PRODUCTS COMMONLY TREATED WITH IRRADIATION

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TECHNICAL TIP #04

Irradiation is an especially attractive method for the sterilization of medical devices and pharmaceuticals. It results in minimal or no rise in temperature, leaves no residue, and requires no quarantine time post processing. Each individual product has it's own unique composition and function that must be considered for which method is best suited for it's sterilization (See Technical Tip #02 Product Qualification for Gamma Processing and Technical Tip #01 Introduction To Gamma Processing). The following is a sample of products commonly treated with gamma irradiation. Remember, each product must be evaluated for its compatibility with whatever method of sterilization is chosen. This list is not intended to be an exhaustive list or to indicate gamma irradiation is the only option available.

List of products commonly processed by Cobalt 60:

Surgical Products:	
Airways and Tubes	Laparoscopy Accessories
Alcohol Wipes	Luer Lock IV Injection Sites
Bandages	Marking Pens
Biopsy Punches, Guns, Accessories	Needle Counters
Bone Saw	OR Towels
Catheters (foley, angiographic, urinary)	Ostomy Appliances, Accessories
Cement (implants)	Prostheses (arterial, vascular, orthopedic)
Colostomy Appliances, Accessories	Scalpel Blades
Drainage Bags	Shunts
ECG Electrodes	Sponges, Gauze
Electrocautery Devices	Sterile Water
Fetal Probes	Stockinettes
Grounding Pads	Stopcocks
Hypodermic Needles and Syringes	Surgeons Gloves/Powders
Implants (hips, knees, fingers, etc.)	Surgeons Scrub Brushes (plain and impregnated)
Instruments	Surgical Drapes and Gowns
Intrauterine Devices	Surgical Procedure Packs and Trays
Irrigation Kits (surgical, ophthalmic)	Sutures
IV Administration Sets	Swabs
Laboratory Pads	Syringes - filled and unfilled (water, saline, etc.)

Medical/Pharmaceutical Products:

Aluminum Hydroxide
Aluminum Tubes
Artificial Insemination Pipettes
Bandages, Impregnated and Plain
Bioassay Dishes and Tubes
Blood and Bleeder Bags
Blood Collection Tubes
Blood Lancets
Blood Gas Syringes
Blood Serum
Body Bags
Burn Blankets, Pads, and Ointments
Centrifuge Tubes
Charcoal Suspension
Cleanroom Supplies
Closures (inserts, caps, plugs, rings, etc).
Cotton Balls
Culture Flasks, Tubes, and Trays
Dental Anchors, Burrs, and Sponges
Drainage Bags
Drug Delivery Pumps
Drug Products
Saline Solutions and Wipes
Specimen Containers
Taurine
Test Tubes
Drug Mixing/Dispensing Systems
Drum Liners
Diagnostics
Empty Poly Bottles and Closures
Enteral Feeding Bags and Kits
Enzymes
Equipment Covers
Excipients
Eye Droppers and Ointments
Fetal Blood Sampling Kit
Fetal Calf Serum
Filters (syringe, IV, membrane)
Garments (disposable and re-usable)
Lubrication Gels
Magnesium Aluminum Silicate
Magnesium Glycerophosphate
Mastitis Ointments and Test Kits
Petri Dishes
Pipettes
Plasma Pooling Bottles
Proteins
Pump/Trigger Spray Assembles
Thermometers/Covers
Tissue Culture Labware
Tongue Depressors
Topical Ointments

Examples of Products where Gamma Irradiation is the Method of Choice:

Certain products, due to their design & manufacturing process, are compatible only with gamma sterilization. The following is a list of products that can only be treated by Gamma radiation technology (electron beam aside) for sterility or bio-reduction purposes.

- Labware products – made of styrene and other plastics are temperature sensitive (eliminates heat or steam technologies) and are also sensitive to chemical residuals. If contaminated by Ethylene Oxide (EtO) or other byproducts from a technology that leaves chemical residuals, cell growth in tissue culture studies, microbiological studies, and other serum and biological high tech cell growth applications will be affected and is unacceptable. Gamma radiation is the only technology that is free of chemical residuals for these types of products
- Human/animal tissue implants to include bone allographs
- Specific soft tissues used for implants
- Sterile saline/water/bicarbonate and other solutions and liquids that cannot be filter sterilized due to final packaging or viscosity
- Products with Pyronema (although steam has been validated for this as well, gamma is clearly the method of choice)
- Filled media plates (microbiological/medical)
- Certain products, both medical and non-medical with high moisture content (ingredients, bioglue, etc.) that are temperature sensitive may form unwanted chemical residuals if processed with EtO (chlorohydrins, if chloride is present, ethylene glycol and ethylene oxide)
- Wet dressings that are temperature sensitive and/or hermetically packaged
- Prep pads, such as alcohol or PVP
- Serums (bovine & others)
- Stop – cocks and other devices or device components that are temperature sensitive and designed with occluded areas
- Filled syringes
- Certain biological products

Factors Preventing the Use of Other Sterilization Technologies:

- Closed packaged products – Many products are designed with high strength, non-breathable materials that cannot be processed with technologies that require permeation of steam or gas and changes in atmospheric pressure. These products range from medical devices to raw materials and consumer products such as peat moss, poly-lined drums, teething rings, and hermetically sealed products
- Dense materials – Many raw materials are packed in boxes and drums and are very dense, limiting permeation of steam or gases into the container. Further, steam and gas may cause clumping, change partical size, and have other physical effects that render the product useless. Spices, talc, raw materials, water soluble materials, powders, and other like materials are processed only with gamma radiation for this reason
- Unwanted chemical residuals – Certain products have a propensity to absorb/adsorb chemical sterilants. Gamma radiation is considered a “clean” process – no chemicals are involved, only pure energy

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