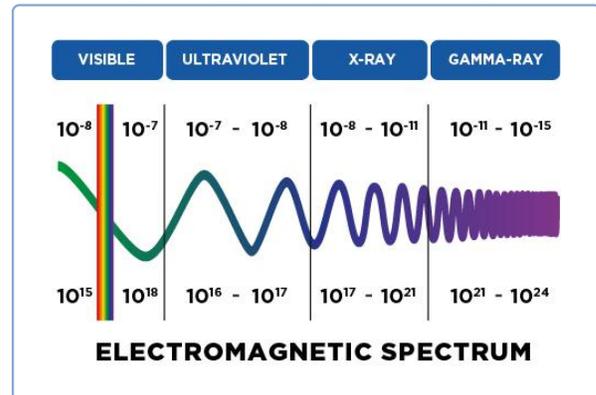
E-beam is another form of sterilization using electron beams, which are powerful and the exposure time of the device is much less.

Neither method results in any radioactivity. In fact sterilization through irradiation is considered a "clean and efficient process" as it does not leave any residue on the device and there is no quarantine period required once the desired sterilization level has been reached.

What effect does gamma radiation have on epoxy?

Epoxy adhesives are routinely used in medical device assembly from single use disposable items, to implantable microelectronics, to reprocessed surgical instruments. Many medical devices are gamma sterilized. Let's take a look at what happens to the epoxy after exposure to gamma radiation.

A study was performed on EPO-TEK® 301, under a 24hr continuous dose of gamma (15Mrad, at 6MeV peak photons). The goal was to see if changes might occur in optical, mechanical and physical properties.



EPO-TEK® 301 Properties Before & After Gamma Radiation

Property	301 Before Gamma	301 Post Gamma
T_g (Glass Transition)	62°C	65°C
Shore D Hardness	79	84
E' Modulus, @ 23°C	225 Kpsi	256 Kpsi
Outgas @ 200°C	0.71%	0.73%
Outgas @ 250°C	1.37%	1.06%
Outgas @ 300°C	7.49%	2.56%

RESULTS OF STUDY

Mechanically > Gamma radiation was found to increase the T_g, Shore hardness and storage modulus. The results suggest that additional cross-link density was realized due to the exposure.

Optically > Pictures of “dummy” molded discs of EPO-TEK® 301 are shown in fig 1. Severe discoloration, yellowing and even darkening was observed after 24 hours of continuous radiation.

Physically > The weight loss, or thermal stability was compared, suggesting that irradiated samples had higher temperature performance, through lesser outgassing of materials.

EPO-TEK® 301's reaction to gamma radiation is presumed to be a post-cure mechanism, evidenced by increasing mechanical properties. It is unknown whether it was gamma itself, or a side effect of increased temperature from within the radiation chamber, that contributed to the additional cross-linking.

CONCLUSION

Gamma radiation resulted in no physical and mechanical degradation, however users should take special consideration in applications where the epoxy is located within the optical beam pathway, as the epoxy discoloration can effect optical properties.

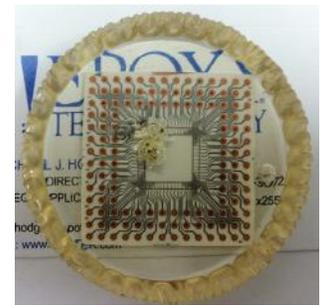


FIG. 1 Photos of EPO-TEK® 301 before and after gamma

