

Chapter 12

Cleaning, Disinfection, and Sterilisation

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Key points

- Cleaning, disinfection, and sterilisation are the backbone of infection prevention and control.
- Proper cleaning is essential before any disinfection or sterilisation process.
- Failure to sterilise or disinfect reusable medical devices properly may spread infections.
- The type and level of device decontamination depends upon the nature of the item and its intended use.
- Thermal decontamination is safer and more effective than chemical decontamination.
- Steam sterilisation is effective only when preceded by thorough pre-cleaning, proper packaging/loading, and careful monitoring of autoclaves.
- Chemical disinfectants must be selected, used, and discarded so as to minimise harm to humans and the environment.
- All those responsible for processing contaminated items must be fully trained and wear protective clothing when necessary.
- Clearly written policies and procedures must be available on-site for training personnel and for monitoring their performance.

Introduction

Cleaning, disinfection, and sterilisation are the backbone for preventing the spread of infections. In spite of this, many health care facilities either lack these basic facilities for infection prevention and control (IPC) or their personnel receive insufficient training. The following is a critical overview of the fundamentals for cleaning, disinfection, and sterilisation with particular emphasis on reprocessing reusable medical devices. See references for more detailed advice.¹⁻⁶

Cleaning and Pre-cleaning

Everyone responsible for handling and reprocessing contaminated items must:

- Receive adequate training and periodic retraining.
- Wear appropriate personal protective equipment (PPE).
- Receive adequate prophylactic vaccinations.

While 'cleaning' means to get rid of visible dirt, 'pre-cleaning' refers to the removal of body fluids and other contamination before disinfection or sterilisation. Proper pre-cleaning can substantially reduce the pathogen load while removing organic and inorganic residues to facilitate reprocessing. *Thorough pre-cleaning is vital for successful disinfection and sterilisation.*

Effective cleaning and pre-cleaning of devices often requires chemicals, combined with mechanical action and heat. It can be performed manually and/or with machines. Equipment must be regularly checked and maintained.

Reusable items must be disassembled safely and cleaned as soon as possible after use to prevent any contaminants from drying. Manual pre-cleaning requires detergents or enzymes with friction (rubbing, brushing, flushing) to remove soil from the outside and inside of the items being reprocessed. After cleaning or disinfection, items must be rinsed and flushed thoroughly to remove any chemical residues and then dried. *All reprocessed items must be stored properly to prevent damage or recontamination.*

The Spaulding Classification

In 1968, Spaulding classified medical/surgical devices as: critical, semi-critical and non-critical based on their potential to spread infections.

Critical items enter normally sterile tissues, the vascular system, or equipment through which blood flows for example: surgical instruments and vascular catheters. *These items must be properly and safely pre-cleaned and sterilised before use.*

Semi-critical items come into contact with intact mucous membranes or non-intact skin; flexible fiberoptic endoscopes, vaginal probes, and respiratory therapy equipment are examples. *These items require proper pre-cleaning and, at a minimum, high-level disinfection before use.*

Non-critical items (such as blood pressure cuffs, stethoscopes) which only contact intact skin have a low risk for spreading infections, except by transferring pathogens to the hands of healthcare personnel. *Periodic cleaning and wipe-down of such items with a neutral detergent or 70% (volume/volume) ethanol in water is usually adequate.* (Reusable bedpans, also non-critical items, require more rigorous cleaning, washing, and disinfection, especially when suspected of contamination with, for example, vancomycin-resistant Enterococcus or *Clostridium difficile*.⁷)

Most environmental surfaces in patient rooms and throughout a health care facility are non-critical and do not require routine disinfection. However, high-touch surfaces, particularly those in a patient's immediate surroundings, need regular decontamination to prevent the transfer of pathogens to hands. *Currently, there are no generally accepted guidelines regarding: if, when, how, and how often such surfaces are to be decontaminated.*⁸

While the Spaulding classification system remains useful, it needs adjusting to suit current requirements. Prions with their unusual resistance to many physical and chemical agents and the emergence of the spore-former *Clostridium difficile* as a healthcare-associated pathogen, are forcing a re-examination of medical device reprocessing. Prion-contaminated devices require sterilisation protocols well beyond those in normal use.⁹ Some disinfectants (e.g., glutaraldehyde) normally used to reprocess gastrointestinal endoscopes need prolonged contact times to kill *C. difficile*

spores. Heat-sensitive devices such as flexible fibreoptic endoscopes are increasingly being used for operations in which the integrity of a mucous membrane is deliberately breached, thus blurring the line between 'critical' and 'semi-critical'.

Reprocessing Medical Devices

Disinfection

'Disinfection' means to reduce the number of pathogens on an inanimate surface or object using heat, chemicals, or both. Most disinfection procedures have little activity against bacterial spores; any reduction in the spore load is mainly achieved by mechanical action and flushing.

Pasteurisation and boiling

Semi-critical items, such as respiratory therapy and anaesthesia equipment, can be pasteurised by heating in water. All their parts must remain well-immersed throughout; holding the heat at about 65-77°C for 30 minutes is sufficient. Locations at higher elevations require a longer time because the boiling point of water gets lower the higher one gets from sea-level.¹⁰ Immersion of heat-resistant items in boiling water for about 10 minutes can substantially reduce the pathogen load, but must never be regarded as 'sterilisation'. Pasteurisation and boiling are thus low-tech and chemical-free methods (as long as the water is pure); treated items must be retrieved carefully for safe transport and storage.

Chemical disinfection

Common chemical disinfectants include alcohols, chlorine and chlorine compounds, glutaraldehyde, *ortho*-phthalaldehyde, hydrogen peroxide, peracetic acid, phenolics, biguanides, and quaternary ammonium compounds (QAC). Such chemicals can be used alone or in combination. They must be used in accordance with the manufacturer's instructions and only on surfaces with which they are compatible. Table 12.1 lists chemical disinfectants common in health care facilities.

Ideally, commercial products should pass standard tests to support label claims before being sold for use in health care settings. However, requirements for product registration and allowable label claims vary widely from region to region. This not only interferes with global harmonisation, it also makes testing products prohibitively expensive.

There are often serious disparities between what is claimed on the product label and its actual use. For example, the recommended contact time for environmental surface disinfectants is usually much too long for practical use. While wiping is the norm in the disinfection of non-porous inanimate surfaces, label claims of a product's microbicidal activity almost never support this. Chemical disinfectants vary widely in the harm they can cause to humans and the environment, so must be used carefully, and only when no suitable alternatives are available.

Disinfectants are placed into three categories depending on microbicidal activity:

High-level disinfectants

High-level disinfectants (HLD) are active against vegetative bacteria, viruses (including the non-enveloped ones), fungi, and mycobacteria. They may also have some activity against bacterial spores with extended contact times. HLDs are used to disinfect heat-sensitive and semi-critical devices such as flexible fiberoptic endoscopes.

Aldehydes (glutaraldehyde and *ortho*-phthalaldehyde) and oxidisers (e.g., hydrogen peroxide and peracetic acid) are HLDs. The aldehydes are non-corrosive and safe for use on most devices. However, they can fix organic materials, therefore it is particularly important to remove any embedded microbes prior to disinfection. Unless properly formulated and carefully used, oxidisers can be corrosive. However, they can be faster-acting, non-fixative and safer for the environment than aldehydes.

HLDs typically require 10-45 minutes contact time for disinfection, depending on the temperature. After disinfection, items require thorough rinsing with sterile or filtered water to remove any chemical residues; they must then be dried with an alcohol rinse or by blowing clean and filtered air through the device's channels prior to safe storage.

Intermediate-level disinfectants

Disinfectant active against vegetative bacteria, mycobacteria, fungi and most viruses. They may fail to kill spores, even after prolonged exposure.

Low-level disinfectants

Low-level disinfectants (LLD) are active against vegetative bacteria (except mycobacteria), some fungi, and only enveloped viruses. In many cases, washing with unmedicated soap and water would be sufficient in place of LLD.

Sterilisation

Sterilisation is any process that can inactivate all microorganisms in or on an object; routine sterilisation procedures may require modification to address prions. Heat is the most reliable sterilant; most surgical instruments are heat-resistant. Moist heat, when used as steam under pressure in an autoclave, kills microbes by denaturing their proteins. Dry heat in an oven kills by oxidation, which is a much slower process. Dry heat is used to sterilise moisture-sensitive materials (powders) or items which steam cannot penetrate (oils and waxes). Heat-sensitive items require low-temperature sterilisation; ethylene oxide (EO) gas, hydrogen peroxide gas-plasma, and steam-formaldehyde are often used for this purpose.¹¹

Sterilised items must be stored in a clean, dust-free, and dry place and the integrity of the wrapping must be protected. Packages containing sterile supplies should be inspected before use to verify barrier integrity and dryness. If packaging is compromised, the items should not be used and instead cleaned, wrapped, and resterilised.

Steam sterilisation

Steam is the most reliable means of sterilisation. It is non-toxic (when generated from water free of volatile chemicals), has broad-spectrum microbicidal activity, and good penetrating ability, while being cheap and easy to monitor for efficacy. Sterilisation requires direct contact of an item with steam at a required temperature and pressure for a specified time. Autoclaves are specially designed chambers in which steam under pressure produces high temperatures. They are based on the same principle as pressure-cookers. There are two main types of steam sterilisers:

- In gravity (downward) displacement autoclaves, steam is introduced at the top of the chamber to purge out the cooler and denser air-steam mixture from the bottom of the chamber. The exhaust valve closes when all the air has been removed, thus allowing the pressure to build and temperature to rise. Such autoclaves are used for sterilising

Table 12.1. The most widely used chemical disinfectants in health care

Agents	Spectrum	Uses	Advantages	Disadvantages
<p>Alcohols (60-90%) including ethanol and isopropanol</p>	<p>Low- to intermediate-level disinfectant.</p>	<p>Used for decontaminating the outside of some semi-critical and noncritical items, e.g., oral and rectal thermometers and stethoscopes. Also to disinfect small surfaces such as rubber stoppers of multi-dose vials. Alcohols with detergent are safe and effective for spot disinfection of countertops, floors, and other surfaces. Also common in handrubs.</p>	<p>Fast acting. No residue. Non-staining. Low cost. Widely available in many countries for medicinal and research purposes.</p>	<p>Volatile, flammable, and an irritant to mucous membranes. Inactivated by organic matter. May harden rubber, cause glue to deteriorate, or crack acrylate plastic.</p>
<p>Chlorine and chlorine compounds: the most widely used is an aqueous solution of sodium hypochlorite 5.25-6.15% (domestic bleach) at a concentration of 100-5000 ppm free chlorine</p>	<p>Low- to high-level disinfectant.</p>	<p>Used for disinfecting tonometers and for spot disinfection of countertops and floors. Can be used for decontaminating blood spills. Concentrated hypochlorite or chlorine gas is used for disinfection of large and small water distribution systems, such as dental appliances, hydrotherapy tanks, and water distribution systems in haemodialysis centres.</p>	<p>Low cost, fast acting. Readily available in most settings. Available as liquid, tablets or powders.</p>	<p>Corrosive to metals in high concentration (>500 ppm). Inactivated by organic material. Decolourises or bleaches fabrics. Releases toxic chlorine gas when mixed with ammonia. Irritant to skin and mucous membranes. Unstable if left uncovered, exposed to light, or diluted; store in opaque container.</p>

Agents	Spectrum	Uses	Advantages	Disadvantages
<p>Aldehydes</p> <p>Glutaraldehyde: ≥2% alkaline or acidic solutions. Also formulated with phenol-sodium-phenate and alcohol.</p>	<p>High-level disinfectant.</p>	<p>Widely used as high-level disinfectant for heat-sensitive semi-critical items such as endoscopes.</p>	<p>Good material compatibility.</p>	<p>Allergenic and irritating to skin and respiratory tract. Must be monitored for continuing efficacy levels when reused.</p>
<p>Ortho-phthalaldehyde (OPA) 0.55%</p>	<p>High-level disinfectant.</p>	<p>High-level disinfectant for endoscopes.</p>	<p>Excellent stability over wide pH range. Superior mycobactericidal activity compared to glutaraldehyde. Does not require activation.</p>	<p>Expensive. Stains skin and mucous membranes; may stain items not thoroughly cleaned. Eye irritation. Poor sporicide. Must be monitored for efficacy during reuse. Contraindicated for reprocessing certain urological instruments.</p>
<p>Peracetic acid 0.2-0.35% and other stabilised organic acids.</p>	<p>High-level disinfectant/sterilant.</p>	<p>Used in automated endoscope reprocessors. Can be used for cold sterilisation of heat-sensitive critical items, e.g., haemodialysers. Also suitable for manual instrument processing when properly formulated.</p>	<p>Rapid sterilisation cycle time at low temperature (30-45 min. at 50-55°C). Active in presence of organic matter. Environmentally-friendly by-products (oxygen, water, acetic acid).</p>	<p>Corrosive to some metals. Unstable when activated. May be irritating to skin, conjunctivae and mucous membranes.</p>

Agents	Spectrum	Uses	Advantages	Disadvantages
Hydrogen peroxide 7.5%.	High-level disinfectant/sterilant.	Can be used for cold sterilisation of heat-sensitive critical items. Requires 30 minutes at 20°C.	No activation. No odour. Environmentally-friendly by-products (oxygen, water).	Not compatible with brass, copper, zinc, nickel/silver plating.
Hydrogen peroxide 7.5% and peracetic acid 0.23%	High-level disinfectant/sterilant.	For disinfecting haemodialysers.	Fast-acting (high-level disinfection in 15 min.). No activation required. No odour.	Not compatible with brass, copper, zinc, and lead. Potential for eye and skin damage.
Phenolics	Low- to intermediate-level disinfectant.	Has been used for decontaminating environmental surfaces and non-critical items. Concerns with toxicity and narrow spectrum of microbicidal activity.	Not inactivated by organic matter.	Leaves residual film on surfaces. Harmful to the environment. No activity against viruses. Not recommended for use in nurseries and food contact surfaces.
Iodophores (30-50 ppm free iodine)	Low-level disinfectant.	Used on some non-critical items, e.g., hydrotherapy tanks; however, main use is as an antiseptic.	Relatively free of toxicity or irritancy.	Inactivated by organic matter. Adversely affects silicone tubing. May stain some fabrics.
Quaternary ammonium compounds	Low-level disinfectant unless combined with other agents.	Used mainly on environmental surfaces. Can be used on skin.	Stable with good detergent properties (cationic detergent). Usually non-irritating.	Relatively narrow microbicidal spectrum, but range of activity can be expanded when combined with other agents, e.g., alcohols.

ppm = parts per million

liquids and items in wraps that steam can penetrate. The sterilisation step itself normally lasts about 15 minutes at 121°C at 103.4 kilopascal (15 pounds/square inch).

- In high-vacuum autoclaves, the air from the steriliser chamber is first vacuumed out and then steam is introduced allowing faster and better penetration throughout the entire load. The pressure and temperature rise quickly allowing process times of three minutes at 134°C at about 206.8 kilopascal (30 pounds/square inch).

Instruments to be autoclaved must be wrapped in materials that allow steam penetration while keeping the processed item sterile during storage. Over-loading of autoclaves must be avoided to permit free access of steam throughout a load. Packages must be marked to identify their contents and date of sterilisation along with steriliser and load number to facilitate any recall and to aid in rotation of supplies.

All steam sterilisers must be tested upon installation and regularly thereafter; written records of routine operation and maintenance must be kept. *All staff must be thoroughly trained in autoclave operation and safety.*

Monitors

Biological and chemical indicators are available and must be used for routine monitoring of autoclaves.

Biological indicators (BI) contain the spores of the bacterium *Geobacillus stearothermophilus*. Commercially-available spore strips or vials containing the spores are strategically placed in the load to be sterilised. After a cycle, the BI are cultured or evaluated for growth and they must all indicate no growth to declare the sterilisation process a success.

Chemical indicators (CI) are used to assess if the required time and temperature were attained during the sterilisation process. One type of CI is an autoclave tape that can be affixed to the outside of a package; it shows a colour change if the package was exposed to heat. Though CIs are not meant to indicate that a product has been sterilised, they can help to detect equipment malfunctions and identify procedural errors.

For the high vacuum process, steam penetration of the load depends on adequate air removal. This can be monitored in two ways – firstly by a

'leak test' - can the vacuum be maintained or will air leak in (often around the door) - and secondly by the ability of steam to penetrate a small pack of towels used in the 'Bowie Dick' test. If these tests are satisfactory then an alternative monitoring approach is 'parametric release'. This system relies on ensuring that the autoclave cycle has fulfilled all specifications with regard to temperature, pressure and time using calibrated instruments in addition to, or in place of, BIs. Since this approach is based on measurable data and calibrated equipment, the results tend to be more reliable and much more rapid than the use of BIs.

Other Sterilisers

Steam is also used in two other types of sterilisers. In the low-temperature steam-formaldehyde (LTSF) process, steam (50-80°C) is used with vapourised formaldehyde to sterilise heat-sensitive medical devices (even those with narrow lumens). As usual, devices are cleaned and then processed. First, a vacuum is created; steam is introduced in several pulses followed by vapourisation of formaldehyde. At the end of the cycle, the formaldehyde is evacuated and completely purged out with several pulses of steam and high vacuum. Chemical and biological indicators are used to monitor the steriliser performance. It cannot be used with liquids and the potential toxicity of formaldehyde remains a concern.

In a Flash steriliser, steam is used to process surgical items for use when a critical item has become accidentally contaminated during an operation or when no other means of sterilisation are available. It should never be used for implantable items or to compensate for a shortage of essential instruments. Either a gravity-displacement or pre-vacuum autoclave can be used for flash sterilisation of porous or non-porous items without wrapping or with a single wrap. Waiting to read any included BIs is not possible due to the rapid turn-around needed for flash-sterilised items. *Unless suitable containers are used, there is a high risk of recontamination of the processed items and also thermal injury to personnel during transportation to the point-of-use.*

Microwaves

Exposure of water-containing items to microwaves generates heat due to friction from rapid rotation of water molecules. Thus far this process has only been used for disinfecting soft contact lenses and urinary catheters for intermittent self-catheterisation. However, small volumes of water could possibly be made safe for drinking by microwaving in a glass or plastic container. Similarly, small glass or plastic objects could be immersed in water and 'disinfected' in a microwave oven.

Dry-heat sterilisation

Hot-air ovens are used for dry-heat sterilisation. They can reach high temperatures and should be equipped with a fan for even distribution of heat. Preheating is essential before starting the sterilisation cycle. Hot-air ovens are simpler in design and safer for use than autoclaves and are suitable for sterilisation of glassware, metallic items, powders, and anhydrous materials (oil and grease). Sterilisation takes two hours at 160°C, or one hour at 180°C. Plastics, rubber, paper, and cloth must not be placed in them to avoid the risk of fires.

Ethylene oxide

Ethylene oxide (EO) is used to sterilise items that are sensitive to heat, pressure, or moisture. EO is a colourless gas that is flammable, explosive, and toxic to humans. Two EO gas mixtures are available, one with hydrochlorofluorocarbons (HCFC) the other a mixture of 8.5% EO and 91.5% carbon dioxide; the latter mixture is less expensive.

EO concentration, temperature, relative humidity (RH), and exposure time must all be maintained at the right levels during the process to ensure sterilisation. Gas concentration should be 450 to 1200 mg/l, temperature ranges from 37 to 63°C, RH from 40% to 80%, and exposure times from one to six hours.

Parametric release is not possible since gas concentrations and RH cannot readily be measured; a BI should be included with each load. The recommended BI is *Bacillus atrophaeus*; loads should be quarantined until the incubation time of the BI is complete. The main disadvantages of EO sterilisation are the long cycle times and high cost. Sterilised items must be aerated well after processing to remove all residues of EO.

Hydrogen peroxide gas plasma

Gas plasmas are generated in an enclosed chamber under deep vacuum using radio frequency or microwave energy to excite hydrogen peroxide gas molecules and produce charged particles, many of which are highly reactive free radicals. Gas-plasma can be used to sterilise heat- and moisture-sensitive items, such as some plastics, electrical/electronic devices, and corrosion-susceptible metal alloys. The spores of *G. stearothermophilus* are used as BIs.

This is a safe process, and, as no aeration is needed, sterilised items are available for immediate use or storage. However, it is not suitable for devices with dead-end lumens, powders, or liquids. Other disadvantages include the high cost and need for special packaging material since paper or linen cannot be used. In addition, any liquid or organic residues present interfere with the process.

Fumigation

Recently, there has been much interest in using fumigants to deal with healthcare-associated pathogens such as methicillin-resistant *S. aureus* and *C. difficile* in the environment. Several devices are now available which vary in cost, the process used, and the degree of field testing they have undergone.

A common process is to vaporise a solution of hydrogen peroxide into a sealed room, such as a patient room, for surface decontamination. No post-treatment aeration is necessary because hydrogen peroxide readily breaks down into oxygen and water. Spore strips are strategically placed throughout the room and retrieved later to monitor the effectiveness of the process. Disadvantages include incompatibility with cellulosic materials and potential corrosion of electronic devices.

Chlorine dioxide generated on-site may be released as a gas for room decontamination. The rooms must not only be sealed but also darkened to prevent daylight accelerating the breakdown of the gas. Like hydrogen peroxide, chlorine dioxide naturally breaks down into innocuous by-products.

Ozone can decontaminate surfaces in enclosed spaces, however it is highly unstable and potentially damaging to a variety of the materials common in health care facilities. However, an ozone-based medical device steriliser is now available. It generates the gas from oxygen and at the end of the cycle converts it to oxygen and water by catalysis. The machine claims wide materials compatibility and the ability to handle narrow-lumened devices.

Filtration

A simple means of removing microbes from air or heat-sensitive liquids is by passage through membrane or cartridge filters. This process retains physical microorganisms based on their size, without killing them unless the filter matrix is impregnated with or exposed to a microbicidal agent.

High efficiency particulate air (HEPA) filters are frequently used to remove microbial contamination from air in surgical theatres, microbiology laboratories, and for sterile manufacturing of pharmaceuticals. Their use in hospital wards and waiting rooms is also increasing to reduce the risk of spread of airborne pathogens. HEPA filters must be checked for integrity after installation and have a scheduled maintenance programme. Cartridge filters may be used on air-supply lines to remove microbial contamination.

Membrane and cartridge filters with a nominal pore diameter of 0.2 μm are quite commonly used in the manufacture of a variety of heat-sensitive biologicals and injectables. Such filters cannot remove viruses due to their much smaller size. Cartridge filters are also common on taps for potable water and inside automatic endoscope reprocessors to protect processed devices from recontamination with bacteria in rinse water. Liquids passed through such filters are often referred to as 'sterile', although this is not strictly true.

Automatic Endoscope Reprocessors

Medical devices are frequently manually disinfected. However, such an approach is operator-sensitive and exposes staff to infectious agents and potentially toxic chemicals. Automated endoscope reprocessors (AER) are a safer alternative, resources permitting. They require reliable

supplies of electricity and water, and require expensive maintenance and consumables (disinfectants, filters, etc.). The water quality is especially important to forestall premature clogging of filters and prevent the growth of opportunistic pathogens, such as environmental mycobacteria and pseudomonads.

Ultraviolet Radiation

Recent advances in ultraviolet (UV) lamp technology make the microbicidal potential of short-wave UV radiation viable for a variety of uses. UV lamps are increasing popular for disinfection of water and wastewater. UV-based devices are also being marketed for the disinfection of air in hospitals and clinics to reduce the spread of airborne pathogens. Devices are now being marketed for the disinfection of environmental surfaces in hospitals as well.

UV radiation does not add any chemicals to the water and air being treated, except for the generation of low levels of ozone. However, it cannot penetrate through dirt, and items require direct exposure to the radiation. Such lamps require regular cleaning and periodic replacement; they can still emit visible light even after the UV radiation has diminished.

Single-use Items

Single-use items are not designed for reprocessing; manufacturers will not guarantee safety and performance after reprocessing these items. If reprocessing is contemplated, satisfactory answers are required for the following questions.

1. Is the device undamaged and functional?
2. Can the device be disassembled for cleaning, decontamination, and further processing?
3. Can its sterility be validated, if needed?
4. Is the reprocessing cost-effective?
5. Is a person of authority at the site available and willing to take responsibility for any negative consequences from the use of the reprocessed item?

General Points

The main IPC priorities (regardless of resources) are:

1. Development of reprocessing protocols for instruments and equipment based on generally recognised standards and manufacturer's recommendations.
2. Use of clean water for cleaning items thoroughly.
3. Maintenance, use, and monitoring of equipment, e.g., autoclaves.
4. Discarding items that cannot be cleaned or reprocessed adequately.
5. Storing reprocessed items away from potential sources of contamination.

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