Plastics Topics – Sterilisation of plastics

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1. Introduction

The rising use of plastics in medical devices means that the capability of being sterilised is rapidly becoming a key selection criterion for any plastic to be used in a medical device.

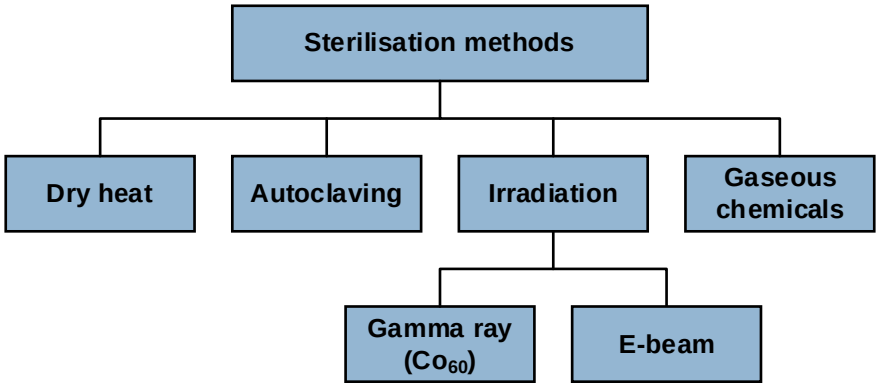
The objective of sterilisation is to prevent the introduction into the body of pathogenic organisms not normally present. Sterilisation can be defined as 'the removal or destruction of all living organisms, including resistant forms such as bacterial or fungal spores'. Bacterial spores are the most resistant of biological life to destruction and if the sterilisation is effective in killing bacterial spores, then it can generally be assumed that all other pathogenic and non-pathogenic organisms have been killed.

Disinfection is a lower grade and involves only the destruction of pathogenic organisms in the vegetative (or non-sporing) state; it does not involve the destruction of spores.

Sterilisation is the only acceptable standard for surgical purposes although disinfection may well be suitable for other purposes.

2. Sterilisation methods

Sterilisation can be achieved through a variety of methods and these will be considered individually with particular emphasis on the applicability of the method to the sterilisation of plastics devices. Whichever sterilisation method is used, the objective is to reduce the bioburden (the number of micro-organisms present) to a safe level. Production in a 'clean room' (of any standard) does not make a device sterile; it simply reduces the initial bioburden and concentration of foreign particles to make sterilisation more effective.



The main sterilisation methods for medical devices

Dry heat

Dry heat is not generally regarded as being suitable for plastics due to the low thermal transmission properties of plastics and the difficulty of ensuring that all parts of the product have been exposed to the required temperature for an adequate time. Most plastics will degrade during prolonged dry heat sterilisation.

Autoclaving

Autoclaving uses saturated steam to allow lower temperatures and shorter times than in the dry heat process. Steam will penetrate well into a product, as water vapor is lost due to condensation. Ideally the autoclave should be evacuated to allow the steam to reach all of the surfaces and for them to reach the required temperature for sterilisation. The temperatures and times used for autoclaving vary depending on the particular cycle chosen (lower temperatures must be held for longer times) but it is common for the temperature to be around 121^{o}C @ 0.5 bar for reasonable cycle times. Conditions that prevent the steam from reaching the surface, e.g., poor cleaning, packaging or over-tight packing of the autoclave can seriously reduce the effectiveness of autoclaving as a sterilisation method.

Some materials will lose structural integrity at the temperatures used for autoclaving, devices made from such materials need to be supported to prevent slumping and distortion of the product. Even products where the softening temperature is higher than the autoclaving temperature can suffer from the release of moulded-in stresses and subsequent distortion. Where autoclaving is to be used, the

effect of multiple sterilisation cycles needs to be considered to prevent cumulative effects of the treatment on the plastic. If the devices are to be packaged before autoclaving then the packaging material and packaging method needs to be carefully chosen. The suitability of a package for autoclaving will depend on the material, the size of the package, the wall thickness of the package and the contents.

As a general rule autoclaving is used significantly in hospitals for the sterilisation of repeated use articles but is not the predominant in the commercial sterilisation of medical devices because of the difficulties involved with autoclaving packaged products.

Irradiation

Irradiation is commonly used for sterilisation and can be generated by either gamma rays from a Co_{60} source or an electron beam (E-beam). In both cases the capital cost of equipment is high but high throughputs will reduce the cost.

Dosage for either process is measured in Megarad (Mrad) and as a general rule a radiation dose of around 2.5 Mrad will sterilize clean articles in air – the required dosage will approximately twice as high in anaerobic conditions. It is important to recognize that this is the minimum dosage and equipment will be set to deliver this as a *minimum* dosage – the actual delivered dosage is often much higher.

Both gamma and E-beam sterilisation use radiation and the effect on plastics materials is the same for both. Many plastics are resistant to radiation at doses of up to around 2.5 Mrad but the actual doses used will be higher than this to achieve sterilisation and complete sterilisation and radiation damage of some magnitude will inevitably occur. The effect of radiation is cumulative and for items that must be repeatedly sterilised the total dosage can rise rapidly and records need to be kept to ensure that safe limits are not exceeded. Irradiation is very effective for fully packaged and sealed single-use items (most plastics films are effectively transparent to radiation) where only one radiation dose is required.

Plastics devices subjected to radiation sterilisation will inevitably be affected by the radiation and the environment used during sterilisation and will experience changes in the polymer structure such as chain scission and cross-linking. These processes will lead to changes in the tensile strength, elongation at break and impact strength. The exact changes seen will depend both on the basic polymer and any additives used. The changes in mechanical properties may not be immediately apparent and there can be some time delay in their development. One visible side effect of irradiation sterilisation is that many plastics will discolour or yellow as a result of the processing (although this may fade with time).

Radiation sterilised devices are completely safe to handle and can be released and used immediately after sterilisation.

Gamma rays

Gamma rays are produced from a Co_{60} source and have a high penetrating power (up to 50 cm). This allows a high packing density in the sterilising chamber but can mean that products at the outer edges of the packing can be subjected to much higher radiation doses than those at the centre of the pack in order to achieve the required dose at the centre. Materials to be gamma sterilised need a margin of error in their resistance to radiation to ensure that there is no excessive degradation if they are at the outer edges.

E-beam

E-beam sterilisation uses an E-beam generator (between 1 MeV and 12 MeV) to produce a beam of high energy electrons that kills the organisms. The E-beam electrons have a much lower penetrating power but higher dose rates than gamma rays and will only penetrate around 5 cm. This means that the packing density must be low to ensure that the electrons reach the centre of the pack. As with gamma rays, products at the edges of the pack are subjected to higher doses than products at the centre to ensure that full sterilisation is achieved.

The higher dose rates and shorter times used for E-beam sterilisation can slightly improve the dosage to produce substantial damage due to the reduced exposure to oxygen during the process.

Gaseous chemicals (EtO)

Ethylene oxide is a powerful alkylating agent and is regarded by the EPA as a toxic and possibly carcinogenic gas (exposure to EtO is regulated by the EPA and OSHA). When mixed with air, EtO is not only flammable but can also be explosive.

The effectiveness of EtO sterilisation depends on many variables such as time, gas concentration, temperature and relative humidity (necessary to moisten bacteria to ensure effective destruction). This has made monitoring EtO sterilisation difficult and time consuming in the past although the development of parametric release methods as a substitution for standard biological indicators is reducing the time taken for clearance and approval.

EtO sterilisation requires evacuation of the sterilising chamber, the introduction of moisture, the introduction of the EtO gas (either in the pure state or as a 10 to 15% mixture with an inert gas) and keeping the internal pressure of the chamber lower than one atmosphere to prevent leakage of the EtO to the atmosphere. After the specified exposure time the EtO is purged and the chamber is flooded with filtered sterile air to remove any residual EtO. This complex process and subsequent monitoring takes longer than radiation sterilisation but recent technology advances have greatly reduced the cycle time for EtO sterilisation.

The majority of plastics are unaffected by EtO sterilisation treatment but some can absorb EtO and these must be treated to eliminate any EtO before use.

Some plastics are relatively permeable to EtO and the process can then be used to sterilise fully packaged articles by using thin packaging films, such as PE, that allow the EtO gas to enter the package and sterilise the contents. The packaging film must also be permeable to water vapor and air to be effective.

Standards

AAMI and ISO have produced a range of standards for sterilisation such as:

- ISO 11135 – Medical devices – Validation and routine control of ethylene oxide sterilisation.
- ISO 11137 – Medical devices – Validation and routine control of radiation sterilisation.
- ISO 11737 – Sterilisation of medical devices – Microbiological methods
  - Part 1: Estimation of population of microorganisms on products.
  - Part 2: Tests of sterility performed in the validation of a sterilisation process

3. The response of plastics

Design for sterilisation – polymer selection

One of the greatest difficulties with sterilisation of medical devices is the range of plastics used in any given device or kit. A simple device or kit may contain up to 10 different plastics for a range of uses, e.g., housings, tubing, connectors, valves and seals. The plastics used may be chosen for a variety of reasons such as transparency, mechanical strength or inertness depending on the application. The difficulty is that every plastic behaves in a different manner to the various sterilisation methods used - manufacturers can easily find that the completed device cannot be effectively sterilised if they make unwise materials choices, i.e., each material may preclude a specific sterilisation method and if disassembly not possible then it may be impossible to adequately sterilise the completed device.

The possible sterilisation methods therefore need to be considered as an integral and early part of the materials selection process for all medical devices using plastics. An additional complication in the materials selection process is the multiplicity of grades available, even for a nominally identical plastic material. For example, PVC is available in several different major materials families depending on the production method, e.g., suspension PVC, emulsion PVC and mass polymerized PVC, and in tens of thousands of different grades which will vary according to plasticizers, fillers and other additives. Each of these grades will vary in their response to the main sterilisation methods – simply giving the response of ‘PVC’ to a specific sterilisation method is not a definitive answer, the response of the specific and selected grade is required to be absolutely confident of the actual service behaviour.

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It is often not possible to state if a given material can be sterilised by a specific method, especially in a short Plastics Topic and often the best information simply gives guidance on the methods which *cannot* be used. The general performance of a range of plastics is given in the table below but specific guidance for individual materials combinations and products is recommended.

	Autoclave	Radiation (Dosage to produce substantial damage)		EtO
		Gamma	E-beam	
Acetal (POM)	✓	✗ < 2.5 Mrad	✗ < 2.5 Mrad	✓
ECTFE / ETFE	✓	100 Mrad	100 Mrad	✓
FEP	✓	10 - 20 Mrad	10 - 20 Mrad	✓
PA	✓	✗ <2.5 Mrad	✗ <2.5 Mrad	✓
PC	✓	100 Mrad	100 Mrad	✓
PE-HD	✗	100 Mrad	100 Mrad	✓
PE-LD	✗	100 Mrad	100 Mrad	✓
PET / PBT	✓	100 Mrad	100 Mrad	✓
PMMA	✗	5 - 10 Mrad	5 - 10 Mrad	✓
PP - GP	✓	10 Mrad	10 Mrad	✓
PPS	✓	5000 Mrad	5000 Mrad	✓
PS	✗	1000 Mrad	1000 Mrad	✓
PSU	✓	1000 Mrad	1000 Mrad	✓
PCTFE	✓	10 - 20 Mrad	10 - 20 Mrad	✓
PTFE	✓	✗ < 1 Mrad	✗ < 1 Mrad	✓
PVC - plasticized	✗	50 Mrad	50 Mrad	✓
PVC - unplasticized	✓	50 Mrad	50 Mrad	✓

Table 1: Selection table for sterilisation

4. Summary

Plastics are being used increasingly in medical devices (both single and multiple use) and their sterilisation capabilities are important to everybody from the designer through to the final patient. For medical devices, the preferred sterilisation method can dictate the available materials and if poor materials selection processes are used then the materials chosen can dictate the sterilisation process.