

Radiation Sterilization of Medical Products – Green and Efficient Technology

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International Atomic Energy Agency Scientific Forum

ATOMS IN INDUSTRY

Radiation Technology for Development

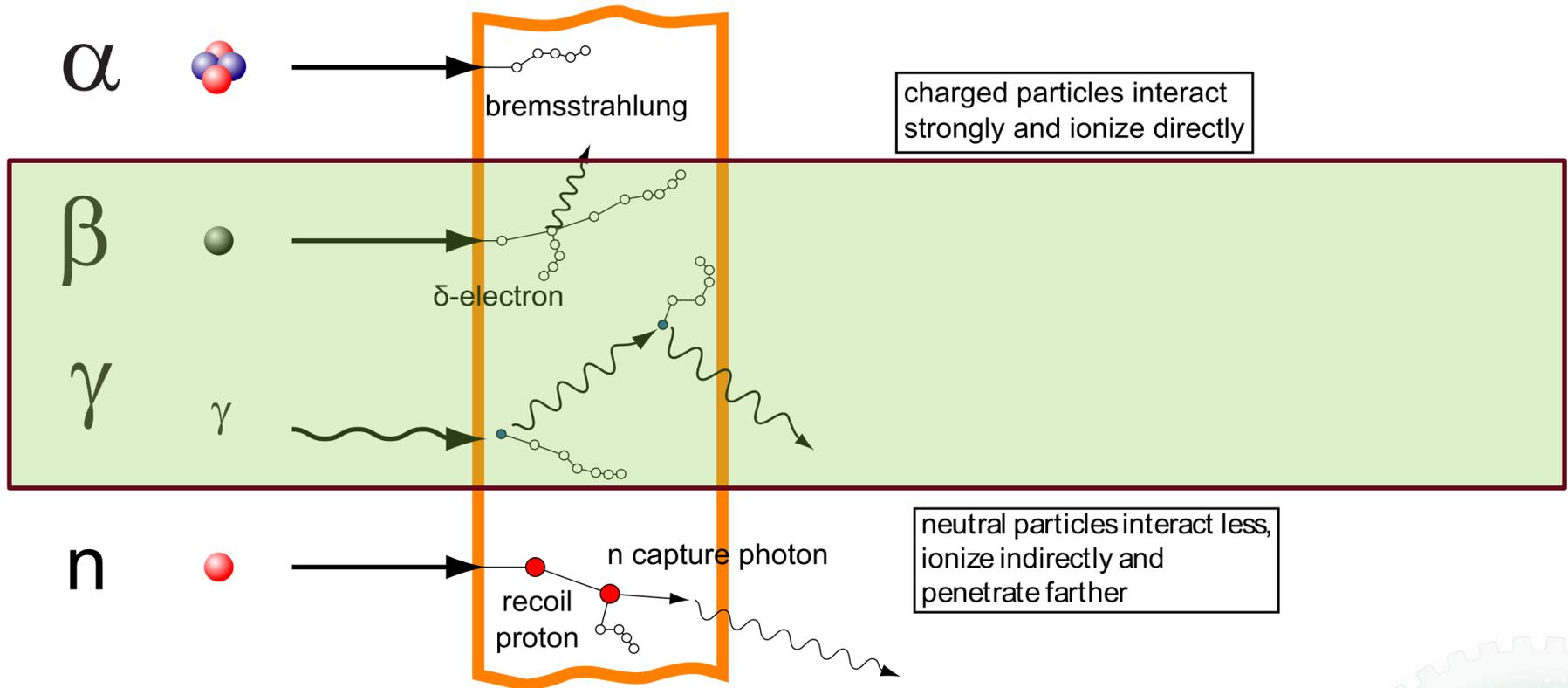
15–16 September 2015, Vienna, Austria

Sterilization - Eliminate Biological Pathogens



Ionizing Radiation

Interaction of ionizing radiation with matter

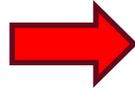
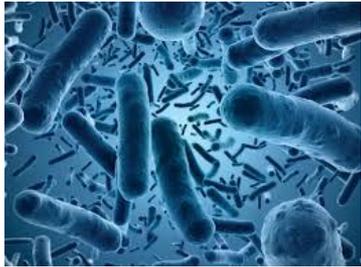


Source: https://en.wikipedia.org/wiki/Ionizing_radiation 27.07.2015

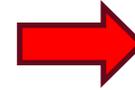


Parametric Radiation Dose Setting

Radiation
Resistivity
(D_{10} -Value)



Sterility
Requirement:
Sterile: SAL = 10^{-6}

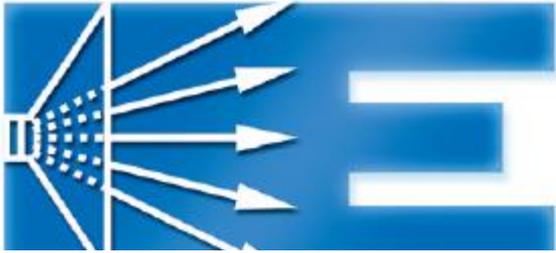


**Sterilization
Dose [kGy]**

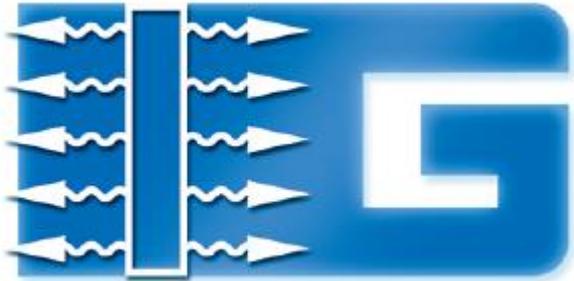
**Dose Setting Method
(VD_{max})
Dose Audit**



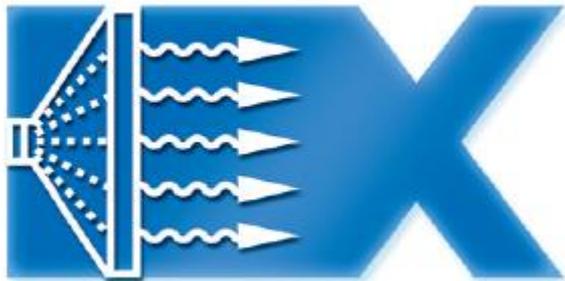
Radiation Sources



Electron Beam
Fast & Efficient



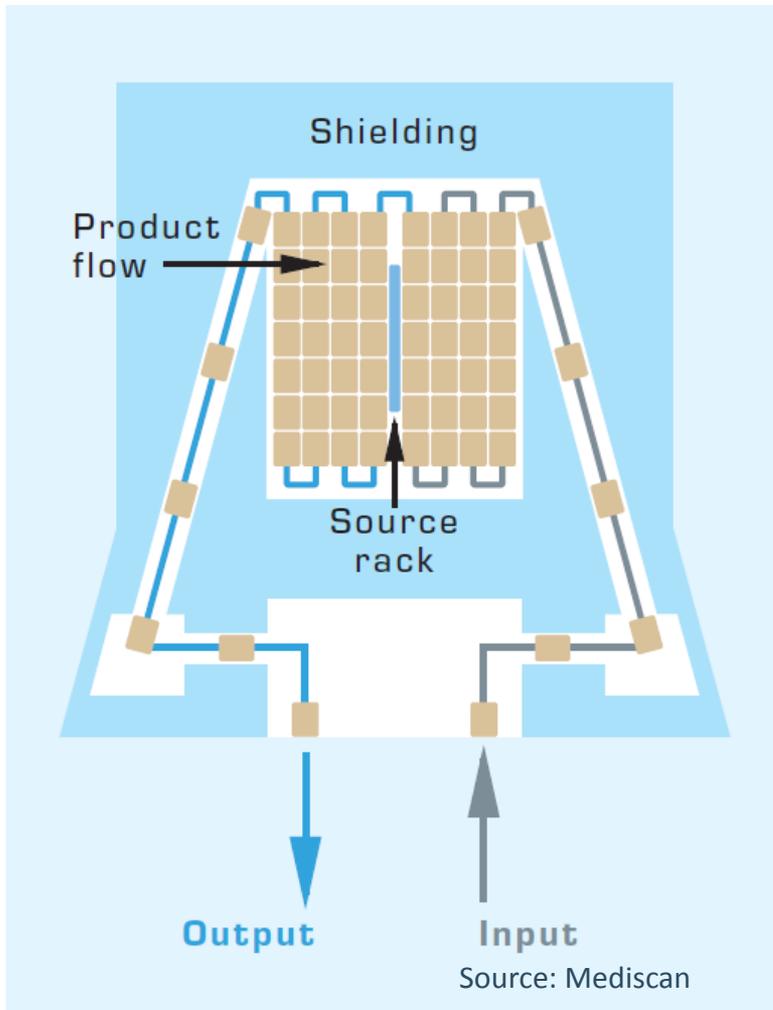
Co-60 Decay (Gamma)
Proven & Reliable



X-Ray (7 MeV)
Smart & Innovative



Radiation Source - Gamma



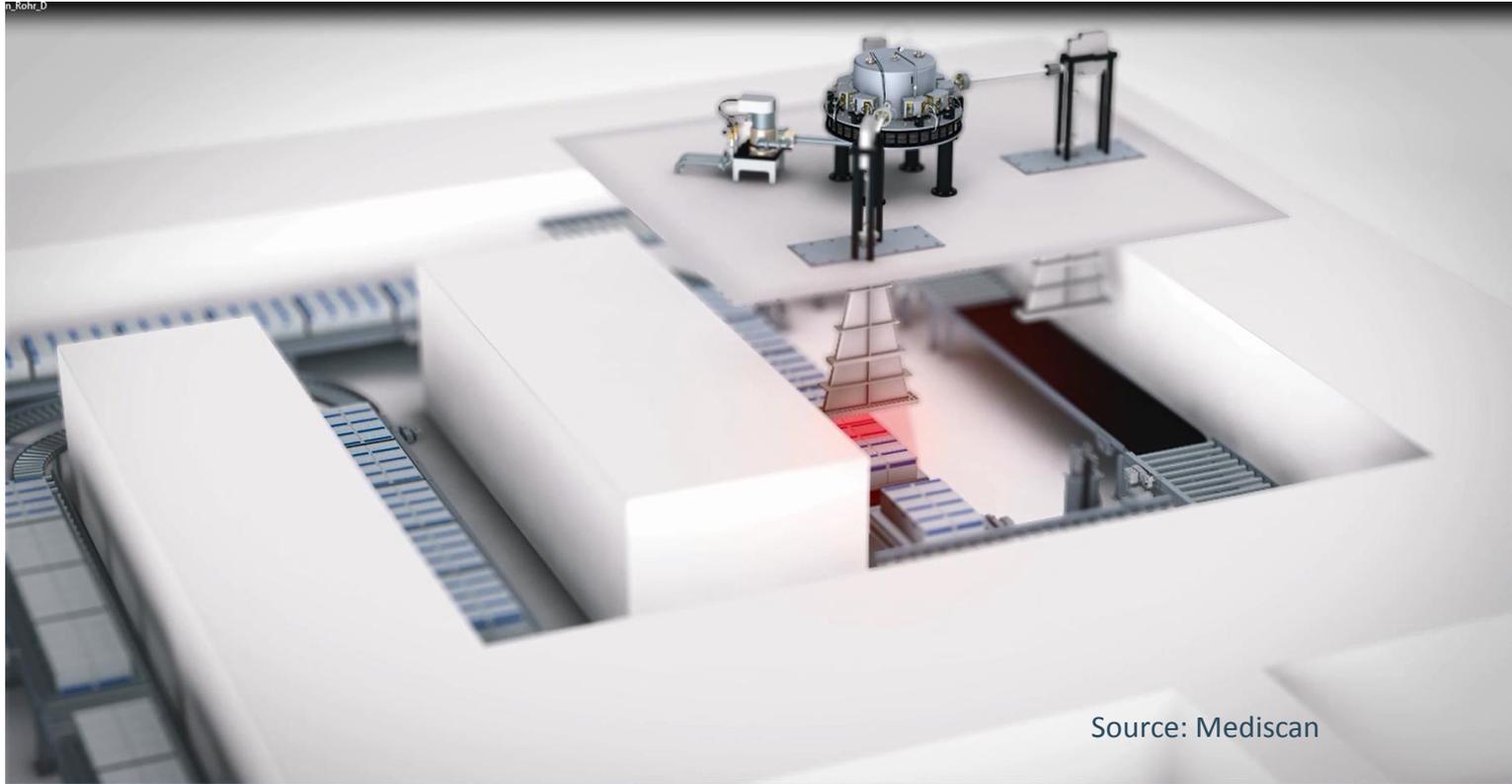
Reliable & Proven:
Co-60 Isotope Decay
High Throughput
Good Penetration



Source: sterilityassurancelab.com



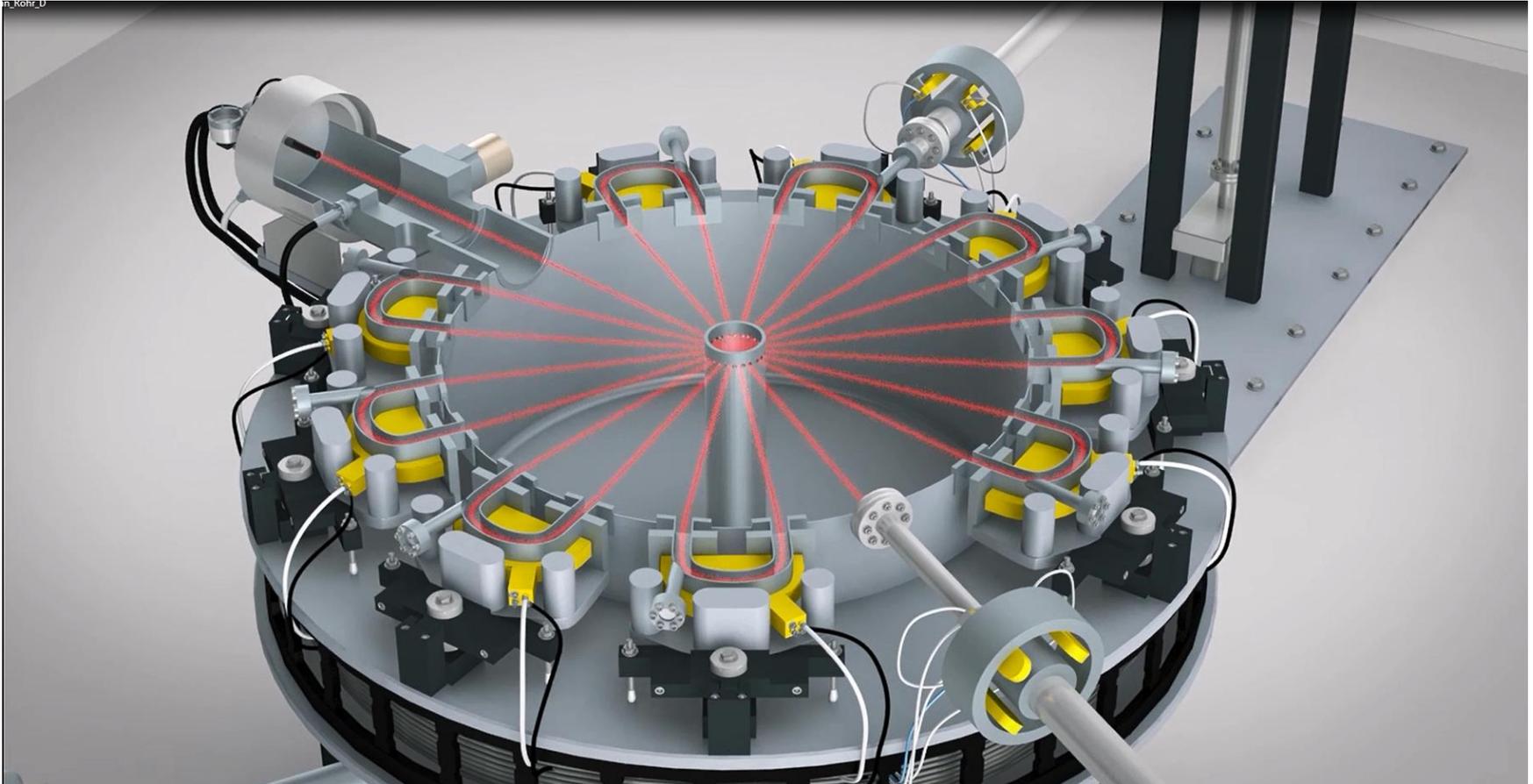
Source – Electron Beam



State-of-the-art Mediscan Facility in Austria
Fast & Efficient – Limited Penetration



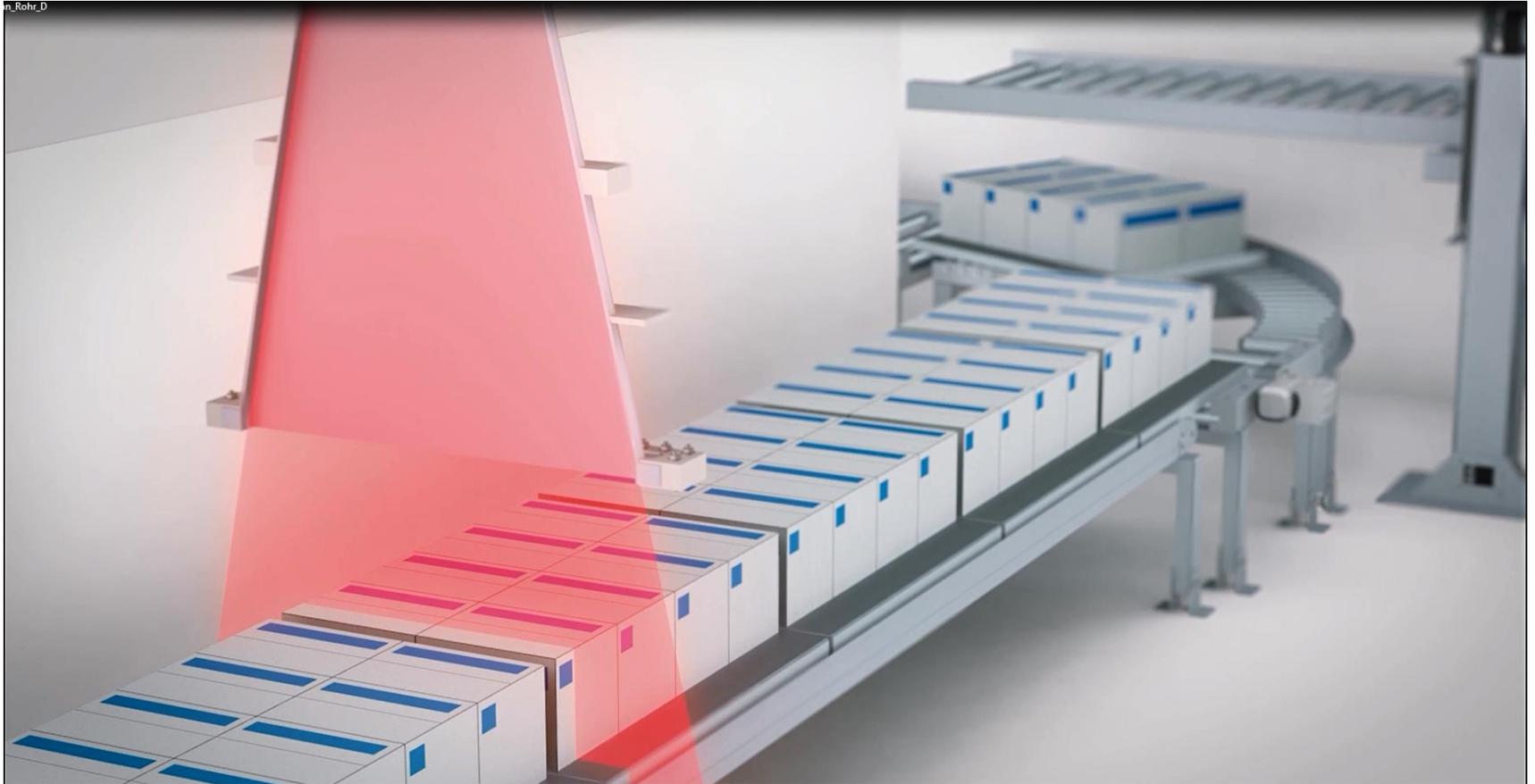
Source – Electron Beam



10 MeV Rhodotron 190 kW Power



Source – Electron Beam

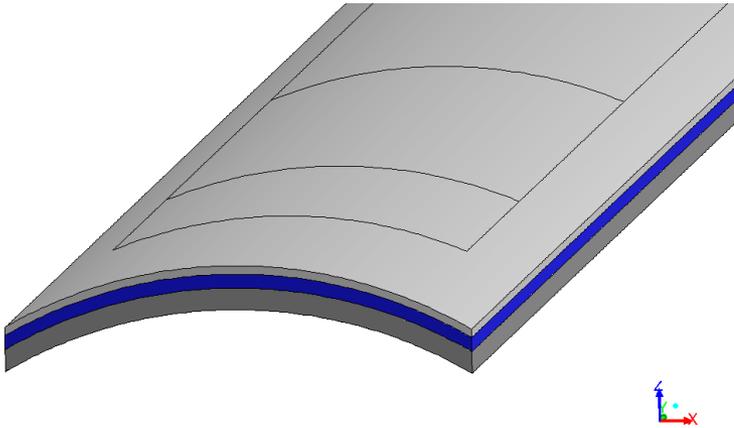


Irradiation in seconds – a truck in 2 hours

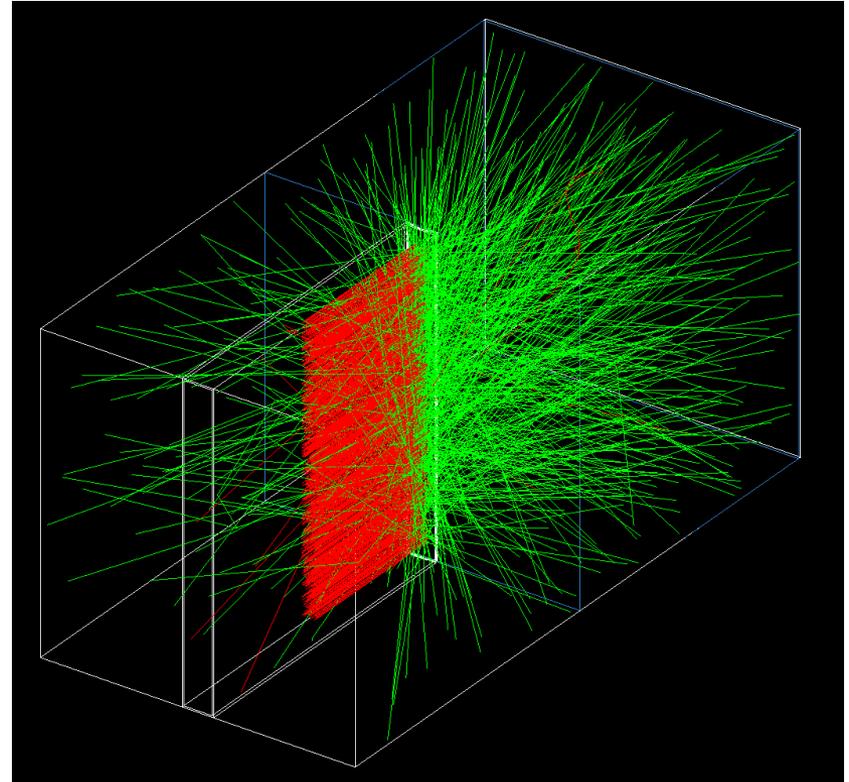


Source – X-Ray

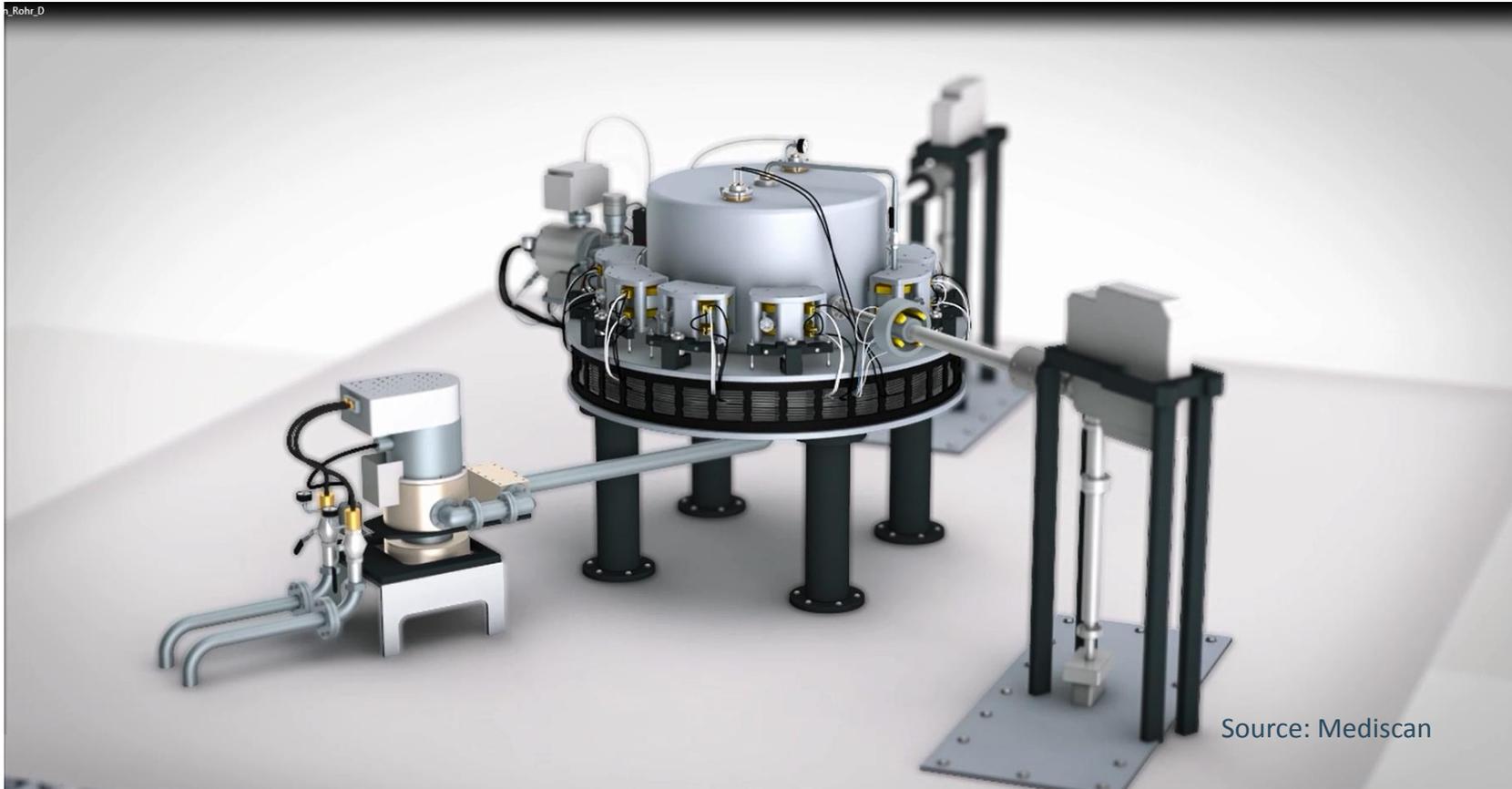
Smart & Innovative



7 MeV Electrons
on a Tantalum, Water, Steel Sandwich



Source – X-Ray



State-of-the-art Mediscan Facility in Austria
Excellent Penetration and Dose Uniformity



Radiation Sterilization Green & Efficient



Fast & Proven Sterilization Methods for Medical Devices

Green: No Residuals

Challenge: Narrow Dose Window for Combination Products



Thank you!

