JABIL | HEALTHCARE

Medical Device Sterilization

Jabil's In-house Capabilities

Jabil — the largest provider of manufacturing solutions to the healthcare market — is expanding sterilization services for our customers.

At select manufacturing sites, we're offering options for gamma, x-ray, and EO sterilization. No matter your requirements, Jabil has the solutions you need.

GAMMA IRRADIATION

Albuquerque, New Mexico

World-class operation, with 2 large gamma "tote-over-pass" irradiators

EO STERILIZATION

Dominican Republic

High volume capacity, co-located for seamless packaging and sterilization

X-RAY STERILIZATION

Byhalia, Mississippi

Central US location with efficient logistics via proximity to the Port of Memphis

As a single source for managing your sterilization needs, Jabil will support your production volumes with an unmatched combination of global scale, proven quality track record, and vertically integrated capabilities, including complete sterilization cycle documentation, overall logistics, and finished pack and procurement.

Sterilization Market — At A Glance

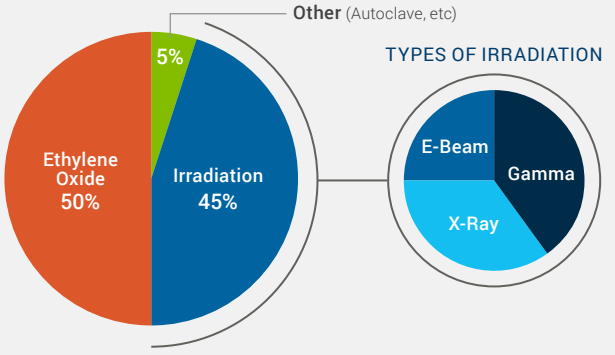
The rise in chronic disease worldwide, aging demographics, and increased vigilance in prevention of healthcare-associated infections (HAIs) are all driving accelerated growth for dependable, cost-effective options in sterilization services.

Medical device manufacturers rely on two main terminal sterilization modalities:

- Chemical — via exposure to ethylene oxide (EO) gas
- Irradiation — via exposure to radiation (gamma, x-ray, or e-beam)

EO is the dominant sterilization technique due to its broad compatibility across a diverse range of materials. In use by the healthcare industry since the mid-20th century, EO capacity has in recent years come under pressure due to environmental and safety concerns relating to fugitive emissions. Demand is shifting towards irradiation-based methods, when appropriate, from EO sterilization — and more specifically, towards x-ray from gamma.

STERILIZATION MODALITIES



Source:
Approximate values per the International Irradiation Association (iia) and the FDA

Sterilization Modalities in the Spotlight

EO PROCESS

Sterility Assurance Level (SAL) is achieved via controlled exposure to ethylene oxide gas

Jabil ensures full compliance to all applicable standards and regulations for the protection of employees, the community, and environment

WHY CHOOSE EO?

- Particularly well-suited for products with embedded electronics
- Commonly used for plastics and rubber containing devices, and instruments
- Terminal sterilization of sealed combination device/drug devices (filled syringes, drug coated stents, etc.)
- Best choice for products that cannot withstand high temperature processes or are degraded by irradiating processes
- Products can be sterilized in their final packaging

CHALLENGES

- Ensuring gas penetration and elution
- Reliance upon Tyvek® stocks (and supply chain) for breathable packaging
- Aeration of residual gas can require up to 48 hours
- Strict regulatory standards and facility safety protocols

IRRADIATION PROCESS

Sterility Assurance Level achieved via controlled exposure to radiation sources

WHY CHOOSE IRRADIATION?

- Compatible with most materials; limitations re: polymer compatibility addressable via dosimeter management
- Prompt product release, per rapid alanine dosimetry measurement processes
- No toxic residues or byproducts on the product
- Fully automatable processes, minimizes human error
- Reliable and dependable performance regardless of density
- Simpler regulatory landscape than EO

CHALLENGES

- Aesthetic impacts: yellowing and embrittlement for some polymers based on radiation exposure
- Change over to irradiation modalities may require revalidation
- Potential supply chain constraints related to Cobalt 60 sourcing* for gamma only — no impact on x-ray and e-beam

In 2023, recognizing ongoing supply chain considerations for Cobalt 60 as well as EO-site capacity constraints, the FDA launched its **Radiation Pilot Program to facilitate more timely changes to alternative sterilization methods, processes, or sites among sterilization providers who use gamma radiation and/or are seeking to shift, where appropriate, away from EO.*

IRRADIATION MODALITY CONSIDERATIONS

	Gamma	X-Ray	E-Beam
Process Radiation Agent	Radioactive isotope Cobalt-60 emits gamma rays	Radioactive x-rays	Accelerator emits electron beams
Process Impact	Radiation causes DNA damage and cell death of all pathogens	Radiation causes DNA damage and cell death of all pathogens	Radiation causes DNA damage and cell death of all pathogens
Penetration & Processing Unit	• High penetration - full pallets or boxes • Fully automated process	High penetration - full pallets or boxes	• Challenged by complex product geometries • Boxes only / no pallets
Issues to Consider	• Inelastic supply per growing shortage of Cobalt-60 rods • Higher validation costs	• Excellent performance across all densities • Suited to high-volume production	• Smaller scale runs • No radioactive waste
Outlook	Growth – demand ramp per shift from EO	Growth – replacing gamma for DUR-sensitive products	Growth - efficient, sustainable technology

For more information on Jabil's medical device and healthcare product sterilization capabilities contact your Jabil representative.

Visit jabil.com/healthcare to learn more about Jabil solutions across healthcare sectors.