

Background

Decontamination of medical devices plays an important role in the prevention of health care-associated infections. It includes cleaning, disinfection and/or sterilization. The processes involved in decontamination are complex, require specific infrastructure and equipment, and involve several sequential steps that need to be performed correctly – from device collection and receipt by the decontamination unit to processing, storage and distribution throughout the facility. Quality control procedures (such as validation) at each step of the decontamination process are of the utmost importance to ensure the correct functioning of the equipment and processes.

Important Information

Decontamination is the process of removing soil and pathogenic micro-organisms from objects – such as medical devices – so that they are safe to handle, whether that involves further processing (sterilization), use or disposal.

This resource is intended to provide information on cleaning, disinfection and sterilization of **reusable** patient-care and medical equipment. It does not describe endoscope reprocessing and is not applicable to cleaning and disinfection of the environment.



Single-use devices

Single-use devices should only be used as recommended by the manufacturer and should not be reused. Such items have not undergone extensive testing, validation and documentation to ensure that they are safe to reprocess and reuse.

Reuse of a single-use device may compromise its intended function and performance. It may not withstand – or come with instructions for – decontamination.

Spaulding's classification

Spaulding's classification is a system of classifying the potential risk of reusable medical equipment/devices. It recommends an appropriate method of decontamination before using the device on another patient (Table 1).

Table 1. Spaulding's classification

Classification	Definition	Decontamination method	Examples
High risk (critical)	Medical devices that are involved with a break in the skin or mucous membrane or enter a sterile body cavity.	Sterilization	Surgical instruments, delivery sets, dental instruments
Intermediate risk (semi-critical)	Medical devices in contact with mucous membranes or non-intact skin.	High-level disinfection	Respiratory and anaesthetic equipment, reusable vaginal specula, endoscopes
Low risk (non-critical)	Items in contact with intact skin	Low-level disinfection (i.e., cleaning with detergent and disinfectant).	Blood pressure cuffs, stethoscopes, and electrocardiogram lead.



Decontamination and reprocessing environment

Water quality for decontamination and reprocessing should be soft, with low mineral and salt content.

The decontamination area, where used medical devices are received for reprocessing, should be physically separated from all other work areas, with a one-way work flow from the dirty area to the clean area. It should also be in a low-traffic area of the facility.

Staff working in the decontamination area should:

- wear appropriate personal protective equipment (PPE) when handling medical devices;
- ensure that “dirty” and “clean” activities are kept physically separate;
- clean and disinfect work surfaces at least daily, moving from clean to dirty areas while doing so;
- use separate cleaning equipment for clean and dirty areas;
- clean spills immediately, in accordance with local guidance;
- keep the environment clean, dry and dust-free.



Quality assurance

Several checks need to be in place to ensure the functioning and sterility of equipment and medical instruments/devices.

Policies and standard operating procedures should be in place for:

- all steps of the decontamination process;
- decontamination of each device;
- management of damaged medical devices;
- purchasing of new equipment (such as sterilizers), medical devices/equipment and products (such as disinfectants).



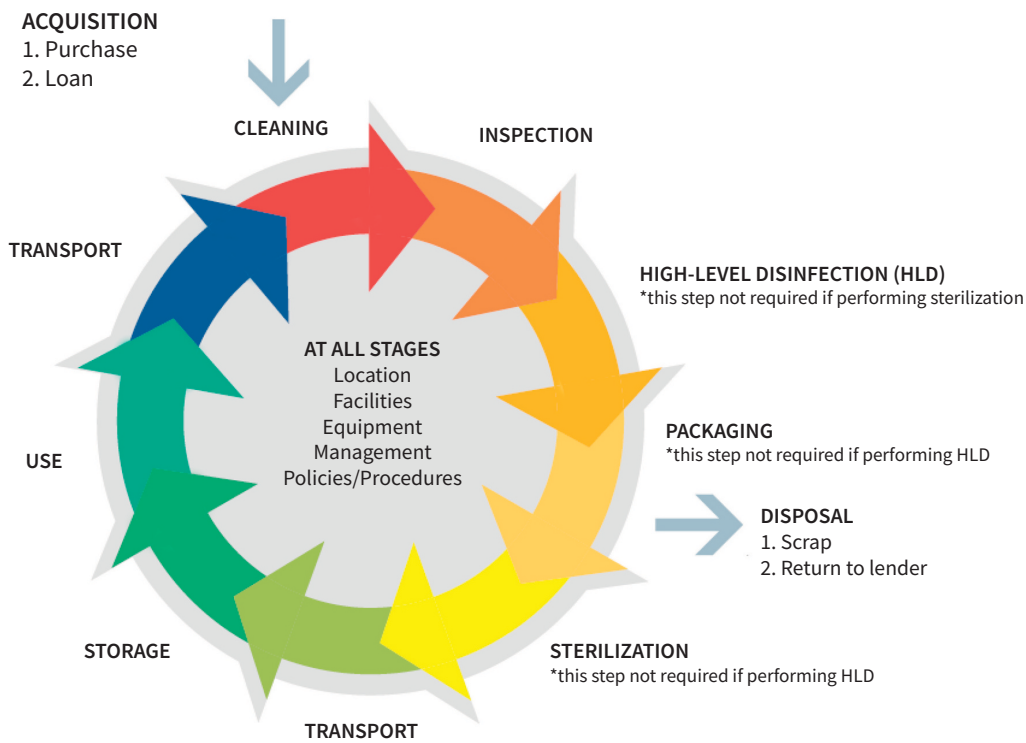
Staff education

Training should be provided to staff and should be documented. It should cover:

- risk assessment, use of PPE and how to handle chemicals safely;
- all aspects of the decontamination cycle;
- how to decontaminate any new equipment purchased (such as robotics or laser systems);
- use and understanding of the cycles for specific equipment (such as washer/disinfector and sterilizers);
- the anatomy/construction of medical devices and routine maintenance;
- interpretation of validation tests (to ensure recognition of failed indicator results) and record-keeping;
- occupational health and safety;
- provision of hepatitis B immunization (if not already immunized) following exposure to blood-borne pathogens;
- sharps injury prevention;
- PPE appropriate to the various tasks performed;
- auditing of practice for competency testing and consistency with best practice.

Summary of decontamination lifecycle

The life cycle of decontamination illustrates the features of the decontamination process. These steps are further described as key elements below.



Source: adapted from Department of Health, United Kingdom (2).

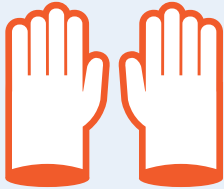
For additional information, consult [Decontamination and reprocessing of medical devices for health care facilities](#) (3), [Global guidelines for the prevention of surgical site infection](#) (4) and the online OpenWHO course [Decontamination and sterilization of medical devices](#) (1).

KEY ELEMENTS AT A GLANCE



Receipt and transportation (dirty area)

- Remove gross soil and sharps at point of use to prepare instruments and equipment for transport to the decontamination and reprocessing area.
- Transport contaminated equipment in clearly labelled, fully enclosed, leak and puncture-proof containers.
- Keep soiled instruments moist (for example, with enzymatic spray or a water-moistened towel).
- To prevent damage to devices, **do not** soak them in saline or hypochlorite solution.

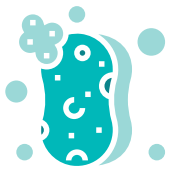


Cleaning (dirty area)

- If a device has not been cleaned, it cannot be disinfected or sterilized.
- Manual cleaning is necessary to remove visible soil from devices prior to placing it in a mechanical washer, if used (such as an ultrasonic cleaner, automated washer or washer-disinfector).
- Use clean, lint-free cloths, soft bristle brushes, spray guns and flushing devices.
- Use appropriate PPE: wear long, heavy-duty gloves (or nitrile gloves), waterproof aprons or gowns, facial protection for mucous membranes (such as a mask with visor, face mask with goggles or full visor) and closed-toe shoes or boots.
- Disassemble the device to facilitate the cleaning of all surfaces.
- Use a detergent solution compatible with the instrument/device to facilitate cleaning.
- Prepare detergent according to the manufacturer's instructions.
- Immerse devices below the level of the detergent solution when brushing, to limit splashes/sprays when cleaning surfaces and lumens.
- Inspect medical devices during cleaning to ensure that all soil has been removed.
- Rinse instruments/equipment with tap water and dry (mechanically, by air or by hand with lint-free cloth, depending on the instrument/device design).
- Where possible, clean devices by mechanical means to:
 - clean difficult-to-reach areas;
 - achieve the required exposure;
 - reduce potential risks to staff.

Cleaning Process

This cleaning process figure describes the key components required for effective cleaning.



Mechanical action: mechanical action is essential to cleaning. This is best accomplished by using soft nylon brushes, which do not damage equipment surfaces. Use wiping, flushing, brushing and spraying actions.



Contact time: the recommended contact time for detergent to interact with the various surfaces must be adhered to. Do not rush.

Solvent water: availability of good-quality water is essential; the water should be soft (with low mineral and salt content). Water-softening systems are available.



Chemical action: water alone is not an effective cleanser; a detergent (see section below) that attracts and holds organic matter is necessary. Be sure to use a detergent that is recommended for use with medical devices.

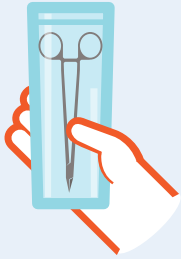


Temperature: heat improves detergent performance, but not at temperatures over 45 °C. Make sure the temperature is not too high, or materials with protein will coagulate.

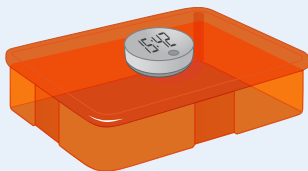
Source: OpenWHO course *Decontamination and sterilization of medical devices (1)*

Inspection, assembly and packaging (clean area)

- Change PPE worn while working in the cleaning area prior to entering the inspection, assembly and packaging area.
- Perform hand hygiene prior to handling clean devices.
- Inspect instruments for cleanliness, damage and function.



- Assemble instruments prior to packaging if recommended by the manufacturer's instructions.
- Pack instruments to allow penetration of sterilant, maintain sterility of the device and facilitate removal of instruments using an aseptic technique.
- Place an internal chemical indicator inside the package so that it will be visible for inspection when the pack is opened.
- Use an external chemical indicator to differentiate between clean and sterile instruments.
- Label the package with contents, expiry date and/or sterilization date and load number.

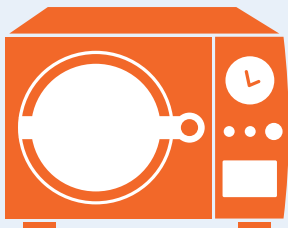


High-level disinfection or sterilization

When undertaking **high-level disinfection**:

- perform a risk assessment when handling chemicals;
- wear PPE in accordance with risk assessment and the manufacturer's instructions;
- immerse all surfaces in the disinfectant, adhering to the recommended contact time, and document this;
- test the concentration of the disinfectant daily, and document the results.

Note – instruments do not require high-level disinfection and sterilization.



When undertaking **sterilization**:

- use steam sterilization (preferred) for heat-stable devices;
- use low-temperature (ethylene oxide, gas plasma, hydrogen peroxide) and dry-heat methods if steam is not an option because of the material and design of the medical device;
- to promote contact with steam, don't overload the sterilizer/autoclave;
- inspect packages for chemical indicator change, damage and moisture when unloading the sterilizer;
- place packs or racks to allow air circulation and facilitate cooling;
- validate sterilization by monitoring and documentation of process indicators – for example:
 - document physical parameters (time, temperature and pressure) for each cycle;
 - monitor internal and external chemical indicators for each package;
 - perform biological indicator test and document results each day the sterilizer runs and with each different cycle.



Storage

- Store instruments in a dry, clean, dust-free environment, with no water tapping or drain points.
- Packages should be stored off the floor and should not touch the walls or ceiling.
- Ideally, room temperature should be in the range 15–25°C, with humidity between 40% and 50%.
- Check expiry dates regularly.

References

1. Decontamination and reprocessing of medical devices for health-care facilities. Geneva: World Health Organization; 2016 (<https://apps.who.int/iris/handle/10665/250232>, accessed 15 July 2022).
2. Health Technical Memorandum 01-01: management and decontamination of surgical instruments (medical devices) used in acute care. Part A: management and provision. London: Department of Health; 2016. © Crown copyright 2016.
3. Decontamination and sterilization of medical devices. In: Infection Prevention and Control [online course series]. Geneva: World Health Organization; 2016 (<https://openwho.org/courses/ipc>, accessed 15 July 2022).
4. Global Guidelines for the Prevention of Surgical Site Infection. Geneva: World Health Organization; 2016. (<https://apps.who.int/iris/handle/10665/250680>, accessed 15 July 2022).