

## Simulation of Radiation Sterilization: Selection and Optimization of the Right Source

When using radiation sterilization, medical device and pharmaceutical companies are faced with the choice of gamma, electron-beam, or x-ray sources. But which one to choose? While it may be tempting to go with the familiar option, each of these techniques has its own benefits that might make it the ideal choice for a particular product. With a new simulation approach, we can guide companies toward the most efficient, cost-effective, and reliable sterilization method for their product.

### Triple Ring Technologies

Triple Ring Technologies, headquartered in Newark, CA, is an ISO13485 certified innovative R&D company that partners with clients to deliver complex technical solutions. Founded in 2004, Triple Ring's team of scientists and engineers provides leading edge, integrated technical design, engineering, and business services. Clients include entrepreneurs, established companies, and investors in the medical device, life sciences, optics, clean technology, and digital imaging fields.

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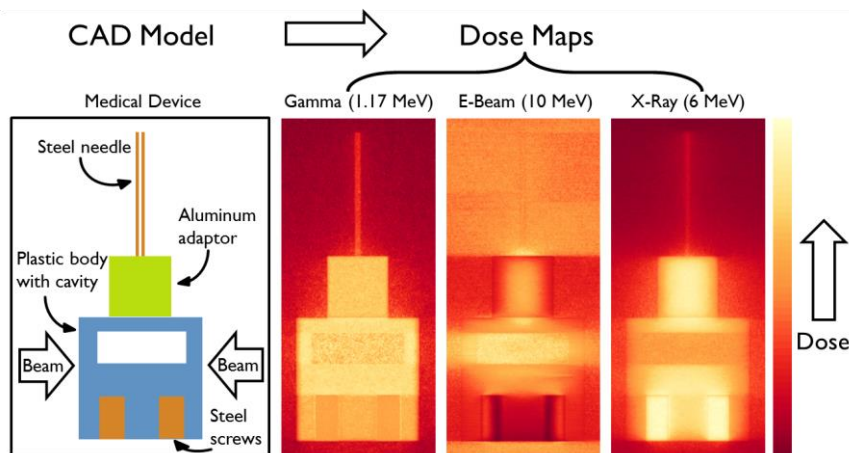
### Steri-Tek

Steri-Tek, opening in April 2016, will be a high-volume E-beam/X-ray contract sterilizer and R&D innovation center that provides on-demand sterilization, microbiology, crosslinking, and expert consultative services to the medical device, biotech, pharmaceutical and other industries. Particularly with sensitive products, Steri-Tek has developed a proprietary system for radiation-sensitive materials such as combination devices, bioabsorbables, implantables, advanced polymers and other complex products. Steri-Tek will be an ISO13485 and ISO11137 certified facility that will be FDA registered and DEA licensed, bringing over 75 years of combined medical device, biopharma and sterilization expertise to its customers.

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### Our solution

One way to compare gamma, electron-beam, and x-ray sterilization would be to experimentally measure the dose received by a product when exposed to each source. However, this would be an expensive endeavor, and so is not feasible in practice. Instead, powerful computer simulations can be used to study the equivalency of the different radiation sources.



By changing a few parameters, simulations offer the ability to directly compare gamma, electron-beam, and x-ray sources. This is demonstrated in the figure above, which shows the simulated dose map received by a prototypical medical device phantom by various types of radiation. Such information allows the device manufacturer to make an informed decision about the type of sterilization method they should use.

### How do we do it?

Triple Ring Technologies has developed a powerful software tool capable of realistic simulations of radiation sterilization. The physics in the simulations is powered by the GEANT4 toolbox; developed at CERN, GEANT4 is the most sophisticated and accurate physics library in existence. Our tool can simulate the full three-dimensional dose distribution received by any product from gamma, electron-beam, or x-ray sources.