TECHNICAL PAPER

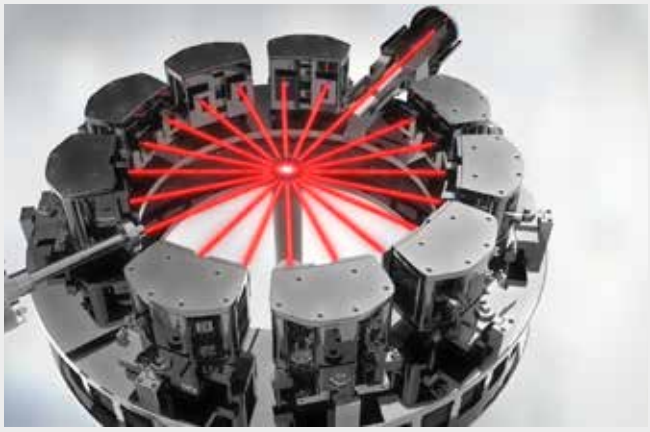
Radiation Sterilisation - Technology with a Future

Medical devices have a high value. Large resources are invested in their development, design and production. Many of these Medical devices are not usable without a final sterilisation. Reason enough to look at the various possibilities of sterilisation more precisely.

In addition to the sterilisation process with ethylene oxide or steam, sterilisation with ionising radiation is increasingly becoming the method of choice. As well as the established gamma irradiation (radionuclide Kolbalt 60 as a radiation source) and the sterilisation using electron beam technology (E-Beam) the latest technology - the use of X-radiation (X-Ray) - also gains increasing importance. On the one hand, the advantage of using X-Ray sterilisation is that it offers a more flexible selection of the radiation dose and in addition allows fewer overdose factors (ratio of radiation dose maximum to radiation dose minimum in the product). Furthermore, the product sterilisation using X-Ray or E-Beam is completely independent of radionuclide sources.

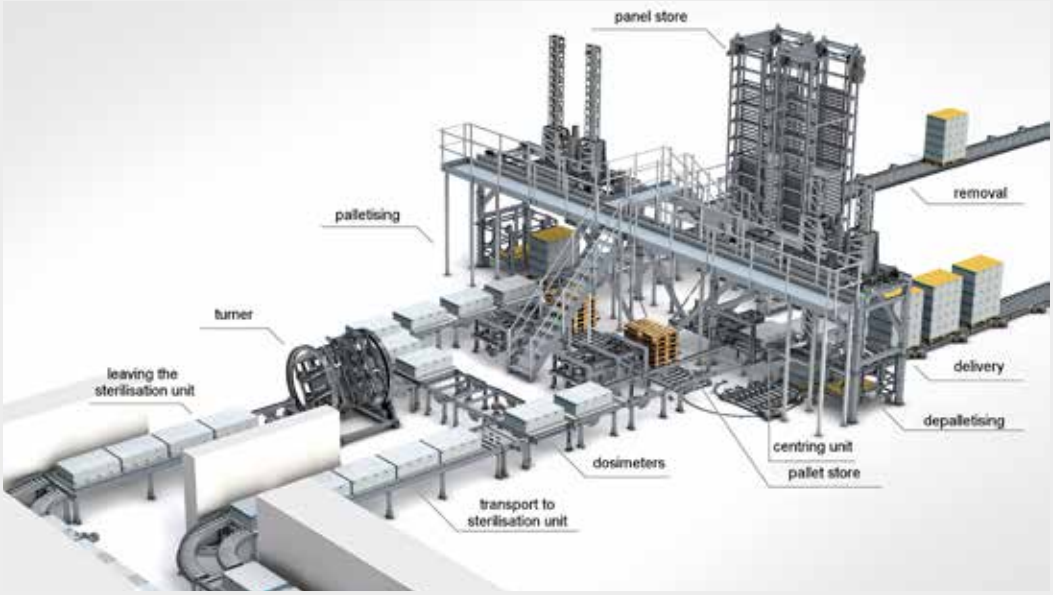
The principle of radio sterilisation is based on the influence of radiation on different biologically organisation levels (molecular, cellular, sub-cellular). The radiation effect mainly used for the sterilisation influences the molecular level. The radiation treatment leads to damage on macromolecules like DNA, RNA, and functional proteins. Thus, viruses and microorganisms reliably lose their reproduction ability or rather die.

Considering the E-Beam irradiation process, the electrons are created in an electron gun and injected in the so-called cavity.



Structure of the Rhodotron Electron Accelerator; the red lines represent the electron beam.

According to the Rhodotron principle the radial electric field accelerates the electrons until they have reached the desired energy. Using E-Beam treatment for medical products, the electrons are ejected from the cavity with a maximum energy of 10MeV.



Dual-Line Plant, Overview.

Rhodotron Electron Accelerator.

Considering X-Ray technology, electrons are generated out of the electron beam. For this purpose, electrons require lower energy and are ejected at an earlier state form the cavity and then impinge on a sandwich plate, the so-called “Target.“ By the time the electrons permeate into the “Target” they are decelerated and deflected. The electrons lose energy which is released in form of X-Rays that are used for the sterilisation of the products afterwards.

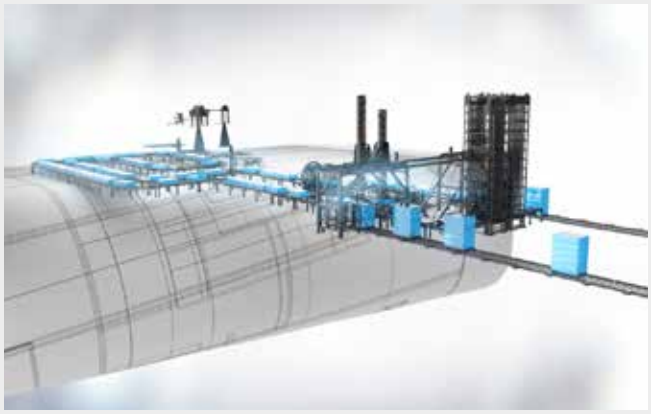
X-Ray technology comprises a combination of E-Beam and Gamma technology. As well as Gamma, X-Ray technology provides high penetrating radiation that permits the sterilisation of goods with larger volumes and higher density than using E-Beam technology.

The primary electrons generated in both variants are guided into a 270° magnet into a vertical direction. To achieve homogeneous treatment the electron or rather X-Ray beam is oscillated over the products to be sterilised by scan magnets.

Until now, the systems used have been built separately depending on their energy carrier. The latest technology of a dual-line electron accelerator, combined with a highly-developed conveyor system, allows both E-beam and X-ray sterilisation to be carried out in a single system. Considering sterilisation in such a modern dual-line system, the goods are lifted from the pallets in complete layers and get prepared for sterilisation in the first section of the treatment. Placed on conveyor belts the pallet layers reach the irradiation unit.

Depending on the chosen particle type one of two conveyer systems is used. The first conveyer leads the products to the E-Beam the second conveyer to the X-Ray scan horn. This saves time in the process.

Moreover, the dual-line electron accelerator also offers logistical advantages as both E-beam and X-ray sterilisation can be performed within one plant with highly accurate results. The sterilisation of the products is carried out in their final packaging, is of short duration and without the use of chemicals – thus, it is free of residues.



The products on their way through the sterilisation plant.

The latest technologies have succeeded in establishing the complex radiation technologies as a simple, safe and traceable sterilisation process in the medical device sector.

The authors

Dr. Josef Mittendorfer

DI Dr. Markus Niederreiter MSc

Marie-Christine Stelzhammer, B.Eng.

Mediscan GmbH & Co KG

Bad Haller Straße 34

A-4550 Kremsmünster

office@mediscan.at

www.mediscan.at