

# Disinfection and Sterilization of reusable medical devices in General Practice

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## Introduction

**Transmission of infection through reused medical devices is well documented.**

This bulletin provides general information about cleaning, disinfection and sterilization to assist those responsible for these functions in General Practice.

For the disinfection and sterilization of reusable devices to be effective, meticulous attention to detail is essential. Staff must be properly trained and equipped to perform these duties in a safe and responsible manner.

There is now a joint Australian/New Zealand Standard document (AS/NZS 4815:2001) that provides detailed information on the requirements for disinfection and sterilization of reusable items in office based practice. The AS/NZ Standard also details the requirements for sterilizing wrapped instruments.

Some portable steam sterilizers (bench top sterilizers) have a drying phase that is not associated with a vacuum. Without a vacuum, the drying inside the wrapping may be incomplete. The AS/NZ Standard stipulates that a drying phase is necessary for items that are to be stored as sterile packs. The contents of packs must be dry immediately on completion of the cycle. There is no accepted method for measuring the complete removal of steam remaining on the enclosed items, so the claim that a drying cycle without a vacuum is sufficient for 100% drying cannot be substantiated. If steam remains inside the package, then the process is compromised.

The British standard (BS 3970: Part 4: 1990) for transportable steam sterilizers states: **“The absence of a forced air removal stage and a post sterilization vacuum drying stage precludes the use of such machines for wrapped instruments or porous goods.”** Porous goods include dressings.

**Flexible endoscopes and heat sensitive equipment require special methods for sterilization. Readers should refer to the NZ Standards Guideline for Microbiological Surveillance of Flexible Hollow Endoscopes and the Australian Standards document AS 4187.**

## Cleaning

Cleaning is the removal of visible dirt, organic matter or other foreign material from an item. Cleaning is essential because the presence of organic material will negate the processes of disinfection and sterilization.

Cleaning is normally accomplished with water, mechanical action and detergents. Enzymatic products may be used in an initial step to help remove biological material.

There should be a designated area for cleaning with a dirty to clean workflow. The cleaning area should be designed to minimise contamination of the operator and surrounding environment. Protective clothing should be worn.

Instruments or devices that have come into contact with blood or body substances must be considered hazardous. Staff who clean such items must practise Standard Precautions to avoid exposure to pathogenic micro-organisms.

Items such as brushes that are used for cleaning are themselves a means of cross infection. They should be decontaminated daily by thorough cleaning or steam sterilization and stored dry.

Cleaning instruments should be a non-abrasive procedure.

Cleaning solutions should be within the pH range of 8 to 10.8, non-toxic, non-corrosive, non-abrasive, free rinsing and biodegradable. A material safety data (MSD) sheet needs to be held for each solution used. Standard detergents may damage some aluminium, plastic and rubber objects.

**When purchasing reusable items it is important that the supplier provides documentation regarding the cleaning requirements.**

**Suction tubing** is difficult to clean and single use tubing is often a safer option.

## Safety

Staff who clean used medical devices must be offered Hepatitis B virus vaccine. If instruments with faecal contamination are being cleaned then Hepatitis A virus vaccine must also be considered. If the staff member declines the offer, then both the offer and the response should be documented.

Staff should be provided with appropriate safety attire for protection from aerosols, splashes, and injuries from sharp objects. Plastic aprons and eye protection are important. Gloves should be thick, strong and water proof, i.e. thick household ones, not the thin disposable variety.

Reusable sharps must be placed in puncture resistant containers that conform to the appropriate standards: AS/NZS 4261 and AS 4031.

## The reprocessing of reusable medical devices is guided by the application of Spaulding's classification system. This is summarised below:

**Critical** items are those that enter sterile tissue, e.g. scalpels, needles and surgical instruments. They must be sterilized before they are reused.

**Semi-critical** items are those that touch mucous membranes or non-intact skin, e.g. thermometers. They should be subjected to either high or intermediate level disinfection.

**Non-critical** items are those that contact intact skin; e.g. stethoscopes, sphygmomanometer cuffs, ECG leads, bedpans and bench tops. Cleaning is usually sufficient for these items.

**High-level disinfection** kills all micro-organisms with the exception of high numbers of bacterial spores. The term is usually used when the process is achieved by means of a chemical agent. It is used for heat sensitive items that require a process that more or less guarantees sterility.

**Intermediate-level disinfection** kills all or most pathogenic micro-organisms except spores and some viruses. It is suitable for items such as endoscopes. Hypochlorites are the agents most commonly used for intermediate level disinfection.

**Low-level disinfection** is only effective against vegetative bacteria, e.g. *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Enterococcus* spp., and some viruses, e.g. HIV, HBV, herpes simplex, and respiratory syncytial virus (RSV).

Low-level disinfection is used for non-critical items in circumstances where there is an increased risk of transmitting an infectious agent, e.g. methicillin-resistant *Staphylococcus aureus*. Disinfection with chlorine based agents such as sodium hypochlorite, e.g. Domestos, and chlorhexidine with alcohol have been recommended. These agents must be used according to their manufacturers' instructions with attention to dilution/contact time requirements.

## Disinfection

Items to be disinfected must be completely clean. The level of microbial contamination, the temperature, and the exposure time may affect the performance of the disinfectant. The configuration of objects such as hinges or the presence of a lumen can prevent the penetration of the agent to all parts of the device.

Do not use any disinfectant that is not registered with the Therapeutic Goods Administration/Medsafe New Zealand.

Disinfectants are a widely divergent group of agents and must be used strictly in accordance with manufacturers' instructions. MSD sheets must be held for each disinfectant used.

**Thermometers** should be cleaned and then soaked in a disinfectant for the period recommended by the disinfectant manufacturer. Thermometers should be stored dry. Oral and rectal thermometers should be labelled as such and stored separately. Digital thermometers and tympanic mercury thermometers should be used with disposable eartips or sleeves.

**Nebulisers** should be dismantled and cleaned after use. Disinfection should be according to the manufacturer's instructions. If these are unavailable then the device should be dismantled, rinsed in hot water and then soaked in a disinfectant for the prescribed time and stored dry. Because of the possibility of transmitting *M. tuberculosis*, when a chemical agent is used, it must have a label claim for tuberculocidal activity.

### The inappropriate use of disinfectants.

Disinfectants usually require five to fifteen minutes contact time to kill micro-organisms. If a surface is wiped with a disinfectant and then dried immediately, the disinfectant is simply being used as a cleaning agent as there is not sufficient contact time for the agent to be effective. This is a waste of money and may promote disinfectant resistant bacteria.

A plain (non-antimicrobial) soap should be used for routine hand washing. Alcohol based hand rubs are an alternative that can be used when performing clean procedures. Hand creams and soaps that contain antimicrobial agents should only be used in specific circumstances such as during the control of outbreaks, periods of hyperendemic infections, for preoperative hand scrubbing, in neonatal units, in intensive care units and in settings where antibiotic resistant bacteria are endemic. Their use in other situations is inappropriate and may lead to bacterial resistance or allergy.

## Sterilization

Sterilization is the complete destruction of all forms of microbial life.

Sterilization of heat stable reusable items can be achieved by means of a portable steam sterilizer (bench top sterilizer). All surfaces to be sterilized must come into contact with saturated steam; the time required is dependent on the temperature. Dry heat sterilization requires higher temperatures for longer periods and is less commonly used. Chemical sterilization is prolonged high-level disinfection.

**There is a requirement in the AS/NZ Standards document that staff operating steam sterilizers in health care facilities require formal training.**

Training programs should cover the principles of disinfection and sterilization, infection control and correct cleaning procedures. There must be practical training on how to load and unload the machine. Incorrect loading can result in failure of sterilization, e.g. flat surfaces should be placed vertically so that moisture will drain off rapidly. Correct wrapping and packaging are important. Items must be wrapped in appropriate material and packed to allow adequate steam penetration.

The supplier's representative, who installs a portable steam sterilizer, will usually train current staff in its use. The information must be documented for new staff who are employed at a later date. If a new staff member is expected to operate the sterilizer and has had no formal training then it must be arranged. Seminars arranged by the College of Practice Nurses, Diagnostic Medlab, and medical supply companies will often cover the principles and practices associated with sterilization.

## Portable Steam (Bench Top) Sterilizers

**Models that have no vacuum drying cycle** are suitable for instruments intended for immediate use. These sterilizers are also suitable for items that require sterilization after use to prevent transfer of organisms between patients, but do not need to be stored or used in a sterile state, e.g. vaginal speculae.

Packaged items should not be sterilized in these machines because the wrapping and contents remain moist at the end of the cycle. Micro-organisms can immediately penetrate moist wrapping and render the items non-sterile.

Models that allow drying by keeping the door ajar are unsuitable for wrapped items because the dryness of the wrapping and contents cannot be assured.

**Bench top sterilizers with a vacuum cycle** are suitable for packaged items that are to be stored. The vacuum at the start of the cycle ensures that the steam will penetrate the wrapping and the vacuum at the end of the cycle will remove all moisture. Any items that are damp when removed from the sterilizer should be repacked and re-processed. In this situation it is also advisable to check the sterilizer's function and the packing method.

The temperature and time must be recorded at the end of each cycle and kept for future reference in case of suspected failure of sterilization.

**Note: neither of these sterilizer types is suitable for sterilizing liquids.**

## Validation

All bench top sterilizers require regular validation by a trained and certified person. This should be carried out every 6 to 12 months according to the manufacturer's recommendation.

The validation process includes checking that all the gauges are accurate and that the timing of the cycles is within defined limits. Drains, gaskets, filters, switches, lights, etc. are checked. The machine must be tested using packs and biological indicators.

Biological monitors (spore strips) are only required as part of the calibration and validation processes and do not need to be used routinely, unless the pack size or type is altered. However when multiple operators use the sterilizer or there is variation in the number and type of pack being sterilized it is reasonable to monitor the process with a biological indicator at regular intervals, e.g. weekly.

**Note: A chemical indicator, e.g. 'Test Tape', should be used on the outside of each pack with every load and with each container of unwrapped instruments. The indicator shows that a certain temperature has been reached but does not indicate for how long. It does not, therefore, indicate sterility.**

## Documentation

There must be written instructions for the person using the sterilizer. All those using the sterilizer should sign and date the instructions to show that they have read and understood them.

The operational manual should specify the dangers relating to the use of the machine: it is dangerous to open the door before the pressure is down to atmospheric and it is important to wear heat resistant gloves when removing hot contents.

Maintenance and validation records must be stored. Items must be labelled with the date of sterilization and the batch number.

## Packaging of items

Packaging and wrapping of items for sterilization must maintain sterility of the contents.

The materials used must permit removal of air and penetration of steam during the sterilization process. Unsuitable materials for wrapping include polyethylene film, aluminium foil, nylon and sealed metal or glass containers.

The materials used and the size of the pack must allow the contents to be dry immediately on completion of the sterilizing cycle. If the contents are wet, sterility is compromised and the pack should not be used.

## Storage of cleaned and sterile items

The storage drawer or cupboard must be kept secure to prevent unauthorised tampering and to ensure that items are kept dry. Splashes, droplets of water, or steam exposure onto the surface of the packing will compromise the sterility of the contents.

The cupboard itself must be kept clean and free from vermin such as ants or other insects.

## References

Australian/New Zealand Standard: AS/NZS 4815:2001. Office-based health care facilities not involved in complex patient procedures and processes-Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of the associated environment. Standards Australia. Standards New Zealand. 2001.

This standard can be purchased from Standards New Zealand, Private Bag 2439, Wellington 6020, or from their web site [www.standards.co.nz](http://www.standards.co.nz)

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