SYENSQO
ADVANCING HUMANITY

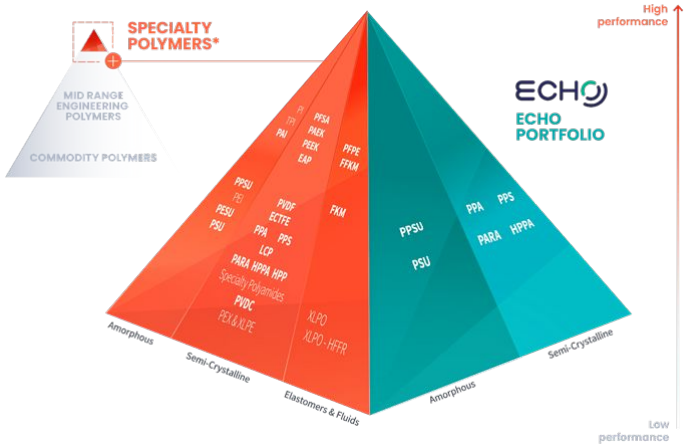
The Evolving World of Medical Device Sterilization

Syensqo

We are a science company whose technologies bring benefits to many aspects of daily life.

Our innovative solutions contribute to safer, cleaner, and more sustainable products found in homes, food and consumer goods, planes, cars, batteries, smart devices, healthcare applications, water and air purification systems.

Our Group seeks to create sustainable shared value for all, crafted around three pillars: protecting the climate, preserving resources and fostering better life.



€7.9bn
Net Sales

€1.9bn
Underlying EBITDA

23.6%
Underlying EBITDA Margin

13,200
Employees

12
Major R&I Centers

62
Industrial Sites

1. In-house Sterilizers
2. Application Development Laboratories
3. Moldflow and FEA analysis
4. Residual Stress testing of molded parts
5. Chemical Compatibility testing
6. Wide variety of molded samples available for customer testing
7. UV, Near IR and Far IR laser marking and cutting machines
8. In house high temperature 3D fuse filament and powder printers

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Medical Device Sterilization Market

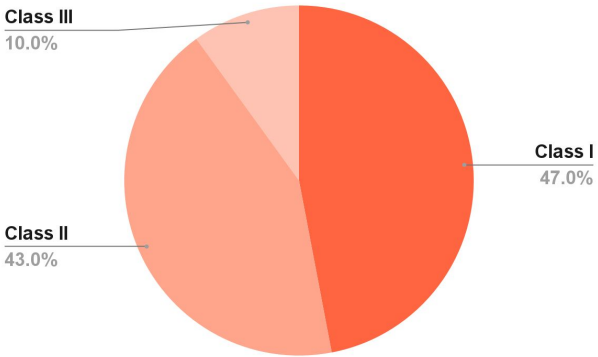
Estimated **~40 Billion** Medical Devices Sterilized annually

Global Market for Medical Device Sterilization Technologies (2023): **~$3 Billion**

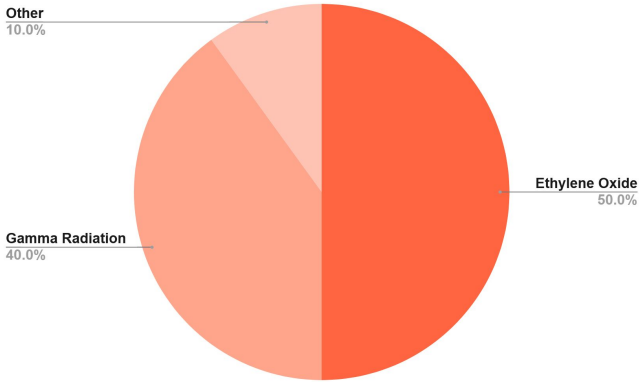
CAGR 2022-2027: **9.3%**

BCC Research
American Journal of Infection Control

Medical Device Classifications Market



Medical Device Sterilization Market



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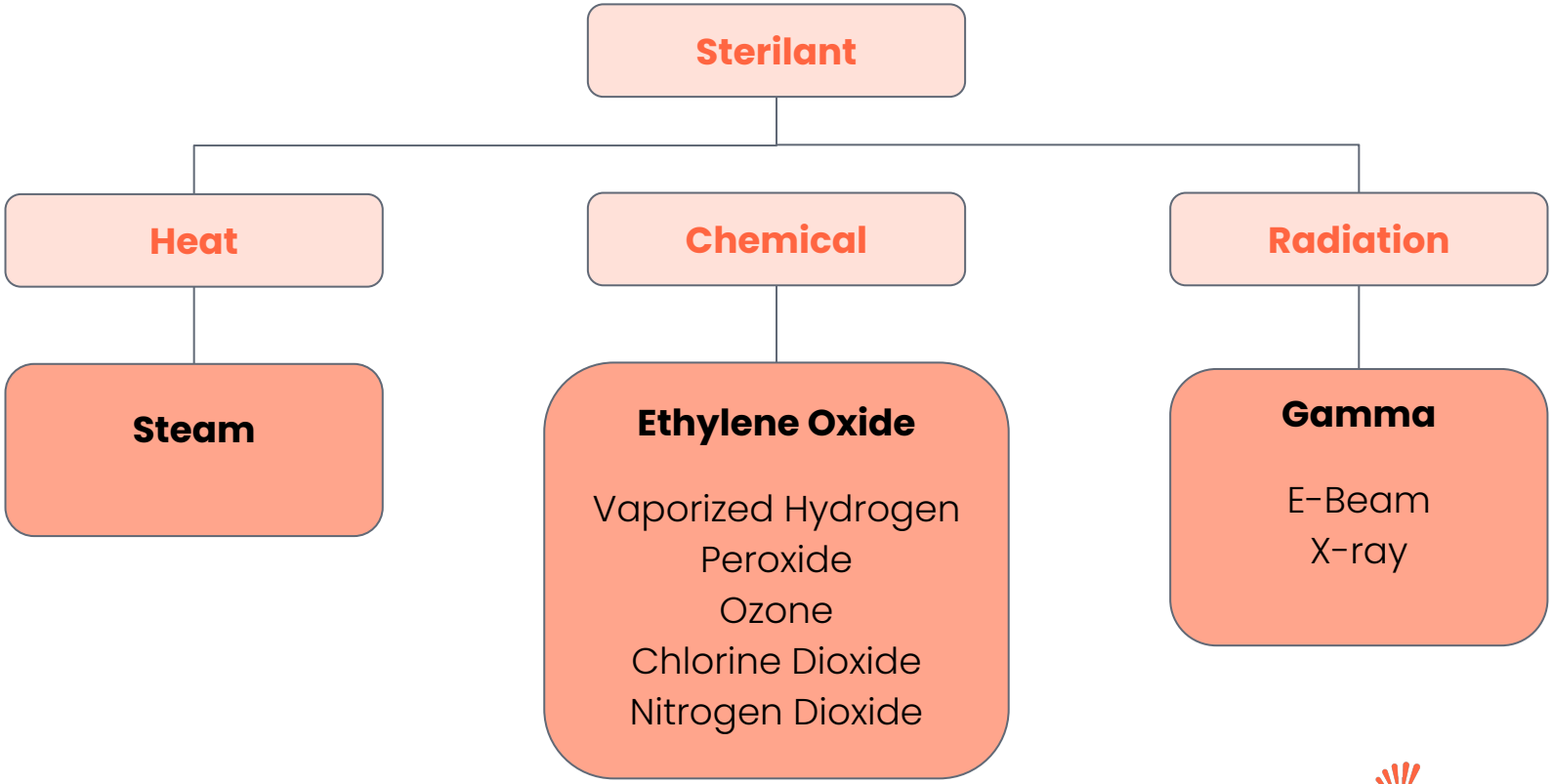
Sterilization Methods



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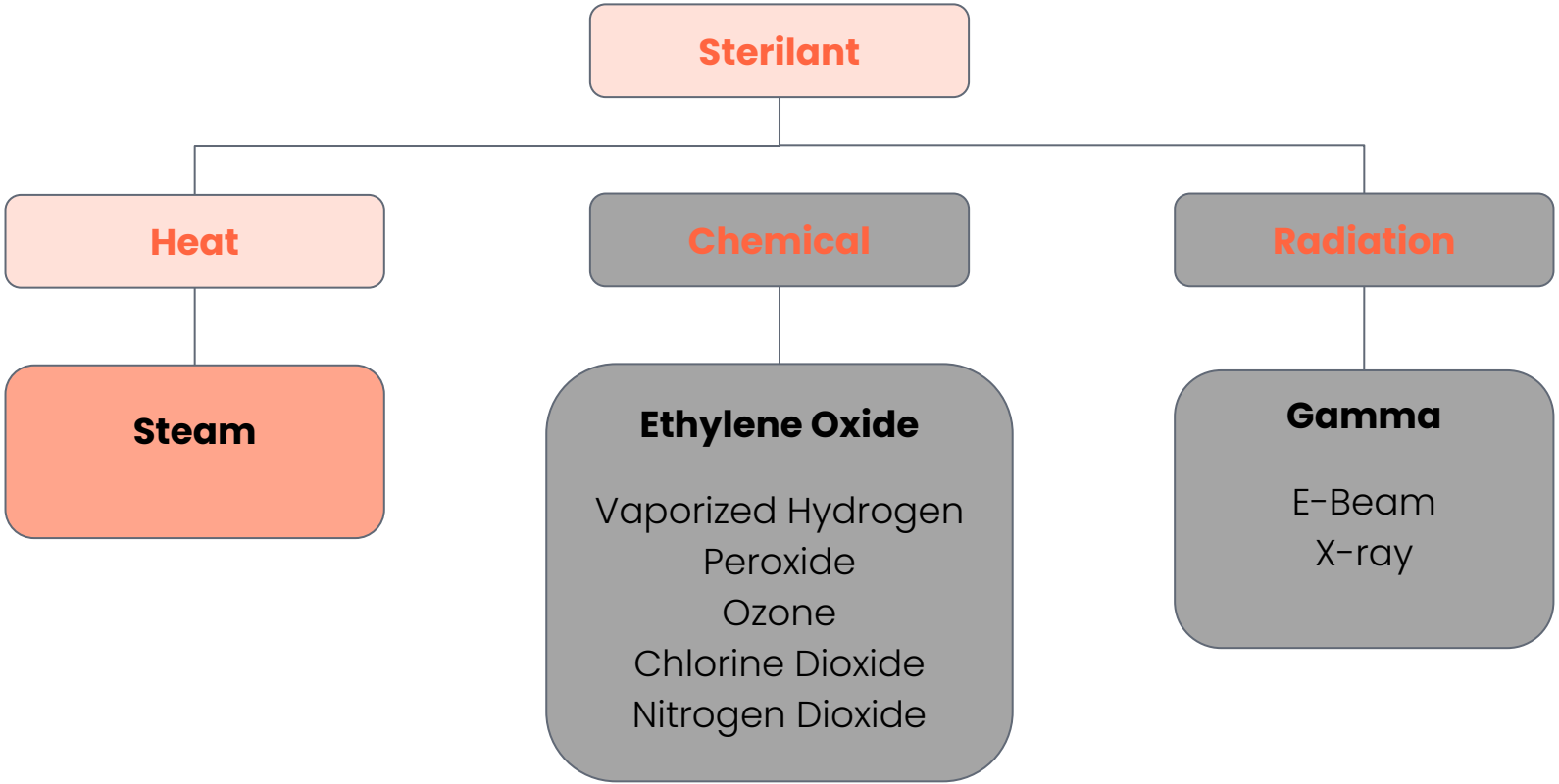
Sterilization Methods



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Steam Sterilization

Mode: Coagulation and denaturation of proteins due to **high heat and moisture**

Typical Sterilization Conditions:

- **Temperature:** 121 C - 134 C (250 F - 273 F)
- **Humidity:** 100%
- **Pressure:** 15-30 psi
- **Time:** 15-30 min

Benefits	Challenges
❖ Rapid turnaround ❖ No hazardous chemicals ❖ Cost effective	❖ Materials must be heat and moisture resistant ❖ Corrosion risk ❖ Energy intensive

Key Applications:

- Surgical instruments, implants, syringes, vials, flexible liquid containers

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Steam Sterilization Effects on Polymeric Materials

Potential Detrimental Effects:

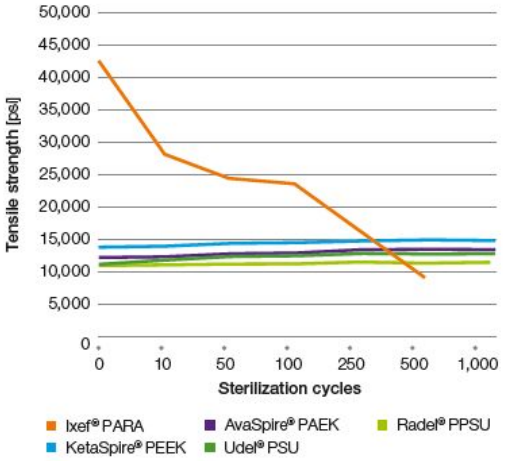
- Hydrolysis
- Moisture absorption
- Softening
- Oxidation

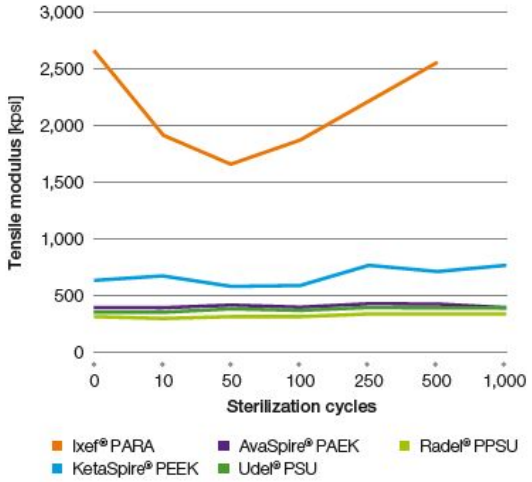
→ Decrease in mechanical properties
→ Loss of dimensional stability
→ Decrease in chemical resistance
→ Discoloration
→ Surface roughening
→ Loss of additives

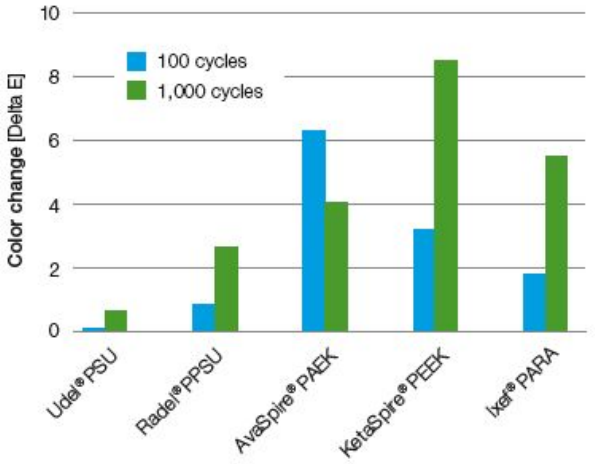
Test Conditions

- Equipment: Amsco® Century® Sterilizer SV-136H
- Cycle: Pre-vac
- Temperature: 135.5 °C (275.9 °F)
- Pressure: 31 to 33 psig
- Vacuum: 27 inHg
- Sterilization time: 18 minutes
- Drying time: 10 minutes
- Total time: 33 minutes

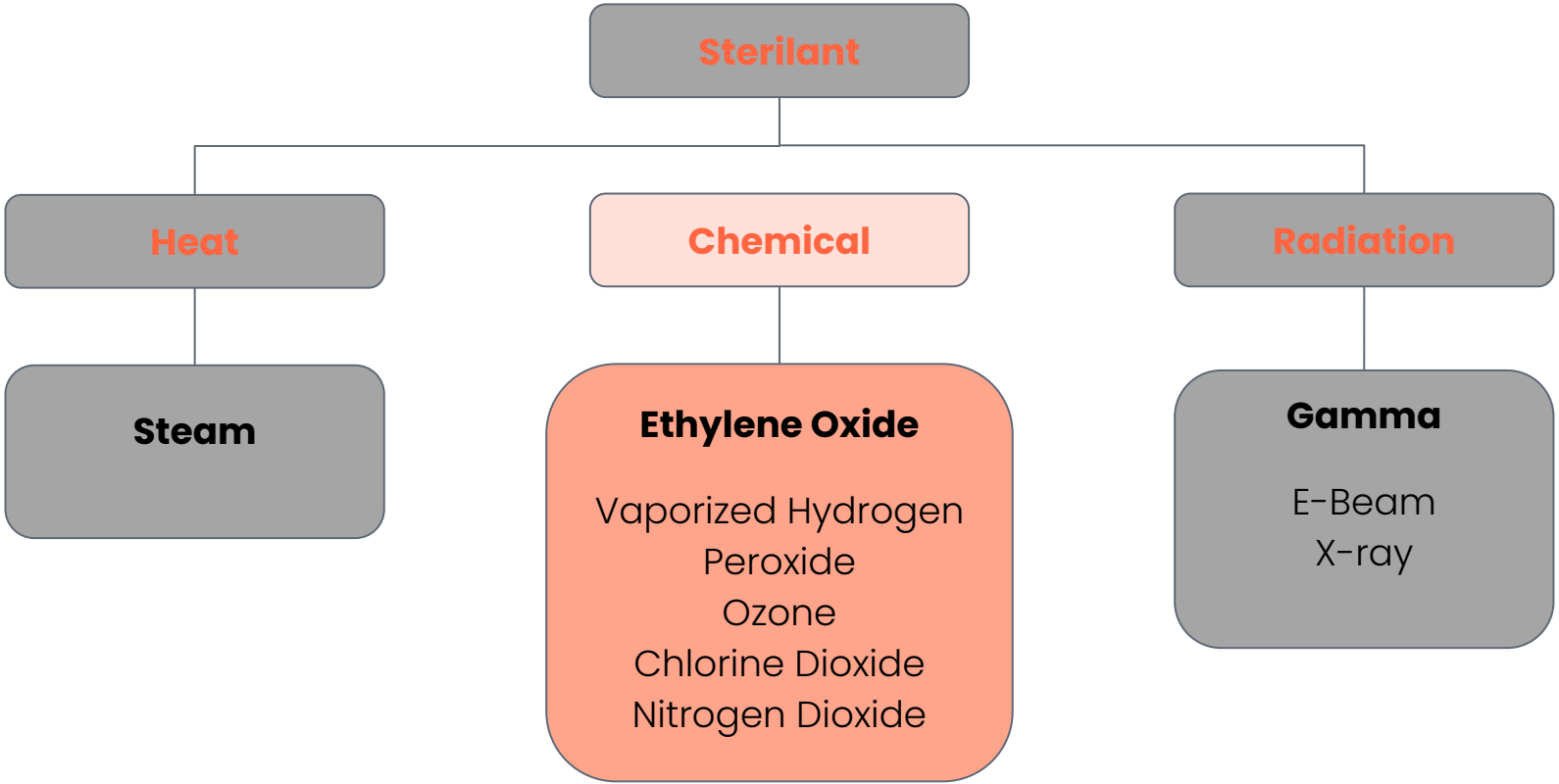
Steam Sterilization Results:







Sterilization Methods



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Ethylene Oxide Sterilization

Mode: Alkylation of proteins, DNA, and RNA, disrupting cellular metabolism and replication

Typical Sterilization Conditions:

- **Temperature:** 30 C - 60 C (86 F - 140 F)
- **EtO Concentration:** 450 - 1200 mg/L
- **Time:** 2-6 hrs, 8-12 hrs for aeration (removal of residual gas)

Benefits	Challenges
❖ Effective for wide range of materials, including polymers and electronics ❖ High penetration of sterilant ❖ Scalability - suitable for both small and large batch loads ❖ Effective for breathable packaging	❖ Cannot be used on sealed air tight medical devices or densely packaged devices ❖ Long turnaround time ❖ Stringent regulations due to toxicity of EtO ❖ Transportation logistics

Key Applications:

- Heart valves, pacemakers, surgical kits, syringes, catheters, ventilators, bulk sterilization

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Chemical Sterilization Methods

	Ethylene Oxide	Vaporized Hydrogen Peroxide	Ozone	Chlorine Dioxide	Nitrogen Dioxide
Disinfection Ability	High Penetration - preferred for small lumens, enclosed spaces	Moderate Penetration - Limited for narrow lumens	Low Penetration - best for surface sterilization	Moderate Penetration	Moderate Penetration
Sterilization Speed	Slow	Fast	Fast	Fast	Fast
Infrastructure	Widely Available	Moderately Available	Limited	Limited	Limited
Cost	Low	Moderate	Moderate	Moderate	Moderate
Batch Size	Large	Small to Medium	Small to Medium	Small	Small
Regulatory Considerations	Higher Risk - toxic gas handling	Lower Risk	Higher Risk	Moderate Risk	Lower Risk

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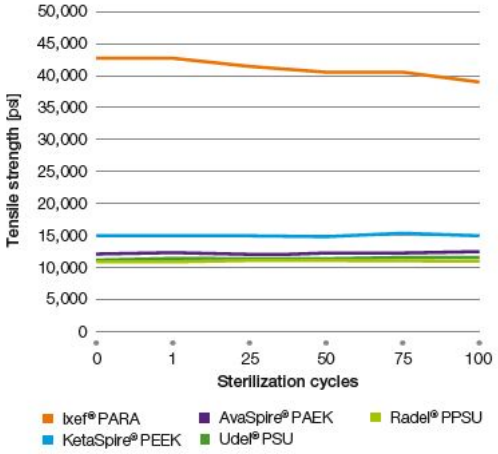
Chemical Sterilization Effects on Polymeric Materials

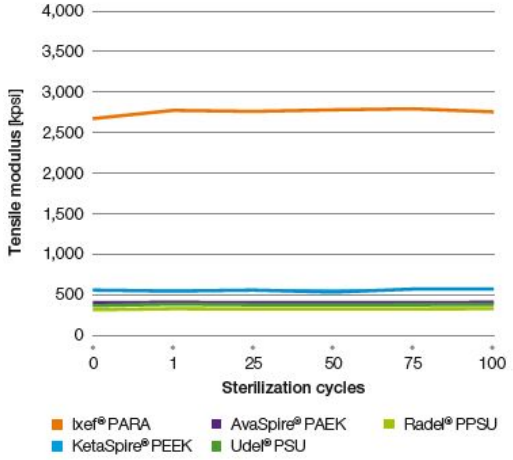
Potential Detrimental Effects:

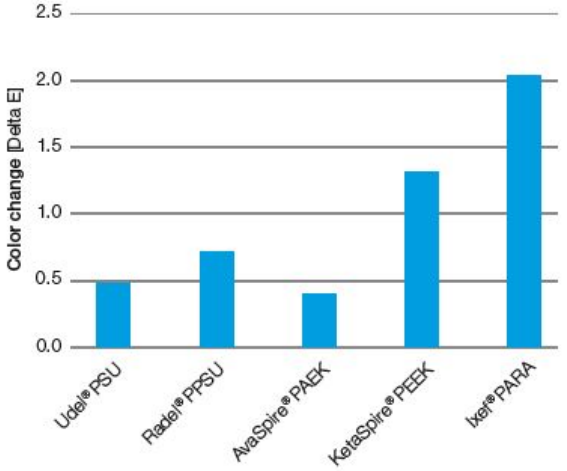
- Cross-linking (EtO)
- Oxidation
- Additive leaching

→ Embrittlement
→ Discoloration
→ Surface roughening
→ Loss of additives

EtO Sterilization Results:







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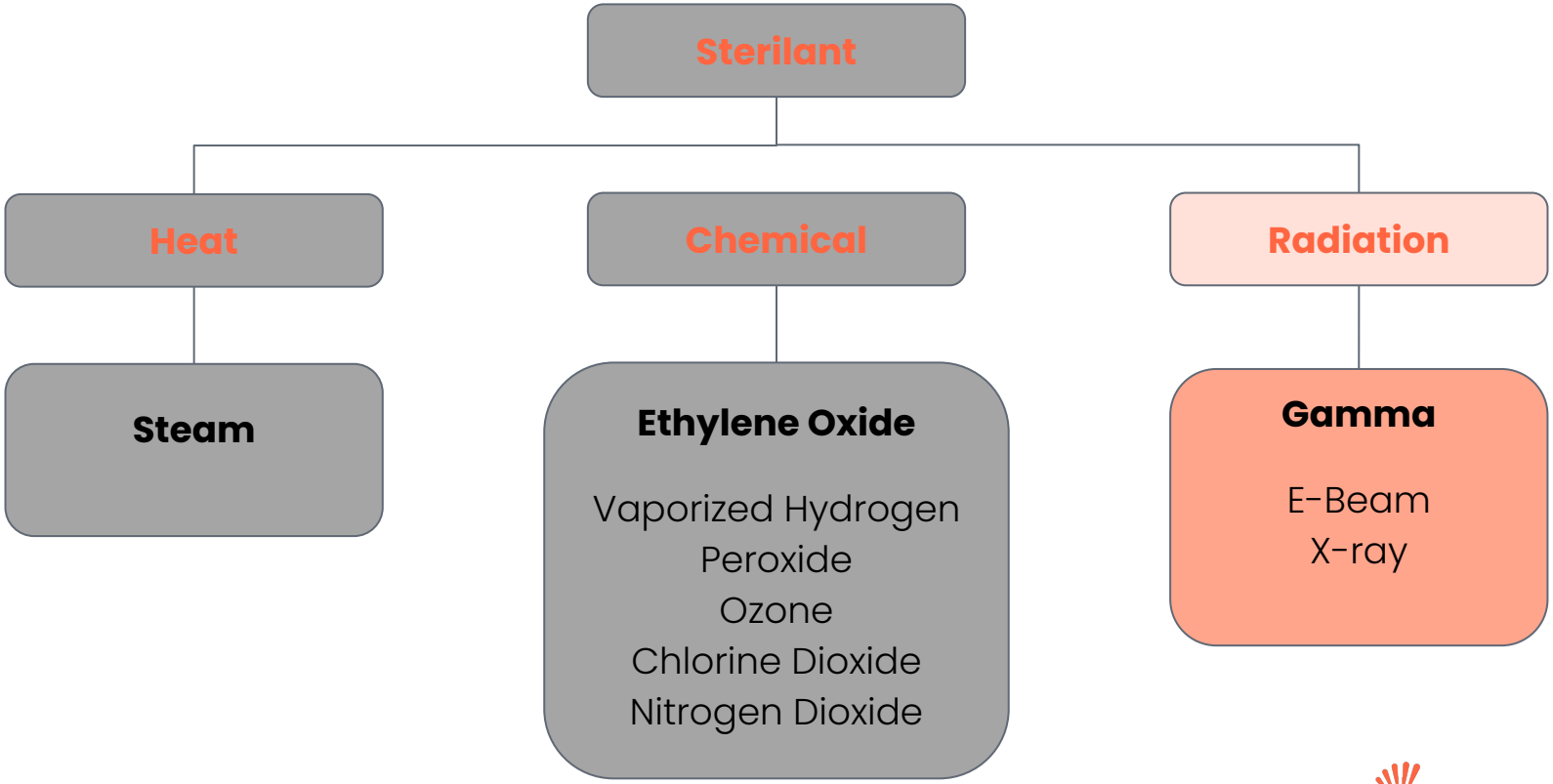
Sterilization Methods



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Gamma Sterilization

Mode: Ionization of cellular molecules, causing breaks in DNA and oxidative damage to cellular components

Typical Sterilization Conditions:

- **Dose:** 25-50 kGy
- **Time:** sec - hrs

Benefits	Challenges
• High penetration of sterilant • Effective on heat-sensitive and moisture-sensitive products • No need for post-sterilization aeration • Effective on sealed packaging	• High capital investment for facilities and reliance on specialized centers • Degradation in certain materials • Transportation logistics • Stringent regulations around radiation safety from Cobalt-60

Key Applications:

- Single-use devices, complex geometries, syringes, needles, scalpels, adhesive dressings

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Radiation Sterilization Methods

	Gamma	E-beam	X-ray
Disinfection Ability	High Penetration - best for dense, large, bulk packaged products	Moderate Penetration - best for thin, flat, small products	High Penetration - best for dense, large, bulk packaged products
Sterilization Speed	Slow	Fast	Moderate
Infrastructure	Widespread but limited	Widely Available	Moderate and Growing
Cost	High	Low	Moderate
Batch Size	Large	Small - Moderate	Moderate - Large
Regulatory Considerations	Higher Risk - radioactive material sourcing and handling	Lower Risk	Lower Risk

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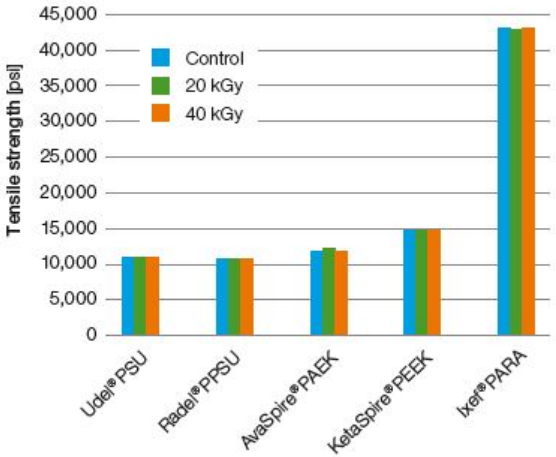
Radiation Sterilization Effects on Polymeric Materials

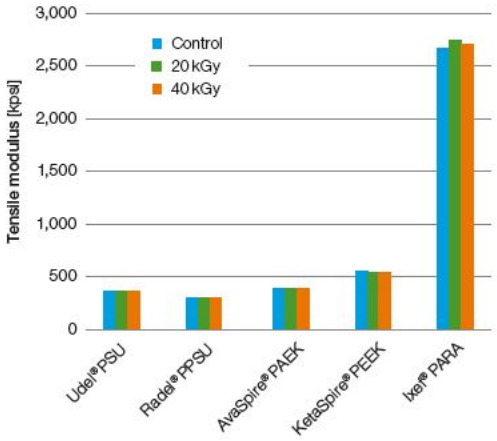
Potential Detrimental Effects:

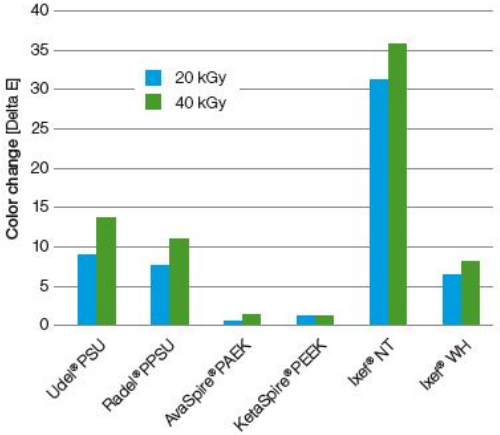
- Chain scission
- Cross-linking
- Oxidation

→ Loss in tensile strength
→ Embrittlement
→ Discoloration
→ Loss of dimensional stability
→ Surface roughening
→ Loss of additives

Gamma Sterilization Results:







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Conclusion: The Future of Medical Device Sterilization

- Growing Demand - With ~40 billion medical devices sterilized annually, the sterilization market is expanding to meet the demand

- Diverse Sterilization Methods - Driven by evolving regulations, environmental concerns, and the need for material compatibility, new sterilization technologies continue to emerge

- Material Considerations - Polymeric medical devices can be affected by sterilization processes, requiring careful material selection and testing to maintain performance and longevity

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Thank You

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