Sterilization Technology Overview

Latest developments in Gas and Radiation based Sterilization Technologies

Brian McEvoy
Senior Director Global Technologies

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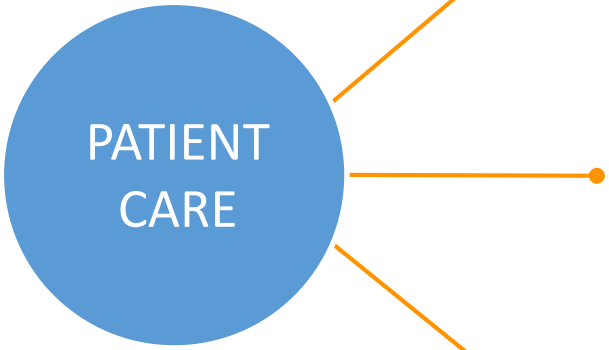
Agenda

- Customer Needs and Core Technologies
- Gas Sterilization
- Radiation Processing

STERIS: Focused on Patient Care



Healthcare Products

Serves patient care facilities.
Sterilizers and accessories
Washers
Lights and tables

Healthcare Services

Serves patient care facilities.
On/off-site decontamination services
Surgical instrument management (IMS)
Equipment service and parts

Applied Sterilization Technologies

Serves medical products manufacturers.
Global locations
Radiation processing, ethylene oxide, steam
Microbiological laboratories

Life Sciences

Serves research/pharmaceutical facilities.
GMP sterilizers
Washers
VHP
Chemical cleaners

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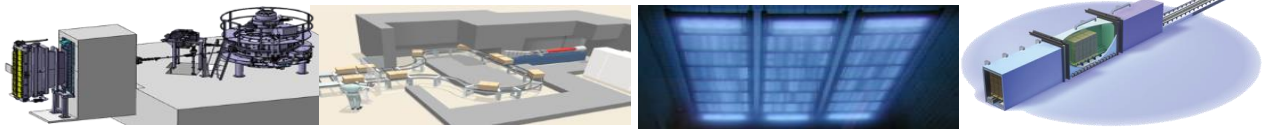
STERIS AST: Supporting Our Customers

- Understand the current and future needs of our Customer
- Focus on quality assurance and regulatory compliance
- Deliver efficient, economical and secure technologies
- Expand our network to offer optimized supply chain options
- Technology neutral
- Technology diverse
- Connect AST Customers to the total portfolio of patient care solutions from STERIS

www.steris-ast.com



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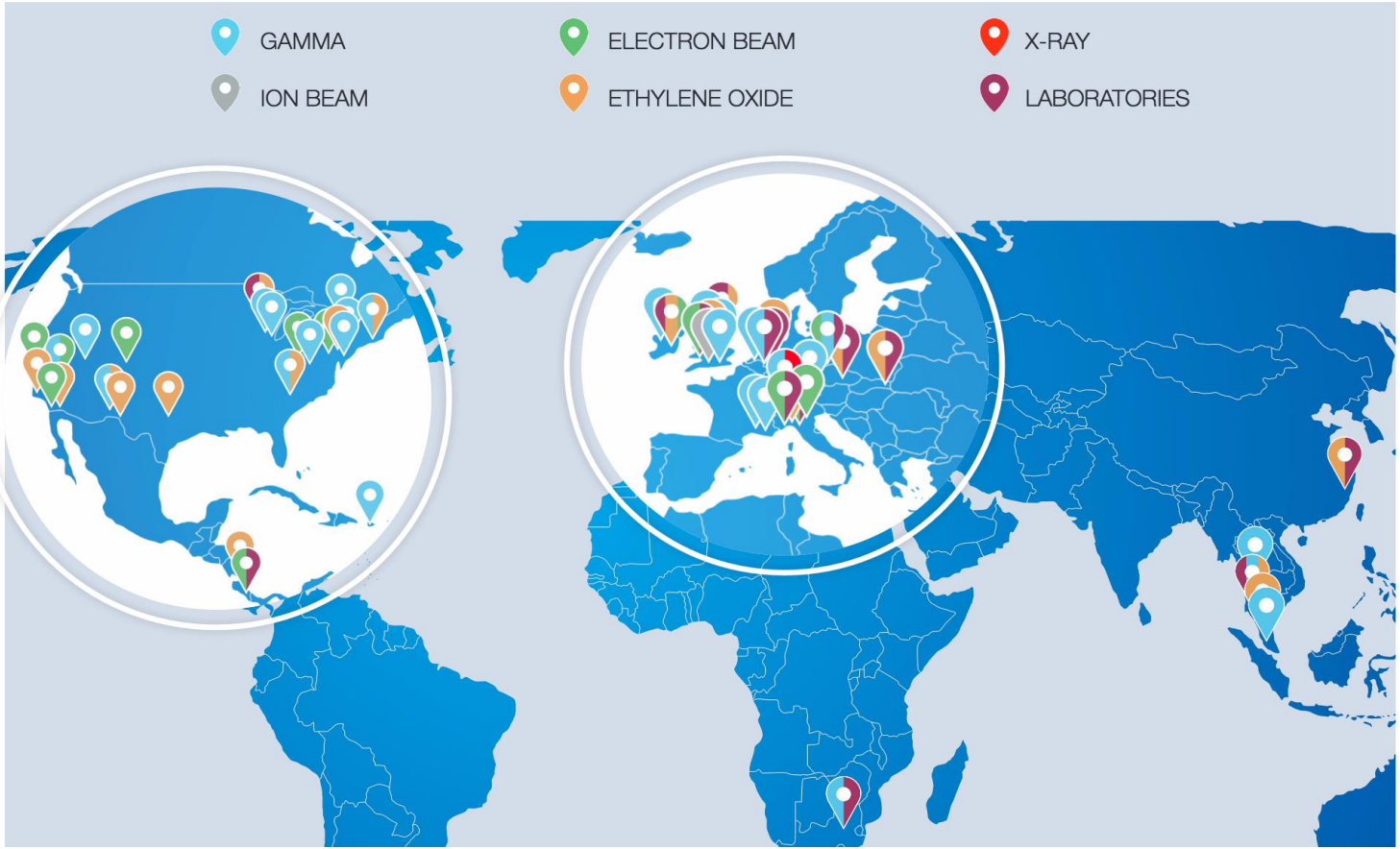
Over 50 Global Sterilization and Laboratory Facilities



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Voice of the Customer

- Safe products: EO degassing
- Sustainability: Technology options, business continuity planning, reduced risk
- Efficient processes: Lean
- Flexibility: Multiple processing capabilities
- Secure supply of sterilization processing
- Access to multi-modality and network
- Product Compatibility – Additive Manufacturing
- Supporting services: Laboratory, technical support, logistics

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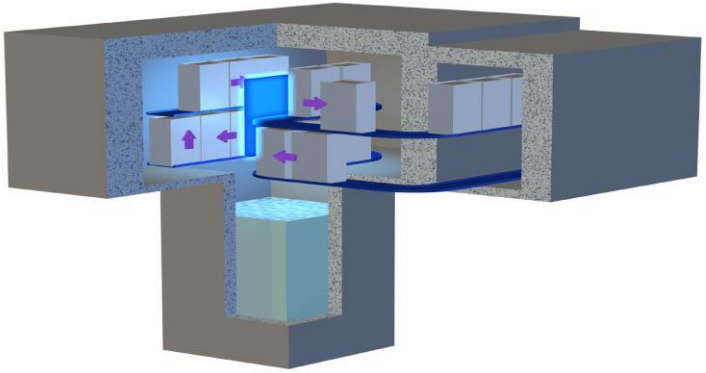
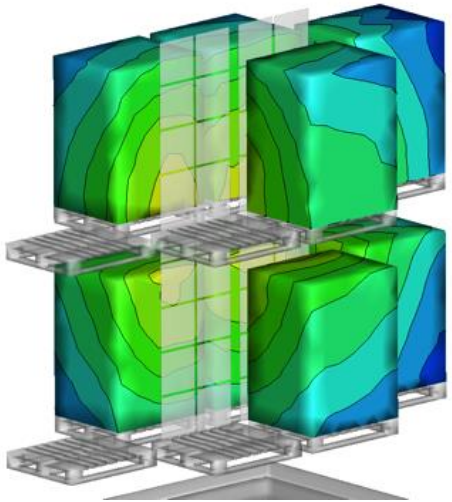
Gamma radiation

- Ionising radiation from Cobalt 60 source
- In excess of 200 large-scale commercial gamma irradiators in ca.50 countries,*
- 400 million curies (Ci) of Cobalt-60 to irradiate more than 400 million cubic feet of product*
- 50% is sterilization of medical devices*





*Source: iia

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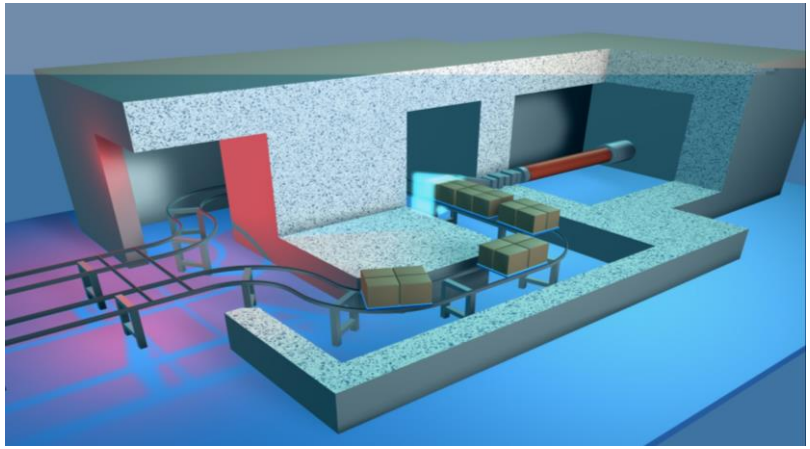
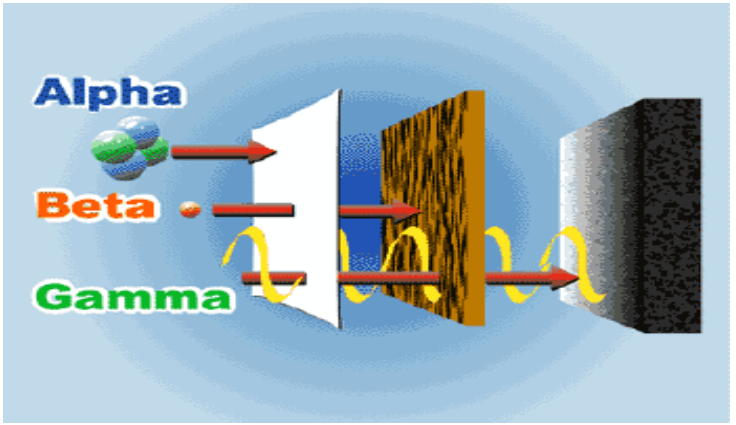
AST: Electron beam

- Irradiates products with high energy beam of electrons
- Sterilisation, polymer modification, special applications
- >1400 High Current Ebeams worldwide*
- Processing in excess of $85bn of product*





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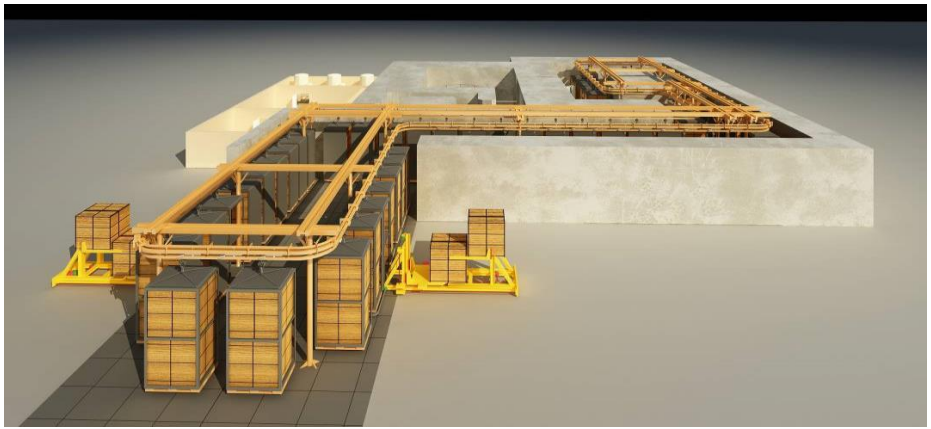
AST: X-ray processing

- High-energy X-rays are a form of ionizing energy, allowing irradiation of large packages and pallet loads of medical devices
- STERIS AST Daniken is the only exclusive medical device x-ray facility worldwide
- Faster more accurate process compared with gamma
- Avoids licencing, tranport and replenishment programs required for radioactive isotopes



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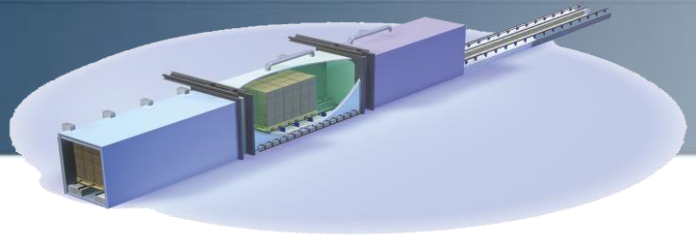
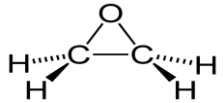
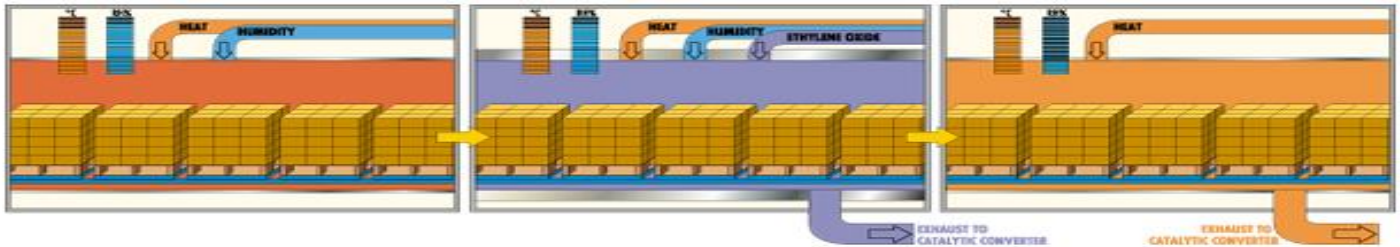
AST: Ethylene Oxide (EO)



- Chemical sterilization using EO gas
- Different sized vessels, processing from very small loads to full batches
- Wide ranging application due to good material compatibility
- Safety critical: EO is an explosive, highly flammable gas which is highly toxic, carcinogenic and mutagenic



Pre-conditioning → Sterilisation → De-gas



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Technology Comparison

	Ethylene Oxide	Gamma (Co-60)	E-beam	X-ray
Global MarketShare (%)*	50	40.5	4.5	5
Mode of action	Injection of toxic gas into sealed packages	Ionizing radiation in form of gamma rays	Ionizing radiation in form of a beam of electrons	Ionizing radiation in form of X-rays generated by electrons hitting a target
Process	Air in packages is replaced by EO gas, at a defined moisture, pressure and temperature. Gas is eliminated from package, kill is verified	Package is exposed to gamma rays for an established period of time to achieve a desired dose.	Package is exposed to an electron beam for an established period of time to achieve a desired dose.	Package is exposed to X-rays for an established period of time to achieve a desired dose.
Product requirements	Package and all parts of product to be sterilized must be permeable to air, irrespective of density	Materials are compatible with radiation, penetrate even at densities $<0.40 g/cm^3$	Materials are compatible with radiation, densities between $<0.25 g/cm^3$	Materials are compatible with radiation, even at densities $>0.50 g/cm^3$
Material Compatibility	Less compatible with moisture sensitive materials such as cellulose	Not compatible with some biological material, possible oxidation of some polymers	Not compatible with some biological material, less oxidation of some polymers	Not compatible with some biological material, less oxidation of some polymers

*Source: GIPA/iia Whitepaper A Comparison of Gamma,
E-beam, X-ray and Ethylene Oxide Technologies for the Industrial Sterilization of Medical Devices and Healthcare Products
AUGUST 31, 2017

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Gas Sterilization

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EO Sterilization: A Vital Gaseous Modality

- ✓ EO accounts for approximately 50% of the global demand for single-use device sterilization
- ✓ Good material compatibility
- ✓ Suitable for high volume processing
- ✓ Known, trusted, overkill approach per ISO11135
- ✓ Ease of acceptance in regulatory submissions

- X Carcinogenic, mutagenic, teratogenic, toxic, flammable gas
- X Elongated process times due to degassing requirements
- X Occupational safety and environmental concerns

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Regulatory Environment

Increased scrutiny and focus on a technology vital to sterilization of healthcare products

Region	Regulation	Description
Global	ISO 10993-7	Specifies allowable EO residual limits from sterilization and states that the manufacturer must ensure the level of exposure to these substances is as low as possible
France	ANSM requirements	Market surveillance of enteral feeding tubes in neonatology and pediatrics. Outcomes include taking into account the neonate birth weight and concomitant of other devices. Report issued with requirements regarding ISO10993-7 application.
European Union	Regulatory announcement	Directive to set exposure limits for carcinogens, including EO. Minimum requirements will be set for eliminating/reducing all carcinogens and mutagens. Employers will have to identify/assess risks to workers who associated with exposure to specific carcinogens, and must prevent exposure where risks exist.
United States	EPA Integrated Risk Information System	US States examining the proposed reduction of Ambient Benchmark Concentration for EO from 0.01µg/m3 to 0.0003µg/m3

WHAT: Optimizing the amount of EO sterilant used results in:

- Lower product residuals to meet current and future patient safety requirements
- Improved occupational safety
- Fewer fugitive emissions released into the environment
- Improved supply chain efficiencies due to reduced aeration (off-gassing) of ethylene oxide gas

HOW:

- Industry Awareness of need for change
- Validation Approaches: PCD; validation approach
- Cycle Design




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Awareness & PCD's

Future IPCD Process

Most Challenging Location → **Most Appropriate Location**

Not necessarily representative of product bioburden challenge

Creation of false challenge

- Occlusion
- Dead leg
- All BI population (10^6) in single location

Typically limits validation options to Half Cycle approach

Appropriateness of PCD based on comparative resistance to product bioburden

Test of Sterility of complete product establishes relationship with BI/PCD, including tortuous pathway and mated surfaces

See 8.6, D.8.6 of ISO11135:2014

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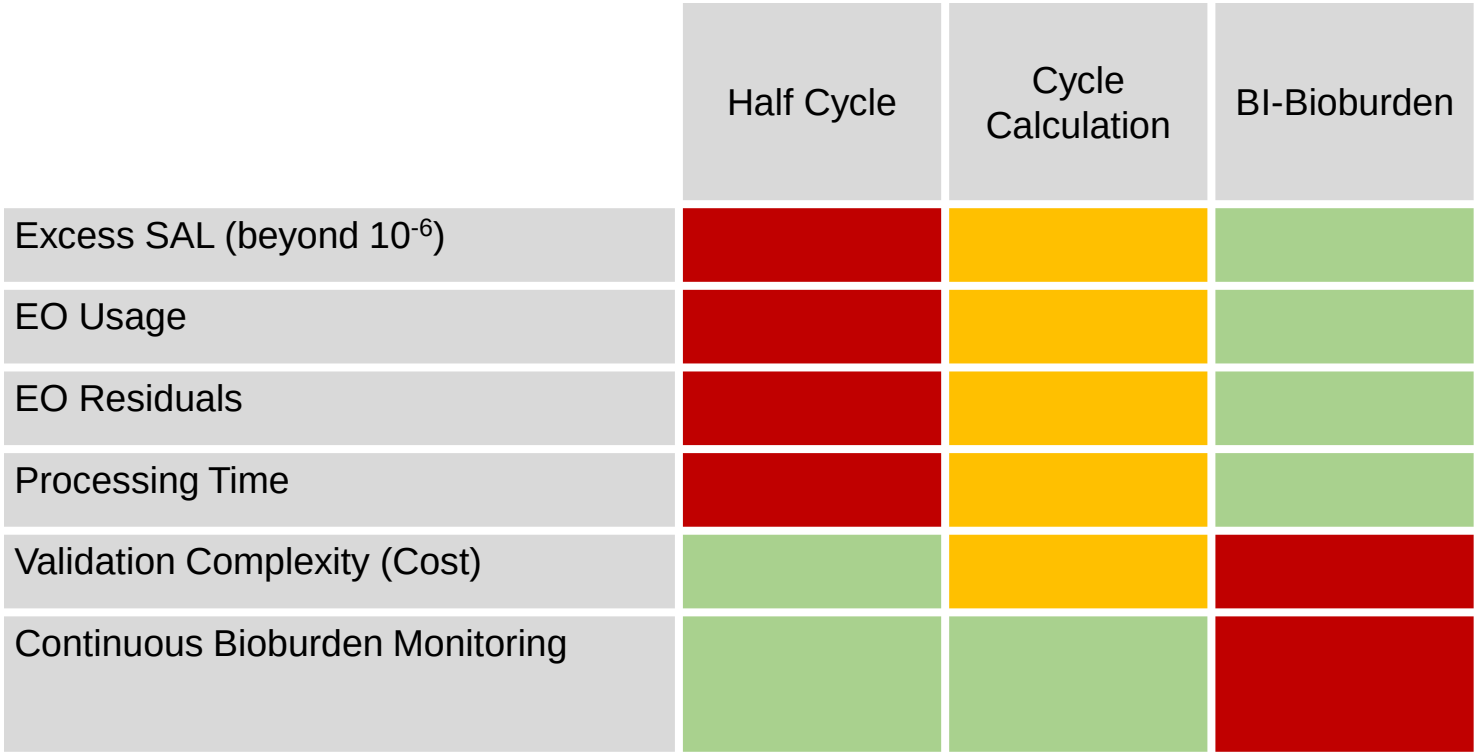
EO Validation Approaches: ISO11135



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Changing Culture

Moving from engineers to scientists

Sterilization Engineering

(1) Designing, Developing and Installing Sterilization Equipment

(2) Designing the Sterilization Process

(3) Developing and Maintaining Test Equipment, Including Standards; Calibrating Measuring Equipment in the Plant

(4) Establishing Equipment and Process Operating Parameters

(5) Validating the Equipment and the Process

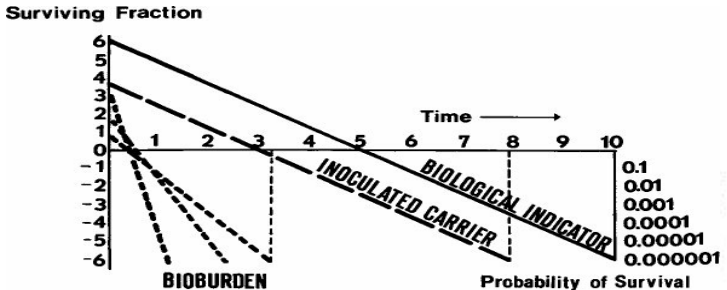
Sterilization Science

(1) Carrying out Research Directed Toward Developing an Understanding of Microbial Death Kinetics

(2) Developing Microbial Destruction Data for Specific Microorganisms in Specific Products and Sterilization Systems.

(3) Determining the Microbial Bioburden on Products to be Sterilized

Pflug, J. I. (1986). Wet-Heat Sterilization, Including Both the Design of the Process and Equipment Used to Sterilize Product. Sterilization of Medical Products. (Kilmer Conference proceedings) Vol IV.



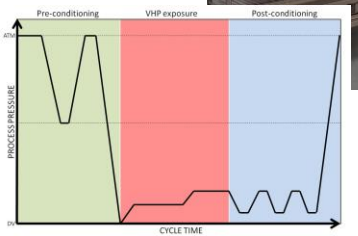
Gas Technologies – adding to the AST portfolio

Mixed Gas Pressure process

- EO:CO2 mixture process acquired with Bioster S.p.A.
- Efficient use of EO
- New Hybrid process being developed and installed in Europe
- Ongoing R&D studies to compare pure and mixed gas process

Low Temperature sterilization using vaporised Hydrogen Peroxide

- Equipment sold by STERIS Lifesciences Applied to pharmaceutical manufacturing applications related to aseptic packaging
- Efficient Cycle design
  - Deep vacuum: 1…10 mbar level
  - Processing temperature range: +28…40 °C
  - Cycle times: 2…4 hours (depending on product)
  - Typical residue targets: <1 ppm



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Radiation Processing

Gamma v Accelerator Technologies

Gamma	Accelerator	
	Ebeam	**Xray**
Cobalt	Electricity	Electricity
NNSA Concerns	Market Penetration	Market Penetration
Extensive Global Availability	Growing	Single Site
Wide Product Range	Penetration Limitation	Wide Range

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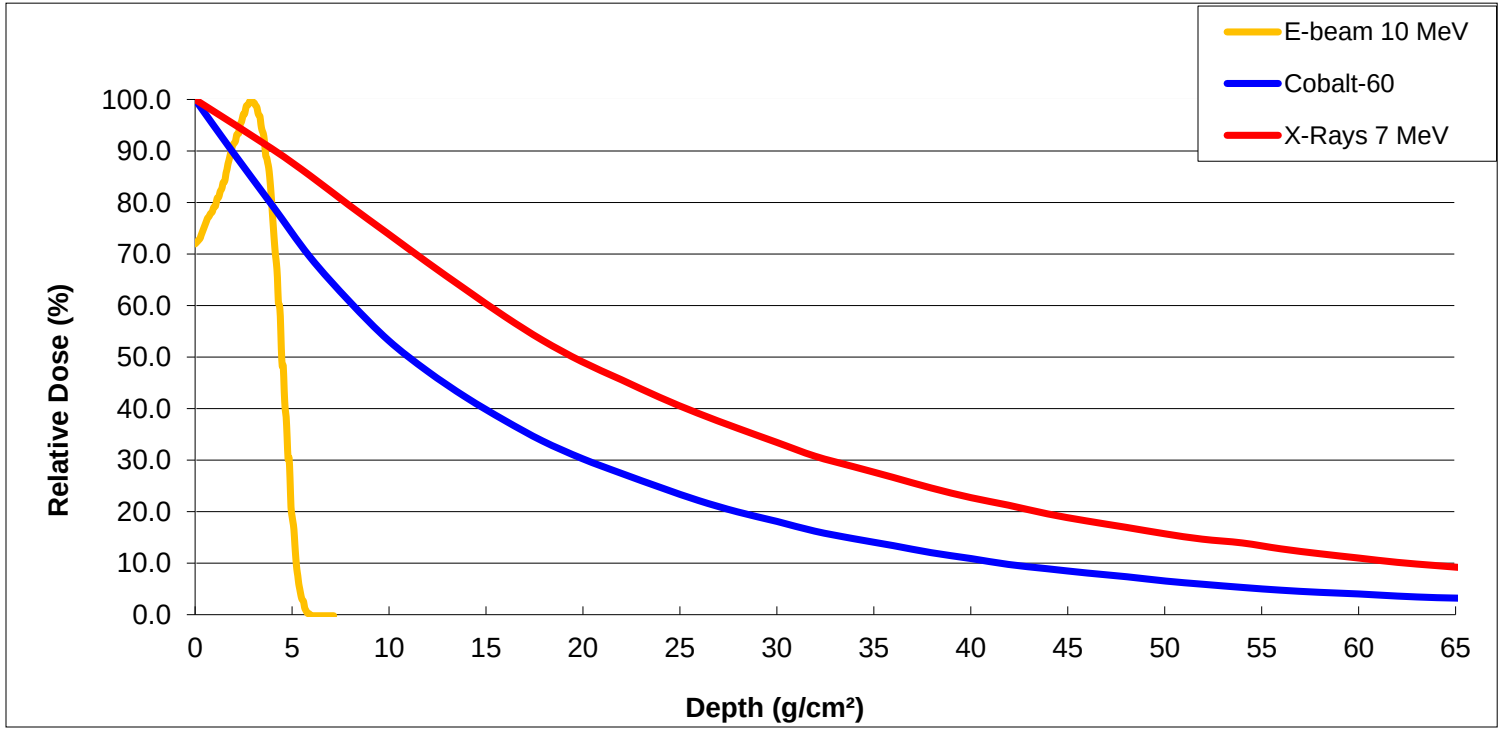
Accelerator Technologies

Product Penetration Comparison



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Dosimetry

- Need for more precision
- Traceability through the measurement chain

- Development of alanine Tapetab technology

- Further development on ESR technology

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VDMax

kGy

Max CFU

TS 13004 → ISO11137

TS 13004 has been added as ref doc and will completely replace the VDmax25 and VDmax15 method in next revision

potentially allow to reduce the min dose and give more flexibility to the process = sustainability.

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Industry Conferences 2019

https://imrp-iia.com

INTERNATIONAL IRRADIATION ASSOCIATION

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Thank you

Brian McEvoy
brian_j_mcevoy@steris.com

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