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Electron Beam Sterilization Process

How it works

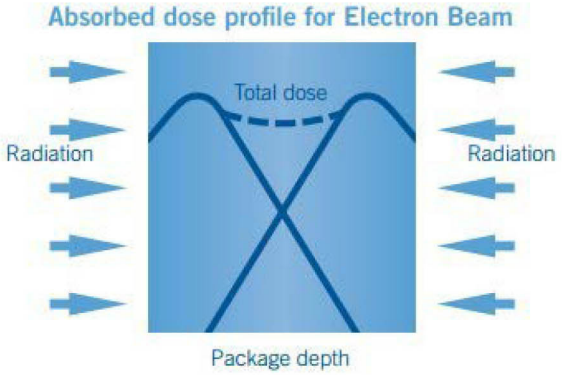
The Electron Beam process can achieve these widely differing effects, such as polymer modification, sterilization, cross linking and chain scission, via its action as an ionizing radiation. In its simplest terms, the bombardment of a material with high-energy electrons results in a cascade of these electrons moving through the target material. These electrons are free to interact with molecules within the material, ejecting electrons from their orbits and generating free radicals. It is primarily the reactions of these species that are responsible for the ability of the beam to modify polymers. In the context of the beam's sterilization capability it is generally accepted that these same species induce breaks in the DNA double helix, preventing replication or expression, resulting in the ability to sterilize.

Dose mapping validation (performance qualification):

Dose mapping (feasibility study) is carried out on products to ensure adequate penetration to achieve the required absorbed dose. Secondary electrons are generated and will be distributed within the product. Therefore significant importance is placed on product/packaging configuration to ensure even distribution of dose. Two-sided irradiation allows greater thickness of material to be handled, the absorbed dose being the sum of irradiation from each side. Traditional dose mapping validations will be carried out in triplicate for laboratory devices. We operate in accordance with ISO 11137-1:2006 Sterilization of health care products, which outlines requirements for routine control of a sterilization process for laboratory devices. Processing with Electron Beam differs from processing with Gamma radiation in two key aspects. Firstly the process time is much shorter, usually minutes with Electron Beam as opposed to hours with Gamma. This results in some differences in radiation chemistry (the dose effect) between the two systems, which may offer improved material compatibility on Electron Beam processing. Secondly, product penetration by accelerated electrons is less than by Gamma radiation which will mean a wider dose range than Gamma. This process is also more compatible with lower density materials. Penetration power is directly related to the energy of electrons (i.e. voltage); processing speed is related to the quantity of electrons generated by the accelerator i.e. the current consumed (amperage).

Product Release

The absorption of electrons by products undergoing Electron Beam irradiation at Synergy Health is monitored using a variety of thin film dosimetry systems. The unit of absorbed dose is the Gray, expressed as kGy. The absorbed dose is determined by product density, pack size, dose rate, and exposure time and to some degree by plant design. Typical dose range for laboratory sterilization via beam is 15-60 kGy; in all cases dosimetry systems calibration is traceable to National Physical Laboratory Standards. Stability trials and materials effects analysis should also be undertaken after dose mapping.



Box to box system, Synergy Health Tullamore