The importance of the decontamination life cycle: Part 2

The second article in a two-part series focuses on the importance of inspecting surgical instruments after the disinfection stage, packaging, and the various sterilisation methods available. By Trina Briody, UCD Veterinary Hospital; NHS National Decontamination Programme, City and Guilds accredited; SSD Supervisors/Managers Course, City and Guilds accredited

After medical devices have been cleaned and disinfected, they are then sent for inspection. All surgical instruments must be inspected for cleanliness, stains, corrosion, cracks, breakage, and stiffness of movable parts before being placed in instrument sets. If possible, instruments should be checked under magnification because small pieces of bioburden or debris can otherwise be difficult to see. Careful attention should be paid to instrument handles, serrations, box locks or hinges, cannulas or lumens, and instrument teeth. Each of these features can harbor small amounts of debris or bioburden.

The entire instrument surface must be inspected to ensure there are no fine cracks or small breaks. Small cracks can cause instrument malfunctions, and a portion of an instrument could be lost inside a surgical wound if the crack breaks during surgery. Instruments containing cracks should be discarded. All movable parts on instruments must be checked as part of the inspection process. Instrument tips must be inspected to ensure they are not broken and function correctly. Stiff parts should be lubricated, and it may be necessary to operate joints until they move freely. If problems persist, the instrument should be repaired or replaced. Failure to detect a problem with an instrument can cause serious problems during a procedure and cause possible harm to the patient.

PACKAGING

If the instruments pass inspection, they are assembled and packaged. The packaging materials that are used prevent microbes from contaminating the devices inside. The packaging you apply to reusable medical devices ensures that:

- Sets of devices remain together up to the time of use;
- Sterilising agents can penetrate through and circulate around all the devices;
- The package withstands the temperatures and pressures of sterilisation;

- Devices stay sterile after going through the sterilisation process; and
- The package can be opened aseptically for use.

There are many types of packaging systems. These include:

- Woven fabrics, usually 100% cotton, cotton-polyester blends, and synthetic blends;
- Non-woven materials, made of plastic polymers, cellulose fibers or washed paper pulp bonded under pressure into sheets, not woven on a loom. These are usually designed for single use;
- Peel pouches of plastic and/or paper, made of a variety of materials, including paper, cellophane, polyethylene, Tyvek and various paper-plastic combinations; and
- Rigid container systems that are specially designed metal or plastic containers.

When selecting a packaging material, several factors must be taken into consideration. The selection should be dependent on many things, including size and weight of device, sterilisation method, and storage location.

Packaging systems should be compatible with the specific type of sterilisation intended. Not all packaging methods are appropriate for all types of sterilisation. Some systems, such as those made of plastic or polymers, may require an increased drying time. Some rigid container systems can only be used in dynamic-air-removal (eg. pre-vacuum) steam sterilisers. Some peel packs are not appropriate for all types of low temperature sterilisation.

The user must be able to identify the contents of a package before it is opened; therefore, it is imperative that the package is labelled completely and correctly. Proper labelling is also important for quality assurance, inventory control and stock-rotation purposes. Each package should include:

- A description of the package contents;
- The expiration date or a shelf-life statement;
- The initials of the person assembling the package;
- The department where the package is to be sent after sterilisation;
- Identification of the steriliser and cycle number; and
- Date of sterilisation (load sticker).

Labelling should not harm the package material. A felt tip, quick-dry, non-toxic marker may be used to record the necessary information. With wrapped packages, the information should go on the sterilisation indicator tape, never the wrap itself. Labelling on paper-plastic pouches must be done on the clear plastic side only to avoid damaging the paper or bleeding of the ink that may damage the contents of the package.

Some sterile processing departments utilise an automated bar code tracking system that has all the necessary information

on preprinted labels. These labels are much easier to read and decrease the chance of mislabelling due to human error.

STERILISATION

The next stage in the cycle is sterilisation. Sterilisation means the killing of all micro-organisms, including bacterial spores. As you might imagine, sterilisation is therefore an essential step in preventing the spread of infection.

Steam or moist heat is the most dependable, cost-effective and widely used method of sterilisation. Steam acts on the biological make-up of microorganisms to destroy them.

There are three key factors that help in the process of steam sterilisation:

- Very high temperatures must be achieved to kill microbial life;
- The amount of time a medical device spends exposed to high-temperature steam affects the sterilisation process – if the device is not exposed for a sufficient length of time, sterilisation will not take place; and
- A low-pressure environment means that steam can penetrate the medical device more easily.

Two programmes have become the gold standard in steam sterilisation:

- Temperature – 121°C / sterilisation time – 15 minutes; and
- Temperature – 134°C / sterilisation time – three minutes.

Steam is not the only method of sterilisation – there are many different ways in which a medical device can be sterilised.

The following are some of the different methods that you might encounter:

- Ethylene oxide (EO) sterilisation – ethylene oxide is a toxic gas that kills micro-organisms. This method of sterilisation is not routinely used in decontamination facilities – medical devices are normally sent to centres that specialise in EO sterilisation;
- Low-temperature steam and formaldehyde sterilisation – dry saturated steam and formaldehyde combine to kill bacteria, fungi and most viruses at lower temperatures;
- Gas plasma sterilisation; and
- Chemical sterilisation – not routinely used in healthcare decontamination facilities. Its primary use is in the controlled conditions of an endoscopy unit.

Once the instruments are sterilised they are then transported and stored in a storage area. The sterile devices must be protected against dust, light, extreme temperatures and mechanical stress. Hence it is recommended that they be stored at room temperature in dry and dustproof cabinets or drawers. Such cabinets/drawers should be smooth and undamaged so that they can be regularly disinfected.

The first-in, first-out principle is of paramount importance for storage, with the older devices being used first.

The maximum storage period for packaged sterile devices will depend on the type of packaging and storage method used. The general rule for double-wrapped instruments in sterile supply packaging is six months stored in the right conditions; after the six months, the device is not considered sterile and must be sent back to be reprocessed. Hence the decontamination life cycle starts again.