

Modern methods of sterilisation

Those guarding against infection now have a wider range of sterilisation options than ever before. Philippa Barr looks at some of the choices.

As far back as 300 BC, Hippocrates, appropriately known as 'the father of healing', emphasised the importance of keeping wounds dry and clean, and the practice was to disinfect them with substances including boiling water.

Anyone working in health care now knows the importance of guarding against infection - particularly to a wound. Therefore the careful study of sterility and product management is vital in order to maintain a risk-free environment for the patient.

'Sterile' means 'free from viable micro-organisms' and 'micro-organisms' covers bacteria including mycobacteria and bacterial spores, fungi and fungal spores and viruses.

The setting in place of a quality system for sterilisation activities is crucial for everyone whose work involves producing, handling or using sterile medical devices. Sterilisation methods and processes are usually developed by the suppliers of the sterilising equipment being used, but for all significant processes such as sterilising and packaging/sealing where the output cannot be fully verified, a full validation is necessary.

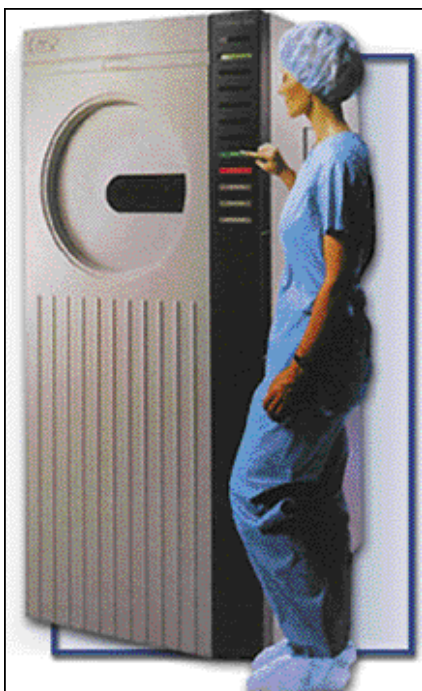
Validation should establish documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.

In fact, validation is so

important that a newly-installed steam steriliser may not be used routinely until a successful validation has been completed. And after the quality system is operational, staff should continue to look for problem areas or factors that can have an impact on product quality. These factors include:

- Change in number and/or competence of personnel
- Uncomfortable working conditions
- Increase in workload
- Introduction of new products or equipment
- Change in sources for purchased materials as well as change in components, devices, packaging materials or process techniques.

There are many different methods of sterilisation but the 'mother' of all methods is steam sterilisation. This is the most common method used in hospitals and stems from the development of the first autoclaves in the late 19th century. Heat (energy) is transferred to the steriliser load when steam condenses on the surface of the object to be sterilised. The steam used must be saturated, which means that it contains neither non-vaporised water nor air and that the pressure/temperature relationship is correct.



The Sterrad 100s system, proven to be one of the most productive low temperature sterilisation systems in the world, uses the hydrogen peroxide gas plasma method.

As part of the daily routine control of a steam steriliser one should carry out a leak test and steam penetration test (Bowie Dick) before the steriliser is taken into use. Modern sterilisers have these tests built in as one of their programs.

Other methods of sterilisation include:

Sterilisation with low temperature steam and gaseous formaldehyde

This is a rational process for sterilising packed medical

devices using low temperature (maximum 100 degrees centigrade) steam and gaseous formaldehyde. It was first developed in Britain in the 1960s and used for sterilisation in hospitals of heat-sensitive devices to be reused.

Formaldehyde residues in sterilised devices is a difficult issue as the knowledge of known health hazards to the patient is not detailed enough for a threshold value to be established. Some countries, such as Sweden, have chosen to stipulate the lowest levels of formaldehyde residues achievable through modern technology.

An LTSF steriliser must be validated after installation and before being taken into routine use and penetration of the sterilising media into long, narrow luminae must be monitored. If an automatic leak test is not included in each sterilisation process it must be carried out manually, at a suggested frequency of once a week.

Ethylene Oxide sterilisation

"War - what is it good for?" asked the Motown recording artist Edwin Starr in song

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about four decades ago. Well, World War II was 'good for' developing a new kind of sterilisation method. During the war, for practical reasons, single-use devices became an increasingly popular alternative to re-processable ones. Most of the materials used could not withstand the high temperature in steam sterilisation so sterilisation with different gases became an alternative. Ethylene oxide at low temperature had been found appropriate for decontaminating objects which had been exposed to biological weapons. It then became the most common sterilisation method within industry to sterilise medical devices. As with steam sterilisation, ethylene oxide produces a denaturation of the proteins in the cells as a result of a chemical reaction between ethylene oxide, water and the protein.

As ethylene oxide is a highly toxic substance - and, alarmingly, an explosive one! - health and safety regulations must be adhered to with extra vigilance. So routine control of an ethylene oxide sterilisation process is more complicated to maintain than in the case of steam sterilisation because there are so many factors which may affect the result. Therefore, biological indicators are normally used in conjunction with process parameter registration to check the process.

Sterilisation with hydrogen peroxide gas plasma

Commercially available for some years, this system runs in a dry environment and at an approximate temperature of 45 degrees centigrade, making it suitable for heat and/or moisture labile devices.

The hydrogen peroxide process is limited in its ability to ensure penetration of the sterilisation medium into long, narrow luminae. At least two generations of



Getinge offers a wide range of sterilisation solutions.

processes have been made available, with differences in the lumen penetration capacity, so no single exact recommendation can be given on minimum inner lumen diameter and maximum lumen length for devices to be sterilised. It is advisable to comply strictly with the manufacturers' recommendations.

Sterilisation with peracetic acid in a closed, automated process

A machine which sterilises thermo-labile endoscopes by flushing them, including their channels, with liquid peracetic acid is now available. Although the acid is normally corrosive the composition of the sterilising medium in this machine is stated to have overcome this problem. The machine is a steriliser only and requires endoscopes which have already been thoroughly cleaned and disinfected. The machine sterilising thermo-labile endoscopes by flushing them with liquid peracetic acid requires that the scopes are not packed during the procedure. Unfortunately, this represents a serious limitation for this process, which

therefore cannot be used for terminal sterilisation of medical devices. If it is stored before use the scopes must therefore be packed after processing in a way that keeps them sterile during storage and transportation.

Sterilising with sterilising liquids

The traditional hospital method of sterilising very heat-labile medical devices has been to immerse them in a sterilising liquid, usually one based on glutaraldehyde, for around ten hours. As glutaraldehyde is a powerful allergen, adequate protection for workers is imperative, albeit expensive. The sterilised devices must be rinsed thoroughly to remove glutaraldehyde residues but this easily compromises sterility. Items cannot be packed during liquid sterilisation and if they are not immediately used they must be packed after sterilisation. The process cannot be adequately monitored.

Due to all these factors, sterilising with liquids cannot properly be designated as a sterilising process. However, effective compounds may be considered as powerful, high-level disinfectants and can, with adequate precautions,

be used for devices which, in their intended use:

- Do not penetrate skin or mucous membranes
- Are not flown through with liquids supplied to sterile areas or regions of the body
- Are not to be implanted.

For such devices, high-level disinfection can often clinically be considered to be sufficient.

Irradiation

This involves products being treated with ionising radiation. Two of the common current methods are radiation with electrons or radiation from radioactive isotopes, both of which entail destroying the DNA structure of the target microbes. These methods mean high capital investment and therefore large numbers of products to be sterilised to be cost effective, so are only used within industry.

One advantage of irradiation is the opportunity to use gas/air tight packaging, which can make the shelf life of the sterilised product longer than with permeable packaging material. Equipment sterilised by these methods cannot become radioactive because of the relatively low energy delivered.