R&D Notebook: When it comes to sterilization, matching methods with materials is paramount

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Article Focus:

- Basic methods
- Production-scale methods
- Radiation methods

Sterilization methods and material for medical devices are numerous. This article will provide the basics for knowing the characteristics of each method and for which materials each is suited.

Basics
The most basic sterilization method is autoclave (heat), where you cook germs at high temperatures and pressure to kill them. Metal holds up well to this method. Autoclave is simple, effective, but pretty hard on most thermoplastics. Some engineering plastics can take the heat like PEEK, Delrin, and polysulfone, and are good for reusable devices. However, they may not be great choices for affordable disposables.

There are hospital-scale batch processes that use oxidizing agents such as peracetic acid and hydrogen peroxide to sterilize items such as endoscopes. Another hospital-scale batch process involves soaking in sterilants like gluteraldehyde. Sometimes these can be used for sterilizing R&D-scale device builds. However, this method isnft usually appropriate for manufacturing-scale processes.

Production-scale sterilization methods
Ionizing radiation such as gamma rays from a Cobalt 60 or Cesium source, (gGammah) and high energy accelerated electrons (E-Beam)

EtO (ethylene oxide) is a low-temperature process that kills pathogens by alkylation and has little effect on most plastics. It can be a good choice if you have a device with radiation sensitive materials such as PTFE (Teflon) or heat sensitive components. EtO is also capable of sterilizing large, bulky quantities of product economically. However it is toxic and must be purged from the product and packaging before use. Products need to be designed as not to trap EtO residues.

There had been a concern with EtO being ozone-depleting. However this was due to the presence of CFCs in older formulations of the sterilizing gas mix[i] as EtO gas itself is not ozone-depleting. Newer formulations have replaced CFCs, and EtO seems to be here to stay for the forseeable future. About half of all disposable medical devices are sterilized with EtO, and EtO is available at many hospitals.

Radiation
The use of Gamma rays from a Cobalt 60 or Cesium source and high-energy accelerated electrons, or E-Beam, are convenient low-temperature production scale sterilization methods that kill pathogens with ionizing radiation and by generating free radicals. It is this effect that also causes effects in plastics. Radiation is measured in gGraysh (Gy) A typical sterilization dose is 25 kGy (kiloGray)

Both Gamma and E-Beam are convenient for sterilizing smaller loads with faster turn times and lower sterilization validation costs than EtO. However the cost per load and therefore unit cost for sterilization can be higher. Gamma penetrates parts very well. E-Beam can be more economical, however due to its lower penetration ability, more thought needs to go into how products are configured in the sterilization load to ensure complete sterilization.

Radiation exacerbates molded-in stress, therefore it is important to follow good part design practice to avoid sharp corners, stress risers, molded-in stress, bad knit lines, and uneven shrinkage. Radiation can make bad parts even more stiff, brittle and weaker due to polymer chain scissioning and crosslinking. Other effects of radiation are discoloration (non-radiation stable polycarbonate turns yellowish) and odor (radiation can attack oil-based plasticizers in PVC)[ii]

There are only a few real radiation gproblem plasticsh: which are: PTFE (disintegrates at >4kGy) acetal, (Delrin) which suffers embrittlement, and nonstabilized polypropylene. One attractive feature of acetal is that it is easy to machine, holds up to steam sterilization, and therefore a popular material for fabricated prototypes, and may find its way by default into higher production products where it may no longer be appropriate. This is a reason to plan ahead for manufacturing scale-up, not just R&D convenience.

These radiation-unfriendly materials may be sterilized using other methods such at EtO. Plastics containing a benzene ring structure such as styrene, ABS, and PC/ABS tend to be radiation stable. Most elastomers, such as TPEs and silicones, are usually stable as well.

When testing plastics for radiation stability, it is best to test parts that are irradiated with twice the normal dose of radiation to ensure a margin of safety. Any products that might be resterilized after expiration will need to be run through additional sterilization cycles and testing to ensure that the product and packaging will tolerate the additional radiation without loss of mechanical and functional performance.

Most plastics hold up to radiation sterilization, and only a few do not tolerate it. EtO does not affect most plastics, and can be a viable production sterilization approach if you need to use this method, or have enough volume to justify it. Look for gradiation stableh versions of plastics. These contain oxidation inhibitors to counteract some to the effects of radiation. Check with your supplier to gain their insight on what the maximum radiation dose is for the plastic specified.

Table 1 Sterilization Effects on Plastics

Radiation Stability[iii]	Material	Notes
Excellent	Polyimide, Polyphenylene Sulfide, Styrene Acrylonitrile (SAN) Polycarbonate, PC/ABS, Polysulfone, Polyethyleneterpthalate, (PET), Liquid Crystal Polymer (LCP) Phenolics, Epoxies, Polyester, Polyurethanes, Urethane, Styrenic TPE's	Clear polycarbonates yellow, RS grades available. Polystyrenes tend to be radiation stable.
Good/Excellent	Polyethylene, Polyvinyl Fluoride (PVF) Polyvinylene Fluoride, (PVDF) Polyamides (Nylon) Polyurethane, Natural Rubber, Nitrile,	
Good	Silicone, Acrylics (PMMA), PVC, neoprene	
Poor	Polypropylene (non-stabilized) PTFE (Teflon), FEP, Acetal (Delrin) Butyl Rubber	PTFE disintegrates under radiation. Delrin (acetal) becomes brittle.

References

[i] http://www.infectioncontroltoday.com/articles/2000/06/the-future-of-ethylene-oxide-sterilization.aspx

ii http://www.mddionline.com/article/polymer-materials-selection-radiation-sterilized-products

iii For a more detailed chart of radiation effects on plastics see Material Considerations, Irradiation Processing by Steris Corporation http://www.sterigenics.com/services/medical_sterilization/contract_sterilization/material_consideration__irradiation_processing.pdf

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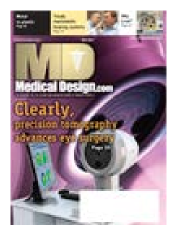

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