Sterilization is indispensable in medical diagnostics and for safe application of sensitive medical devices.

Safe Sterilization with rays

According to the DIN EN 556-1 standard, a medical product is claimed sterile if the theoretical probability of finding a viable reproducible germ on the product is less than 1:1,000,000. In order to achieve this state, products have to undergo a subsequent sterilization process. Different procedures and technologies are available to this end. Among the most common is sterilization using beta or electron and gamma rays, since this process offers a number of advantages. X-ray sterilization is in the early stages of development. In addition, chemical processes can be used for sterilizing, for example, exposure to ethylene oxide (EO or EtO) or to heat.

Similarities and differences between electron and gamma rays

Beta or electron and gamma rays cause damage of the DNA molecule in the nucleus of microorganisms. In this way, they reliably lose their ability to reproduce and die; the devices become sterile. Both technologies follow this principle. The most important parameter is the radiation dose in order to make this type of sterilization measurable, documentable and reproducible. This parameter determines the achieved degree of sterility (SAL = Sterility Assurance Level). The dose rate is decisive for the final properties of the device.

Beyond these similarities, there are some differences between electron and gamma rays as Table 1 shows.

The main difference between the two types of radiation is the penetrability. Irradiation with beta rays is more like particle radiation with accelerated electrons and therefore has a limited penetration depth. By contrast, gamma rays as electromagnetic wave have a much higher penetration depth.

In plants with electron accelerators, high dose rates are used with a limited penetration depth, whereas gamma plants have high penetrability and low dose rates. The dose rate depends on the installed total activity. In terms of application technology, this means that the dose is applied in electron accelerators within seconds; to this end, it is necessary to irradiate the cartons delivered on a pallet individually.

Parameter	Electron radiation	Gamma rays
Dose rate	high	low
Depth of penetration	medium	very high
Irradiation time	a few seconds	several hours
Energy source	Electric current	Cobalt-60
Irradiation unit	Single cartons	Pallets
Description of procedure	Electrons are emitted from a heated cathode and then accelerated to a very high velocity in a high vacuum by means of a strong electric field. Upon leaving the accelerator, the electron beam is deflected by a magnetic field onto the product in lines at a high frequency.	Gamma rays are created through the decay of a radioactive isotope, e.g. Cobalt-60. The rays have a high penetration depth and penetrate entire pallets or lots. Individual sources of Cobalt-60 are arranged and integrated into the source rack, by which means a unique radiation field is generated. The products to be sterilized are transported through this radiation field via a fixed pre-specified path. In the process, the necessary radiation dose is emitted into the product.

Table 1: Technological differences between electron radiation and gamma rays.

In the BGS gamma plants, the total radiation dose is applied by circulating around the source rack multiple times – large volumes are possible, allowing irradiation of whole pallets at once. The dwell time in the radiation field varies depending on the product; this is usually several hours for medical devices.

For physical reasons, the applied radiation sources – electron accelerators up to a maximum energy of 10 MeV and gamma rays starting from the cobalt isotope Cobalt-60 – generate no radioactivity. In order to protect employees and the environment from radiation exposure at all times, operation of the corresponding facilities are subject to a series of high requirements in respect to occupational health and safety. Knowledge of the rules, the expense and effort of operating a facility are reasons why sterilization processes are often outsourced to a specialized service provider.

Prerequisites for application of radiation sterilization

If the design of a new device to be sterilized is pending, it first has to be clarified whether the method of radiation sterilization can be used. The same applies when changing from another method of sterilization to radiation sterilization. When evaluating this, amongst other things, the technical design, functionality, packaging, packaging scheme of the device, and particularly the materials used play an important role. This is because material properties change through radiation. Especially with plastics, the resistance towards ionizing rays has to be checked, as irradiation can result in discoloration or even a reduction in functionality. In addition: Radiation sterilization is not suited for devices containing microelectronic components.

In some cases, radiation sterilization cannot be applied due to the materials used; exposure to ethylene oxide is an optional procedure in this case. Ethylene oxide sterilization is a chemical procedure with several process parameters, amongst them gas concentration, humidity, temperature, and diffusion time. EtO is an alkylating agent that deactivates the DNA of microorganisms, so that these can no longer reproduce themselves. The procedure is suited e.g. for the sterilization of complex, fully assembled instruments or devices with integrated electronics, provided these are gas-permeable. Powdery substances, products that cannot become moist, or which are packed gas-tight, however, are unsuitable for this type of sterilization. Here in turn, the advantages of radiation sterilization come into effect. Exposing devices to gas is associated with a desorption phase of several days, i.e. the devices cannot be used immediately. In general, the use of combustible, toxic and carcinogenic gas requires stringent monitoring of the production environment.

> "A major advantage of radiation sterilization is the enormous time saving. Under optimal conditions, a complete truckload can be sterilized in a few hours. Following treatment, the device is ready for use without a waiting period and can be placed on the market."

Radiation sterilization saves time

Radiation sterilization is the only process of sterilizing devices in the sealed final packaging without increasing the temperature appreciably or using chemicals. Since the entire device is irradiated, radiation sterilization is also recommended in the case of complex geometries, whereby irradiation with electrons has some limitations depending on the structure and density of the device. A major advantage of radiation sterilization is the enormous time saving. Under optimal conditions, a complete truckload can be sterilized in a few hours. In this case, the approved parameter is the applied dose rate, which is verified with the help of the dosimeter affixed to the box. Following treatment, the device is ready for use without a waiting period and can be placed on the market.

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