Introduction

Ionizing radiation is commonly used to sterilize disposable medical devices. This radiation has an effect on the materials used, specifically polymers. The total dose and dose rate are the main parameters that control the effect on the polymer properties.

Dose

In irradiation processing, the dose is defined as the amount of energy absorbed by the target material. In the SI system, this is reported in units of Gray, where 1 Gy is equal to 1 Joule per kilogram, or more frequently in units of kiloGray, where 1 kGy = 1,000 J/kg.

Dose Rate

For any irradiation process, be it gamma, e-beam, or x-ray technology, the dose rate can be defined as dose delivered per unit time. The amount of time that the product needs to spend under ionizing radiation is inversely proportional to the dose rate. The table below shows an example of a typical gamma cell and a low-power, 1 kW, e-beam. It should be noted most commercial e-beams are at least 10 kW, and therefore will have an even shorter exposure time. In this example, it takes 40 times longer to receive the 20 kGy dose using the gamma process than in the e-beam process.

Dose Rate Effects

The radiation response of polymeric materials depends on both the total dose and the dose rate. For a given polymer, irradiation typically results in competing beneficial and deleterious effects on mechanical and physical properties. The magnitude of detrimental dose rate effects will differ based on macromolecular structure, formulation, and environmental conditions. Dose rate effects have an impact through both physical and chemical mechanisms.

Physical dose rate effects result from oxygen diffusion into the irradiated polymer. Atmospheric oxygen penetrates the molecular structure and interacts with the radicals created when the polymer molecules are excited by the ionizing radiation. Known as oxidative degradation, this process cleaves the carbon-carbon bonds in the polymer backbone (see chemical equations 1, 2 and 3 on the next page). Oxidative degradation leads to noticeable declines in tensile strength, barrier properties, impact strength, and other key physical properties of the polymer. However, at high dose rates oxygen does not diffuse into polymers fast enough to cause these deleterious radical reactions.