Packaging

For radiation sterilization, the single-use products are individually packed in their primary packing, which is critical for maintenance of their post-irradiation sterility especially during handling, transportation and storage. Immense amount of flexibility is offered here by gamma radiation since the products can be sterilized in the fully packed form. Also materials like bags, drums and tote boxes are used as packing material.

Behavior of Packaging Material (Packaging Integrity)

Radiation may also influence the properties of materials used for packaging. Initial dosimetric analysis is essential to determine the extent to which the material is affected. The following table shows the maximum tolerable doses for primary packaging material, as notified by the International Atomic Energy Agency. Guidelines for industrial radiation sterilization of disposable medical products. Co-60 gamma irradiation. TEC DOC-539, Vienna IAEA, 1990

This table is intended only as a guide and may not serve as a substitute for practical radiation tests on products.

Radiation Tolerance Levels of Polymers Used for Medical Application

Material	Tolerance Level (kGy)	Comments
Elastomers		
Butyl	50	Sheds particulate after irradiation.
Ethylene-Propylene Diene Monomer (EPDM)	100-200	Crosslinks, yellows slightly.
Fluoro Elastomer	50	Avoid multiple sterilization.
Natural Rubber (Isoprene)	100	Very stable with sulfur or resin cure systems. Avoid stressing product by not bending, folding or wrinkling in packaging.
Nitrile	200	Avoid multiple sterilization.
Polyacrylic	50-200	Avoid multiple sterilization.
Polychloroprene (Neoprene)	200	Avoid multiple sterilization.
Silicones (Peroxide & Platinum Catalyst System)	50-100	Crosslink density increases more in peroxide systems than in platinum systems. Silicones retain a slight memory of coiling shape in packaging.
Styrene-Butadiene	100	Avoid multiple sterilization.
Urethanes	100-200	Wide variations in urethane chemistry applied to medical devices. Requires testing of part process and geometry to validate.
Thermosets		All thermosets as a class are highly resistant.
Allyl Digylcol Carbonate (Polyester)	5,000-10,000	Retains clarity.
Epoxies	1,000	Many good formulations available. Test the formulation selected for use. Frequently substituted for toxic solvents in assembly. Success depends on joint design and application process.
Phenolics	50,000	
Polyesters	10-1,000	Use of glass and other fillers improves physicals.
Polyurethanes	100-1,000	Wide formulation variations for urethanes. Dose tolerance depends on monomers used in formulation. Minimum 100-1,000 kGy are tolerated for thermosets.
Thermoplastics		
Acrylonitrile/Butadiene/ Styrene (ABS)	1,000	Protected by Benzene ring structure. Butadiene impact modifier degrades above 100 kGy. Avoid high dose on high impact grades.
Aromatic Polyesters (PET, PETG)	1,000	Very stable, retains excellent clarity. Drying is essential. Good in luer connectors.
Cellulosics		
Esters and Ethers	50	Thin films and fibers embrittle above 50 kGy.
Paper, Card, Corrugated Fibers	100-200	Papers discolour and embrittle, but are acceptable for single use.
Cellulose, Acetate, Propionate, and Butyrate	50	Plasticized versions slowly embrittle above 50 kGy.
Fluoropolymers		
Tetrafluoroethylene (PTFE)	5	Liberates fluorine gas, disintegrates to powder. Avoid use.
Polychlorotrifluoroethylene (PCTFE)	200	
Polyvinyl Fluoride	1,000	
Polyvinylidene Fluoride (PVDF)	1,000	

Radiation Tolerance Levels of Polymers Used for Medical Application

Material	Tolerance Level (kGy)	Comments
Thermoplastics		
Ethylene-Tetrafluoroethylene (ETFE)	1,000	
Fluorinated Ethylene Propylene (FEP)	50	
High Performance Engineering Resins	1,000-10,000	Substitutes for metal, these resins have high strength and good elongation that tolerate radiation well. Resins include nylon, polycarbonate, ABS, polysulfone, polyester, polyether ketone, liquid crystal polymer, polyetherimide, polyimide, and others.
Polyacetals (Delrin, Celcon)	15	Avoid use due to embrittlement.
Polyacrylics		
Polymethylmethacrylate	100	Yellows at 20-40 kGy; clarity recovers partially on aging.
Polyacrylonitrile	100	Yellows at 20-40 kGy.
Polyacrylate	100	Yellows at 20-40 kGy.
Polycyanoacrylate	200	Many good formulations. Adhesives function at 100 kGy with less than 30% degradation.
Polyamides (Nylons)		
Aliphatic & Amorphous Grades	50	Discolours, no re-sterilization. Avoid thin films and fibers. Nylons 11 and 12 perform better. Dry before molding.
Aromatic Polyamide-imide	10,000	High heat/strength grade. Stabilized by Benzene ring structure.
Polycarbonate	1,000	Discolours, clarity recovers on aging. Dry before molding.
Polyethylene (LDPE, LLDPE, HDPE, UHMWPE)	1,000	Crosslinks to gain strength, loses some elongation. All polyethylenes tolerate radiation well. Low density is most resistant. HDPE packaging film including spin-bonded porous packaging may lose 40-50% elongation at doses of 50kGy. Implants of UHMWPE have reports of early wear at 50 kGy.
Polyamides	10,000	
Polymethylpentene	20	Subject to oxidation degradation. Avoid use.
Polyphenylene Sulfide	1,000	
Polypropylene, Radiation Stabilized		Higher tolerance levels reported using e-beam.
Homopolymer	20-50	Used with marginal success in syringes. Subject to orientation and oxidation embrittlement. Degrades over time. Validate with real time aging. Avoid use of non-stabilized Polypropylene.
Copolymers of propylene-Ethylene	25-60	More stable than Homopolymer. Successful in syringe applications using suitable stabilizer package.
Polystyrene	10,000	All styrenes are stabilized by Benzene ring structure.
Polysulfone	10,000	Amber colour before irradiation.
Polyurethane, Polyether and Polyester	100-200	Excellent physicals and chemical resistance to stress-cracking.
Rigid and flexible		Drying is essential to success. Good in luer connectors. All types show irreversible yellowing.
Polyvinylbutyral	100	Yellows.
Polyvinylchloride (PVC)	100	Yellows, can be tinted for colour correction. Success depends on quality of material, formulation and processing. Tubing crosslinks becoming slightly stiffened.
Polyvinylidene Chloride (PVDC)	100	Yellows, releases HCL.
Styrene /Acrylonitrile (SAN)	1,000	Yellows at 40 kGy.

Packaging Requirements

Products for irradiation should be sent to Universal ISO-MED in a final packed corrugated box of the dimensions mentioned in the table.

Length (mm)	Width (mm)	Height (mm)	Max. Gross Weight (kgs.)
550	400	350	15 Kgs.
550	400	530	25 Kgs.