

IFPN Guideline for Decontamination and Sterilisation

Introduction

The purpose of the guideline is to highlight best practice, and to assist in the development of standardising practice to reduce hospital acquired infections.

Decontamination and sterilisation play an important role in ensuring that surgical instruments, medical devices and key environmental surfaces are not the cause of cross transmission of micro-organisms and are safe for patients and staff to handle. Its' essential purpose is to make reusable items, safe for future use by patients.

Decontamination of surgical instruments consists of thorough cleaning of the item combined with disinfection or sterilisation.

Decontamination

The main objective of cleaning a surgical instrument is to remove organic matter which may be body fluids, pus or tissue which may contain or have the potential to support the growth of pathogenic organisms. A poor level of cleaning can increase the likelihood of transmission of harmful microorganisms by preventing the sterilant (steam, heat or a chemical) accessing all surfaces of the instrument.

<u>Point of use cleaning</u> by scrubbed staff removing blood and saline can help reduce instrument deterioration and make them easier to clean by sterile service staff. Some operating departments will spray with enzymatic chemicals after use and prior to transporting used instruments to sterile services. This is not essential but makes the removal of soil a great deal easier. Staff should use PPE for this spraying process particularly facial protection.

<u>Pre-cleaning soaking</u> in chlorine is no longer recommended as it fixes proteins and corrodes instruments causing them to rust. The disinfectant may be inactivated by blood and body fluids, which could become a source of microbial contamination and formation of biofilm.

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Cleaning is usually performed using water with detergent. It is helpful if the water is warm. The means may be manual, utilising brushes to ensure each surface is cleaned of soil, or by using fluids under pressure. Mechanical cleaning methods are preferred to protect staff handling, using washer disinfectors as well as ultrasonic washers. The latter processes can be validated and recorded.

To effectively clean a surgical instrument or other reusable medical device, it should be disassembled if possible. The manufacturer's instructions for use regarding detergent to water dilution rate should be followed as the ratio has a direct effect on the efficacy of the cleaning process.

Manual Cleaning

If the instrument is to be manually cleaned, it should be submersed under the surface of the water (immersion method) to reduce the likelihood of contaminated aerosolisation which will affect the operator. If the device cannot be immersed (eg battery packs) it should be wiped with detergent and a cloth and then with a clean cloth. Internal lumens of an instrument should be brushed their entire length with an appropriate soft brush. Box joints and serrations should be brushed to remove any trace of tissue or soil.

Rinsing is a necessary part of the process with clean water. Drying should also be undertaken of every individual device.

Mechanical cleaning

Whenever possible, to effectively clean surgical instruments use mechanical means. Ultrasonic washers are recommended for devices that have joints, crevices, lumens or other areas that are difficult to clean. Washer disinfectors are strongly recommended for any device that can withstand the mechanical process and high temperatures utilised in the process. Regular maintenance of the equipment is recommended, particularly cleaning of spray arms in the machine and engineering requirements.

Care must be taken when loading a washer disinfector to expose all the instrument surfaces to the cleaning process.

<u>Inspection</u>

All items which have been cleaned, by whichever method, should be examined to ensure that they emerge from the process, clean. If not, they should be returned for a further cleaning process.

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Function testing to ensure scissors remain sharp for example, can be undertaken during the inspection phase.

All devices are re-assembled. Checked and scanned (where computerised traceability is installed). Where manual traceability is in place, medical devices are documented on an instrument tray list.

Packaging

Depending on the steriliser to be used, most items will be wrapped or packaged. Common packaging types include:-

- Paper wrap systems using disposable wraps in two layers
- Single paper wrap systems using a disposable paper two layer bonded wrap
- Reusable barrier fabric wraps in two layers
- Reusable barrier fabric outer wrap with an inner paper wrap
- Rigid sterilisation containers with filters or valves
- Peel pouch wraps with paper/ film

The items should be clearly labelled with a name and expiry date.

Sterilisation

Sterilisation is the elimination of all disease- producing micro-organisms, including bacterial spores. Prions are not susceptible to routine sterilisation. The preferred method for sterilisation of heat resistant critical devices is steam/ moist heat sterilisation. Pre-vacuum sterilisation is preferred. Fortunately, most surgical instruments and re-usable devices are made of materials which are heat stable and can therefore undergo heat, primarily steam, sterilisation.

Steam sterilisation is a process that uses saturated steam under pressure as the sterilant. The removal of air from the autoclave chamber is essential to ensure an efficient sterilisation process –sterilisation cannot occur in the presence of air. There are several different types of steam sterilisers that utilise different methods of removing air such as the pre-vacuum which creates a vacuum during the early stages of the autoclave process.

The steam flush pressure pulse machines remove air from the chamber and packaged items using a sequence of steam and pressure to remove the air. Gravity sterilisers use gravity to displace the air from the chamber and packaged devices.

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Operators need to know which of their sterilisers are able to sterilise porous items such as textiles, wrappers, paper, rubber or plastic items and can be challenging to sterilise. Non-porous items such as surgical instruments do not trap air and thus allow surface contact to be readily achieved. Longer cycle times may be necessary for gravity displacement sterilisers for porous items. In all circumstances, users must follow, monitor and record the sterilisation time and temperature requirements specified by the manufacturer when sterilising non-porous and porous medical devices.

<u>Chemical indicators</u> show that items have been exposed to physical conditions during a sterilisation cycle to render the items sterile. Chemical indicators do not replace quality assurance measures such as time, pressure and temperature monitoring; biological monitoring; proper packaging; proper maintenance of the sterilisers; and proper storage and handling. Chemical indicators should be clearly visible on the outside of packs to be sterilised. Some sterile service units choose to put a chemical indicator on the inside of the pack as well.

Low temperature sterilisation

There are several types of low temperature sterilisation means available. The most common is vapourised hydrogen peroxide (with or without gas plasma) and ethylene oxide sterilisers. In addition there are ozone machines, low temperature steam formaldehyde and chemical disinfection. Each device will come with instructions as to the functional compatibility with different methods. Staff should be familiar with these.

<u>Liquid Chemical sterilisation</u>

Is not recommended by the World Health Organisation but there is recognition that many health clinics and rural health facilities have interrupted supplies of electricity and steam, rendering other means of sterilisation difficult. The chemistry is rarely used for sterilisation but for high-level disinfection.

All the items which are to be chemically disinfected need to be cleaned thoroughly and dried before immersion in the chemical. To be effective, the chemical needs to be in contact with all surfaces of the item.

High level disinfection is the process of killing or removing many of the pathogenic organisms – except for bacterial spores from inanimate objects to a level that is not harmful to health and is safe to handle. A few disinfectants,

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known as chemical sterilants, will kill bacterial spores with prolonged exposure times. Processes are difficult to control, have a high probability of recontamination during rinsing or drying and do not allow later storage.

A 2% gluteraldehyde solution is most commonly in use and has a disinfection time of ten minutes, a high level disinfection time of 45 minutes and ten hours for sterilisation. The chemical rapidly destroys vegetative bacteria and viruses including HIV and Hepatitis B but is only slowly effective against spores and mycobacterium.

Gluteraldehyde vapour can cause respiratory irritation, has a strong smell can cause allergic contact dermatitis and also coagulated blood and fixes tissue to surfaces. The container which is used for soaking items should have a tight fitting lid to reduce harm from vapours. The time items are submersed in the chemical should be notes for all staff.

Every items should be rinsed and dried before it is used. Various chemicals are used for high level disinfection which are not amenable to heat sterilisation due to components which are not heat tolerant.

Further reading

Solon G J, Killeen S 2019 Decontamination and Sterilization Accessed at https://www.surgeryjournal.co.uk/article/S0263-9319(18)30240-0/pdf

World Health Organisation 2016 Decontamination and Reprocessing of Medical Devices for Healthcare Facilities. https://www.who.int/infection-prevention/publications/decontamination/en/

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