

Ethylene oxide sterilization				
	(●) = poor (●●) = fair (●●●) = good (●●●●) = excellent		(NL) = not likely (L) = likely (U) = unknown	
Material	Single use (1 or 2 cycles)	Comments	Resterilization (> 10 cycles)	Comments
Polystyrene (PS)	● to ●●●	Some embrittlement and loss of tensile strength for some formulations has been reported.	NL	Generally not recommended for large number of cycles.
Polysulfones	●●●●		L	
Polyurethane (PU)	● to ●●●	Performance depends on formulation, cure conditions, material thickness, and end-use stresses.	L	Performance depends on formulation, cure conditions, material thickness, and end-use stresses.
Polyvinylacetates (PVA)	●		NL	
Polyvinylchloride (PVC)	●●●●	Rigid PVC might have reduced impact resistance after exposure.	L	
PVC, plasticized	●●●●	Medical-grade plasticized tubing might contain significant residual levels until aerated.	L	
Styrene acrylonitrile (SAN)	● to ●●●	Generally acceptable for one cycle, but might embrittle and lose tensile properties after multiple cycles. Might exhibit surface cracking and stress cracking after multiple cycles.	NL	Might embrittle and lose tensile properties after multiple cycles. Might exhibit surface cracking and stress cracking after multiple cycles.
Polyglycolic Acid (PGA)	U			
Polyethylene terephthalate (PET)	U			
Ethylene vinyl acetate (EVA)	U			

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Thermosets				
Epoxy	●●● to ●●●●		L	
Phenolics	●●●		L	
Polyester, unsaturated	●●●●		L	
Polyimides	●●●●		L	
Polyurethanes				
Aliphatic	● to ●●●		L	
Aromatic	● to ●●●		L	
Adhesives				
Acrylic	●●	Some loss in tensile properties reported on multiple cycles with HCFC-124/EO blends. Some crazing could occur.	L	Some loss in tensile properties reported on multiple cycles with HCFC-124/EO blends. Some crazing could occur.
Epoxy	●●● to ●●●●		L	
Fluoroepoxy	U		U	
Silicone	●●●●		L	
Elastomers				
Butyl	●●●●	Butyl is even stable in liquid EO.	L	
Ethylene propylene diene monomer (EPDM)	●●●●	Generally compatible, but changing curing method from peroxide cure to sulfur cure might result in formation of small amounts of polyethylene oxide inside the matrix of the material.	L	

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Natural rubber	●●●		L	Can be limited number of cycles.
Nitrile	●●●●		L	
Polyacrylic	●●		NL	
Polychloroprene (Neoprene)	●●●		L	
Santoprene thermoplastic vulcanizates (TPV)	U			
Silicone	●●●●		L	
Styrenic block copolymers (e.g., styrene-butadiene-styrene, styrene-ethylene-butylene-styrene)	●●● to ●●●●		L	
Urethane	● to ●●●		L	
Metals				
Aluminum	●●●●		L	
Brass	●●●●		L	
Copper	●●●		L	
Gold	●●●●		L	
Magnesium	U		U	
Nickel	●●●●		L	
Nitinol	U			
Silver	●●●●		L	
Stainless steel	●●●●		L	
Titanium	●●●●		L	
Ceramics/glasses				
Aluminum oxides	●●●●		L	
Silica	●●●●		L	
Zirconium oxides	●●●●		L	
Other materials				
Bioabsorbables				
Polyglycolides	●		NL	
Polylactides	●		NL	

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Poly(lactic-co-glycolic acid) (PLGA) [Class 6 implantable]	U			
Cellulosics				
Cellulose ester	●●●●		L	
Cellulose acetate propionate	●●●●		L	
Cellulose acetate butyrate	●●●●		L	
Cellulose, paper, cardboard	●●●●		L	
Liquid crystal polymer (LCP)	U		U	
Lubricants				
Silicone oils and greases (polydimethylsiloxane [PDMS] fluid)	U			
Poly (p-xylylene) polymers (dry)	U			
Liquid or solid lubricants containing PTFE	U			

Annex C (informative)

Moist heat sterilization—Material compatibility fundamentals

Table C.1 lists various materials and their general compatibility with moist heat sterilization. The information in this table is not exhaustive, and device manufacturers should use it only as a general guideline for the selection of materials. Before a material is selected, the vendor or manufacturer should always be consulted for more information.

Table C.1—Material compatibility guidance for moist heat sterilization—Specific materials

Moist heat sterilization				
	(●) = poor (65°C–104°C) (●●) = fair (105°C–120°C) (●●●) = good (121°C–127°C) (●●●●) = excellent (132°C–138°C)		(NL) = not likely (L) = likely (U) = unknown	
Material	Single use (1 or 2 cycles)	Comments	Resterilization (> 10 cycles)	Comments
Thermoplastics				
Acrylonitrile butadiene styrene (ABS)	● to ●●	Typically not recommended, depending on grade and filler. Run heat-resistant grade in a low temperature process.	NL	Possibly compatible with very-low-temperature cycles.
Fluoropolymers				
Polytetrafluoroethylene (PTFE)	●●●	Compatible at temperatures up to 170°C or higher.	L	Degrades with long-term service.
Perfluoro alkoxy (PFA)	●●●●	Compatible at working temperatures up to 204°C or higher.	L	Compatible at continuous use temperatures up to 170°C.
Perchlorotrifluoroethylene (PCTFE)	●●●●	Compatible up to 150°C; in packaging, a moisture barrier.	L	Continuous use temperature <150°C.
Polyvinyl fluoride (PVF)	●●● to ●●●●	Compatible at heat deflection temperatures up to 125°C or 134°C.	NL	Limited use; requires low temperatures.
Polyvinylidene fluoride (PVDF)	●●●●	Compatible at temperatures up to 150°C depending on grade; some grades might only tolerate temperatures up to 125°C.	L	Multiple sterilization cycles at a maximum operating temperature of 130°C.
Ethylene tetrafluoroethylene (ETFE)	●●●●	Compatible at temperatures up to 150°C.	L	

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Material	Single use (1 or 2 cycles)	Comments	Resterilization (> 10 cycles)	Comments
Fluorinated ethylene propylene (FEP)	••••	Compatible at temperatures up to 170°C or 200°C.	L	Repeatable.
Polyacetals (e.g., polyoxymethylene)	•• to ••••	Compatible at temperatures up to 121°C or higher; might degas.	L	Can be used in up to 100 cycles at 121°C.
Polyacrylates (e.g., polymethylmethacrylate)	• to ••	Poor to fair compatibility; some high-resistant grades.	NL	
Polyamides (e.g., nylon)	•• to ••••	Poor to excellent, depending on grade, form, formula, and function or fit. Biaxially oriented and cast nylon are autoclavable/retortable.	NL	Possible under some conditions to resterilize.
Polycarbonate (PC)	•• to ••••	Typically compatible at temperatures up to 121°C, but some grades can be sterilized at 134°C. Some have heat deflection up to 145°C.	NL to L	Some only compatible with a few cycles; others compatible with up to 200 cycles.
Polyesters, saturated	• to •••	Possible to good, depending on type, grade, form, and function. Some polyethylene terephthalate (PET) is acceptable (if metalized). Oriented PET (OPET) is more autoclavable.	L	Polyethylene naphthalate (PEN) is compatible with moist heat. PEN is compatible with temperatures up to 120°C.
Polyethylene (PE), various densities	• to ••••	Low-density polyethylene (LDPE) is poorly compatible. High-density polyethylene (HDPE) is fair to good up to 127°C and good up to 135°C. HDPE softens.	NL	Reinforcement of HDPE is required to improve its temperature compatibility.
Polyimides (e.g., polyetherimide)	•• to ••••	Possible to excellent, depending on grade, form, and function.	L	Polyetherimide withstands up to 4,000 cycles (e.g., 1,000 to 2,500 at 5 min and 134°C).

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Material	Single use (1 or 2 cycles)	Comments	Resterilization (> 10 cycles)	Comments
Polyketones (e.g., polyetheretherketone)	●●●●	High temperature resistance.	L	Polyetheretherketone has great heat resistance. Good up to 2,000 hours of steam exposure. Typically, long service.
Polypropylene (PP)		Compatibility depends on grade, form, formula, and function or fit. Typically compatible at temperatures up to 125°C.	L	Heat-resistant grades are required.
Natural	●●	Unstabilized PP degrades. Some types can be affected by stress during sterilization.		Unstabilized PP becomes stiffer after sterilization.
Stabilized	●● to ●●●	Stabilized PP is more heat-resistant.	L	Resterilization is possible.
Polystyrene (PS)	● to ●●●●	Syndiotactic polystyrene (SPS) and styrene/polyphenyloxides (PPO) are good to excellent.	L	SPS is compatible with high temperature and up to 750 moist heat sterilization cycles.
Polysulfones	●●●●	Excellent	L	Compatible with up to 1,500 moist heat sterilization cycles.
Polyurethane (PU)	● to ●●	Poor in general, but some grades might be fair. Caution: aromatic PU resin might form toxic 4,4 - methylenedianiline (MDA).	NL	
Polyvinylacetates (PVA)	● to ●●	Compatibility depends on form, function, formulation, and copolymerization. For heat-stable PVA, hot-melt adhesives can be used.	U	
Polyvinylchloride (PVC)	● to ●●	Rigid PVC possible with some modifiers; heat stabilizers.	NL	

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Material	Single use (1 or 2 cycles)	Comments	Resterilization (> 10 cycles)	Comments
PVC, plasticized	● to ●●●	Plasticized PVC has fair compatibility, depending on form, formulation and function.	NL	
Styrene acrylonitrile (SAN)	● to ●●	Not recommended for moist heat sterilization. Poor to fair compatibility, depending on formulation and grade.	NL	
Polyglycolic acid (PGA)	U			
Polyethylene terephthalate (PET)	U			
Ethylene Vinyl Acetate (EVA)	U			
Thermosets				
Epoxy	●● to ●●●	There are numerous types of unreinforced and reinforced epoxies, and physical properties vary significantly. Heat distortion temperatures up to 243°C in some formulations.	L	
Phenolics	●● to ●●●	Moist heat sterilization can lead to phenolic degradation and extractables into fluids.	NL	
Polyester, unsaturated	● to ●●●	There are a variety of unsaturated polyesters (e.g., vinyl esters). Stability is better when cross-linked.	L	Isophthalic acid–based polyester and PE naphthalate are highly temperature-resistant, and compatibility is possibly excellent.
Polyimides	●●●●	Bis maleimides (BMI) and acetylene-terminated polyimide (ACTP) have use-service temperatures of 127°C–232 °C and 316°C.	L	

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Material	Single use (1 or 2 cycles)	Comments	Resterilization (> 10 cycles)	Comments
Polyurethanes	•• to •••	Typically possible, depending on grade, formulation, and function. There are heat-resistant cross-linked polyurethanes.	NL	
Aliphatic	• to ••	Radiation cross-linking increases its heat resistance.	NL	
Aromatic	• to ••	Thermoset PU resins do not form MDA in polyurethane (aromatic).	NL	
Adhesives				
Acrylic	• to ••	Some can tolerate moist heat sterilization, depending on grade formulation; compatibility is fair. There is an acrylic adhesive film in a tape that is heat-resistant up to 137°C.	NL	
Epoxy	• to ••••	Depending on grade and formulation, deflection temperature from 93°C–260°C.	L	Some can lose retention of initial strength after only 5 cycles.
Fluoroepoxy	••• to ••••	The compatibility of epoxy adhesives depends on cure and formulation.	L	Epoxy adhesives cured with high heat are more heat-resistant than those cured at room temperatures.
Silicone	•• to ••••	Typically good to excellent compatibility, depending on form, formulation, and function.	L	Some have good compatibility for only 6 to 8 cycles.
Elastomers				
Butyl	•• to ••••	Good compatibility, depending on type grade. Resistant to water and heat-resistant up to 120°C.	L	Halobutyl (halogenated polyisobutylene) can withstand multiple sterilization cycles.

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Material	Single use (1 or 2 cycles)	Comments	Resterilization (> 10 cycles)	Comments
Ethylene propylene diene monomer (EPDM)	●●● to ●●●●	Good compatibility up to 125°C in water and up to 134°C–150 °C in air.	NL	Requires temperatures near 105°C.
Natural rubber	● to ●●●	Possible to fair compatibility; there are moist heat sterilizable grades. Plastomers enhance thermal stability.	L	Hardens with use. Withstands repeated moist heat sterilization at 121°C for 20 min.
Nitrile	●● to ●●●	Good resistance to moisture and water; tolerates temperatures up to 120 °C.	L	Requires lower processing conditions, below 132°C.
Polyacrylic	● to ●●	Polyacrylate is a heat-resistant rubber. Water resistance can be improved with reduction in heat.	NL	Resistance to water is poor.
Polychloroprene (neoprene)	●● to ●●●	Fair resistance to moisture at temperatures up to 110°C; intermittent moisture resistance at temperatures up to 121°C.	L	Requires lower processing conditions, below 110°C.
Santoprene thermoplastic vulcanizates (TPV)	U			
Silicone	●● to ●●●●	Resistant to water, barrier to moisture vapor. Also good low temperature performance.	L	Silicone rubber might become soft and sticky (tacky) after multiple exposures.
Styrenic block copolymers (e.g., styrene-butadiene-styrene, styrene-ethylene-butylene-styrene)	● to ●●	Possible to fair compatibility depending on grade, type, form, and formulation.	NL	Possible at temperatures up to 99°C.
Urethane	● to ●●	Some grades are heat-resistant, depending on type, form, and formulation. Aliphatic versions are typically compatible, some up to 135°C. Aromatic versions can form MDA.	NL	

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Material	Single use (1 or 2 cycles)	Comments	Resterilization (> 10 cycles)	Comments
Metals				
Aluminum	••••	Aluminum foil; typically single use with inhibitors.	L	Corrosion might occur unless anodized.
Brass	••••	Used in steam traps.	L	
Copper	•••	No reaction when heated in steam, but surface blackens when heated strongly in air.	L	Copper and brass corrosion inhibitor includes triazole.
Gold	••••	No reaction when heated in air and no reaction when heated in steam.	L	
Magnesium	•••	Magnesium metal is moist heat sterilizable as titanium, but not as magnesium powder.	L	
Nickel	••••	Used in moist heat sterilizers.	L	
Nitinol	U			
Silver	••••	Virtually no reaction when heated in air and no reaction when heated in steam. Moist heat sterilization does not remove activity.	L	
Stainless steel	••••	Varies with grade and content of inhibitors.	L	Chrome: stainless steel pitting and dulling of cutting edges after sterilization cycles.
Titanium	••••	Resists corrosion.	L	Nickel-titanium alloy has improved compatibility. Titanium molybdenum is nickel-free and has good corrosion resistance.
Ceramics/glasses				
Aluminum oxide	••• to ••••	Withstands corrosion better than (anodized) aluminum.	L	