Table 17.7 Limitations of sterilization processes

Sterilization processes	Limitations
Heat sterilization	
Steam	Heat; damage to preparation Vapour; damage to the container (wetting of final product, risk of contamination post sterilization) Pressure: air ballasting: damage to the container
Dry heat	Heat: damage to preparation Potentially longer exposure time needed
Gaseous sterilization	
Ethylene oxide	High toxicity: risk to the operator Decontamination required post process Explosive: risk to the operator Slow process[a] Many factors to control
Formaldehyde	High toxicity: risk to the operator Damage to some materials (e.g. cellulose-made materials) Decontamination required post process Slow process[a] Many factors to control
Radiation sterilization	
γ-radiation	Risk to the operator Water radiolysis: damage to the product Discolouration of some glasses and plastics (including PVC), destructive process may continue after sterilization finished Liberation of gases (e.g. hydrogen chloride from PVC) Hardness and brittleness properties of metals may change Butyl and chlorinated rubber are degraded Changes in potency can occur High costs
Particle radiation	β-radiation: risk to the operator Water radiolysis: damage to the product Poor penetration of electrons exacerbated by density of product Significant product heating may take place at high doses High costs
Chemosterilants	
Glutaraldehyde and ortho-phthaladehyde	Toxicity: risk to the operator Activity: reports of microbial resistance
Peracetic acid	Corrosiveness: damage to the product/device Activity: reports of microbial resistance
Filtration sterilization	
	Not efficient for small particles (viruses, prions) Requires strict aseptic techniques Integrity of membrane filter Growth of microbial contaminants in depth filter Shedding of materials from depth filter

[a]Relative to moist heat sterilization.