衞生防護中心
Centre for Health Protection

Recommendations on Disinfection and Sterilisation of Surgical Instruments for Hospital Setting

Scientific Committee on Infection Control, and
Infection Control Branch,
Centre for Health Protection,
Department of Health

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I. Introduction

Medical device can pose a significant risk of transmitting infection to patients or healthcare workers if they are not properly handled, disinfected or sterilised. The processes of disinfection and sterilisation of medical devices, especially surgical instruments are complex. Essential elements include specific infrastructure; appropriate equipment and supplies; adequate spacing; qualified and competent personnel. Quality assurance and management system should be in place (1-4).

2. Reprocessing means all steps that are necessary to make a contaminated reusable medical device ready and safe for its intended use. These steps include cleaning, functional testing, packaging, labelling, disinfection and sterilisation (1). Healthcare facilities should have policies and procedures (e.g. written policies and working protocols) to ensure that protocols are in place for each reprocessed medical device, and monitor adherence to approved procedures. Before procurement of reusable medical devices, the manufacturer's instructions should be carefully studied, assessed and evaluated. The functions of a medical device, as dictated by its intended purpose, must not be adversely affected when the device is reprocessed. Staff training must be provided. The type of instrument and its intended use will determine the method of reprocessing and, as a general rule, if an instrument cannot be cleaned it cannot be properly disinfected or sterilised (1,2,5).

3. This recommendation aims to provide guidance in sterile services in hospital setting across private and public healthcare sectors using a risk control approach. The recommendations on preferred methods for cleaning, disinfection and sterilisation are based on reusable medical devices that can undergo proper reprocessing. Single-use devices and devices potentially contaminated with prions does not fall into the scope of this document (6).

II. Spaulding Classification

4. Spaulding classification is a recognized strategy and rational approach for reprocessing contaminated medical devices. This system classifies medical device as critical, semi-critical or non-critical on the basis of risk of infection from contamination of the device. The system also established **three levels of germicidal activity** (sterilisation, high-level disinfection and low-level disinfection) for the **three classes of medical devices** (critical, semi-critical, and non-critical) (1,7,8).

(a) Critical devices

Critical devices are instruments or objects that are introduced directly into the human body, either into or in contact with the blood stream or other normally sterile areas of the body and products with sterile fluid pathways (3).

Critical devices present a high risk of transmitting infection if contaminated with any microorganism and **must be sterile at the time of use**. These items must be used immediately after sterilisation or the sterility must be maintained by proper packaging and storage until use.

(b) Semi-critical devices

Semi-critical devices are instruments or objects that contact intact mucous membranes or non-intact skin of the patient during use, but they do not usually penetrate the blood barrier or other normally sterile areas of the body (3).

Semi-critical devices **should be sterilised if possible. At a minimum, they must be subjected to high-level disinfection which** is expected to eliminate all microorganisms except for large numbers of bacterial spores (3). In most cases, meticulous physical cleaning followed by high-level disinfection provides reasonable assurance that the items are free of pathogenic microorganisms.

(c) Non-critical devices

Non-critical devices are instruments or objects that usually contact only the intact skin of the patient. Depending on the particular item and degree of contamination, **low-level disinfection is generally sufficient**.

5. If there is a discrepancy between the reprocessing level recommended by the manufacturer and the intended use of the instrument by Spaulding classification, the higher level of disinfection / sterilisation must be used (3,5).

III. Cleaning

6. The process of cleaning physically removes contaminants from the equipment / device, rather than killing microorganisms. Cleaning is the **most important step prior to disinfection or sterilisation**, since the efficacy of disinfection and sterilisation will be reduced if soiling e.g. organic matter such as blood and tissues remains on the surface of equipment / device which protects microorganisms from exposure to the disinfectant or sterilant. All medical devices should therefore be scrupulously cleaned to reduce the bioburden (9-12).

(a) **Pre-cleaning**

i. Pre-cleaning at point of use may be needed for items that are heavily soiled with feces, sputum, blood, or other material (1,2).

ii. Gross debris should be removed and if cleaning cannot be done immediately the device may be submerged or flushed with either one of the following to prevent drying of organic matter (1-3):

- water with detergent
- distilled water
- reverse osmosis (RO) water
- enzymatic cleaner
- another **suitable agent** recommended by the manufacturer

iii. Instruments should be maintained in a moist state (e.g. spray with an enzymatic spray, soak with alkaline detergents) before cleaning in order to prevent the drying of surgical debris onto or within them. For some devices, such as ophthalmic viscoelastic devices (OVDs), surgical debris can become dried onto the instruments very quickly following use which in turn make the removal process more difficult during subsequent cleaning (1-3).

iv. **Do not use saline** as a soaking solution as it damages some medical devices (1). Ensure the detergent-based products used should be in right

concentration as recommended by the manufacturer. Avoid prolonged soaking (e.g. overnight) of medical devices (1-3).

(b) **Manual and Mechanical Cleaning**

(Follow medical device manufacturer's instructions when performing manual and/or mechanical cleaning.)

i. Manual cleaning may be indicated for:
   - Medical devices that cannot be immersed (i.e. electrical or battery-powered devices).
   - Devices that require special cleaning (i.e. narrow bore lumen or delicate devices).
   - Pre-cleaning step prior to mechanical cleaning in ultrasonic and/or washer-disinfector.

ii. Mechanical means of cleaning is preferred if available as it can provide a controlled and uniformly reliable result. It improves cleaning effectiveness, decreases worker exposure to blood and body fluids, and increases productivity.

iii. Examples of mechanical cleaning equipment include ultrasonic cleaners and automated washer-disinfectors.

iv. Ensure that the device to be cleaned is **compatible** with the mechanical cleaning equipment, cycle parameters and cleaning chemicals that are being used. Also, manufacturer's instructions of the mechanical cleaning equipment need to be followed.

v. **Ultrasonic cleaners** and **washer-disinfectors** are strongly recommended for medical devices, especially for semi-critical or critical medical device that has joints, crevices, lumens or other areas that are difficult to clean.
   - Ultrasonic cleaning should be followed by thorough rinsing to remove dislodged particles.

vi. **Washer-disinfector** uses pressurised water to physically remove bioburden followed by thermal disinfection.
   - When a washer-disinfector is used, care should be taken in loading instruments: hinged instruments should be opened fully to allow adequate contact with the detergent solution; stacking of instruments in washers should be avoided; and instruments should be

disassembled as much as possible.

(c) **Cleaning agents**

i. **Compatibility** between the cleaning agents and the instruments to be processed, and the equipment for cleaning (e.g. washer-disinfectors or ultrasonic cleaners) should be considered.

ii. **Mild alkaline detergents** with pH value from 8.0-10.8 are more efficient in cleaning and thus are preferred for manual cleaning, ultrasonic cleaning, and washer-disinfectors. Only use appropriate detergents for instrument cleaning. Detergents used for home cleaning or laundry use are not suitable.

- Prepare at the concentration recommended by manufacturer or supplier for optimal results.
- Rinse thoroughly after cleaning to remove loosened soil and chemical residues, which may cause tissue irritation and react with disinfectant or sterilant.

iii. **Enzymatic detergents** are used to remove protein from the surface of the instrument after gross soil is removed. Instruments with dried or hardened blood on the surface should be soaked with enzymatic detergent in a warm solution. Rubber or nitrile gloves should be used when handling enzymatic solutions since enzymatic cleaners cause degradation of latex.

IV. Cleaning Validation and Verification

7. Definitions of terminology (1)

(a) **Validation** is the documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently disinfect and sterilise instruments and other medical devices.

(b) **Verification** is the confirmation through the provision of objective evidence that specified requirements have been fulfilled.

- Two principles are involved in verifying a cleaning process. The first consists of establishing, clarifying, and documenting a standard cleaning process that is based on published and validated recommended practices or guidelines. The second concerns measuring

and evaluating residual contaminants on medical devices after applying the established cleaning process (3).

(c) **Monitoring** refers to the process of audit to measure the level of compliance with related policy, reviewing the environment and processes related to equipment decontamination with feedback provided to managers.

8. One of the methods to ensure adequate cleaning is to conduct a reprocessing verification test (e.g. microbiologic sampling), but this is not routinely conducted. Visual inspection is routinely used to verify the cleaning process before it is released for disinfection or sterilisation (1,2). Other methods of verification include measurement of adenosine triphosphate (ATP), protein residues and artificial soil (2, 7).

9. Cleaning verification tests that enable quick testing of the medical devices after cleaning and will not damage the device or require re-cleaning should be used (3). Verification of a cleaning process consists of: (1,3,7,13)

(a) Defining and documenting a cleaning process and its critical aspects so that each step is fully verifiable through personnel training and observation to ensure important steps can be reliably followed completely, accurately, and without variation by all individuals who perform it; and
(b) Validating the mechanical cleaning process to ensure adequate, consistent cleaning levels.
(c) Regular auditing on selected samples, and monitoring of mechanical cleaning equipment.
(d) Quality improvement processes should be in place to handle irregularities.

V. Disinfection

10. Low-level disinfection eliminates vegetative ('live') bacteria, some fungi and enveloped viruses. It is used for noncritical medical equipment, devices and some environmental surfaces. High-level disinfection destroys vegetative bacteria, mycobacteria, fungi and enveloped (lipid) and non-enveloped (non-lipid) viruses, but not necessarily bacterial spores.

11. High-level disinfection is needed for semi-critical patient-care equipment (e.g. gastrointestinal endoscopes, endotracheal tubes, anesthesia breathing circuits, and respiratory therapy equipment) that touches either mucous membranes or non-intact skin. High-level disinfection can be performed by thermal or chemical method.

(a) **Thermal disinfection**

The number and types of microorganisms killed on clean items, and thus the level of decontamination achieved depend on **exposure time and exposure temperature**

i. Washer-disinfectors employ hot water temperatures of 60°C to 95°C (140°F to 203°F). The user should carefully follow the written instruction supplied by the washer-disinfector manufacturer as well as any instructions supplied by the manufacturer of the device to be decontaminated (2,3,13). Instruments and devices that are heat- and moisture-stable may be decontaminated by thermal disinfection processes.

ii. **The A_0 Concept:** Thermal disinfection with moist heat, based on the A_0 concept (EN ISO 15883-1), is the most common method for disinfection of medical devices in the hospital setting. A_0 is a physical parameter denoting the inactivation of microorganisms. The concept of A_0 is intended to allow equivalent disinfection efficiencies to a reference time / temperature to occur at other disinfection temperatures (8,9,13).

iii. For disinfection processes deployed against bacteria, including mycobacteria, fungi and heat-sensitive viruses, an A_0 value of 600 is specified, corresponding to a hold time of 600 seconds = 10 minutes at 80 °C. The A_0 value of 600 can also be achieved at 90 °C with one tenth of the hold time, i.e. 1 minute (8,9,13).

Table 1: Guide values for temperature and exposure time for thermal disinfection

Temperature In °C	A_0 = 600		A_0 = 3,000	
	Time in seconds	Time in minutes	Time in seconds	Time in minutes
80	600	10	3000	50
90	60	1	300	5
93	30	0.5	150	2.5

- An A_0 value of at least 600 is required for a medical device that **will** undergo sterilisation after disinfection.
- An A_0 value of at least 3,000 is required for a medical device that **will not** undergo sterilisation after disinfection (EN 15883-2).

iv. Time and temperature should be monitored by equipment timers and temperature gauges. Temperature-sensitive indicators are also available to monitor the internal temperature achieved during processing.

(b) **Chemical disinfection**

Due to inherent limitations with liquid chemicals compared to heat, e.g. lower ability to penetrate organic barriers, need to rinse with sterile or filtered water after processing, etc., chemical disinfection should only be used for products that **cannot be treated** using thermal disinfection methods. Certain chemicals used as **high-level disinfectant are the same agent as chemical sterilant** but differ in terms of concentration, exposure time and temperature required to achieve sporicidal effect (2,14).

i. In selecting a chemical disinfectant, the following properties should be considered: efficacy and spectrum of antimicrobial activity, contact time, material compatibility, effectiveness in the presence of organic compounds, chemical stability, toxicity, environmental safety and cost.

ii. Chemical disinfection process can be performed manually or by means of automated equipment such as washer-disinfectors, which provide a cycle of cleaning, rinsing, disinfection and drying (3).

iii. Manufacturers' instructions should be followed to prepare the disinfectant solution including the need to test for minimum effective concentration (MEC) to monitor solution potency. If a solution falls below its MEC, it should be discarded, even if the expiration date has not been reached. Results of disinfectant MEC testing should be recorded (9).

iv. The surgical instrument should be completely immersed in the chemical agent, be thoroughly rinsed of all chemicals and then dried.

v. Health and safety precautions, such as adequate ventilation to evacuate the released chemical vapour, proper storage of the chemical agents in a closed container, use of appropriate personal protective equipment and where necessary, monitoring of exposure should be strictly followed.

VI. Packaging

12. Devices require packaging prior to sterilization (1). The primary functions of a package containing a medical item are to allow the sterilization of the contents, to maintain the sterility of the contents until the package is opened, and to provide for the removal of the contents without contamination (3). Packaging should be selected according to the sterilization method and the devices to be prepared.

13. Packaging systems must be appropriate to the items being sterilized, the method of sterilization, and used according to the manufacturers' instructions (1). The instruction should include configuration of contents and organizing inserts, total weight, inner wrapping, and absorbent materials (9). Policies and procedures should be developed for packaging techniques (3).

VII. Sterilisation

14. Sterilisation means elimination of all disease-producing microorganisms, including bacterial spores. Sterilisation is indicated for critical medical devices and, whenever possible, semi-critical medical devices (1).

(a) **Choice of sterilisation process**

i. Choosing correct sterilisation process is important so as not to cause damage to the instrument or compromise sterility.

ii. Heat, primarily steam, is recommended for medical devices made of materials that are heat stable.

iii. Chemical sterilants should be considered for heat-sensitive instruments that cannot withstand steam sterilisation.

iv. Written, validated, device-specific instructions from the device manufacturer and steriliser efficacy testing from the steriliser manufacturer (e.g. type or work test, relevant certificate or manufacturer's instruction for use) must be studied before use.

(b) **Steam Sterilisation**

Steam sterilisation is a process that uses saturated steam under pressure as the sterilant. It is the most efficient and reliable method to achieve sterility. The

complete removal of air is essential to ensure an efficient sterilisation process. Steam sterilisers vary in chamber size from small table top models to large floor-loading models. The basic principle of steam sterilisation is to expose each item to direct steam contact at the required temperature and pressure for the specified duration (2). There are four parameters of steam sterilisation (2):

i. **Steam:** Ideal steam for sterilisation is dry saturated steam and entrained water (dryness fraction ≥97%).

ii. **Pressure:** Serves as a means to obtain the high temperatures necessary to quickly kill the microorganisms.

iii. **Temperature:** Specific temperatures must be achieved to ensure the microbicidal activity. The two common steam-sterilising temperatures are 121°C and 132°C.

iv. **Time:** Minimal time (holding time) to kill the microorganisms at specific temperatures. Recognized minimum exposure periods for sterilisation of wrapped healthcare supplies are 30 minutes at 121°C in a gravity displacement steriliser or 4 minutes at 132°C in a pre-vacuum steriliser.

(c) **Chemical / Low-Temperature Sterilisation Methods**

Chemical gas (low temperature) sterilisation is used to sterilise heat- and moisture-sensitive medical devices. Device compatibility will vary with each low temperature sterilisation method (1,2,5,7,9).

Low temperature (gas) sterilisation can be achieved using different chemicals including hydrogen peroxide gas/plasma, ozone, low temperature steam formaldehyde. Liquid chemical disinfection such as glutaraldehyde, and peracetic acid is not recommended (1). **Sterilisation with gaseous chemical methods should be carried out in chambers with automated cycles that provide safety for the user and guarantee the processes**.

i. **Hydrogen peroxide gas (plasma)**

Gas plasmas have been referred to as the fourth state of matter (i.e., liquids, solids, gases, and gas plasmas). The mechanism of action is the production of free radicals within a plasma field that are capable of interacting with essential cell components (e.g. enzymes, nucleic acids) and thereby disrupt the metabolism of microorganisms. Hydrogen peroxide gas sterilisation activity is primarily dependent on the gas concentration,

exposure time (28-75 minutes), as well as the process temperature (less than 60°C) (1).

Microbicidal Activity: This process has the ability to inactivate a broad range of microorganisms, including resistant bacterial spores. Depending on the concentration and contact time, peroxide gas is considered an effective antimicrobial, including rapid bactericidal, fungicidal, virucidal and sporicidal activity.

- Safe for use on most device and material types, including electrical components, corrosion-susceptible metal alloys and plastic.
- Absence of toxic waste and chemical residues
- Cannot sterilise materials that absorb hydrogen peroxide (e.g. linen, gauze, cellulose / paper, wood).
- Low penetration power. The effectiveness can be altered by lumen length, lumen diameter, inorganic salts, and organic materials.

ii. **Ozone**

Ozone consists of O_2 with a loosely bonded third oxygen atom that is readily available to attach to, and oxidize, other molecules. This additional oxygen atom makes ozone a powerful oxidant that destroys microorganisms but is highly unstable (i.e., half-life of 22 minutes at room temperature). The steriliser creates its own sterilant internally from United States Pharmacopoeia (USP) grade oxygen, steam-quality water and electricity. The sterilant is converted back to oxygen and water vapour at the end of the cycle by passing through a catalyst before being exhausted into the room. Duration of the sterilisation cycle is approximately 4 hours 15 minutes, and it occurs at 30-35°C.

Microbicidal Activity: Demonstrate microbial efficacy by achieving a reduction of 10^{-6} with a variety of microorganisms to include the most resistant microorganism, *Geobacillus stearothermophilus.*

- Compatible with a wide range of commonly used materials, including stainless steel, titanium, anodized aluminium, ceramic, glass, silica, PVC, teflon, silicone, polypropylene, polyethylene and acrylic.
- Fast action and safe for the environment (oxygen end products)

15. Unacceptable sterilisation methods for reusable medical devices include boiling, glass bead sterilisers, microwaves and ultraviolet light.

VIII. Immediate Use System Sterilisation (IUSS) / Flash Sterilisation

16. IUSS is formerly known as flash sterilisation, a modification of conventional steam sterilisation in which the flashed item is placed in an open tray or is placed in a specially designed, covered, rigid container to allow for rapid penetration of steam (1-3,5,7,9).

17. This sterilisation method **should be avoided** as the material is sterilised without packaging and the cycle eliminates drying. As a result, the possibility of recontamination of the material increases.

18. IUSS should only be used in emergency situations and should never be used for implantable devices / equipment because of the potential for serious infections. (1,2) Implantable device refers to a device that is placed into a surgically formed cavity of the human body if it is intended to remain there for a period of 30 days or more. (7)

19. If IUSS is unavoidable, ensure all the following requirements are adhered to:

(a) Work practices should ensure proper cleaning, inspection, and arrangement of instruments before sterilisation (1).

(b) Physical layout of the area ensures direct delivery of sterilised items to the point of use e.g. located within the operating room (1,5).

(c) Procedures are developed, followed and audited to ensure aseptic handling and staff safety during transfer of the sterilised items from the steriliser to the point of use (1).

(d) Items are needed for use immediately following IUSS but only after the device cools so as not to burn the patient (1).

(e) Ensure proper record keeping (load identification, patient's name / hospital identifier, and biological indicator result) for epidemiological tracking and assessment of reliability of the sterilisation process (1,9).

IX. Sterilisation Cycle Verification

20. A sterilisation process should be verified before it is put into use in healthcare settings. Monitoring of each steriliser and every cycle is essential to ensure sterility of the reprocessed medical devices (1,13).

21. Monitoring and verification of the sterilisation process can be achieved by using **physical, chemical and biological** monitors and indicators (1,2,15). Sterilisation indicators should be used according to the indicator manufacturer's instructions.

(a) **Physical indicators (PI)**

A physical monitor is a device that monitors the physical parameters of a steriliser, such as time, temperature and pressure that are measured during the sterilisation cycle and recorded (as a printout or electronic record) on completion of each cycle.

(b) **Chemical indicators (CI)**

A chemical indicator is a system that responds to a change in one or more predefined process variables with a chemical or physical change (e.g. change in colour). They indicate an item has been exposed to the sterilisation process but do not prove sterilisation has been achieved. Thus they do not replace the need to use a BI. There are six types of chemical indicators by ISO 11140 (1). The classification structure is solely to describe the characteristics and intended use of each type of indicator and has no hierarchical significance. CIs can be external or internal, depending on whether they are placed outside or inside the package undergoing sterilisation.

Table 2. Types of chemical indicators

Types	Purpose
Type 1 Process indicators	These indicators are intended for use with packs or containers to indicate that they have been directly exposed to the sterilisation process and to distinguish between processed and unprocessed units
Type 2 Indicators for use in specific tests	These indicators are intended for use in specific test procedures, such as, the **Bowie-Dick test** for air removal

Type 3 Single variable indicators	These indicators are designed to react to one of the critical sterilisation variables, e.g. time and temperature, and are intended to indicate exposure to a predetermined sterilisation process variable, e.g. 134°C
Type 4 Multivariable indicators	These indicators are be designed to react to two or more of the critical sterilisation variables, e.g. time and temperature, and are intended to indicate exposure to predetermined sterilisation process variables, e.g. 134°C, 3 minute
Type 5 Integrating indicators	These indicators are designed to react to all critical variables of the sterilisation process, e.g. time, temperature and presence of moisture, and are intended to be equivalent to or exceed the performance requirements given in the ISO 11138 series for biological indicators
Type 6 Emulating indicators	These indicators are designed to react to all critical variables of the sterilisation process, e.g. time, temperature and presence of moisture, and are intended to match the critical variables of specified sterilisation cycles

(c) **Biological indicators (BI)**

A biological indicator is a test system containing viable microorganisms (e.g. spore-laden strips or vials) providing a defined resistance to a specified sterilisation process. They measure the lethality of the sterilisation process directly by using Bacillus spores that are more resistant and present in greater numbers than are the common microbial contaminants found on patient-care equipment. Thus inactivation of BI strongly implies that other potential pathogens in the load have been killed. Once sterilised, a BI is incubated to see if the microorganism will grow, which indicates a failure of the sterilisation process. The manufacturer's instructions regarding the type of BI to be used in a particular steriliser should be followed.

The recommended test microorganisms generally used as BIs are:

- *Geobacillus stearothermophilus (formerly Bacillus stearothermophilus)* spores for sterilisers that use steam, hydrogen peroxide gas plasma or peracetic acid, as well as immediate use steam sterilisers.
- *Bacillus atrophaeus (formerly Bacillus subtilis)* spores for sterilisers that use

dry heat or ethylene oxide.

Most BIs require 48 hours to 7 days of incubation before the test is complete. Rapid readout biological indicators (e.g. one hour for 132°C gravity sterilisers and three hours for vacuum sterilisers) are available that provide BI results in much shorter time period (2). The mechanism involves enzymatic breakdown of a nonfluorescent substrate into a fluorescent product and detection of acid metabolites produced during growth of the Bacillus spores.

BIs are intended to demonstrate whether the conditions were adequate to achieve sterilisation. A negative BI does not prove that all items in the load are sterile or that they were all exposed to adequate sterilisation conditions (3).

(d) **Frequency of monitoring**

Sterilisation shall be monitored with biological indicators. The recommended frequency of BI testing for steam sterilisation is daily (1-3,5,7) whilst for gaseous sterilisation (hydrogen peroxide gas plasmas sterilisation) are for every load with BI testing (7, 9).

All loads containing an implantable device shall be monitored with an additional biological indicator and should be quarantined until the results of that biological indicator testing are available. (1)

Chemical indicators should be used in each package and physical indicators should be used in each cycle (1,9). Additional monitoring of pre-vacuum steam sterilisers shall include a dynamic air removal test (daily).

All steam and other low-temperature sterilisers should be tested with biological and chemical indicators upon installation, when the steriliser is relocated, redesigned, after major repair and after a sterilisation failure has occurred to ensure they are functioning prior to placing them into routine use.

X. Storage

22. Sterile items should be stored in well-ventilated area that provides protection against dust, moisture, insects, and temperature and humidity extremes, in

order to reduce the potential for contamination (2, 3). Besides, sterile items should be stored far enough away from the floor, the ceiling, and outside walls to allow for adequate air circulation, ease of cleaning, and compliance with local fire codes (3). Sterile items should be handled as little as possible (1). Please refer to organization guidelines for details on storage requirements.

23. Label sterilized items with a load number that indicates the sterilizer used, the cycle or load number, the date of sterilization, and, if applicable, the expiration date (2).

24. There should be written policies and procedures for how shelf life is determined and how it is indicated on the product (3). The shelf life of a packaged sterile item depends on the quality of the wrapper, the storage conditions, the conditions during transport, the amount of handling, and other events (moisture) that compromise the integrity of the package. If event-related storage of sterile items is used, then packaged sterile items can be used indefinitely unless the packaging is compromised (2).

25. Devices that has been sterilized should not be used after the expiration date has been exceeded or if the sterilized package is wet, torn, or punctured (2). When sterile devices are exposed to any event (e.g. exposure to water, damage to package, dropping, compression, excessive handling, and exposure to pests, insects and dust etc.), it should be reprocessed (1, 9).

XI. Tracing and Tracking System

26. Disinfection and Sterilisation quality control relies on historical data, especially when quality assurance measures yield conflicting evidence (3). Record-keeping is needed for both epidemiological tracking and ongoing assessment of the reliability of the sterilisation process (3).

27. Traceability in a sterilisation department contributes to the effective management of the medical devices and the legal protection of the healthcare institution. The setting up of a tracing and tracking system allows the medical devices to be monitored in all phases of treatment and use, as well as the proactive management of the desired processes. It is strongly recommended to implement the

tracing and tracking system of medical devices, and computerized system is preferred. This forms an essential part of a quality system.

XII. Recall of Processed Medical Devices

28. Quality Assurance (QA) must be in place to ensure recall of improperly reprocessed medical devices for the interest of patient and staff safety (1). Written policies and procedures for recall of medical devices from issued or stored loads should be developed in the healthcare facility. Product recalls can be evaluated by reviewing records of actions following documented sterilisation cycle failures. Whenever there is evidence of a sterilisation failure, the infection prevention and control professional should be notified so that follow-up surveillance of patients can be conducted (3).

XIII. Water Quality for Cleaning and Sterilisation

29. The quality of water is integral to the cleaning process, as well as the steam produced for sterilisers (1). The possible interactions between very hard water and water with elevated levels of dissolved chemicals justify the attention required concerning the quality of water used for cleaning of salts and other elements dissolved in the water.

30. Water used in sterilisation unit should be soft, which means that the mineral and salt content is low and does not affect devices or processing equipment (1).

31. Water can be softened by several methods:

(a) Filtration which selectively removes minerals and salts.

(b) Reverse osmosis (RO). An RO system is sometimes recommended by manufacturers of modern and highly sophisticated washer-disinfectors and sterilisers. It is worth checking this before purchasing equipment, particularly if the budget is restricted.

32. It is recommended that soft water be used only for the final rinse if not affordable as processing of water can be expensive. Water and resource economisation should not take precedent over operational imperatives, such as water

quality and critical parameters for processes.

XIV. Steam Quality for Sterilisation

33. Proper steam quality will prolong the life of reprocessed medical devices by reducing adverse effects that water impurities can have on device materials. Lime, rust, chlorine and salt can all be left as deposits on devices if demineralised water is not used. These compounds can lead to stress corrosion, pitting and discolouration of the device. Pitting, corrosion and precipitates must be avoided as their formation provides areas where organisms can readily accumulate and be protected from the killing effects of the steam process, i.e. increased risk of infection transmission due to inadequate sterilisation (1).

34. Steam systems should be designed to ensure that a continuous and adequate supply of saturated steam is available to the steriliser in accordance with the steriliser manufacturer's specifications. The steam delivered to the steriliser should be at a steady, not fluctuating, pressure within the range of the manufacturer's recommendations.

35. The quality of the steam used in sterilisation should be known and controlled as a quality assurance measure (9,13). Users are suggested to arrange regular testing of the steam quality together with regular testing of the steriliser, which provide assurance that the steam specification is consistently met (13). Suggested maximum values of contaminants (9) are listed in table 3.

Table 3. Contaminants in condensate from steam supply to the sterilizer measured at the sterilizer inlet (9)

Determinand	Condensate
Silicate (SiO2)	≤ 0.1 mg/L
Iron	≤ 0.1 mg/L
Cadmium	≤ 0.005 mg/L
Lead	≤ 0.05 mg/L
Rest of heavy metals except iron, cadmium, lead	≤ 0.1 mg/L
Chloride (Cl')	≤ 0.1 mg/L

Phosphate (P2O5)	≤ 0.1 mg/L
Conductivity (at 25 ℃)	≤ 3μS/cm
pH value (degree of acidity)	5 to 7
Appearance	Colourless clean without sediment
Hardness (Σlons of alkaline earth)	≤ 0.02 mmol/L
NOTE: This Table is made reference from EN 285, Table B.2	

XV. Calibration and Maintenance

36. Instruments used to control or monitor reprocessing equipment e.g. timers, gauges and temperature monitoring devices, shall be recalibrated regularly to prove their accuracy, at least annually and immediately prior to requalification (7).

37. Preventive maintenance should be carried out in accordance with device manufacturer's instructions for use by a qualified individual. Pay special attention to inspection, maintenance and replacement of components subject to normal wear and tear such as recording devices, filters, steam traps, drain pipes, valves and door gaskets (7).

38. Maintenance records should be kept for each piece of reprocessing device with essential information such as identity of the equipment, date and reason of maintenance or repair, details of the parts replaced, and name of person completing the work and releasing the device back to use. Supervisor of the facility or whoever deemed appropriate should be responsible for keeping the records of maintenance (7).

XVI. Education and Training

39. Comprehensive orientation and training for new, temporary and existing personnel accountable for reprocessing reusable medical devices should be offered to ensure awareness in the importance of reprocessing and assure proper implementation of such tasks (2,9).

40. All personnel should be qualified according to their grade of work.

Personnel should be supervised until competency is documented for each reprocessing procedure and competency should be assessed at initial employment and regularly afterwards (e.g. annually). Training record should be properly kept. Education, training and written instructions should also be given to the personnel whenever there are new devices and instruments (2,7,9-11,13-17).

41. Written policies specifying requirements for and frequency of education, training and competency assessment, procedures and work instructions for reprocessing activities should be offered at all times, which are reviewed regularly to guarantee compliance with scientific literature and manufacturers' instructions (2,3,5,7,9).

42. Personnel operating steam steriliser should attain a Class III, Class V or Class VI Certificate of Competency for Steam Receiver issued under the Boilers and Pressure Vessels Ordinance, Chapter 56 of the Laws of Hong Kong. All sterile processing personnel is recommended to be certified as a condition of employment and should maintain the certification throughout their employment (3).

43. Possible sterilisation failures that resulted in instrument recall should be monitored and assessed if supplementary training for the personnel involved or equipment maintenance is required (2). Personnel performance and capability to follow institution procedures should be evaluated regularly and, if deficit is detected, personnel should be retrained or the institution should pursue related human resources policies (17). Quality control program should be developed and maintained to strengthen performance and supervise reprocessing efficacy (6).

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