

PRODUCTS COMMONLY TREATED WITH IRRADIATION

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.

<u>List of products commonly processed by Cobalt 60</u> Surgical Products:

- Airways and Tubes
- Alcohol Wipes
- Bandages
- Biopsy Punches, Guns, Accessories
- Bone Saw
- Catheters (foley, angiographic, urinary)
- Cement (implants)
- Colostomy Appliances, Accessories
- Drainage Bags
- ECG Electrodes
- Electrocautery Devices
- Fetal Probes
- Grounding Pads
- Hypodermic Needles and Syringes
- Implants (hips, knees, fingers, etc.)

- Instruments
- Intrauterine Devices
- Irrigation Kits (surgical, ophthalmic)
- IV Administration Sets
- Laboratory Pads
- Laparoscopy Accessories
- Luer Lock IV Injection Sites
- Marking Pens
- Needle Counters
- OR Towels
- Ostomy Appliances, Accessories
- Prostheses (arterial, vascular, orthopedic)
- Scalple Blades
- Shunts
- Sponges, Gauze
- Sterile Water
- Stockinettes
- Stopcocks
- Surgeons Gloves/Powders
- Surgeons Scrub Brushes (plain and impregnated)
- Surgical Drapes and gowns
- Surgical Procedure Packs and Trays
- Sutures
- Swabs
- Syringes filled and unfilled (water, saline, etc.)

Medical/Pharmaceutical Products:

- Aluminum Hydroxide
- Aluminum Tubes

FOR MORE INFORMATION

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- 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, 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)
- Gaments (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

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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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