

Infection prevention and control guidelines

Reprocessing reusable medical devices

Transition period notice

This document contains the RACGP reprocessing guidance that applied prior to the publication of the updated reprocessing guidance aligned with AS 5369:2023.

A transition period applies until **1 January 2028**. During this period, practices may continue to follow the guidance in this document while preparing to implement the updated reprocessing requirements.

The current reprocessing guidance is available online at: <https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-of-reusable-medical-devices-and-ot/overview-reprocessing-reusable-medical-devices>

Practices are encouraged to commence transition planning as early as possible to ensure implementation by **1 January 2028**.

10. Reprocessing reusable medical devices

Overview – Reprocessing reusable medical devices

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Reusable medical devices that require reprocessing to achieve the required level of asepsis (standard or surgical) include surgical instruments, medical devices, and other equipment.

Practices can choose to reduce the volume of medical devices that require reprocessing by replacing some or most categories with disposable alternatives. However, practices need to be mindful of their environmental impact and to reduce waste, reprocess and correctly recycle where practical to do so.

Practices that reuse medical devices that require sterilisation, such as surgical instruments, can choose either to do all reprocessing on site, or outsource to an off-site provider (eg hospital) for sterilisation. Reprocessing of items that require sterilisation should only occur within the practice if the [current relevant standard \(https://store.standards.org.au/product/as-5369-2023\)](https://store.standards.org.au/product/as-5369-2023) can be met.

For each reusable medical device, practices need to check information provided by the manufacturer on the validated processes for cleaning, disinfection, packaging (if required), and sterilisation.

Practices must ensure that staff involved in reprocessing have received adequate education (eg a course), training and regular competency assessment, and that these are documented.

Practices should have a designated area for processing reusable medical devices, and must establish a workflow pattern that prevents the packaging, sterilisation and storage areas becoming contaminated. This involves systematically moving from 'dirty' to 'clean' within the designated area. The reprocessing area must be segregated from treatment and administration areas. Ideally, there is a dedicated room for reprocessing. In shared spaces, a practice could demonstrate what physical methods or barriers they use for segregation of reprocessing activities (eg locating the patient bed away from the sterilizing area, not processing equipment while the treatment room is occupied by patient/s).

Personal protective equipment must be worn during reprocessing, and may require changing between stages.

Immediately after use, reusable medical devices should be initially wiped/rinsed to remove visible soiling, then thoroughly cleaned in the equipment reprocessing area before sterilisation. This process can involve:

- manual cleaning
- the use of an ultrasonic cleaner followed by manual cleaning, or
- the use of a washer/disinfector that may incorporate an ultrasonic cycle.

Ultrasonic cleaners and washer/disinfectors require performance monitoring and validation. Ultrasonic cleaners and washer/disinfectors are not mandatory. They are an optional precleaning step. If an item cannot be cleaned, it cannot be further processed or reused.

Steam under pressure is the most reliable method for sterilising cleaned reusable medical devices, and is recommended in general practices and other office- and community-based practices.

Using the correct sterile barrier system (pack, pouch, wrap or rigid container) for each item or set of items is important to ensure that they are effectively sterilised and remain sterile. Packages for sterilising should be labelled to enable monitoring, appropriate stock rotation, and other affected items to be identified if a problem with a processed item is later discovered.

Correct loading of the steriliser is important to ensure air is removed and steam can penetrate the load. The correct processing and drying times must be used, according to the load to be sterilised. Correct handling of the sterile load when it is taken out of the steriliser is vital to ensure items remain sterile. If an item contained in a sterile barrier system emerges from the steriliser wet or damaged in any way, it cannot be considered sterile. Correct storage of sterilised packs is also vital.

Every time the steriliser is used, the process must be documented for quality assurance and review purposes.

Routine monitoring of every sterilisation cycle is required to check that the selected cycle parameters (including time, temperature, and pressure) are met. These must be recorded as evidence that the cycle has achieved sterilising conditions.

Chemical indicators are used in addition to physical monitoring, to provide evidence that the load has reached the correct temperature.

Regular routine maintenance is required for all reprocessing equipment, including sterilisers, ultrasonic cleaners, washer-disinfectors with or without ultrasonic capacity, drying cabinets and incubators, and biological indicator readers.

Validation of steriliser cycles must be performed annually and as needed (eg after any major repairs and if the practice changes the type of loads sterilised).

Practices that perform procedures in other locations, such as aged care facilities, home visits and at sporting events, must develop policies and procedures to ensure sterility of equipment during transport, and safe handling of used equipment, including correct pre-cleaning/treatment immediately after use.

Choosing whether to reprocess or use disposables

Choosing whether to reprocess or use disposables

Single-use disposable alternatives are now available for most categories of medical devices that were traditionally reprocessed (cleaned, disinfected and/or sterilised).

The practice's policy on whether to use disposable or reusable medical devices could be determined based on a thorough analysis of factors including risk of contamination and costs (including labour for reprocessing, as well as unit costs), and optimal use of staff time ([Table 10.1. Simple cost-benefit analysis framework for single-use disposable versus reusable medical devices \(#10.1\)](#)).

Table 10.1. Simple cost-benefit analysis framework for single-use disposable versus reusable medical devices  [Download the simple cost-benefit analysis framework for single-use disposable versus reusable medical devices document \(https://www.racgp.org.au/getmedia/116df486-42fa-4aca-a0ad-3edea37d9b60/RACGP-Template-Cost-benefit-analysis-framework-for-single-use-disposable-versus-reusable-medical-devices.docx.aspx\)](https://www.racgp.org.au/getmedia/116df486-42fa-4aca-a0ad-3edea37d9b60/RACGP-Template-Cost-benefit-analysis-framework-for-single-use-disposable-versus-reusable-medical-devices.docx.aspx)

Item	Number used (per day/ week)	Options	Unit cost	Waste	Associated costs	Labour costs	Power and water	Maintenance (steriliser etc)
Ear speculum		Disposable						
		Reusable						
Ear syringe/ pulse/ suction and parts		Disposable						
		Reusable						
Sterile vaginal speculum		Disposable						

Item	Number used (per day/ week)	Options	Unit cost	Waste	Associated costs	Labour costs	Power and water	Maintenance (steriliser etc)
		Reusable						
Dressing pack with forceps		Disposable						
		Reusable						
Spacer		Disposable						
		Reusable						
Artery forceps		Disposable						
		Reusable						
Forceps		Disposable						
		Reusable						
Scissors		Disposable						
		Reusable						
Excision sets		Disposable						
		Reusable						
Scalpel handles		Disposable						

Item	Number used (per day/ week)	Options	Unit cost	Waste	Associated costs	Labour costs	Power and water	Maintenance (steriliser etc)
		Reusable						

Waste: include waste removal costs

Associated costs: include materials used in packaging for sterilisation, other steriliser-associated costs

Labour costs: Include staff time performing reprocessing tasks, supervisor time training staff, costs of training courses

Source: Marjen Education Services. Adapted with permission.

Policies and procedures

Policies and procedures

If a practice reprocesses reusable medical devices onsite or offsite, it must have policies and procedures describing every aspect of instrument and equipment reprocessing, in accordance with the [current relevant standard \(https://store.standards.org.au/product/as-5369-2023\)](https://store.standards.org.au/product/as-5369-2023).

These are guided by:

- assessment of the probability of harm to a patient and the likely seriousness of the harm
- feasibility considerations
- instructions for use by manufacturers of reusable medical devices and manufacturers of reprocessing equipment.

Single-use items must not be reprocessed.

Risk assessment

Risk assessment

The practice's infection prevention and control coordinator must ensure the level of processing for specific reusable medical devices and equipment is appropriate to the risk of infection posed by their reuse.

Risk assessment is based on the Spaulding classification¹ ([Table 10.2. Spaulding classification \(#10.2\)](#)). The site of use (eg intact or non-intact skin, mucous membranes, sterile sites such as surgical wounds) is a key determinant of the level of risk to the patient.

Table 10.2. Spaulding classification – application to reusable medical devices

Classification	Examples	Process	Storage
Critical Contact with sterile tissue, sterile cavity, or bloodstream	Surgical instruments used for excision Podiatry instruments used to penetrate or abrade skin (nail cutters, scalers, files) Sharps used in neurological testing	Sterilisation by steam under pressure (autoclaving)	Sterility must be maintained Integrity of the package must be maintained Must be protected from environmental contamination
Semi-critical Contact with intact nonsterile mucosa or nonintact skin	Vaginal speculum used for routine cervical sampling Instruments used in wound care (eg forceps, scalpel handles, scissors)	Sterilisation by steam under pressure	Must be protected from environmental contamination
Noncritical Contact with intact skin	Stethoscope Plastic* cuff on sphygmomanometer Pulse oximeter Auroscope	Cleaning with detergent or Cleaning and disinfection with low-level disinfectant	Storage in clean, dry place

*Fabric sphygmomanometer cuffs cannot be cleaned.

Summary of steps in reprocessing medical devices that require sterilisation

Summary of steps in reprocessing medical devices that require sterilisation

For items that require sterilisation, reprocessing involves ([Table 10.3. Summary of steps for processing reusable medical devices \(#10.3\)](#)):

- initial treatment (wiping or rinsing immediately after use, at the point of use)
- collection and transportation to the reprocessing area
- pre-cleaning using an ultrasonic cleaner (if the practice has one)
- cleaning (manual scrubbing followed by rinsing and drying, or processing in an automatic washer/disinfector with or without an initial ultrasonic cycle)
- inspection and packaging
- sterilisation.

Packaging and sterilisation steps include:

- packaging items for sterilisation in an appropriate covering material ('sterile barrier system'; pouches, packs, wraps, or rigid containers), using correct materials and technique
- using appropriate indicators in or on every load to identify packs that have been through the steriliser
- labelling packs
- loading the steriliser
- running the cycle
- unloading the steriliser
- before releasing the load for use, checking the printout or data logger to verify that the correct heat, time and pressure parameters were attained for the cycle
- recording the name of the person who loaded the steriliser, the load description and load number, results of cycle monitoring, unloading, pack condition (dry, intact seals, chemical indicators show correct colour change), date and signature of staff member authorising release of the load for use or rejection of the load (with details of the issues causing the rejection, where appropriate), and process abnormalities detected (and corrective action, where appropriate)
- storage, distribution and handling of sterilised packs to the point of use
- daily, weekly and annual steriliser cleaning and maintenance
- annual servicing, calibration and validation.

Regular routine maintenance also is required for all other reprocessing equipment, including ultrasonic cleaners, washer-disinfectors with or without ultrasonic capacity, drying cabinets, heat sealers, incubators, and biological indicator readers.

To achieve consistently reliable sterility, the practice must set up a comprehensive sterility assurance program incorporating every aspect of reusable equipment processing, including staff education, to avoid common errors ([Table 10.4. Common reprocessing errors \(#10.4\)](#)).

Table 10.3. Summary of steps for processing reusable medical devices

Initial treatment (http://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/initial-treatment-at-point-of-use)	Remove visible soiling by damp or dry wiping at point of care (eg in consulting or treatment room). Transport to reprocessing area.
Pre-cleaning (http://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/cleaning-processes-before-sterilisation)	Run ultrasonic cleaner cycle (optional) followed by rinsing (before manual cleaning). ⚠ Items should not be left in detergent solution for later cleaning
Cleaning (https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/cleaning-processes-before-sterilisation)	Manually clean items OR Run a washer–disinfector cycle. ⚠ Use personal protective equipment

Rinsing and drying (https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/rinsing-and-drying-after-manual-cleaning) (required after manual cleaning or ultrasonic cleaning)	Note: Rinsing and drying is not required after cleaning with an instrument washer–disinfector Rinse in designated 'clean' sink. Drain on clean surface. Dry manually or in drying cabinet. ⚠ Wear clean latex-free gloves (eg utility gloves or nitrile chemically resistant examination gloves) while drying
Preparing the load for sterilising (https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/preparing-the-load-for-sterilising)	Check items are clean, intact and functioning. Select packaging of appropriate size – to match the item or set of items to be sterilised. Ensure each package has Class 1 chemical indicator incorporated into its surface. Seal the package – ensure there are no gaps through which air can enter and contaminate the contents. Label packages (date, load number and, if required, description of contents, and the signature of person responsible for packing).
Loading the steriliser (https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/loading-the-steriliser)	Place items in steriliser: • Items that could collect condensate are placed on their sides • Packages are separated to facilitate air removal, steam penetration and drying. Trays are loosely loaded with a single layer of packs per tray, within the boundaries of the loading tray. • Ensure that no pack touches the chamber wall. • Do not exceed the validated challenge load parameters – check validation record. Enter description of contents into the logbook.

Running the sterilisation cycle (https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/running-the-sterilisation-cycle)	Check water level – add if necessary (follow manufacturer’s instructions for use). Choose correct cycle (if steriliser has multiple cycles). Select correct cycle parameters (if steriliser validated for multiple load types) – check validation record. Enter required details in steriliser logbook (date, load description and load number, name of the person who prepared the load). Close door and start steriliser cycle. ⚠ Do not attempt to open the steriliser door while the cycle is in operation.
Unloading the steriliser (https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/unloading-the-steriliser)	⚠ Do not attempt to open the steriliser door while the cycle is in operation. When the cycle is completed: 1. Check the physical parameters 2. Remove trays using tray lifter or heat-resistant gloves – do not touch packages while hot 3. Place trays on drying surface – allow to cool for minimum of 30 minutes 4. With clean hands, check cooled packages for class 1 indicator pass and for moisture or damage. Classify load as PASS or FAIL.
Documenting the cycle (https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/documenting-reprocessing-including-steriliser-cycle)	Record details in the steriliser logbook (in addition to previously recorded details): • confirmation that Class 1 chemical indicators changed colour • results of any other indicators used (eg chemical or biological) • correct time, temperature and pressure was achieved • condition of the packs (ie dry and intact) • comments (eg action taken for failed cycle) • name of the person who released the load.

Storing sterilised equipment (https://www.racgp.org.au/runni-ng-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/storing-sterilised-equipment)	When cool, store sterilised packs in clean enclosed storage area. Only handle packs with clean hands. Rotate stock so that items sterilised earlier are used first.
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TGA: Therapeutic Goods Administration

Table 10.4. Common reprocessing errors

Inadequate instrument cleaning leaving debris Incorrect choice of packaging material type Too many items in package Excessive wrapping material used on package Overloading of steriliser Inadequate maintenance of steriliser Use of sterilisation equipment not registered by the Therapeutic Goods Administration for the purpose

Staff education, training and competency assessment

Staff education, training and competency assessment

Correct reprocessing of reusable medical devices to minimise the risk of infection transmission requires technical expertise and knowledge. Practices must ensure that staff involved in reprocessing have received adequate education (eg a course), training and regular competency assessment, and that these are documented.

It is essential that staff responsible for reprocessing reusable equipment completely understand the tasks, know exactly how to perform all steps (and have immediate access to clear and comprehensive instructions), and can be relied on to follow them completely. Responsibility for reprocessing tasks must not be delegated to administrative staff or other staff without first providing adequate initial and ongoing training.

Courses on these techniques are available from education providers. Additional education and retraining need to be provided when new procedures or equipment are introduced. The Sterilizing Research Advisory Council of Australia provides a [list of sterilising courses \(https://www.fsraca.org.au/sterilizing-courses-available-in-australia/\)](https://www.fsraca.org.au/sterilizing-courses-available-in-australia/) available in all states and territories.

Regular competency checking can be performed onsite as part of ongoing training, to ensure consistency of performance.

Tasks that require competency assessment include:

- correct application of standard precautions, including hand hygiene and personal protective equipment
- cleaning of equipment and the reprocessing area, correctly following the practice's protocols (including cleaning products, cleaning equipment and cleaning methods)
- adherence to workflow protocols in the reprocessing area to avoid cross-contamination
- correct inspection and packaging of reusable medical devices and equipment
- correct loading of the steriliser
- choosing the correct sterilisation cycle
- monitoring and recording the sterilisation cycle
- unloading the steriliser
- parameters for releasing reusable medical devices and equipment for reuse
- correct storage of equipment and reusable medical devices
- tracking of sterilised items used in procedures
- rotation of sterile stock
- detecting abnormalities in the process, recording them, and taking appropriate corrective action
- steriliser cleaning and maintenance requirements (daily, weekly, monthly, quarterly and annual maintenance, annual calibration and servicing, validation)

- cleaning and maintenance requirements for all other reprocessing equipment including ultrasonic cleaners, washer-disinfectors with or without ultrasonic capacity, and biological indicator readers
- following the practice's procedures for steriliser operation and maintenance.

Initial treatment at point of use

Initial treatment at point of use

Initial treatment of reusable medical devices must occur immediately after use at the point of use. This generally involves wiping with damp or dry low-lint or lint-free disposable cloth (eg non-woven gauze) to remove visible soiling, or treatment with a TGA-registered instrument precleaning product, if necessary.

Devices should then be safely transported to the reprocessing area in a cleanable, sealable, puncture- and leak-resistant container dedicated to that purpose.

If cleaning must be delayed, items that have undergone initial treatment to remove visible soiling may be held in a suitable labelled container, covered with a TGA-registered instrument precleaning product that is suitable for metals and plastics, for up to the maximum time specified in the manufacturer's information for use.

 **Items should not be left in detergent solution for later cleaning**

Managing the area for reprocessing for reusable medical devices

Managing the area for reprocessing for reusable medical devices

The reprocessing area must be in a low-traffic area of the practice. It must be set aside for this purpose and not also used for linen or waste processing, or storage of any supplies except personal protective equipment and consumables required for these tasks.

Within the reprocessing area, no materials or equipment may be left out and nothing should be stored on benches or floors. Any materials in the area can contaminate items for reprocessing (eg cardboard boxes can shed paper fibres).

Ideally, a reprocessing area is fitted with a type B handbasin.

One or more (as required) alcohol-based handrub dispensers could be installed on the wall adjacent to the bench areas where reprocessing is done, but not directly over the work area.

For information on the design requirements of sinks and benches, see [12. Planning a practice: design, fit-out, equipment and consumables](https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/12-planning-a-practice-design-fit-out-equipment-an/overview) (<https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/12-planning-a-practice-design-fit-out-equipment-an/overview>).

Workflow planning

It is essential to establish a workflow pattern systematically moving from designated 'dirty' to designated 'clean' zones within the dedicated processing area. A one-way workflow will ensure that dirty reusable medical devices do not come into contact with clean reusable medical devices.

Designating purposes of sinks

The equipment processing area should have two sinks: one designated 'dirty' (for washing used reusable medical devices) and the other designated 'clean' (for rinsing the washed reusable medical devices).

If this is temporarily not possible (eg while refitting the room), a rinsing sink and a separate washing bowl can be used. Avoid routine use of a washing bowl in place of designated sinks.

The reprocessing sinks must never be used for:

- washing hands
- disposing of wastewater from cleaning

- disposing of leftover beverages
- laundering
- washing dishes.

After each reprocessing session, all sinks and fixtures (and the immediate area, including splashback and benches) must be cleaned with water and detergent, then dried.

See also [12. Planning a practice: design, fit-out, equipment and consumables \(https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/12-planning-a-practice-design-fit-out-equipment-an\)](https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/12-planning-a-practice-design-fit-out-equipment-an).

Work benches

Packaging items for sterilisation must take place in the 'clean' zone, away from the 'dirty' zone and drying zone, with adequate space or a physical barrier to minimise contamination.

Equipment, activities and sub-zones within the designated 'clean' zone include:

- the holding area for reusable medical devices awaiting sterilisation (before the steriliser)
- the steriliser
- the cooling area for packages unloaded from the steriliser.

The bench top must be cleaned and dried between uses. Any containers in the area need regular wiping to remove dust. There should be no open shelves with materials that can accumulate dust.

Hand hygiene

Within the reprocessing area, hand hygiene must be performed:

- before putting gloves on
- when moving from 'dirty' to 'clean' areas
- after handling soiled equipment
- after removing gloves
- before opening the steriliser
- before handling or packaging clean items
- before handling sterilised packs.

Appropriate gloves must be worn at all times when handling contaminated reusable medical devices. For example, latex-free, puncture resistant, chemical-resistant utility gloves (preferably longer cuffed).

Alcohol-based handrub should be readily available and accessible in all work zones within the reprocessing area.

Hand cream must not be used when performing reprocessing, because it can contaminate instruments or compromise the integrity of packaging.

Cleaning agents and other materials used in reprocessing

Detergents

If cleaning is delayed, pre-treated items can be held in a labelled container for a short, pre-specified  time, covered with a TGA-registered instrument precleaning product that is suitable for metals and plastics.

Items should not be left soaking in detergent solution for later cleaning because bacteria can multiply at room temperature, leading to excessive contamination, and due to splash risk.

Cleaning agents used in reprocessing reusable medical devices must be:

- listed in the Australian Register of Therapeutic Goods
- suitable for the reusable medical devices being processed and the selected method of cleaning (eg non-abrasive and non-corrosive)
- diluted and used in accordance with the product's instructions
- compatible with the available water quality
- non-toxic at the specified dilution
- low-foaming
- free-rinsing.

For example, a mildly alkaline, free-rinsing, low-foaming, biodegradable liquid instrument-grade detergent can be used.

Avoid:

- abrasive cleaners such as steel wool, domestic cleaning powders and pastes, as these may damage the surfaces of reusable medical devices or leave a residue
- strongly alkaline detergents for manual cleaning. Although these are more effective, they are caustic and are only safe for use in washer disinfectors
- chlorine-based products such as bleach, as they can corrode and rust reusable medical devices and sterilisers
- normal household detergents, as they are generally high foaming and often leave a film that is hard to rinse away and could harbour microorganisms. High-foaming detergents increase risk to staff injury because they make items more difficult to see when washing, and can generate aerosols.

Enzymatic detergents are rarely used in general practice and other office-based practices. These are usually used in automated processes and reserved for lumened instruments with internal surfaces that are difficult to access, such as endoscopes.

Brushes

Clean brushes of various sizes, with firm plastic bristles capable of withstanding cleaning agents, should be kept in the cleaning area for use during the cleaning stage.

Reusable brushes must be reprocessed after each use to reduce cross-contamination and biofilm formation. They can be manually cleaned (if the practice does not have a washer-disinfector) and sterilised, or mechanically cleaned and heat disinfected in a washer-disinfector at the end of each working day. Ultrasonic cleaners are generally not suitable for plastics.

Where reusable validated cleaning brushes for instrument cleaning are used, reprocess them in accordance with the manufacturers' information for users.

Thin disposable brushes (eg cytology brushes) are useful to clean items with lumens, holes or valves. These cannot be reprocessed.

Cloth/paper for drying

Residual lint on instrument surfaces must be avoided because it could cause a foreign body reaction in a patient tissue.

If the practice does not use an automatic washer/disinfector with drying cycle or a drying cabinet, drying must be performed using a reusable lint-free cloth or a disposable low-lint cloth.

If reusable lint-free cloths are used, they must be correctly laundered in accordance with the [current relevant standard \(https://www.standards.org.au/standards-catalogue/sa-snz/manufacturing/tx-016/a-s-slash-nzs-4146-2000\)](https://www.standards.org.au/standards-catalogue/sa-snz/manufacturing/tx-016/a-s-slash-nzs-4146-2000) for laundering of healthcare linen (see [9. Cleaning, laundry and waste management \(https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/9-cleaning-laundry-and-waste-management/overview\)](https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/9-cleaning-laundry-and-waste-management/overview)), following a protocol that ensures they are not exposed to dust or contamination while drying.

Disposable kitchen wipes, paper hand towel or tea towels must not be used because they leave a large amount of lint.

Cleaning processes before sterilisation

Cleaning processes before sterilisation

Effective cleaning to remove all organic matter and other soiling is essential for ensuring successful sterilisation. If items to be sterilised are not cleaned thoroughly, adherent soiling can protect microorganisms from the action of the sterilisation cycle. If any matter is allowed to dry or harden on the item, the cleaning process will be more difficult and may be compromised. If an item cannot be cleaned due to its shape (eg narrow lumen), effective sterilisation cannot be guaranteed.

The sequence before sterilising involves initial treatment (above), optional pre-cleaning using an ultrasonic cleaner, then cleaning in an automatic dishwasher–disinfector (best practice) or by manual cleaning (not best practice). Some automatic dishwasher–disinfectors include an initial ultrasonic cycle ([Table 10.5. Advantages and disadvantages of washing and drying devices used in reprocessing of reusable medical devices \(https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/rinsing-and-drying-after-manual-cleaning#10.5\)](https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/rinsing-and-drying-after-manual-cleaning#10.5)).

⚠ Manual cleaning is no longer acceptable as a method of pre-cleaning before sterilisation, except where specified by the manufacturer of a reusable medical device. Manual cleaning should only be used for pre-treatment before using a washer-disinfector, or if the practice does not yet have a washer-disinfector.

Pre-cleaning with ultrasonic cleaners

Ultrasonic cleaners pass ultra-high frequency sound waves through water, creating microscopic bubbles which implode, causing high-energy vacuum and movement (cavitation). Cavitation pulls dirt and contaminants from the surfaces of the items being cleaned. Therefore, before packaging for sterilisation, items must immediately be thoroughly cleaned after the cycle to avoid redepositing of matter, either by thorough rinsing followed by manual cleaning (including scrubbing), or using a washer-disinfector (if the practice's washer-disinfector does not provide an ultrasonic cycle).

Ultrasonic cleaners are efficient and effective in pre-cleaning, but they are not suitable for all items as they may damage some materials (eg soft plastics, rubber, metallic instruments with poor-quality chromium plating, and mirrors). Check the manufacturer's instructions for each reusable medical device.

Ultrasonic cleaners are used for delicate instruments, difficult-to-clean instruments such as jointed and serrated stainless steel instruments.

Ultrasonic cleaners are not suitable for cleaning:

- internal surfaces of cannulated reusable medical devices
- plastics and other similar materials
- cemented glass syringes
- mirrors and lenses (these will be damaged if repeatedly subjected to this process)
- fine-pointed reusable medical devices (the vibration caused by the process can blunt fine points).

Method

When using ultrasonic cleaners:

- operate according to the manufacturer's instructions
- items with gross residual soil must first be dry-wiped, damp-wiped, or rinsed in warm water before immersion into the ultrasonic cleaner
- items must form only one layer in the machine – they must not be placed on top of other items and the basket must not be filled
- the solution must be changed before the next use if it has become cloudy.

After removing items, they must be cleaned using one of the following methods:

- Place in an automatic instrument [washer–disinfector \(#auto\)](#)
- Rinse under running warm water and then scrub manually (see [manual cleaning \(#_Manual_cleaning\)](#)). Wear an apron or gown and face shield during rinsing.

Maintenance monitoring of ultrasonic cleaners

Testing of the ultrasonic cleaner is required every day. This involves filling and degassing according to the manufacturer's instructions. Degassing is necessary after each fill, before instruments are processed.

The use of commercially available validated cleaning verification products is recommended. These use a colour change to indicate that the ultrasonic cleaner is supplying sufficient energy and conditions are correct. Alternative non-validated methods, such as the aluminium foil test or pencil test, are complicated and difficult to perform correctly.

The machine must be emptied, degassed, cleaned and dried at the end of each day of use, in accordance with the manufacturer's instructions for use.

Practices that use ultrasonic cleaners must refer to the manufacturer's instructions.

Record testing, solution changes and degassing in a log.

Washer–disinfectors

The use of automatic washer-disinfectors to clean reusable medical devices before sterilising is now considered to represent best practice, in preference to manual cleaning or ultrasonic cleaning.

Automatic washer–disinfectors use high temperatures and alkaline detergents to clean reusable medical devices. They clean and disinfect (by heat), but do not sterilise.

Their use is preferable to manual cleaning because the process can be validated by objective measures of temperature reached, time at temperature, and cleaning parameters. It also avoids operator contact with contaminated solutions and sharps.

Items that have been subjected to a washer-disinfector cycle do not require further rinsing and drying before being packaged for the steriliser.

Small benchtop or under-bench models are suitable for general practice. Cycles typically take 35–50 minutes.

Practices that use washer disinfectors must refer to the manufacturer's instructions for their appropriate use.

Washer-disinfector cycles must be monitored to ensure that the required variables have been achieved. If not, the load must be failed and the items reprocessed before a steriliser cycle.

Washing/drying devices need regular servicing, maintenance, calibration and validation.

Domestic dishwashers, while similar, are not suitable for washing reusable medical devices and must not be used for this purpose.

Manual cleaning

⚠ When handling soiled devices, staff must use personal protective equipment, including long-cuffed, chemically resistant gloves, eye protection (eg full face shield), and apron/gown, as appropriate.

It is not appropriate to limit pre-cleaning to manual cleaning, unless validated instructions provided by the manufacturer of a reusable medical device specifies this (eg for a very delicate item that cannot be machine-cleaned). Automatic cleaning is recommended as best practice. Manual cleaning should only be used for pre-treatment before using a washer-disinfector, or if the practice does not yet have a washer-disinfector.

Manual cleaning involves the following steps:

- Fill the designated 'dirty' sink or bowl with warm water and dilute instrument-cleaning detergent.
- Scrub all used devices (even those not visibly soiled) under the surface to reduce generation of aerosols.

Rinsing and drying (after manual cleaning)

Rinsing and drying (after manual cleaning)

 **Note:** This step is not required after cleaning with an instrument washer–disinfector

Rinsing and drying after manual cleaning involved the following steps:

- In the designated ‘clean’ sink, rinse all devices in gently running warm-to-hot running water.
- Drain on a suitable clean surface (eg a corrugated insert in a container with a lid, or low-lint towel) but do not allow to air-dry.
- Wearing clean latex-free gloves (eg utility gloves or nitrile chemically resistant examination gloves), dry with a disposable lint-free or low-lint cloth or place in drying cabinet.
- Check that all items are clean, intact and functioning.

If the next step (steriliser cycle) is delayed, place cleaned and dried items in a clean (nonsterile), labelled, sealable container and store it where it cannot be accidentally used. Items can remain safely stored indefinitely, provided that recontamination is prevented.

Table 10.5. Advantages and disadvantages of washing and drying devices used in reprocessing of reusable medical devices

	Advantages	Disadvantages
Ultrasonic cleaners	Clean surfaces and cavities without scratching, brushing or scraping Time-efficient (short cleaning times) Reduce the work health and safety hazards of instrument cleaning by staff, compared with manual cleaning Very simple and easy to use May require lower concentrations of chemicals than conventional cleaning Smaller models are inexpensive	Unsuitable for some reusable practice equipment Less time-efficient for large loads (require longer cleaning times due to energy absorption) Large, heavy items can cause poor cleaning due to 'shadowing' effect Immediate rinsing required after cycle ends before debris resettle on items, followed by cleaning (unless ultrasonic pre-cleaning followed by washer-disinfector cycle) Solution must be changed if it becomes cloudy Verification of cleaning effectiveness using validated cleaning verification products is recommended Machine must be emptied, degassed, cleaned and dried at the end of each day of use or more frequently
Automatic washer-disinfectors	Clean, disinfect and dry items ready for packaging and sterilisation Process can be validated Reduce the work health and safety hazards of instrument cleaning by staff, compared with manual cleaning (no splash, less handling) Manual drying not necessary	Expensive to purchase, run and maintain Cycles can take up to approximately 1 hour Requires validation Requires soil test
Automatic washer-disinfectors with ultrasonic cycle	Pre-clean, clean, disinfect and dry items ready for packaging and sterilisation Process can be validated Reduce the work health and safety hazards of instrument cleaning by staff, compared with manual cleaning (no splash, less handling) Manual drying not necessary	Expensive to purchase, run and maintain Long cycles Requires validation Requires soil test

Sterilisers

Sterilisers

In general practices and other office- and community-based practices, sterilisation of instruments should be achieved by steam sterilisation under pressure (autoclaves). Other sterilisation systems that use dry heat, ionising radiation, ethylene-oxide, peracetic acid or hydrogen peroxide plasma sterilisation are not generally applicable due to cost, size or complexity.

Routine cycle monitoring and validation are required for all sterilisers to ensure they are performing correctly. The practice must also ensure that the steriliser is operated and maintained according to the practice's documented procedures, based on the manufacturer's instructions.

Under Therapeutic Goods Administration regulations, all new devices sold in Australia must perform the essential functions of their intended purpose. Practices must only use a steriliser model with an Australian Register of Therapeutic Goods certificate. Older sterilisers without certification should be replaced.

Steam sterilisers are classified according to the type of cycles they perform (class N, S or B). Dry-heat sterilisers must no longer be used.

Benchtop steam sterilisers (autoclaves)

Steam under pressure kills/inactivates organisms on the surfaces of the reusable medical equipment by using the latent heat of condensation to coagulate protein. The use of steam under pressure is the most reliable method for sterilising cleaned reusable medical devices.

Steam sterilisers are recommended as the method of choice for sterilisation of items in general practices and other office- and community-based practices.

Benchtop and portable sterilisers sold in Australia must be listed on the Australian Register of Therapeutic Goods. Sterilisers must also comply with state or territory regulations.

'Small steam sterilisers' are benchtop (portable) sterilisers that are unable to accommodate a sterilisation module and have a chamber volume of less than 60 litres. 

Steriliser classification

Sterilisers are classified according to the types of cycles they can run ([Table 10.6. Steriliser types \(#1 0.6\)](#)). Some sterilisers can run more than one type of cycle.

Class S cycles

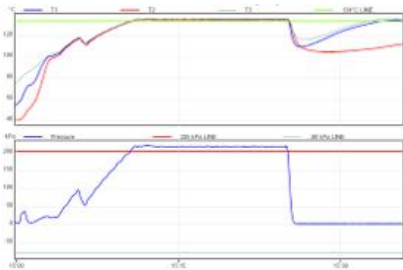
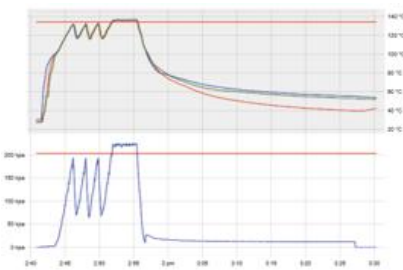
Class S cycles are defined as those provided by sterilisers that have an active drying cycle and are capable of sterilising unwrapped solid goods and at least one of the following:

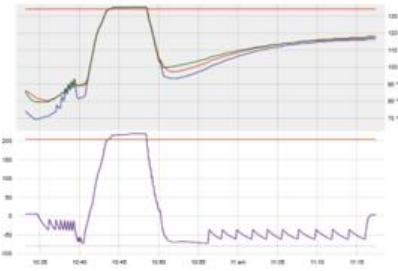
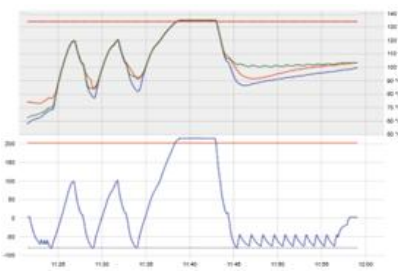
- porous products (limited/no relevance to office-based practice)
- small porous items (such as gauze swabs; limited relevance to office-based practice)
- narrow-lumen (hollow A) items: long, thin hollow items – these are not sterilisable by most sterilisers that provide Class S cycles and are generally reprocessed using a Class B cycle
- simple hollow items (hollow B): shorter hollow items such as punch biopsy tips
- single wrapped products
- multiple wrapped products.

The use of Class S cycles is adequate for most general practices and other office- and community-based practices. Various steriliser designs can provide Class S cycles ([Table 10.6. Steriliser types \(#1 0.6\)](#)).

Gravity (downward displacement) sterilisers are the easiest to monitor and the most cost-efficient.

Table 10.6. Steriliser types

Type	Class	Description	Example of temperature-pressure curve
Gravity (downward displacement) and active drying	N	Traditional type Relatively slow drying phase Air removal by continual release of air/steam mixture via chamber drain line (eg back to internal water reservoir)	
Purge under pressure (assisted air removal)	S	Air removal by alternating inflow and outflow of steam	

Type	Class	Description	Example of temperature-pressure curve
Single vacuum pulse (pre-vacuum, preliminary vacuum, vacuum assisted)	S	Air removal assisted by pump before sterilisation stage Drying time reduced by active ('post-vacuum') removal of steam by pump	
Multiple vacuum pulse (fractionated)	B	Complete air removal via vacuum pump in multiple vacuum pulses before the sterilisation phase, to ensure complete air removal and steam penetration into complex hollow and porous items. Pulsed vacuum is also used in the drying phase to reduce the time and temperature during drying to ensure the porous / wrapping/ packaging is dry at the end of the cycle	

Class B cycles

Class B classes are cycles capable of sterilising:

- all packaged items (single and double wrapped)
- narrow lumen items ([Table 10.7. Definitions of hollow medical devices \(#10.7\)](#))
- solid and porous items.

Class B cycles are suitable for sterilising very long narrow hollow devices, which are rarely used in general practices and most other types of office-based practices. Class B sterilisers are commonly used in dentistry due to the frequent use of long, hollow reusable medical devices and the need for rapid processing of instruments.

In this type of steriliser cycle, air is removed by one or more vacuum stages to vent the air and allow in pressurised steam under pressure (fractionated vacuum system). Chamber pressures vary between types of systems: above and below atmospheric pressure (trans-atmospheric), above atmospheric pressure (supra-atmospheric) or below atmospheric (sub-atmospheric).

Sterilisers with Class B cycles (fractionated vacuum) are the most expensive to buy and operate and may require an onsite supply of deionised water.

Table 10.7. Definitions of hollow medical devices

Type	Definition	Examples
Not hollow	Ratio of the length of the cavity to the diameter is <1	Kidney dish Bowl
Simple hollow	Single-ended open-space items where the ratio of length to diameter of the cavity is ≥ 1 and ≤ 5 and where the diameter is ≥ 5 mm or Double-ended open-space items where the ratio of the length to diameter of the cavity is ≥ 2 and ≤ 10 and where the diameter is ≥ 5 mm.	Punch biopsy tip
Narrow lumen	Hollow device beyond the range for a simple hollow item, and neither solid nor porous	Hormone implant insertion device

Disposable materials used in the sterilisation process

Disposable materials used in the sterilisation process

Sterile barrier systems (packaging)

The purpose of sterile barrier systems is to provide an effective barrier against sources of potential contamination during storage, and permit aseptic removal of the contents of the sterile barrier system at the time of subsequent use.

Sterile barrier systems need to allow for air removal, steam penetration, removal of steam and drying of the contents. Using the correct sterile barrier system ensures that reusable medical devices are sterilised and remain sterile. Sterile barrier systems standardised for quality.

Types of barrier systems include:

- bags made of paper that require tape for sealing
- self-sealing pouches made of paper backed with clear plastic (laminate)
- rolls of paper with laminate, which must be cut to size and sealed at both ends using tape or heat sealing
- sheets of low-lint single-use nonwoven material made from spunbond-meltblown-spunbond polypropylene and/or cellulose
- rigid reusable sterilisation containers and cassettes.

Reusable linen wraps are no longer used in general practices and other office- and community-based practices.

Sterile barrier systems need to be suitable to their purpose. The type of sterile barrier system chosen depends on:

- the size and contents of the sterile barrier system (eg laminate pouches come in a limited range of sizes, while nonwoven purpose-designed fabric is suitable for large packs.)
- the type of reusable medical devices/equipment to be placed in the sterile barrier system.

Most practices use pre-made bags or pouches, which are suitable and convenient for most small-to-medium items or sets of items.

Larger items (such as surgical instruments on a tray) require wrapping using specific approved techniques, which require specialist training to perform correctly. The Sterilizing Research Advisory Council of Australia provides a [list of sterilising courses \(https://www.fsraca.org.au/sterilizing-courses-available-in-australia/\)](https://www.fsraca.org.au/sterilizing-courses-available-in-australia/) available in all states and territories.

Whichever type of barrier system is used, an external Class 1 chemical indicator must be incorporated into the pack. Pouches and bags are made of material that incorporates a Class 1 indicator. When using rolls or sheets, the wrapped package is secured and sealed with adhesive tape that contains a Class 1 indicator.

Pouches and bags must be correctly sealed to reduce risk of contamination. Laminate rolls require a heat sealer (spare elements should be kept as they can burn out) or tape to seal the ends.

Annual validation confirms the suitability of the sterile barrier system.

Packs of pouches or rolls of barrier system materials must not be exposed to dust and contamination. They must be stored in cupboards or drawers, not on open shelves or benches.

Class 1 chemical indicators

All items placed in a sterile barrier system must incorporate a Class 1 chemical indicator on the bag or pouch, or on the tape used to seal the item.

Class 1 chemical indicators are designed to demonstrate that the sterile barrier system has been exposed to the physical conditions of the sterilisation process, but do not guarantee sterility. They are designed to react to one or more of the critical variables (eg change colour when the correct temperature is reached).

Distilled water

Most new sterilisers capable of Class S or B cycles require a large amount of demineralised (distilled or deionised) water, which can be purchased in containers of 5–20 litres from a commercial supplier or produced on site using a demineraliser. The steriliser draws the water through a tube placed in the water supply under the bench.

Installation of small reverse osmosis water filtration systems to supply small sterilisers and washer-disinfectors avoids the inefficiency and high costs of purchasing demineralised bottled water.

Most modern sterilisers employ inbuilt water recycling. With some older sterilisers, water must be added to the chamber and the reservoir must be topped up.

Water that is discharged from any steriliser is not suitable for reuse.

Preparing the load for sterilising

Preparing the load for sterilising

Reusable medical devices required to be sterile at the time of use must be protected by a sterile barrier system (bags, pouches or wrap; see [Sterile barrier systems \(packaging\) \(#barrier\)](#)).

Packaging of cleaned, dried reusable medical devices for sterilisation into sterile barrier systems takes place in the 'clean' zone of the reprocessing area, protected from splash and movement in the 'dirty' area.

Reusable items may be dried and placed in packs directly while wearing clean nonsterile latex-free, puncture resistant, chemical-resistant utility gloves (preferably longer cuffed). However, gloves are not necessary if dried items are being placed in packs – hands must be clean.

General principles for packing devices into sterile barrier systems

Packaging must be large enough to contain the items in accordance with the manufacturer's instructions for use and allow for adequate air removal, steam penetration and drying.

Before sealing a pack, as much air as possible must be expelled from the inside.

Individual packs must not include combinations of types of devices that would require different sterilisation parameters, such as combinations of hollow items, instruments, gauze dressings, drapes and tubing.

All hinged or ratcheted items must be open and unlocked to allow for expansion of the metal and steam contact with all surfaces. Scissors must only be loosely opened, not to the maximum extent. Multi-part instruments must be disassembled or loosened.

Validated tip protectors can be used to prevent sharp reusable medical devices from perforating the sterile barrier system and protect the tip, following the device manufacturer's instructions.

Reusable medical devices with handles should be placed with the handle towards the end of the pack/pouch that will be opened. This allows aseptic removal and decreases the possibility of injury from the instrument tip when the bag is opened.

Kidney dishes, gallipots or bowls that require sterilisation should be placed with the open side against the non-laminate surface (for example, the paper surface) to avoid condensation on the inside of the item if being sterilised in paper/laminate rolls or pouches. They should be tilted on their edges (ie in a draining position) to allow steam to displace the air and adequate drainage of condensate.

If placing several of these type of items together in a sterile barrier system, ensure that all openings are facing the same way and that each item can move freely. This allows adequate steam penetration and drying. Use spacers between tightly fitting identical items (eg when sterilising two or more identical and stackable kidney dishes).

If instruments trays are used, they must be metal and perforated to allow air removal and steam penetration during sterilisation.

Sterilising of textiles (eg gauze, towels or drapes) is not recommended. It is preferable to use single-use disposables.

Each package must be checked to ensure it does not exceed the contents of the validated 'challenge pack' (the test pack representing the hardest to sterilise; see [Validation \(https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/validating-reprocessing-procedures\)](https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/validating-reprocessing-procedures)). **!** Photographs of the validated contents and their arrangement within the sterile barrier system are useful as a valuable ready reference.

If reprocessing items from a failed sterilisation cycle, they must be repacked in a new sterile barrier system, but do not require recleaning unless they have been contaminated (eg dropped on the floor) after opening.

Rubber bands must not be used when transporting or storing packs.

Packaging items for sterilisation in pack/bag/pouch-type barrier systems

(For information on the use of rolls and sheets, see [Packaging items for sterilisation using wrapping-type barrier systems \(#barrier\)](#).)

Remove the number of packs anticipated and close the container before returning to its storage cupboard/drawer.

Check each pack for damage and check the expiry date.

Choosing the correct size

Choose correct-sized pouch for contents:

- Fill only three-quarters of the volume of each pack.
- Leave approximately 2 cm space around each item.
- Allow an empty space of at least 5 cm from the seal area for aseptic opening.

Sealing the pouch or bag

The pouch or bag must be sealed with no gaps that could allow contaminants to enter after removal from the steriliser. Follow the instructions provided by the manufacturer of the sterile barrier system.

Pouches and bags are self-sealed, heat-sealed or sealed with sterilising indicator tape, depending on the type.

If using a self-sealing pouch, precisely fold seals along the 'dotted' line, from the middle to the edges with both thumbs to facilitate an effective seal.

Sterilising indicator tape must not be used on self-sealing or heat-sealed pouches.

If using sterilising indicator tape to seal a non-self-sealing bag or pouch, the open end of the bag/pouch should be sequentially folded over 2–3 times, then taped across the folded edge with one continuous piece of tape extending across at least 25 mm around the back of the pouch on both sides.

String, non-adhesive tape, staples or elastic bands must not be used to seal bags and pouches because these items can compromise the integrity and sterility of these barrier systems.

Packaging items for sterilisation using wrapping-type barrier systems

Preparing packages for sterilisation using barrier systems supplied as sheets or rolls (including wrapping and the use of class 1 chemical indicators) requires specific, validated (envelope-fold or square-fold) techniques that are outside the scope of this document.

The Sterilizing Research Advisory Council of Australia provides a [list of sterilising courses \(https://www.fsraca.org.au/sterilizing-courses-available-in-australia/\)](https://www.fsraca.org.au/sterilizing-courses-available-in-australia/) available in all states and territories.

The wrapping material must be checked before use to ensure that it is not damaged or past the expiry date.

Instrument trays used to contain instruments must be metal and perforated to allow air removal and steam penetration.

Labelling

All packages for sterilisation must be labelled with the date of sterilisation and the batch number (which includes the cycle or load number if more than one load processed on the same day), as a minimum. This enables appropriate stock rotation and the identification of other affected items if a problem with a processed item is identified.

If appropriate, additional labelling may include:

- steriliser identification number (in practices using more than one steriliser)
- identification of the contents, if items are not clearly visible (eg when using paper bags or wraps or if reusable medical devices within a kidney dish are sterilised in laminate pouches, as the hollow side faces the paper)
- identification of the person responsible for cleaning and placing items in the sterile barrier system (if more than one staff member prepares items for sterilisation)
- location of storage post-sterilisation (this may be applicable in larger practices to enable storage of different packs near their locations of use).

This information can be recorded using various codes, which varies in complexity.

Packages for sterilisation can be labelled with barcode adhesive labels (using barcode generator and scanner), prepared sterilisation labelling systems, or manually using a felt-tipped marking pen with non-toxic, water-resistant ink (preferably a validated purpose-designed sterilisation marker) or rubber stamp.

Sharp-tipped, water based or ball-type pens must not be used as they may compromise pack integrity.

When writing on laminate pouches and reels, the writing must be on the laminate side outside the sterile window area. Typically, flat wrappers are labelled by writing on the chemical indicator (steriliser) tape.

Loading the steriliser

Loading the steriliser

Correct loading of the steriliser is important to ensure steam can reach and sterilise every surface of the load, to prevent sterile barrier systems from damage, and to facilitate drying ([Table 10.8. Principles of steriliser loading \(#10.8\)](#)).

A load must not exceed the practice's validated parameters. This means a load cannot be larger or more difficult to sterilise than the 'challenge load' tested at time of annual validation/performance re-qualification. Any new load configurations that could possibly exceeding that of the validated 'challenge load' require re-validation (or the use of a Class 5 or 6 chemical indicator in emergency situations until validation is able to be performed as soon as possible).

It is preferable not to sterilise wrapped and unwrapped items in the same load. If this is necessary, do not place unwrapped items above the tray of wrapped items, because condensate may drip onto the wrapped packs below it.

Equipment used when loading the steriliser

Separators, trays and racks assist with correct loading.

Only validated, ARTG-listed sterilisation containers, load separators, perforated metal trays or cassettes may be used. The correct type depends on the steriliser model. These can be obtained through the steriliser manufacturer or medical supply company if not provided with the steriliser.

Load separators are used to space items (eg identical kidney dishes that would stack closely together, hindering air removal, steam penetration and drying).

Trays used in the steriliser must be perforated to allow steam penetration and condensation drainage during the sterilisation cycle. Use trays specifically designed and validate for the specific model of steriliser. Multiple trays may be required if packs are sterilised flat as single layers.

Solid trays must not be used as they inhibit steam movement and steam can condense on them, leaving pools of moisture and possibly wetting packs.

Method of loading

Follow the loading instructions provided by the manufacturer.

General principles apply:

- Follow the manufacturer's instructions on placement of packs and use of equipment.
- Ensure adequate space between each pack/pouch to facilitate air removal, allow steam penetration and facilitate drying – load trays loosely with a single layer of packs on each tray,

within the boundaries of the loading tray.

- Load the steriliser so that no items touch the walls. A square frame insert to achieve this may be supplied with the steriliser.
- Loading of the steriliser follows the same pattern of loading described in the validation protocol.

Photographs or diagrams of the validated loading pattern and any lesser loading patterns used are useful as a reference.

Table 10.8. Principles of steriliser loading

✓ DO	✗ DON'T:
Place only a single layer of packs on each tray and allow space between packs for air removal and steam penetration.	Do not place into the steriliser until the complete load is ready to be loaded.
Place lighter items on top shelves and heavy items on lower shelves.	Do not overload the chamber or allow packs to overlap.
For items that are prone to entrap air and condensate, such as bowls, tilt on sides (eg 45° angle using a vertical rack) to allow air removal and steam penetration, and facilitate drainage and drying at the completion of the cycle.	Do not allow packages to touch the sides of the steriliser chamber.
Place single laminated pouches vertically in a spacer with paper to laminate, or horizontally, according to steriliser manufacturer's instructions.	Do not exceed the maximum weight or volume specified by the steriliser manufacturer
Load items within the boundaries of the shelf.	Do not exceed the challenge load.
	Do not place instrument trays, hollow items or items that could collect moisture (eg bowls) above packs containing soft materials.

Running the sterilisation cycle

Running the sterilisation cycle

For sterilisers that produce printouts, the paper position and ink levels must be checked before running each cycle to ensure the data are recorded.

Processing time

The time (and temperature, if more than one option) selected for sterilising a load is a critical factor in ensuring sterility of the load. The processing time is the sum of the penetration (equilibration) time and the holding time.

Often manufacturers pre-set the processing time on sterilisers. These times must be checked during the validation process when the steriliser is commissioned, and altered if necessary to ensure adequate time at temperature to kill all microorganisms.

The penetration time is the time it takes for the hardest to reach part of the load to achieve the required temperature, once the chamber has reached that temperature). It is determined at the time of validation using a 'challenge' pack.

The holding time is the time the load must be held at the sterilising temperature, and includes a safety factor. The holding time for the cycle will depend on the type of items loaded. It must be determined by the steriliser technician during validation procedures for the steriliser.

Drying time

The validation process determines the minimum drying time for cycles, based on the challenge load(s).

Heat distribution

Heat distribution studies are not required for small steam sterilisers (< 60 L) and may not be effective in identifying a 'cold spot' in a small benchtop steriliser).

For large sterilisers, a heat-distribution study is required to ensure that monitoring reflects the temperature in the coolest part of the chamber. This study is only required once and may be available either from the manufacturer, a previous validation, or can be determined by the service technician.

This can be checked during routine calibration and should not be an additional expense.

Unloading the steriliser

Unloading the steriliser

The steriliser must be unloaded correctly by following a standardised protocol ([Table 10.9. Steps for unloading the steriliser \(#10.9\)](#)). Sterile barrier systems, chemical indicators and printouts are checked during this stage (see [Monitoring the sterilisation cycle \(https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/monitoring-each-sterilisation-cycle\)](https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/monitoring-each-sterilisation-cycle)).

The cycle must not be interrupted or the sterilisers door opened until the steriliser has completed the entire cycle and the pressure has returned to zero.

Loads must be removed from the steriliser as soon as the cycle has finished. Do not allow the load to cool in the steriliser.

Any pouches or packs that are wet (see More information: wet packs below), dropped, torn, damaged, or have broken seals are considered unsterile and must be completely reprocessed.

Recleaning is required only if the reusable medical devices have been contaminated. Any reprocessing must be recorded.

More information: wet packs

All packs should be dry. A wet pack is a sign that the steriliser may not be operating correctly or there has been processing error. The problem should be identified and corrected immediately.

A wet pack can lead to contamination because excessive moisture can act as a pathway for microorganisms, re-contaminating the sterilised load. Handling wet packs can cause microorganisms to migrate inside the package, contaminating the contents.

Table 10.9. Steps for unloading the steriliser

⚠ Do not attempt to open the steriliser door while the cycle is in operation.

1. Cleanse hands.
2. Before opening the steriliser, check the printout or onscreen digital display to confirm the sterilisation parameters have been met. Check and sign/initial the printout or verify electronic record to confirm that the sterilisation process has achieved the correct sterilisation parameters.
3. Open the steriliser and carefully remove the load, using a tray lifter (supplied with the steriliser) or heat-resistant gloves. Handle only the loading trays, if possible; packaging is easily contaminated until it has cooled.
4. Place the load on a perforated tray or rack (not on a solid surface) so that air can move underneath to both facilitate rapid cooling and prevent condensation. The drying area must be in a low-activity area (eg adjacent the steriliser in the dedicated reprocessing area), protected from splash. Doors and windows must be closed and there must be no fan or boosted air conditioning.
5. Check class 1 external chemical indicators.
6. Without touching, visually check that the load is dry.
7. Allow the load to cool in the 'clean' zone of the reprocessing area, away from high levels of activity, before handling. Ideally, items should be allowed to cool for a minimum of 30 minutes (more than 1 hour for large items) before handling or storing. Do not use fans or high-flow air conditioning to dry items.
8. Cleanse hands. Using dry hands, check that each pack is dry, intact with seal secure.
9. Check that the batch/item information matches the load documents and that the batch label and/or ID label has/have not dislodged during sterilisation.
10. Check and record results of process challenge devices (if used) on steriliser cycle record.
11. Record results of biological indicator (if used) on steriliser cycle record.
12. Classify load as failed if any of the following occur:
 - Packs are wet or damaged.
 - Class 1 (and any other chemical indicators used) do not show the correct colour change.
 - Cycle monitoring parameters are not correct.
13. Report any failures. All items in a failed load must be rejected, the fault identified, corrected and recorded, and the entire load completely reprocessed. (A single wet pack does not fail the load, but the cause must be identified so it does not recur.)
14. In the steriliser cycle log, record the time of release and name of the person releasing the load.
15. When a load has passed the checks, store the contents correctly.

Documenting reprocessing including steriliser cycles

Documenting reprocessing including steriliser cycles

Logbooks are required when using washer-disinfectors or sterilisers.

Types of logbooks

Practices may develop their own logbook, use templates provided by RACGP or other organisations, or use commercially available logbooks. The log can incorporate tracking functions.

There are links to examples of logbooks in the [resources \(https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/resources-and-references\)](https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/resources-and-references) section.

Logbooks must be retained with the records of validation and maintenance details. These are treated as medical records and retained for the required period in accordance with state/territory regulations.



Information required for steriliser logs

For every cycle, record the following information in the steriliser logbook:

- date
- steriliser identity (if the practice has more than one steriliser)
- load number
- load contents
- name of the person who prepared the load
- results of the cycle monitoring (pass/fail) – See [Monitoring the sterilisation cycle \(https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/monitoring-each-sterilisation-cycle\)](https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/monitoring-each-sterilisation-cycle)
- confirmation of change in Class 1 chemical indicators
- results of any other indicators used (eg chemical or biological)
- condition of the sterile barrier systems (ie dry, seals intact and no damage)
- signature of the person releasing or rejecting the load
- comments on any faults/fails identified and the corrective action that was taken.

The printout of the cycle can be attached to the logbook and verified as correct in the logbook. If a data logger is used, verify in the logbook that the data logger recording was viewed and the cycle met required parameters.

In larger practices where more than one person is responsible for reprocessing reusable medical devices, the identity (eg initials) of the staff member who performed each stage of the process should be logged to enable follow-up.

On completion of each sterilisation cycle, the staff member responsible for releasing the load should:

- view the process record (printout/data logger/onscreen digital display chart) to verify that the time, temperature and pressure parameters were correct for the load contents in accordance with the validated specification
- record that they have completed this check, with their name or initials to enable later identification of the staff member who released the load.

Printouts should be checked for legibility as well as verification of correct parameters, then signed or initialled before filing.

Any variation from the normal parameters should be reported immediately to a supervisor, and the load should not be released. The discrepancy must be recorded and corrective action taken.

Note: Older sterilisers without process recorders need to be upgraded or replaced to ensure automatic monitoring of cycle parameters.

Documenting performance data for other equipment

Documenting performance data for other equipment

If the practice uses an ultrasonic cleaner, performance testing, solution changes and degassing should be recorded in a log.

If the practice has an automatic washer-disinfector, monitoring, servicing, maintenance, calibration and validation. This includes checking of charts, gauges, or printouts to verify that the correct variables were achieved.

Storing sterilised reusable medical devices

Storing sterilised reusable medical equipment

Maintaining integrity of sterile stock is crucial to ensuring sterility of reusable medical devices at the time of use. Correct storage and handling of sterile stock is critical to the maintenance of sterile barrier system integrity.

Requirements for sterile stock storage

All sterile stock must be stored in a way that keeps it clean, dust-free, and dry. It must be stored away from sources of moisture (eg not next to or below sinks, above sterilisers, or on open shelves).

Suitable storage areas include clean, well-sealed cupboards, drawers, or enclosed shelving (sliding doors must be kept closed), or sealable plastic containers with plastic dividers (not cardboard). Packs/pouches can be covered in protective packaging such as plastic dust covers, bags or containers.

Avoid paper/cardboard dividers because these shed fibres which settle on pouches. When opened, the fibres may contaminate the instrument.

Drawers must be deep enough so that pouches are not damaged by opening and closing.

Use cleaned hands when accessing sterile packs and fully close lids or doors every time.

Keep packs/pouches out of sunlight, because it can affect the integrity of some types of sterile barrier systems. Sterilised laminate can become brittle over time, so unused laminate packs must be checked regularly (eg every 2–3 months). If brittleness is noted, the contents must be fully reprocessed, including cleaning (in case dust has penetrated packaging) and sterilisation.

Duration of sterility

If items contained within a sterile barrier system are stored and handled correctly, there is no specific time limit on storage. However, the practice's system for stock rotation must ensure that sterilised packages are not left indefinitely. If a package has not been used within 12 months, re-sterilisation should be considered.

Unused packs should regularly be checked for moisture, brittleness, damage and other signs that they require reprocessing. The frequency of checking should be documented.

Packs/pouches that are used infrequently can be wrapped in plastic dust covers or stored in sealed plastic containers when cooled, before storage. This will further protect the sterile barrier system from dust and damage.

Repeated or rough handling, the use of rubber bands, unclean or wet hands and other exposure to moisture can compromise sterility by damaging a sterile barrier system. If water is splashed onto the outside of a pack/pouch, this renders it 'unsterile'. The items must be placed in a new sterile barrier system and resterilised.

Unwrapped sterilised reusable medical devices cannot be stored for later use as sterile supplies.

Rotation of stock

Ensure the practice has a procedure for sterile stock rotation such as 'use from the left, restock from the right' or 'use from the front, restock from the rear'. Use the dates on the items within the sterile barrier system to assist.

Practices could develop a protocol for stock rotation that specifies the interval for checking unused items, and what actions should be taken and documented. The system should be designed to avoid frequent handling.

Hands must be cleaned before handling stock.

Monitoring each sterilisation cycle

Monitoring each sterilisation cycle

Effective sterilisation of used instruments to prevent transmission of microorganisms depends on temperature, pressure and time – each of these parameters must be monitored.

The sterilisation cycle is monitored by multiple methods:

- mechanical/physical/electronic indicators recorded by automatic printout or computerised data logger – must be checked for every cycle before the load contents are released for use
- chemical indicators – included with every pack/pouch and load, and placed on each tray containing unwrapped items
- biological/enzymatic indicators – used during validation and when steriliser operation needs to be rechecked.

All sterilisers must automatically generate log data (see [Record keeping \(https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/record-keeping\)](https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/record-keeping)).

Mechanical/physical/electronic monitoring

Sterilisers must be fitted with devices (gauges/timers/digital readout) that provide visible evidence of the time, temperature and pressure during a cycle.

Results are automatically recorded by printout or a data log, which must be viewed after each cycle before sterilised items can be released for use. The printout or data logger shows the temperature and pressure at critical points during the sterilisation cycle as well as the drying time.

Chemical indicator monitoring

There are six classes of chemical indicator (classes 1–6). Higher classes provide more information (including more specific information) than lower classes ([Table 10.10. Types of chemical indicators \(#10.10\)](#)).

A **Class 1** chemical indicator must be used on every pack of every load or in the tray of unwrapped items as evidence that the load has been subject to a heat process. Self-sealing pouches and some sealing tape incorporate Class 1 chemical indicators.

The use of other classes of chemical indicators is optional. For example, chemical indicators may be used to detect a suspected fault.

Chemical indicators must be checked for colour change immediately after unloading the steriliser, because the colour may fade or change over time. Colour viewed after storage does not provide proof of success of a sterilisation process performed days or hours before.

Any monitoring using chemical indicators must be recorded.

Table 10.10. Types of chemical indicators

Class	Description	When used	Cycle type*	Advantages	Disadvantages
1	Process indicator (eg steriliser indicator tape)	On every pack in every load On the tray of every unpacked load	All classes	Can assist in easily distinguishing between processed and unprocessed loads	Designed to reach their endpoint after an exposure to a cycle that may be less than adequate for sterilisation
2	Specific test indicator (eg Bowie–Dick-type tests)	According to practice risk assessment	Class B	Designed to show air removal and the rapid and even penetration of steam	Designed to reach their endpoint after an exposure to a cycle that may be less than adequate for sterilisation
4	Indicator for two parameters (eg time and temperature)	For extra assurance of successful completion of a sterilisation cycle In the absence of printout/data log	All classes	Designed to reach their endpoint after exposure to a sterilisation cycle at the stated values of the chosen parameter (eg 134°C for 3 minutes) Provides more assurance of a successful sterilisation cycle than that provided by either process (Class 1) or single-parameter (Class 3) indicators and can be used in the absence of a printout	Failure may not identify which specific parameter/s have failed
5	Integrating indicators (eg time, temperature and pressure)	For high-level assurance of successful sterilisation cycle In the absence of a printout	All classes	Provides as much information as a biological indicator by mimicking the conditions necessary to destroy microorganisms and can be used in the absence of a printout or validation in some situations	Failure may not identify which specific parameter/s have failed

Class	Description	When used	Cycle type*	Advantages	Disadvantages
6	Emulating indicators (eg 134°C for 3.5 minutes in steam under pressure)	Assurance that all critical conditions of the sterilisation cycle are met, based on the settings of the selected sterilisation cycles	All classes	Provides a very high level of assurance of a successful sterilisation cycle and can be used in the absence of a printout or validation in certain situations	Failure may not identify which specific parameter/s have failed

*Steriliser type or cycle class of steam steriliser

Note Class 3 indicators (indicators for a single parameter) are no longer used.

Microbiological indicator monitoring

Microbiological indicators are the most reliable method for checking the effectiveness of the sterilisation process. They are not designed for routine monitoring or as a substitute for validation.

Types of biological indicators

There are two types of microbiological indicators: biological and enzymatic.

Biological indicators are designed to measure the killing power of the sterilising process and are considered to be the most accurate method. They consist of a predetermined number of microorganism spores.

Rapid-read biological indicators provide results in 20–25 minutes. Older biological indicator systems require 24 or 48 hours' incubation after the sterilisation cycle before the result can be read.

Enzyme tests are similar to biological indicators but do not require an incubator. They contain an enzyme from a microorganism that is inactivated when sterilising conditions are achieved. The test is performed after the cycle by adding a drop of test solution and observing a rapid colour change. These are not commonly used in office-based practices.

Application

The use of a biological indicator by the steriliser technician is required at operation qualification and performance qualification, recommissioning and performance requalification .

The use of biological indicators by the practice as part of routine testing and performance monitoring, and in criteria for release of processed items, is optional.¹

A biological indicator can also be used as a quality assurance activity, to investigate cycle failures, or when running any load type that exceeds the previously validated worst-case parameters (in this case, the load must not be released for use until the results are available).

Technique

The biological indicator is placed on the tray with unwrapped items or within the sterile barrier systems of the load to be sterilised. After the cycle is complete, the indicator is incubated according to the manufacturer's instructions. This can be done onsite in practices that own or have access to a loaned incubator. Incubators used for this purpose are annually calibrated.

Record the results in the steriliser logbook before releasing the load.^{[1](#)}

Weekly use of biological indicators was formerly required when using sterilisers that were not calibrated and validated. Unvalidated or uncalibrated sterilisers must not be used.

Record keeping

Record keeping

After each cycle, the designated staff member reviews the printout or download (see [Documenting reprocessing including steriliser cycles \(https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/documenting-reprocessing-including-steriliser-cycle\)](https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/documenting-reprocessing-including-steriliser-cycle)). The result (success or failure of the cycle) must be recorded in the steriliser log at the end of each cycle. The printout or datalogger result may be kept (eg for a month) for evidence and to assess trending temperatures and pressure. Printouts liable to fading need to be transferred to digital medium. Electronic downloads can be stored digitally.

The steriliser log (logbook/steriliser cycle book record) must be retained with the same requirements as a medical record **i**. If the printer is faulty/out of paper, or if the data logger is inoperative or the data cannot be viewed, the load cannot be released until the data are retrieved.

The log for each cycle contains all of the following data ([Table 10.11. Sample steriliser log \(#10.11\)](#)):

1. Data recorded before the cycle by the loading operator:

- date
- cycle number
- load type/description of each pack
- cycle program selected
- identification of loading operator

2. Data recorded at the end of the cycle by the unloading operator:

- whether the physical parameters have been met
- whether internal/external chemical indicators received a pass result
- whether packages meet criteria for conforming: correctly labelled, package and seal intact, and the Class 1 indicator is present with colour change
- identification of the unloading operator.

Sterilisers without a printer or data logger are obsolete and should not be used.

Table 10.11. Sample steriliser log

Record keeping

Date ¹	Load no. ²	Person preparing load (name or ID) ³	Load contents description ⁴	Time and temperature printout or Class 4, 5 or 6 chemical indicator ⁵	Class 1 chemical indicator change ⁶	Packs dry and intact ⁷	Person releasing load (name or ID) ⁸	Steriliser maintenance and repairs ⁹	Comments (including name or ID) ¹⁰
2/ 11/ 22								Cleaned, water changed	M Gale, Registered Nurse
2/ 11/ 22	1	H Hodder	3 x suture sets 4 x scissors 1 x excision set	Printout passed 3.5 min @ 134°C	Pass	Yes	J Ramirez		
3/ 11/ 22	1	K Krane	6 x forceps 2 x scissors	Failed – load rejected					Printer broken (K Krane) Load repacked and repeated with Class 6 chemical indicator (H Hodder, practice nurse)

1. The date of the steriliser batch or maintenance.

2. The load consecutively for each day (eg 2/11/22 load 1, 2, 3; 3/11/22 load 1, 2).

3. Identification of the person preparing the load.

4. Description of each pack in the load.

5. Time and temperature measurement obtained from either a printout of the cycle or a data log. The time and temperature must match the chosen parameters (eg 134°C for 3.5 minutes). If a printout or data log is unavailable or manual recording is not performed, a Class 4, 5 or 6 indicator must be used in each load and the colour change noted (eg 'pass' or 'fail'). If different time and temperature parameters are used, these should be recorded. The printout or data can be kept.

6. A Class 1 indicator indicates exposure to heat, and must be included in each pack or, in the case of unpacked items, on the tray. The results of the colour change are noted (eg 'pass' or 'fail').

7. This is an essential prerequisite to releasing a pack or load for use. If a pack is moist or damaged, or the seal is not intact when it comes out of the steriliser, it is failed, repacked and resterilised. The results of the pack check are recorded (eg 'pass' or 'fail').

8. Identification of the person releasing the load.

9. Maintenance needs to be performed according to the manufacturer's instructions. Refer to the steriliser operating instructions for details.

10. This column is also to record any pertinent information about the steriliser or load, including reason for rejecting the load, and any follow-up action. Both scheduled (eg daily cleaning, weekly water changes, annual calibration and servicing prior to validation) and unscheduled (eg printer repaired, heater element replaced) maintenance is outlined in this column.

Source: [The RACGP Steriliser Record System \(2019\)](https://www.racgp.org.au/running-a-practice/practice-resources/ordering-publications/record-keeping-in-general-practice) (<https://www.racgp.org.au/running-a-practice/practice-resources/ordering-publications/record-keeping-in-general-practice>)

Checking steriliser function

Checking steriliser function

In addition to monitoring every cycle, daily checks of steriliser function are required in accordance with the manufacturer's instructions for use.

Leak-rate tests

For a steriliser that uses a vacuum in any part of its operation, a leak-rate test is required on each day of its use (or weekly, if there is an air detector) to check the leak rate does not exceed the maximum specified in the [current relevant standard \(https://store.standards.org.au/product/as-5369-2023\)](https://store.standards.org.au/product/as-5369-2023).

Refer to the steriliser operating instructions for information on whether an air detector is fitted and how to perform the leak-rate test.

Steam penetration/air removal tests

If the practice uses Class B sterilisation cycles and reprocessed narrow-lumen (hollow A) items, a steam penetration/air removal test must be performed daily in accordance with steriliser instructions for use and process challenge device instructions for use.

Process challenge devices

Various commercially manufactured process challenge devices are available. These mimic particular challenges or worst-case scenarios. For example, the helix device for air removal/steam penetration consists of a coil of thin tubing with one open end and the other attached to a thin sealable cylinder containing a strip. The strip changes colour if the right conditions are met during the steriliser cycle (ie that the steriliser has successfully removed all the air from the cylinder via the narrow tubing).

Steriliser maintenance

Steriliser maintenance

Maintenance is essential to ensure sterility of the equipment processed and longevity of the steriliser.

Maintenance must be performed according to the manufacturer's instructions. Refer to the steriliser operating instructions for details.

Changing the water

Demineralised (deionised or distilled) water must be used to minimise scale build-up and corrosion. Most benchtop models require connection to a water source.

Sterilisers that have a reservoir and recycle water must be topped up as required and the water drained and changed weekly.

Cleaning the steriliser

Regular cleaning of the external surface, chamber, trays and racks is required in accordance with the manufacturer's instructions for use:

- The external surface should be wiped daily and the internal surfaces should be cleaned at least weekly with a cleaning agent recommended by the manufacturer. Check the manufacturer's instructions for details.
- Wiping the chamber walls weekly will reduce scale build up. Scale build-up in areas with high concentrations of calcium can be removed using commercially prepared products containing phosphoric acid (check and carefully follow the manufacturer's recommendations). Using inappropriate cleaners may damage water tanks, filters or hoses.
- Tape, label debris and glue may have to be removed using an approved cleaning agent and/or non-abrasive scourer.
- The drain and other outlets must be checked to ensure they are clear of debris.

Servicing the steriliser

Scheduled maintenance, such as checking the seal, changing the filter, and oiling the hinge should be performed as recommended by the manufacturer (either by a staff member or by a service provider, as appropriate).

Full servicing, including calibration, must be performed at least annually. It should be done more frequently if recommended by the manufacturer, and repeated when repairs are needed.

The service technician checks the temperature, pressures and time achieved during a full sterilisation cycle as well as the gauges, recording devices, seals and filters.

Validation is usually scheduled at the time of annual servicing and calibration (see [Validating the steriliser process](https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/validating-reprocessing-procedures)). (<https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/validating-reprocessing-procedures>)

Annual calibration and servicing to the required standard must be performed by a suitably qualified service technician, and carried out in accordance with the manufacturer's instructions. Practices could contact the manufacturer or distributor to find a qualified technician authorised to service the steriliser model.

Documentation

Documentation of all maintenance (apart from routine cleaning) and servicing is part of the monitoring process and is required as evidence of the correct operation of the steriliser.

Documentation of maintenance includes:

- maintenance performed by staff as per the manufacturer's instructions (for example, changing water, daily cleaning and checking door seal)
- annual (or more frequently if required by heavy usage) servicing and calibration by a qualified technician.

Retain service reports.

The practice needs to have a written policy and procedure to cover all maintenance issues regarding the steriliser.

Step-by-step guide: simple first validation

Step-by-step guide: simple first validation

Some steps are performed by staff and some (such as installations, technician assistance, maintenance and repairs) must be done by a trained technician from an organisation authorised by the Therapeutic Goods Administration sponsor of the equipment.

Glossary note: 'qualification' means checking.

Responsibility

The staff member with designated responsibility for reprocessing reusable medical devices to perform the following:

1. Review the documented procedures covering all parts of the reprocessing procedure to ensure reproducibility:

- workflow issues: dirty through to clean and environmental cleaning
- precleaning and cleaning of instruments, including drying and visual inspection
- packing of contents in a sterile barrier system, including sealing and labelling
- loading of the steriliser
- mechanical/physical monitoring (chemical indicators and recording of exposure time and temperature) of the sterilisation cycle parameters
- unloading of the steriliser and checking the packs are dry and intact and checking monitoring results and correct chemical indicator change
- storage of sterile items
- maintenance of steriliser as required by the manufacturer (including water changes and cleaning).

2. Perform or supervise the documented procedures.

3. Check that the procedures were performed correctly.

4. Record correct completion of each procedure ([Table 10A.1. Validation certificate template \(#10A\)](#)).

Table 10A.1. Validation certificate template  [Download the validation certificate template \(https://www.racgp.org.au/getmedia/171ed0ab-b053-4cbc-a94d-a9bf040b80ce/RACGP-Template-Validation-certificate_2.docx.aspx\)](https://www.racgp.org.au/getmedia/171ed0ab-b053-4cbc-a94d-a9bf040b80ce/RACGP-Template-Validation-certificate_2.docx.aspx)

Clinic name:		Steriliser identification:	
Process	Process documented in policy and procedure manual	Process performance, effectiveness and reliability checked (ie validated)	Sign and date
Cleaning of the reprocessing area			
Workflow (dirty to clean)			
Precleaning and cleaning of instruments			
Drying and visual inspection			
Content, packing and sterile barrier system of challenge pack			
Loading of challenge load			
Monitoring of cycle parameters			
Unloading of the steriliser (steriliser log)			
Storage of sterile items			
Cleaning and maintenance of steriliser (maintenance log)			

Clinic name:		Steriliser identification:	
Cleaning and maintenance of ultrasonic cleaner			
Cleaning and maintenance of washer-disinfector			
Cleaning and maintenance of drying cabinet			
Cleaning and maintenance of incubator			
Name of service company:			
Steriliser technician:			
Date:			
Name of staff member with responsibility for practice sterilisation:			
Signature:			
Date:			

Procedure

Review the following steps and record findings.

Workflow issues: dirty through to clean

- ☐ Review documentation in practice policy and procedure manual or other documentation (such as signage in reprocessing area).

- ☐ Observe performance of the tasks from pre-treatment at point of use, through precleaning, cleaning and sterilisation to storage, including environmental cleaning relevant to instrument reprocessing.
- ☐ Check that workflow from dirty to clean is not compromised and that environmental cleaning is adequate.

Precleaning, cleaning and drying of instruments

- ☐ Review documentation in practice policy and procedure manual or other documentation.
- ☐ Perform or supervise precleaning, cleaning and drying.
- ☐ Check that the instruments are clean, under good lighting using magnification (pay special attention to serrations).

Pack contents, packing and sterile barrier system

- ☐ Review documentation in practice policy and procedure manual or other documentation.
- ☐ Perform or supervise pack preparation with correct contents, packing and sterile barrier system.
- ☐ Check packs:
 - ☐ have the correct contents
 - ☐ are packed correctly in the correct sterile barrier system and do not exceed those of the documented challenge packs 
 - ☐ have seals that are intact
 - ☐ have a Class 1 chemical indicator on the outside of each pack
 - ☐ have been labelled with the date, steriliser number (if applicable), load (batch) number and staff identification of cleaner and packer (if applicable)
 - ☐ have instruments loosely open, not tightly closed
 - ☐ that contain hollowware (eg kidney dishes, bowls), if packed in laminate pouches, are packed with the opening against the paper, not the laminate plastic side
 - ☐ have not had ballpoint pens used on pack surfaces.

Loading the steriliser

- ☐ Review documentation in practice policy and procedure manual.
- ☐ Perform or supervise loading of the steriliser.
- ☐ Check that:

- ☐ the total contents of the steriliser do not exceed those of the documented challenge load ([Table 10A.2. Penetration and drying time \(#10A.3\)](#)) ([#10A.2](#))
- ☐ packs containing hollowware (eg kidney dishes, bowls) are on their sides
- ☐ the paper side of any laminated pack is adjacent to the laminate side of another
- ☐ individual instrument packs are separated on racks
- ☐ trays of unwrapped instruments are not overloaded
- ☐ there is a Class 1 chemical indicator in the tray with unwrapped instruments.

Table 10A.2. Example of penetration and drying time

Challenge pack description	Challenge pack/load loading	Penetration time Steriliser 1 (minutes)	Drying time Steriliser 1 (minutes)
1 x 'Removal of lesion' pack, consisting of: 1 x needle holder 1 x scissors 1 x toothed forceps All instruments in laminated pouch.	Vertical Rack 2 x Bard-Parker scalpel handles in laminated pouch Challenge Pack 2 x scissors in laminated pouch 1 x crocodile forceps in laminated pouch 1 x toothed forceps in laminated pouch Bottom Tray 1 x 'Removal of lesion' pack 1 x needle holder	0	5

Mechanical/physical monitoring of sterilisation cycle parameters, biological indicators

- ☐ Review the documentation in the practice policy and procedure manual for each steriliser used, including:
 - ☐ manufacturer's instructions
 - ☐ heat distribution studies ([Figure 10A.1. Example of heat-distribution study \(#table10a1\)](#))

- description of the challenge pack and load ([Table 10A.2. Example of penetration and drying time \(#10A.2\)](#))
- diagram of chamber loading ([Figure 10A.2. Diagram of chamber loading \(#figure10a1\)](#))
- penetration times (Tables [Table 10A.2. Example of penetration and drying time \(#10A.2\)](#), [Table 10A.3. Example of processing time \(#10A.3\)](#)).
- The service technician should:
 - perform a heat-distribution study (if needed) to check for cold spots in the chamber and record ([Figure 10A.1. Example of heat-distribution study \(#figure10a1\)](#)). Note: This study is only required once and may be available either from the manufacturer or a previous validation. If not, it can be determined by the service technician.
 - establish the penetration time for the 'challenge pack' within the 'challenge load' and record (this combination reflects the greatest challenge to the sterilisation process of any load)
 - set the processing time on the steriliser for all loads (ie holding time plus penetration time) and document ([Table 10A.3. Example of processing time \(#10A.3\)](#))
 - check the drying time (establish that the recommended time is adequate and increase if needed; see [Table 10A.2. Example of penetration and drying time \(#10A.2\)](#), [Table 10A.3. Example of processing time \(#10A.3\)](#))
 - perform additional function checks for validation of the sterilisation cycle (ie during the processing and drying time)
 - perform physical qualification (checking) of the temperature within the challenge pack within a challenge load with a thermocouple throughout the total processing time (ie 'time at temperature' testing) at least once. This check should continue to check the drying time. The penetration time can also be checked while this is being performed.
- The staff member with designated responsibility for sterilisation should perform microbiological qualification (checking) using appropriate indicators in three successive cycles ([Table 10A.4. Results of physical and microbiological qualification \(#10A.4\)](#)).

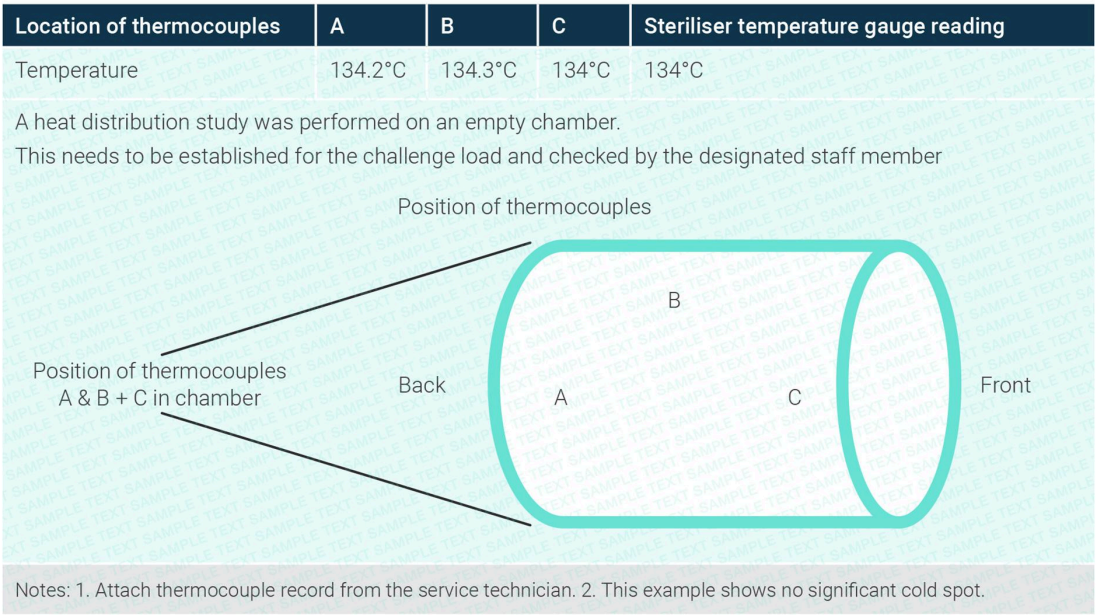


Figure 10A.1.

Example of heat-distribution study

A heat-distribution study is only required once and may be available either from the manufacturer, a previous validation, or can be determined by the service technician.

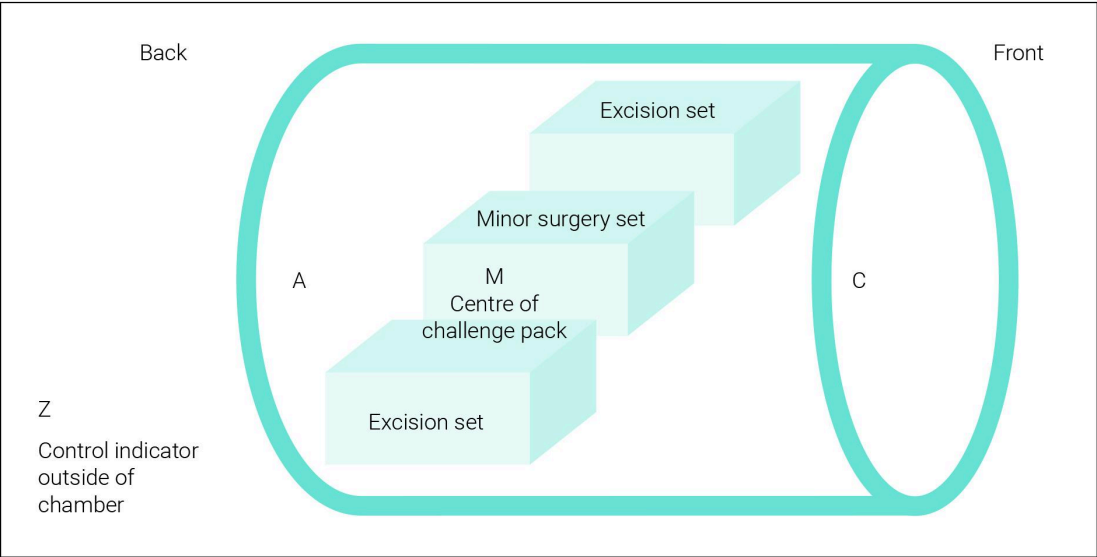


Figure 10A.2.

Diagram of chamber loading

Table 10A.3. Example of processing time

Load description	Sterilising temperature	Pressure in kpa (median)	Penetration time (P) (minutes)	Holding time including safety factor (H) (minutes)	Total processing time (T) (minutes) P + H = T	Drying time (minutes)	Pre-set setting selection (eg 'suture')
2 excision sets and 1 minor surgery set	Set 134°C	203	2	3	5	12	Suture

Table 10A.4. Results of physical and microbiological qualification

Challenge load	Check type	Cycle 1	Cycle 2	Cycle 3
2 excision sets and 1 minor surgery set	Microbiological qualification: Indicator M in centre of challenge pack	No growth	No growth	No growth
	Microbiological qualification: Indicator C in cold spot of chamber	No growth	No growth	No growth
	Physical qualification: Time at temperature	Pass*	Not applicable	Not applicable

*Attach temperature records from service technician supporting this qualification

The indicators

☐ Biological or enzymatic indicators:

- ☐ have a spore count equivalent to 10^5
- ☐ are from the same batch.

☐ A minimum of two indicators are required for each load to be validated plus one control indicator.

☐ Indicators need to be suitable for the type of steriliser and temperature selected (enzymatic indicators on the Australian market are not suitable for gravity displacement bench top sterilisers operating at 134°C and cannot be used for either additional monitoring or validation).

Labelling indicators

Label indicators before starting according to:

- the cycle number (1 for the first, 2 for the second or 3 for the third)
- the position it is to be placed in the steriliser (eg M for middle of challenge pack or C for cold spot if determined or placed anywhere on tray if none), for example:
 - Cycle 1 label one indicator 1/M (1st cycle in the middle of the challenge pack) and the other 1/C (1st cycle on the tray nearest the cold spot)
 - Cycle 2 label one indicator 2/M (2nd cycle in the middle of the challenge pack) and the other 2/C (2nd cycle on the tray nearest the cold spot)
 - Cycle 3 label one indicator 3/M (3rd cycle in the middle of the challenge pack) and the other 3/C (3rd cycle on the tray nearest the cold spot)
- the control (7th) indicator can be labelled Z; this is left outside the steriliser and never sterilised. This indicator, which is treated with the others, will be used to substantiate that the batch of indicators was active.

Repackaging between cycles

The packs will be reused pack(s) from the previous cycle. The contents of the pack(s) must return to room temperature before repackaging and the next cycle run.

Indicator processing

All indicators are to be incubated according to the manufacturer's instructions and results recorded ([Table 10A.4. Example of results of physical and microbiological qualification](#)). (#10A.4)

Interpretation of the results of the indicators

- ☐ If the process has been performed correctly, all the 'M' and 'C' indicators will show colour change, indicating no bacterial growth or equivalent. Colour change indicates a process failure and must be investigated. Some incubators or readers will provide an automated final pass or fail result within a specified amount of time. Record the results.
- ☐ If the process has been performed correctly, the single unsterilised control 'Z' indicator will show growth. If not, the batch of indicators or the incubator is faulty (the service technician needs to check the incubator with the thermocouple as part of annual servicing).
- ☐ A pass result is 100%: all six processed biological indicators (minimum of two in each load over three cycles) should not have changed colour and the control biological indicator should have changed colour after incubation. Any failures must be fully investigated as to cause and corrective action documented and the entire procedure repeated.

Check the steriliser settings and results of steriliser monitoring

- ☐ Ensure:

- ☐ time and temperature were correctly set
- ☐ routine monitoring of each cycle's time at temperature (either by printout, download of data logger, manual recording of time at temperature, or by the use of a Class 4, 5 or 6 chemical indicator) occurred at the correct frequency, was reviewed for adequacy, was signed off and is recorded in a log
- ☐ the physical qualification of temperature ('time at temperature' testing) inside the challenge pack/load showed that the centre of the pack reached the correct sterilising temperature and that was maintained for the required time
- ☐ the microbiological qualification with appropriate indicators placed inside the challenge pack/load showed that the centre of the pack and outside the pack inside the chamber was effective in sterilising these indicators in each of the three cycles.

Unloading of the steriliser

- ☐ Review documentation in the practice policy and procedure manual, or other documentation.
- ☐ Perform or supervise unloading.
- ☐ Check that cooled are dry, undamaged, seals are intact and the Class 1 chemical indicator on the outside of each pack or in the tray with unwrapped items has changed colour.

Storage of sterile items

Review documentation.

- ☐ Perform the task of storage.
- ☐ Check that stored items are kept dry, dust free and undisturbed, and packs have been processed, marked with the date and load number and stored in a manner to allow stock rotation. Check cleaning of the storage area does not compromise sterility.

Cleaning and maintenance of the reprocessing equipment

- ☐ For each piece of equipment used in the practice (ultrasonic cleaner, washer-disinfector, drying cabinet, steriliser, incubator), review documentation in the practice policy and procedure manual, manufacturer's instructions and maintenance log.
- ☐ Perform or supervise routine maintenance procedures as documented.
- ☐ Check that maintenance tasks have been performed and are in accordance with the manufacturer's requirements.
- ☐ Visually inspect cleanliness and check that the documented cleaning schedule has been completed.

Step-by-step guide: complex validation

Step-by-step guide: complex validation

Complex validation is performed when simple first validation has previously been performed. Some steps are performed by staff and some (such as installations, technician assistance, maintenance and repairs) must be done by a trained technician from an organisation authorised by the Therapeutic Goods Administration sponsor of the equipment.

Responsibility

The staff member with designated responsibility for reprocessing reusable medical devices to perform the following:

1. Review the documented procedures covering all parts of the reprocessing procedure to ensure reproducibility:
 - workflow issues: dirty through to clean and environmental cleaning
 - precleaning and cleaning of instruments, including drying and visual inspection
 - packing of contents in a sterile barrier system, including sealing and labelling
 - loading of the steriliser
 - mechanical/physical monitoring (chemical indicators and recording of exposure time and temperature) of the sterilisation cycle parameters
 - unloading of the steriliser and checking the packs are dry and intact and checking monitoring results and correct chemical indicator change
 - storage of sterile items
 - maintenance of steriliser as required by the manufacturer (including water changes and cleaning).
2. Perform or supervise the documented procedures.
3. Check that the procedures were performed correctly.
4. Record correct completion of each procedure ([Table 10B.1. Sample complex validation certificate \(#10b.1\)](#)).

Table 10B.1. Sample validation certificate  [Download the sample validation certificate \(https://www.racgp.org.au/getmedia/cc081af2-a0ef-4c6a-9013-8a7b532210cd/RACGP-Template-Validation-certificate_3.docx.aspx\)](https://www.racgp.org.au/getmedia/cc081af2-a0ef-4c6a-9013-8a7b532210cd/RACGP-Template-Validation-certificate_3.docx.aspx)

Clinic name:		Steriliser identification:	
Process	Process documented in policy and procedure manual	Process performance, effectiveness and reliability checked (ie validated)	Sign and date
Cleaning of the reprocessing area			
Workflow (dirty to clean)			
Precleaning and cleaning of instruments			
Drying and visual inspection			
Content, packing and sterile barrier system of challenge pack			
Loading of challenge load			
Monitoring of cycle parameters			
Unloading of the steriliser (steriliser log)			
Storage of sterile items			
Cleaning and maintenance of steriliser (maintenance log)			

Clinic name:		Steriliser identification:	
Cleaning and maintenance of ultrasonic cleaner			
Cleaning and maintenance of washer-disinfector			
Cleaning and maintenance of drying cabinet			
Cleaning and maintenance of incubator			
Name of service company:			
Steriliser technician:			
Date:			
Name of staff member with responsibility for practice sterilisation:			
Signature:			
Date:			

Procedure

Review the following steps and record findings.

Workflow issues: dirty through to clean

- ☐ Review documentation in practice policy and procedure manual or other documentation (such as signage in reprocessing area).

- ☐ Observe performance of the tasks from pre-treatment at point of use, through precleaning, cleaning and sterilisation to storage, including environmental cleaning relevant to instrument reprocessing.
- ☐ Check that workflow from dirty to clean is not compromised and that environmental cleaning is adequate.

Precleaning, cleaning and drying of instruments

- ☐ Review documentation in practice policy and procedure manual or other documentation.
- ☐ Perform or supervise precleaning, cleaning and drying.
- ☐ Check that the instruments are clean, under good lighting using magnification (pay special attention to serrations).

Pack contents, packing and sterile barrier system

- ☐ Review documentation in practice policy and procedure manual or other documentation.
- ☐ Perform or supervise pack preparation with correct contents, packing and sterile barrier system.
- ☐ Check packs:
 - ☐ have the correct contents
 - ☐ are packed correctly in the correct sterile barrier system and do not exceed those of the documented challenge packs 
 - ☐ have seals that are intact
 - ☐ have a Class 1 chemical indicator on the outside of each pack
 - ☐ have been labelled with the date, steriliser number (if applicable), load (batch) number and staff identification of cleaner and packer (if applicable)
 - ☐ have instruments loosely open, not tightly closed
 - ☐ that contain hollowware (eg kidney dishes, bowls), if packed in laminate pouches, are packed with the opening against the paper, not the laminate plastic side
 - ☐ have not had ballpoint pens used on pack surfaces.

Loading of the steriliser

- ☐ Review documentation in practice policy and procedure manual.
- ☐ Perform or supervise loading of the steriliser.
- ☐ Check that:

- ☐ the total contents of the steriliser do not exceed those of the documented 'challenge load' ([Table 10B.2. Examples of challenge loads: contents and loading c \(#10b.3\) onfiguration \(#10B.2\)](#), [Table 10B.3. Example of penetration and drying time \(#10b.4\)](#).)
- ☐ packs loaded with hollow items are on their sides
- ☐ the paper side of any laminated pack is adjacent to the laminate side of another
- ☐ individual instrument packs are separated on racks
- ☐ trays of unwrapped instruments are not overloaded
- ☐ there is a Class 1 chemical indicator in the tray with unwrapped instruments.

Table 10B.2. Example of challenge load: contents and loading details

Challenge load	Loading details
2 excision sets and 1 minor surgery set	3 packs in the chamber Minor surgery set in middle

Sample only; actual challenge loads and loading configuration will depend on the practice's reprocessing requirements.

Table 10B.3. Example of penetration and drying time

Challenge pack description	Challenge pack/load loading	Penetration time Steriliser 1 (minutes)	Penetration time Steriliser 2 (minutes)	Drying time Steriliser 1 (minutes)	Drying time Steriliser 2 (minutes)
2 excision sets and 1 minor surgery set	3 packs in the chamber Minor surgery set in the middle	2	0	12	12

Mechanical/physical monitoring of sterilisation cycle parameters

- ☐ Review the documentation in the practice policy and procedure manual for each steriliser used, including:
 - ☐ manufacturer's instructions
 - ☐ heat distribution studies

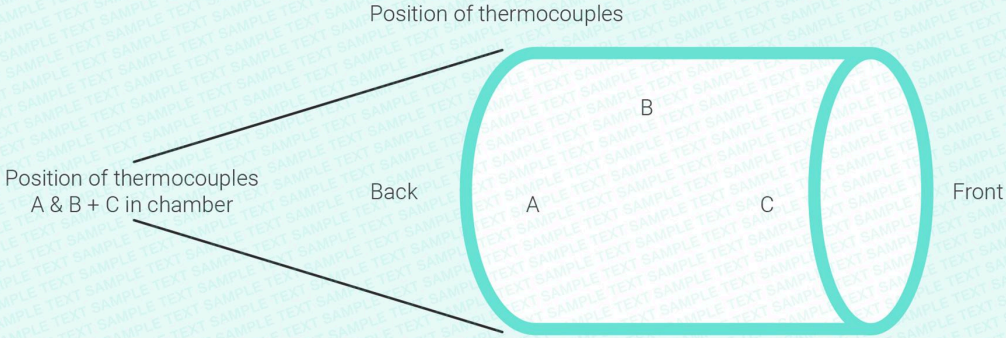
- description of the challenge pack and load ([Table 10B.2. Examples of challenge loads: contents and loading details \(#10b.2\)](#), [Table 10B.3. Example of penetration and drying time \(#10b.3\)](#))
- diagram of chamber loading ([Figure 10B.1. Diagram of chamber loading \(#figure10b1\)](#))
- penetration times ([Table 10B.3. Example of penetration and drying time \(#10b.3\)](#)).
- The service technician should:
 - perform a heat-distribution study (if needed) to check for cold spots in the chamber and record. Note: This study is only required once and may be available either from the manufacturer or a previous validation. If not, it can be determined by the service technician.
 - establish the penetration time for the 'challenge pack' within the 'challenge load' and record (this combination reflects the greatest challenge to the sterilisation process of any load)
 - set the processing time on the steriliser for all loads (ie holding time plus penetration time) and document it ([Table 10B.3. Example of penetration and drying time \(#10b.3\)](#))
 - check the drying time (establish that the recommended time is adequate and increase if needed; see ([Table 10B.3. Example of penetration and drying time \(#10b.3\)](#)))
 - perform additional function checks for validation of the sterilisation cycle (ie during the processing and drying time)
 - perform physical qualification (checking) of the temperature within the challenge pack within a challenge load throughout the total processing time (ie 'time at temperature' testing) at least once (eg by placing temperature sensors and a biological indicator within the most challenging pack and at other sites within the steriliser, including the coldest area to find the chamber reference temperature). Steam penetration can be measured during the sterilisation cycle by calculating the difference between the pack and other temperature sensors, and the chamber reference temperature. The physical qualification should continue to check the drying time. Temperature and pressure qualifications are performed on a minimum of three consecutive cycles.
 - check the temperature of the incubator (if onsite) and calibrate if necessary.
- The staff member with designated responsibility for sterilisation should:
 - perform microbiological qualification (checking) using appropriate indicators in three successive cycles ([Table 10B.5. Sample results of physical and microbiological checking \(#10b.5\)](#)).

Location of thermocouples	A	B	C	Steriliser temperature gauge reading
Steriliser 1 temperature	134.2°C	134.3°C	134.1°C	134°C
Steriliser 2 temperature	134.4°C	134.5°C	134.2°C	134°C

A heat distribution study performed on an empty chamber has been previously obtained (this can be from the manufacturer or performed by the steriliser technician) and is recorded in the table above.

The reading on the steriliser temperature gauge should reflect the temperature at the coldest location in the steriliser drain at the rear of the steriliser chamber (A) (service technician to adjust if practicable when checking calibration).

Position of thermocouples



Position of thermocouples A & B + C in chamber

Back

Front

Notes: 1. Attach thermocouple record from the service technician, 2. This example shows no significant cold spot

Figure 10B.1.

Diagram of chamber loading

A heat-distribution study is only required once and may be available either from the manufacturer, a previous validation, or can be determined by the service technician.

The indicators
☐ Biological or enzymatic indicators:

- have a spore count equivalent to 10⁵
- are from the same batch.

☐ A minimum of two indicators are required for each load to be validated plus one control indicator.

☐ Indicators need to be suitable for the type of steriliser and temperature selected (enzymatic indicators on the Australian market are not suitable for gravity displacement bench top sterilisers operating at 134°C and cannot be used for either additional monitoring or validation).
Labelling indicators
☐ Label indicators ([Table 10B.4. Examples of indicator labelling \(#10b.4\)](#)) before starting according to the:

- steriliser (if more than one steriliser)
- cycle number (eg 1 for the first, 2 for the second or 3 for the third)
- challenge load (eg E for excision set) and the position it is to be placed in the steriliser (eg M

for middle of challenge pack or C for cold spot if determined or placed anywhere on tray if none).

- The control indicator can be labelled Z; this is left outside the steriliser and never sterilised. This indicator, which is treated with the others, will be used to substantiate that the batch of indicators was active.
- The procedure is then repeated for the excision set for both sterilisers, the V being replaced by an 'E'.

Table 10B.4. Examples of indicator labelling

Steriliser 1

Cycle 1 label 1 indicator 1/1/E/M (steriliser 1, 1st cycle, excision set in the middle of the challenge pack) and the other 1/1/E/C (steriliser 1, 1st cycle, excision set, on the tray nearest the cold spot)

Cycle 2 label 1 indicator 1/2/E/M (steriliser 1, 2nd cycle, excision set in the middle of the challenge pack) and the other 1/2/E/C (steriliser 1, 2nd cycle, excision set, on the tray nearest the cold spot)

Cycle 3 label 1 indicator 1/3/E/M (steriliser 1, 3rd cycle, excision set in the middle of the challenge pack) and the other 1/3/E/C (steriliser 1, 3rd cycle, excision set, on the tray nearest the cold spot)

Steriliser 2

Cycle 1 label one indicator 2/1/E/M (steriliser 2, 1st cycle, excision set in the middle of the challenge pack) and the other 2/1/E/C (steriliser 2, 1st cycle, excision set, on the tray nearest the cold spot)

Cycle 2 label 1 indicator 2/2/E/M (steriliser 2, 2nd cycle, excision set in the middle of the challenge pack) and the other 2/2/E/C (steriliser 2, 2nd cycle, excision set, on the tray nearest the cold spot)

Cycle label 1 indicator 2/3/E/M (steriliser 2, 3rd cycle, excision set in the middle of the challenge pack) and the other 2/3/E/C (steriliser 2, 3rd cycle, excision set, on the tray nearest the cold spot).

Repackaging between cycles

The packs will be reused pack(s) from the previous cycle; the contents of the pack(s) must return to room temperature before repackaging and the next cycle run. To save time, the instruments from the pack(s) will be cooled quickly after unpacking and removing the indicator by placing the instruments in cool water. The instruments will be then dried and repacked with the next indicator and the next cycle run.

Interpretation of the results of the indicators

- If the process has been performed correctly, all the 'M' and 'C' indicators should show no growth or its equivalent; otherwise, it indicates a process failure and must be investigated. Record results.

- If the process has been performed correctly, the single unsterilised control 'Z' indicator should show growth. If not, the batch of indicators or the incubator is faulty (the service technician needs to check it with the thermocouple as part of annual servicing).
- A pass result is 100%: all six processed biological indicators (minimum of two in each load over three cycles) should not have changed colour and the control biological indicator should have changed colour after incubation. Any failures must be fully investigated as to cause and corrective action documented and the entire procedure repeated.

Check the steriliser settings and results of steriliser monitoring

- Ensure:
 - time and temperature were correctly set
 - routine monitoring of each cycle's time at temperature (either by printout, download of data logger, manual recording of time at temperature, or by the use of a Class 4, 5 or 6 chemical indicator) occurred at the correct frequency, was reviewed for adequacy, was signed off and is recorded in a log
 - the physical qualification of temperature ('time at temperature' testing) inside the challenge pack/load showed that the centre of the pack reached the correct sterilising temperature and that was maintained for the required time. Similarly, that the temperature during drying was also maintained for the correct time
 - the microbiological qualification with appropriate indicators inside the challenge pack/load showed that the centre of the pack and outside the pack inside the chamber was effective in sterilising these indicators on each of the three cycles (this will take 2 days to verify, as the indicators used require incubation)
 - all points are checked for each total processing time used for different pack/load types (the sterilisation temperature is not changed for different pack/load types). The use of multiple processing times and multiple sterilisers increases complexity and care must be taken to avoid errors when different cycles are selected.

Unloading the steriliser

- Review documentation in the practice policy and procedure manual or other documentation.
- Perform or supervise unloading.
- Check that cooled are dry, undamaged, seals are intact, and the Class 1 chemical indicator on the outside of each pack or in the tray with unwrapped items has changed colour.

Storage of sterile items

- Review documentation.
- Perform the task of storage.

- Check that stored items are kept dry, dust free and undisturbed, and packs have been processed, marked with the date and load number and stored in a manner to allow stock rotation. Check cleaning of the storage area does not compromise sterility.

Cleaning and maintenance of reprocessing equipment

- For each piece of equipment used in the practice (ultrasonic cleaner, washer-disinfector, drying cabinet, steriliser, incubator), review documentation in the practice policy and procedure manual, manufacturer's instructions and maintenance log.
- Perform or supervise routine maintenance procedures as documented.
- Check that maintenance tasks have been performed and are in accordance with the manufacturer's requirements.
- Visually inspect cleanliness and check that the documented cleaning schedule has been completed.

Validating reprocessing procedures

Validating reprocessing procedures

Validation is a documented procedure for obtaining, recording and interpreting results, to establish that the practice's reprocessing procedures, including sterilisation, will consistently yield sterile reusable medical devices and equipment.

Process validation includes:

- validation of the equipment (steriliser and washer-disinfector) performed by an accredited technician at installation and annually
- operational qualification (checking the steps are being performed correctly) performed by practice staff or by a technician
- performance qualification (checking the sterilisation process is effective in killing/inactivating microorganisms) performed by staff or by a technician.

Validation must be performed for each steriliser and for each set of parameters used in cycles. For most practices, validation of the sterilisation cycle will involve only a single steriliser, cycle time, temperature and challenge pack/load. Validation will be more complex for practices that use more than one steriliser or use more than one type of cycle.

Frequency of process validation

Validation of the entire process (all aspects of reprocessing, not just the sterilisation cycle) must be performed at installation (also called commissioning) and then annually.

In addition to technical validation of the steriliser cycle, annual validation should also include reviewing all protocols and procedures for reprocessing of reusable medical devices, from pre-cleaning to storage, and checking staff competency.

Validation of other equipment such as automatic washer/dryers is also required annually.

Validation must be performed again if, between annual validations, any part of the sterilisation process is altered in a way that could affect the sterilisation outcome, for example:

- The practice installs an ultrasonic cleaner.
- The steriliser has been returned after offsite repairs.
- Major repairs to the steriliser have been performed onsite.
- The practice has started using a different sterile barrier system.
- The practice has significantly changed the chamber contents and/or loading protocol.

Responsibility for steriliser validation

Validation is managed by the designated staff member with overall responsibility for the practice's sterilisation process (who may or may not be the infection prevention and control coordinator).

Site of steriliser validation

All aspects of validation should be performed onsite because validation of the sterilisation process outside the practice may not match practice conditions.

Revalidation is required after transporting a steriliser back to the practice after repairs.

When onsite technical servicing is not accessible

Occasionally, in some regional and remote areas, general practices and other office-and community-based practices cannot access onsite technical support.

In cases where annual servicing and calibration occurs offsite, the practice should send a complete 'challenge pack/load' with the steriliser to allow checking of penetration time and appropriate selection of sterilisation times and physical checking of 'time at temperature' of the steriliser.

Provided that the steriliser has been returned to the practice using appropriate transport and has not been grossly mishandled, the validation process can be completed onsite.

Microbiological qualification using appropriate biological or enzymatic indicators must be performed onsite by the practice. The service technician should send a copy of the printout results of a sterilisation cycle of the challenge pack/load to the practice, so that the practice can confirm the parameters that were tested and achieved, and can compare results obtained from onsite microbiological qualification. The onsite test will help check that no adverse changes occurred during transport.

If neither full onsite validation, nor partial onsite validation (microbiological qualification at both the service centre and practice) is possible, special checking of every cycle must temporarily be performed as an alternative to validation (for example, including use of Class 6 indicators). In such situations, the practice should request advice from the technician on how to perform these checks correctly until the steriliser can be properly validated.

More information: components of steriliser validation

For each type of sterilisation cycle (ie set of parameters) used in the practice, the temperature, time pressure is measured using calibrated equipment with a challenge load in the steriliser, to determine if sterilising parameters are reached. Drying is also checked.

Steriliser validation must include:

- heat distribution studies conducted on an empty chamber – available from the manufacturer, a previous validation or determined by the service technician
- a description of the challenge pack and load, and the chamber loading configuration, including a diagram or picture
- penetration time of the challenge pack  of the load to be validated, as determined by the service technician at the current validation
- physical qualification of the sterilisation cycle, including testing time at temperature
- microbiological qualification.

This involves processing of three identical consecutive cycles, using two biological indicators for each cycle (for each different cycle selected).

Tracking reusable medical devices for patient tracing

Tracking reusable medical devices for patient tracing

If there is sterilisation process failure or medicolegal issue relating to sterilisation in the practice, it will be important to identify which patients may be affected.

The practice must therefore set up a system to track which loads of medical devices (eg instruments) were used in procedures with which patients, in order to trace all the patients affected by a non-conforming (and therefore potentially contaminated) load. In some circumstances, traceability of a specific reusable medical device (eg instrument) may be required.

This system must link steriliser cycle batch information to patient identification, including the following information:

- date of sterilisation and sterilising process cycle number
- identification of the steriliser
- identification of the reusable medical device (name of device or name of set of devices) and the number of those items within the load
- identification of the person responsible for loading the steriliser
- other records such as results of performance tests (leak rate test, Bowie-Dick type test), results of chemical and biological monitoring undertaken for individual cycles or periodically, electronic or hard-copy evidence of physical parameters reached during the cycle
- identification of the person responsible for release of the sterilisation load.

The practice's system could be based on either of the following:

- recording patient identification numbers in the steriliser log against the pack/pouch date and load number
- entering data from the steriliser log (eg batch, pack/pouch number) into patient medical records.

Some reusable instruments have a unique identification number, which can be electronically or manually recorded.

If a sterilisation process failure or other reprocessing failure is identified after the release of items for use, the practice must identify, recall and quarantine items in the failed load that may still be in storage or have been used. The practice must follow the recall procedure according to the [current standard \(https://store.standards.org.au/product/as-5369-2023\)](https://store.standards.org.au/product/as-5369-2023),  which includes notifying state/territory public health authorities. Next actions will depend on assessed risk, and may involve contacting all affected patients for testing and counselling, in consultation with health authorities. See also [Criterion GP2.2 – Follow-up systems \(https://www.racgp.org.au/running-a-practice/practice-standards/standards-5th-edition/standards-for-general-practices-5th-ed/general-practice-standards/gp-standard-2/criterion-gp2-2-follow-up-systems\)](https://www.racgp.org.au/running-a-practice/practice-standards/standards-5th-edition/standards-for-general-practices-5th-ed/general-practice-standards/gp-standard-2/criterion-gp2-2-follow-up-systems) of the RACGP Standards.

In the case of a medicolegal issue, the ability to access documented validated and process details of the cleaning and sterilisation process used in any individual case would support the case that reusable medical devices were sterile at the time of use.

Requirements depend on the device use ([Table 10.2. Spaulding classification – application to reusable medical devices \(https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/risk-assessment#10.2\)](https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/risk-assessment#10.2)).

Under current standards applicable to office-based health care facilities not involved in complex patient procedures and processes, instruments used in semi-critical procedures/sites are not required to be sterile at the point of use. Batch control identification (identification and traceability) is not required.

Offsite sterilisation services

Offsite sterilisation services

Given the expense of purchasing and running a steriliser, practices may consider offsite sterilisation (a commercial sterilisation service or another accredited practice, hospital or healthcare provider) or using disposable single-use equipment.

When using an off-site sterilisation service, the practice must have evidence that it complies with the [current relevant standard\(s\)](https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/resources-and-references) (<https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/resources-and-references>).

It is strongly recommended that there is a clear and precise documented contract outlining:

- the scope of the service
- who is responsible for pre-treatment, cleaning, packing and sterilisation of reusable medical devices
- processes for safe transportation of reusable medical devices between facilities
- the traceability/tracking system.

Note: As the turnaround time for the reprocessing of equipment may be slower when performed offsite, more sets of reusable medical devices may be required. The actual number of sets required depends on usage patterns and turnaround time.

Reusable medical devices on loan

Reusable medical devices on loan

If the practice borrows reusable medical devices (eg surgical instruments) from another practice, they must be completely reprocessed before use, even if the sterilised pack has not been opened since it was reprocessed by the lender.

Reprocessing of reusable medical devices used off-site

Reprocessing of reusable medical devices used off-site

Practices that perform procedures outside the practice (for example, during house calls or visits to residential aged care facilities) need to have appropriate risk-based policies and procedures that ensure that the sterility of reusable medical devices is maintained during transport to the site.

Sterile and nonsterile reusable medical devices must be separated into appropriately labelled and cleanable containers.

After use, reusable medical devices must undergo initial pre-treatment/cleaning at the offsite location: damp or drying wiping to remove gross visible soil, rinsing, and use of instrument pre-treatment product for transporting.

Reusable medical devices used off-site must also be logged to enable tracing/tracking.

Offsite infection prevention and control protocols must ensure safe management and disposal of sharps and used single-use medical devices, and the use of standard precautions to prevent exposure to blood and body substances.

Reprocessing of specific categories of medical devices

Reprocessing of specific categories of medical devices

Devices for which sterilisation is not required

Frequently used devices that only contact intact skin, such as glucometers, pulse oximeters, stethoscopes, blood pressure cuffs and non-invasive ultrasound probes, must be cleaned after each use at the point of use.

Each practice should undertake a risk assessment to determine the probability of contamination with pathogens, the vulnerability of the patient population to infection, and potential for exposure. Cleaning method, process, frequency and cleaning agents used should be based on this assessment as well as on the manufacturer's instructions for use.

For example, they may be cleaned with an instrument-grade detergent and, if required, disinfected with a low- or intermediate-level TGA-registered/listed disinfectant (see [Table 9.4. Classification of disinfectant activity \(#9.4\)](#)), or cleaned and disinfected with a combined 'two in one' detergent/disinfect product (solution or wipe).

During an epidemic or pandemic, special protocols may be advised by health authorities.

Invasive devices

Most indwelling invasive medical devices, such as hormonal implants, intrauterine devices and suprapubic urinary catheters, are introduced using disposable single-use devices.

For any commercially prepared implantable materials, the manufacturer's batch lot/number must be recorded.

Practices must develop, implement and review processes to address infection prevention and control issues relating to the insertion, use and maintenance, and removal of invasive medical devices. Devices should be removed when no longer needed.

Respiratory equipment

See also: [Aerosol-generating procedures \(https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/5-levels-of-precaution/transmission-based-precautions\)](https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/5-levels-of-precaution/transmission-based-precautions)

Spacers for administering inhaled medicines

Spacers used with pressurised metered-dose inhalers (eg for patients with asthma or chronic obstructive pulmonary disease) are not required to be sterile. They can be stored in a clean, dry environment.

Spacers must not be shared or used by multiple patients unless sterilised.

Metal spacers (rarely used in Australia) and some plastic spacers can be sterilised.

Most spacers (standard plastic, antistatic polymer or polycarbonate polyurethane) are intended for use by a single patient and cannot be sterilised. They must be discarded after use or given to the patient to re-use.

Spacers can be washed for reuse by one patient (not shared), following the manufacturer's instructions. Practices should advise patients on spacer hygiene.²

Practices can keep cardboard disposable spacers for use in emergencies or when a patient does not have their own spacer.

Masks for administering inhaled medicines

Masks used with spacers and inhalers (eg for administering bronchodilators to infants) or masks used with nebulisers are intended for use by a single patient and cannot be sterilised. They must be discarded after use or given to the patient to re-use, following the manufacturer's instructions.

Before use, they are not required to be sterile and can be stored in a clean, dry environment.

Nebulisers

Nebulisers are no longer recommended for administering inhaled medicines, unless unavoidable (eg a patient with severe acute asthma unable to inhale salbutamol through a pressurised metered-dose inhaler plus spacer).³ The use of nebulisers carries a high risk of transmitting viral infections because they generate droplets and aerosols that can spread infectious particles for several metres and can remain airborne after the patient leaves.³

Nebulisers are not required to be sterile at the time of use. They can be stored in a clean and dry environment.

Tubing is for single patient use only, and cannot be reprocessed. (For nebulisers used at home by a single patient, tubing must be replaced every few months according to the manufacturer's instructions.)

Peak expiratory flow meters

Mouthpieces cannot be shared or reused by another patient. Instruct patients to bring their own peak flow meter, if required during a consultation.

Resources and references

Resources and references

Resources

[Reprocessing of reusable medical devices \(https://app.magicapp.org/#/guideline/Jn37kn/section/jNDMVn\)](https://app.magicapp.org/#/guideline/Jn37kn/section/jNDMVn). In: NHMRC. [Australian guidelines for the prevention and control of infection in healthcare \(https://app.magicapp.org/#/guideline/Jn37kn\)](https://app.magicapp.org/#/guideline/Jn37kn) (2019)

[RACGP Steriliser Record System - logbook and templates \(https://www.racgp.org.au/running-a-practice/practice-resources/ordering-publications/record-keeping-in-general-practice\)](https://www.racgp.org.au/running-a-practice/practice-resources/ordering-publications/record-keeping-in-general-practice)

New South Wales Clinical Excellence Commission [Reprocessing of Reusable Medical Devices \(https://www.cec.health.nsw.gov.au/keep-patients-safe/infection-prevention-and-control/Reprocessing-of-Reusable-Medical-Devices\)](https://www.cec.health.nsw.gov.au/keep-patients-safe/infection-prevention-and-control/Reprocessing-of-Reusable-Medical-Devices) resources

Relevant Australian standards

Royal Australian College of General Practitioners. [GP Standard 4. Criterion GP4.1 – Infection prevention and control, including sterilisation \(https://www.racgp.org.au/running-a-practice/practice-standards/standards-5th-edition/standards-for-general-practices-5th-ed/core-standards/core-standard-4/criterion-c-4-1-health-promotion-and-preventive-care\)](https://www.racgp.org.au/running-a-practice/practice-standards/standards-5th-edition/standards-for-general-practices-5th-ed/core-standards/core-standard-4/criterion-c-4-1-health-promotion-and-preventive-care). In: [Standards for general practices \(https://www.racgp.org.au/running-a-practice/practice-standards/standards-5th-edition/standards-for-general-practices-5th-ed/table-of-contents\)](https://www.racgp.org.au/running-a-practice/practice-standards/standards-5th-edition/standards-for-general-practices-5th-ed/table-of-contents). 5th Edition. East Melbourne, Vic: RACGP, 2020.

AS 5369 – Reprocessing of reusable medical devices and other devices in health and non-health related facilities

Other relevant standards

ISO 17665-1:2006 – Sterilization of health care products

References

1. Spaulding E. Chemical disinfection and antisepsis in the hospital. J Hosp Res 1957; 9: 5-31.
2. National Asthma Council Australia. Use and care of spacers. Australian asthma handbook V22. South Melbourne: National Asthma Council Australia; 2022.
3. National Asthma Council Australia. Australian asthma handbook. Version 2.2. Melbourne: National Asthma Council Australia; 2022.

12. Planning a practice: design, fit-out, equipment and consumables

Overview – Planning a practice: design, fit-out, equipment and consumables

Overview – Planning a practice: design, fit-out, equipment and consumables

It is crucial to consider infection prevention and control when planning and designing a new practice or renovating a practice building, and when planning ongoing maintenance of the site and equipment.

Aspects of building design and organisation that affect infection prevention and control include choice of surface materials for walls, floors, desks and examination/treatment tables (easy to clean), material and design of fixtures and fittings, provision of areas that can be used for isolation is needed, adequate ventilation, design of reprocessing area and storage (if practice uses reusable medical devices that require special processes), waste storage areas, placement and design of hand hygiene equipment.

Aspects of equipment set-up that affect infection prevention and control include choice of disposable versus reusable medical devices and choice of information technology hardware and telephones (ease of cleaning keyboards, handsets and other devices).

Ongoing maintenance of the building and equipment should be carried out as necessary to minimise infection risks.

The infection prevention and control coordinator should be involved in purchasing decisions about consumables, equipment, personal protective equipment, hand hygiene agents, manual or automated cleaning, disinfecting and sterilising systems, furnishings, reusable medical devices, single-use and single-patient use devices including sharps, chemicals used for environmental cleaning and disinfection, waste management systems and other relevant clinical purchases.

Building design and fit-out

Building design and fit-out

Practice design should consider how the building design can facilitate:

- monitoring of entries
- isolation of patients with potentially transmissible infections
- effective cleaning surfaces and fixtures
- adequate ventilation
- appropriate traffic flow of personnel through rooms and corridors, reducing unnecessary contact or proximity between staff, patients and visitors (see [Table 5.1. Managing practice access and patient flow \(#5.1\)](#))
- safe and effective workflow in the reprocessing area.

Materials and fixtures

Surfaces and fixtures should be:

- easily cleanable and nonporous, with no grooves or crevices (such as tiles with grouting)
- able to withstand repeated cleaning
- easy to maintain and repair to avoid cracks or degradation
- resistant to microbial growth.

Hard (non-carpeted), easily cleaned flooring is required in treatment rooms and other rooms that require frequent cleaning and sometimes disinfection, such as waiting areas).

Sharps containers should be placed at the correct height (see [7. Sharps \(https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/7-sharps/overview\)](https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/7-sharps/overview)).

Ventilation

Adequate ventilation, whether achieved by natural airflow or air conditioning, is necessary to reduce the risk of airborne transmission of microbial infections in enclosed indoor environments. Practices could consult a ventilation engineer or an occupational hygienist for advice on optimal ventilation when designing the space, refitting the space or during an airborne-transmitted outbreak.

Ventilation must be designed to achieve 6–8 air changes per hour (ie the number of times per hour that the whole volume of air in each room is replaced by fresh air) in general areas. Fresh air is preferable to recirculated air. Flows less than 6 air changes per hour are inadequate to help prevent airborne microbial transmission. In rooms where aerosol-generating procedures (eg spirometry) occur, a ventilation rate of 12 air changes per hour is recommended.¹

The direction of airflow must be from 'clean' to less clean areas, to avoid dispersing contaminated air.

Standard heating, ventilation, and air conditioning systems are not specifically designed to prevent transmission of airborne infections, but can be used to optimise ventilation to assist in reduction of risk of transmission. Some contain high efficiency particulate air (HEPA) filters, which require regular cleaning or replacement. Heating, ventilation, and air conditioning systems must be well maintained and regularly serviced. Unless the practice has adequate natural ventilation that consistently achieves adequate cross-flow of air (possibly assisted by a ceiling fan), air conditioning must be run to ventilate the area to achieve 6–8 air changes per hour, even when heating or cooling are not needed.

Windows and doors can be opened for additional ventilation when there is a high risk of airborne transmission, although this does not guarantee adequate airflow. Fans can be used to improve air flow. Practices could obtain advice on whether the air conditioning system can be used at the same time.

Air purifiers/cleaners do not provide ventilation. However, if necessary, portable air-cleaning devices with HEPA filtration can be used in addition to other ventilation in areas with inadequate fresh air and circulation. The clean air delivery rate must be sufficient for the room volume. Before buying an air purifier, practices could obtain advice from an expert (eg industrial or occupational hygienist, or heating, ventilation and air conditioning professional) on whether it is likely to improve ventilation significantly, and to determine the most effective placement (generally at the site where there is least air movement).

Toilets must be fitted with exhaust fans. When there is risk of airborne transmission of relevant infections (eg during a respiratory infection outbreak), the practice could ensure that exhaust fans in toilets are functional, operating continuously and at full capacity when the building is occupied. Toilet fans should exhaust directly outdoors and away from windows and air intake systems. Toilets can be fitted with a second passive fan on the external wall, which moves fresh air into the toilet area, while the active fan removes used air. These are located sufficiently apart so that fresh air is not immediately exhausted.

Design of reprocessing area

During reprocessing of reusable medical devices such as instruments, 'clean' and 'dirty' activities need to be segregated (for example, in different sections of the bench as far away from each other as the space allows; [Figure 12.1. Sample design and workflow of reprocessing area \(#figure121\)](#)). The objective is to minimise the risk of cross-contamination of a cleaned, disinfected and sterilised reusable medical device (see [10. Reprocessing reusable medical devices \(https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/overview\)](#)).

Design of the area designated for reprocessing reusable medical devices should include the following considerations ([Figure 12.1. Sample design and workflow of reprocessing area based on best practice \(#figure121\)](#); see also [10. Reprocessing reusable medical devices \(# 10. Reprocessing reusable\)](#)):

- Surfaces (benches, sinks, splashbacks, walls) must be smooth, with no rough or textured areas where soiling can accumulate (such as tiles with grouting or silicon sealant), and made of material that does not shed fibres or particles. Ideally there should be no crevices between the walls and floor, or around any fixtures, where dirt can collect. The floor must be washable non-slip material.
- If the practice does not use an automatic washer-disinfector for cleaning reusable medical

devices, it should contain two sinks: one designated 'dirty' (for pre-cleaning and cleaning) and one designated 'clean' (that is, less contaminated). Sinks must be deep enough to immerse reusable devices during cleaning, and should not have shower-heads. These considerations also apply when using a bowl. Reprocessing sinks must not be used for handwashing.

- Ideally, a reprocessing area is fitted with a type B handbasin.
- One or more (as required) alcohol-based handrub dispensers could be installed on the wall adjacent to the bench areas where reprocessing is done, but not directly over the work area. They must be placed where they will not be splashed.
- The area should be well lit to make it easy for staff to inspect devices for soiling.
- All supplies should be stored in closed cupboards or drawers; no materials, supplies or equipment may be left out or stored on benches or floors. Even clean boxes shed fibres that could compromise device asepsis/sterility.
- The area cannot be shared with linen or waste and should be a low-traffic area.
- The area must include facilities for hand hygiene, either alcohol-based handrub in a hands-free dispenser, or a dedicated sink for handwashing. Handrub must not be placed at a sink.
- Clean, dry gloves and aprons, masks and full-face shields should be easily accessible in the reprocessing area. They must be stored in a closed dry cupboard, well away from possible splashing or contamination.

Storage areas for packs of reusable medical devices (eg instruments) that have been through the steriliser must be well sealed to prevent dust contamination.

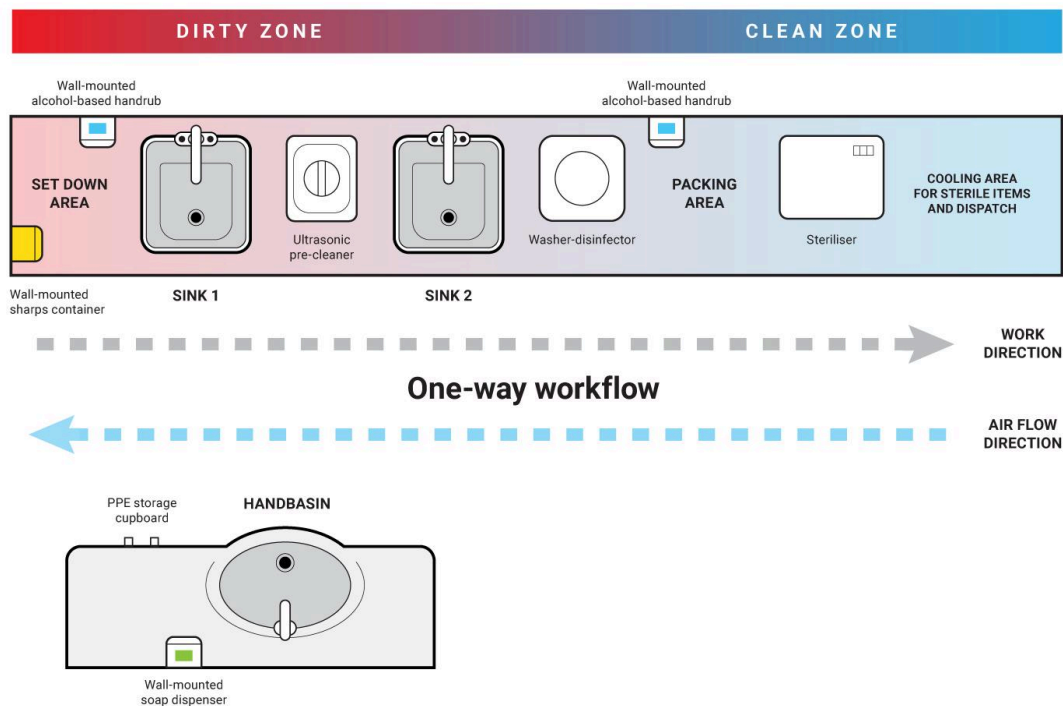


Figure 12.1.

Sample design and workflow of reprocessing area

PPE: personal protective equipment

The workflow is strictly in one direction: the staff member enters the zone with clean hands, dons required PPE, and proceeds to work from the 'dirty' to 'clean' (less contaminated) zones (left to right), washing hands with soap and water if they become visibly contaminated, and reusing alcohol-based handrub after each stage of the process while hands remain visibly clean.

The direction of airflow is from the 'clean' zone to the 'dirty' zone. The ultrasonic pre-cleaner is ideally placed between the two sinks, contingent on plumbing, power and safety considerations.

The diagram is intended as a sample. Alternatives are possible:

- The location of the ultrasonic pre-cleaner (either before Sink 1 or between Sinks 1 and 2) is decided based on a practice's pre-cleaning process.
- If the practice does not have a washer/disinfector, the drying area would take the position of the washer/disinfector in this diagram, to the immediate left of the packing area.
- A washer/disinfector may be on or under the bench.

Wastewater

A sluice or laundry sink can be considered for disposing of wastewater from cleaning, rinsing bloody linen, and cleaning buckets and mops. The sluice or laundry sink is best located in the practice laundry or utility room.

Wastewater must not be poured down the laundry sink.

Equipment

Equipment

When choosing equipment for the practice, consider their potential effect on the risk of infection transmission when new and after long-term use.

Reusable medical devices (eg surgical instruments)

When purchasing reusable medical devices such as instruments, ensure that they can be correctly reprocessed. Check the manufacturer's advice on cleaning and sterilisation before buying.

Avoid devices that require chemical disinfection.

Choosing equipment for reprocessing reusable medical devices

All reprocessing equipment (including ultrasonic cleaner, washer-disinfectors, heat sealers, small sterilisers, drying cabinets, biological indicator incubators, and packaging systems) must conform to relevant equipment and/or safety standards.

If the practice opts to reprocess reusable medical devices onsite, this equipment should be selected to meet the following criteria:

- The model is listed on the Australian Register of Therapeutic Goods as a medical device
- The model complies with an applicable Australian or international standard for performance and safety
- The model is fit for purpose based on assessment of the practice's needs according to the volume and type of reusable medical devices requiring reprocessing
- There is an operator's manual containing documented and validated reprocessing instructions in accordance with ISO 17664-1
- There is a documented schedule for periodic maintenance
- A validation, calibration and maintenance contract can be initiated with the supplier or the practice's preferred provider.

Choosing consumables and reusable equipment

Choosing consumables and reusable equipment

When choosing which consumables and reusable medical devices to stock, practices need to consider in addition to cost ([Table 12.1. Considerations for purchasing consumables and reusable equipment \(#12.1\)](#)).

Table 12.1. Considerations for purchasing consumables and reusable devices

Parameter	Considerations
Quality	The extent to which the product performs its defined function without contributing to transmission of infection
TGA approval	Whether the item is listed in the Australian Register of Therapeutic Goods
Safety	Whether the item can be appropriately cleaned, disinfected or sterilised. Check manufacturer safety data and instructions Whether the item will have infection prevention and control implications for other consumables, equipment or plans Whether any difficulties in cleaning and reprocessing the product may impact on the product's functionality and safety Whether any alternative products that are available may present a lower risk of infection
Cost-benefit analysis	Unit cost, maintenance costs including hidden expenses such as staff time and other resources (eg cleaning and/or disinfection requirements)
Waste minimisation	Disposal requirements in accordance with legislative compliance

Parameter	Considerations
Serviceability and availability	Availability, reliability of supply chain Maintenance requirements Service agreement and warranty

Single-use items

Single-use devices must not be reprocessed for reuse.

A manufacturer may classify its product as single use for several reasons including:

- cleaning difficulties posed by sharp or narrow lumen reusable medical devices
- materials used in the manufacture of the item may not withstand the cleaning and sterilisation process (eg some plastics in nebuliser sets, tubing, spacers and syringes may distort or melt, low-grade stainless steels in disposable sets may rust)
- significant work health and safety risks posed in reprocessing (eg needles for injections, neurological testing, acupuncture and suturing, scalpel blades, lancets and stitch cutters).

Even practices that reprocess their own equipment will still use many single-use items. Practices need to have stock control policies to ensure a ready supply of single-use stock is available as required. For example, practices could have essential disposable instruments available in the event of a reprocessing equipment (eg steriliser) breakdown.

The advantages of single-use items are that they minimise the risk of cross-infection, reduce the work health and safety risks of reprocessing and sterilising, and reduce the staff time and cost of onsite sterilisation. Some practices, especially those that rarely perform procedures requiring sterile reusable medical devices, will find it more economical to maintain a range of pre-packaged, single-use sterile items to manage their anticipated needs.

The disadvantages of single-use items are that their unit cost may be higher, may have a greater environmental impact, require storage space, and require a reliable supply chain (practices may need to keep larger amounts of disposable stock as a buffer). Quality varies between brands.

Lancets for blood testing

Lancets should be of the spring-loaded, retractable, single-use variety for most applications. The main exception is disposable nonretractable single-patient lancets used multiple times for allergy testing on a single patient and then discarded.

Plates or bases of reusable spring-loaded devices are a potential source of cross-infection and pose an unacceptable risk to patients in general practice and other office- and community-based practices. However, their use is appropriate for single-patient home use where instructions on thorough cleaning are provided.

Changing the plates or bases and reloading with new but unprotected lancets poses a work health and safety risk.

Auroscope tips

Practices should use disposable auroscope tips.

Reusable auroscope tips are not appropriate for office-based practices because cleaning is difficult. Although inexpensive, they require significant staff time to carefully clean small lumens with fine brushes to remove wax contamination. Imperfect cleaning is a hazard.

Spirometer and peak flow meter mouthpieces

Single-use mouthpieces must be used in practices. Spirometers must use inline viral/bacterial filters.

Peak flow meters are for single-patient use only.

Spacers for use with pressurised metered-dose inhalers

Practices can keep cardboard disposable spacers for use when a patient does not have their own spacer (see [Respiratory equipment \(https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/reprocessing-of-specific-categories-of-medical-dev#resp\)](https://www.racgp.org.au/running-a-practice/practice-standards/racgp-infection-prevention-and-control-guidelines/10-reprocessing-reusable-medical-devices/reprocessing-of-specific-categories-of-medical-dev#resp)).

Metal spacers (rarely used) and some plastic spacers can be sterilised, but most plastic spacers are for single-patient use and cannot be sterilised.

Resources and references

Resources and references

Resources

Royal Australian College of General Practitioners. [General practice tool kit, Module 2 – Your practice premises](https://www.racgp.org.au/running-a-practice/practice-resources/practice-tools/general-practice-business-toolkit/general-practice-tool-kit/module-2/deciding-on-a-location) (<https://www.racgp.org.au/running-a-practice/practice-resources/practice-tools/general-practice-business-toolkit/general-practice-tool-kit/module-2/deciding-on-a-location>).

Australasian Health Facility Guidelines (<https://healthfacilityguidelines.com.au/>) (Part D. [Infection prevention and control](https://healthfacilityguidelines.com.au/part/part-d-infection-prevention-and-control-0) (<https://healthfacilityguidelines.com.au/part/part-d-infection-prevention-and-control-0>))

Australian Health Protection Principal Committee (AHPPC) statement on the role of ventilation in reducing the risk of transmission of COVID-19 (<https://www.health.gov.au/news/australian-health-protection-principal-committee-ahppc-statement-on-the-role-of-ventilation-in-reducing-the-risk-of-transmission-of-covid-19>)

United States Environmental Protection Agency. [Air Cleaners, HVAC Filters, and Coronavirus \(COVID-19\)](https://www.epa.gov/coronavirus/air-cleaners-hvac-filters-and-coronavirus-covid-19) (<https://www.epa.gov/coronavirus/air-cleaners-hvac-filters-and-coronavirus-covid-19>)

World Health Organization. [Roadmap to improve and ensure good indoor ventilation in the context of COVID-19](https://www.who.int/publications/i/item/9789240021280) (<https://www.who.int/publications/i/item/9789240021280>)

Australian Commission on Safety and Quality in Health Care. [Optimising ventilation for infection prevention and control in healthcare settings](https://www.safetyandquality.gov.au/our-work/infection-prevention-and-control/optimising-ventilation-infection-prevention-and-control-healthcare-settings) (<https://www.safetyandquality.gov.au/our-work/infection-prevention-and-control/optimising-ventilation-infection-prevention-and-control-healthcare-settings>)

Relevant Australian standards

Royal Australian College of General Practitioners. [GP Standard 4. Criterion GP4.1 – Infection prevention and control, including sterilisation](https://www.racgp.org.au/running-a-practice/practice-standards/standards-5th-edition/standards-for-general-practices-5th-ed/core-standards/core-standard-4/criterion-c-4-1-health-promotion-and-preventive-care) (<https://www.racgp.org.au/running-a-practice/practice-standards/standards-5th-edition/standards-for-general-practices-5th-ed/core-standards/core-standard-4/criterion-c-4-1-health-promotion-and-preventive-care>). In: [Standards for general practices](https://www.racgp.org.au/running-a-practice/practice-standards/standards-5th-edition/standards-for-general-practices-5th-ed/table-of-contents) (<https://www.racgp.org.au/running-a-practice/practice-standards/standards-5th-edition/standards-for-general-practices-5th-ed/table-of-contents>). 5th Edition. East Melbourne, Vic: RACGP, 2020.

AS 1668.1 – The use of ventilation and air conditioning in buildings

AS 1668.2 – Mechanical ventilation in buildings

AS 1071 – Placement and presentation of hand hygiene materials in relation to the basin in healthcare settings

Other relevant standards

ISO 17664-1 – Processing of health care products

References

1. World Health Organization. [Roadmap to improve and ensure good indoor ventilation in the context of COVID-19 \(https://www.who.int/publications/i/item/9789240021280\)](https://www.who.int/publications/i/item/9789240021280). [Accessed 3 October 2022].

Glossary

Glossary

A

Antimicrobial agents: Substances or processes that inhibit the growth or tend to destroy or inhibit the pathogenic action of microorganisms including bacteria, viruses and fungi

Autoclave: Common term for small steam steriliser

B

Biofilm: A layer of material on the surface of an instrument or device which contains biological material and in which microorganisms may be embedded

Biological indicator: A carrier on which a defined number of test microorganisms have been deposited, contained within its primary pack and ready for use, that provides a defined resistance to the specified sterilisation process (colloquially known as a 'spore test')

Body substance: Replaces former term 'body fluids'

C

Chemical indicator: A system that reveals a change in one or more predefined process variables based on a chemical or physical change resulting from exposure to a process

Cleaning: The process of removing all visible dust, soils and other material from a surface. Manual cleaning is usually performed by using detergents and a physical action such as rubbing or brushing. Meticulous cleaning of instruments and other reusable equipment is required before disinfection or sterilisation

Contamination: The introduction of microorganisms or foreign matter (or both) to sterile or nonsterile materials or living tissue

D

Decontamination: The removal of microorganisms and foreign matter from materials or living tissue

Disinfectants, levels of: Disinfectants are classed as low, intermediate or high level:¹

Low-level disinfectants are defined as those that rapidly kills most vegetative bacteria as well as medium-sized lipid-containing viruses when used according to the manufacturer's instructions. It cannot be relied upon to kill bacterial endospores, mycobacteria, fungi or all small nonlipid viruses.

Intermediate-level disinfectants kill all microbial pathogens except bacterial endospores, when used as recommended by the manufacturer. They kill bacteria (including *Mycobacterium tuberculosis*), fungi (not necessarily effective against some spores) and viruses, when used according to the manufacturer's instructions.

High-level disinfectants are defined as those that kills all microbial pathogens except large numbers of bacterial endospores, when used according to the manufacturer's instructions. These are not used for general cleaning. General practices and other office-based healthcare practices generally do not use high-level disinfectants.

Disinfection: Any process that kills, inhibits or reduces disease-causing organisms such as viruses, bacteria or protozoa. It may not destroy spores. Disinfection is not the same as sterilisation.

E

Enzymatic indicators: Tablet or strip containing enzymes from microorganisms to imitate biological indicators

Equilibration time: See Penetration time

Exposure-prone procedures: see Procedures

F

Filtering mask: (also called filtering face-piece respirator or N95/P2 masks) – see N95/P2 mask

Full-body gown: A gown (see Gown) that is fluid-impervious and has long sleeves to protect clothing and arms

G

Gown: A fluid-impervious garment worn over clothes, with long or short sleeves

H

Hand hygiene: The practice of minimising pathogenic microorganisms on hands by thoroughly cleaning hands whenever necessary, using either alcohol-based handrub or appropriate liquid soap and water. In this guideline, both 'perform hand hygiene' and 'cleanse hands' means to follow one of the standardised methods.

Health professional: Someone who provides clinical care

Herd immunity: Immunity of a group or community. The resistance of a group to invasion and spread of an infectious agent based on the resistance to infection of a high proportion of individual members of the group

High-efficiency filtration: Filtration with a particle removal efficiency of 90–95%

Holding time: Minimum time at a given temperature that has been established to destroy all microorganisms

Hollow items: If a device is open at one end, it is hollow if the ratio of cavity length to diameter is greater than 1. If a device is open at both ends, it is hollow if the ratio of cavity length to diameter is greater than 2.

Narrow lumen items: Hollow device beyond the range for a simple hollow item, and neither solid nor porous

Simple hollow items: single-ended open-space items where the ratio of length to diameter of the cavity is ≥ 1 and ≤ 5 and where the diameter is ≥ 5 mm **or** double-ended open-space items where the ratio of the length to diameter of the cavity is ≥ 2 and ≤ 10 and where the diameter is ≥ 5 mm.

I

Iatrogenic: Resulting from the professional activities of health professionals. In the infection prevention and control context, this refers to infections acquired by the patient during the course of treatment

Immunity: The state of being protected from infection

Immunocompromised: A person whose immune system is not functioning well (eg those undergoing chemotherapy, or on antirejection medication or high doses of steroids)

Instrument detergent: A detergent developed for cleaning instruments and equipment

L

Low-level disinfectant: see Disinfectant

N

N95/P2 mask: A high-efficiency filtration mask capable of filtering extremely small particles. Used with airborne precautions

P

P2/N95 mask: A high-efficiency filtration mask capable of filtering extremely small particles. Used with airborne precautions

Particulate filter respirator: (also called filtering face-piece respirator or N95/P2 mask) – see N95/P2 mask

Particles: solid or liquid substances in the form of aggregated molecules or particles. Airborne particulate matter is typically in the size range of 0.01–100 μm diameter

Pathogen: Any disease-causing microorganism

Pathogenic: Having the capability to cause disease

Penetration time (equilibration time): The time taken to heat the centre of a pack to the sterilising temperature from when the steriliser chamber has reached the sterilising temperature

Personal protective equipment: Equipment used as an infection prevention and control measure. Includes the use of gloves, waterproof gown, goggles/face shield, mask and appropriate footwear

Physical distancing: Maintaining distance between people to reduce the risk of contact, droplet and airborne spread of disease.

Procedures, non-exposure-prone: (with respect to blood-borne viruses) procedures in which the healthcare worker's hands and fingers are visible and outside of the body at all times, and which do not involve possible hand injury by sharp instruments or exposure to tissues if the healthcare worker follows routine infection prevention and control procedures (eg routine oral examination with appropriate personal protective equipment, insertion and maintenance of intravenous lines).

Procedures, exposure-prone: (with respect to blood-borne viruses) procedures in which there is an increased risk of transmitting blood-borne viruses between healthcare workers and patients. These include invasive procedures in which there is potential for direct contact between the healthcare worker's skin (typically hands) and sharp objects or surgical instruments (eg needles, fractured bones, teeth).

Process challenge device: A device containing a chemical indicator used as a test of steriliser function

Prion: A microorganism resistant to most cleaning, disinfection and sterilisation techniques. Prions are responsible for Creutzfeldt-Jakob disease.

Q

Qualification: process of checking whether reprocessing is being performed correctly (eg includes physical qualification, microbiological qualification and process qualification)

R

Respiratory etiquette: (also called respiratory hygiene and cough/sneeze etiquette) Public health measures used to reduce the spread of respiratory infections by covering the mouth when coughing or sneezing, using tissues to blow the nose, disposing of tissues into waste, and washing hands after touching the nose

S

Safety data sheets: A document prepared by the manufacturer of a hazardous substance which describes its properties, uses, health hazard information, and precautions for use, safe handling information and first aid information. A safety data sheet can be obtained by contacting the distributor/manufacturer

Safety factor: Extra time included in the holding time to ensure sterilisation is achieved. It is a precautionary measure and forms 25% of the holding time

Skin disinfection (antisepsis): a process that involves the application of a disinfectant to reduce levels of microorganisms on the skin/mucosa

Skin asepsis: The removal, or elimination, of transient microorganisms from the skin and a reduction in the resident flora

Soil: Any matter that contaminates objects and may protect microorganisms from disinfection or sterilisation (eg blood and other body substances)

Staff: All people who work in or provide care within the practice, including employees and contractors (eg doctors, nurses, receptionists, practice managers, allied health professionals, administrative staff, cleaners including contract cleaners). 'Clinical staff' refers to health professionals (including doctors, nurses, Aboriginal health workers, and allied health care professionals).

Standard precautions: The range of methods and practices used by health professionals to prevent infection transmission, based on the assumption that all blood and body substances are potentially infectious

Standards, The: The Royal Australian College of General Practitioners. Standards for general practices. 5th edition. East Melbourne, Vic: RACGP, 2020

Sterile: The absence of protozoa, spores, mycobacteria, fungi, Gram-positive and Gram-negative bacteria, chlamydia, Rickettsia, mycoplasma and viruses

Sterilisation: A validated process used to render a product free from all forms of viable microorganisms. The nature of microbial death is described by an exponential function, and although the probability can be reduced to a very low number, it can never be reduced to zero

Sterilisation time: The total time of the sterilisation stage after the sterilising chamber has reached the sterilising temperature (penetration time plus holding time)

T

The Standards: The Royal Australian College of General Practitioners. Standards for general practices. 5th edition. East Melbourne, Vic: RACGP, 2020

Time at temperature testing: Testing performed to check that the correct temperature is maintained within the challenge pack for the entire sterilisation cycle. It is performed during validation and can be extended to check penetration and drying times

Transmission-based precautions: Precautions taken by health professionals, in addition to standard precautions, against a particular mode of transmission. They include droplet precautions, airborne precautions and contact precautions and involve the use of personal protective equipment, isolation and other measures

V

Validation: A documented procedure for obtaining, recording and interpreting the results of testing of sterilisers required to establish that a process consistently yields sterile products

References

1. National Health and Medical Research Council. [Australian guidelines for the prevention and control of infection in healthcare](https://www.nhmrc.gov.au/about-us/publications/australian-guidelines-prevention-and-control-infection-healthcare-2019) (<https://www.nhmrc.gov.au/about-us/publications/australian-guidelines-prevention-and-control-infection-healthcare-2019>) (2019). Version 11.12 Updated March 2022. Canberra: National Health and Medical Research Council; 2019 [Accessed 29 September 2022].

Links

Links

National

[Communicable Diseases Network Australia \(https://www.health.gov.au/committees-and-groups/cdn-a?utm_source=health.gov.au&utm_medium=callout-auto-custom&utm_campaign=digital_transformation\)](https://www.health.gov.au/committees-and-groups/cdn-a?utm_source=health.gov.au&utm_medium=callout-auto-custom&utm_campaign=digital_transformation)

Australian Government Department of Health and Aged Care [communicable diseases topic links \(https://www.health.gov.au/health-topics/communicable-diseases\)](https://www.health.gov.au/health-topics/communicable-diseases)

[Australian Commission on Safety and Quality in Health Care \(http://www.safetyandquality.gov.au\)](http://www.safetyandquality.gov.au)

Australian Government Department of Health and Aged Care: [Health Emergency Preparedness and Response \(https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-strateg-bio-index.htm\)](https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-strateg-bio-index.htm)

Australian Government Department of Health and Aged Care: [Australian Health Management Plan for Pandemic Influenza \(https://www.health.gov.au/resources/publications/australian-health-management-plan-for-pandemic-influenza-ahmpai\)](https://www.health.gov.au/resources/publications/australian-health-management-plan-for-pandemic-influenza-ahmpai)

RACGP [Managing pandemic influenza in general practice and related resources \(https://www.racgp.org.au/running-a-practice/practice-management/managing-emergencies-and-pandemics/managing-pandemic-influenza-in-general-practice\)](https://www.racgp.org.au/running-a-practice/practice-management/managing-emergencies-and-pandemics/managing-pandemic-influenza-in-general-practice) ('pandemic flu kit')

RACGP [Emergencies and pandemics \(https://www.racgp.org.au/running-a-practice/practice-management/managing-emergencies-and-pandemics\)](https://www.racgp.org.au/running-a-practice/practice-management/managing-emergencies-and-pandemics)

Australian Government Department of Health and Aged Care: [COVID-19 management guidelines for primary care providers \(https://www.health.gov.au/initiatives-and-programs/living-with-covid-primary-care-package/covid-19-management-guidelines-for-primary-care-providers\)](https://www.health.gov.au/initiatives-and-programs/living-with-covid-primary-care-package/covid-19-management-guidelines-for-primary-care-providers)

States and territories

Australian Capital Territory

[Disease Surveillance Unit \(https://health.act.gov.au/about-our-health-system/population-health/disease-surveillance\)](https://health.act.gov.au/about-our-health-system/population-health/disease-surveillance)

Northern Territory

[Public Health Unit disease control information \(https://health.nt.gov.au/professionals/centre-for-disease-control/cdc-programs-and-units/notifiable-diseases\)](https://health.nt.gov.au/professionals/centre-for-disease-control/cdc-programs-and-units/notifiable-diseases)

[Public Health Unit disease control contacts \(https://health.nt.gov.au/professionals/centre-for-disease-control/cdc-contacts\)](https://health.nt.gov.au/professionals/centre-for-disease-control/cdc-contacts)

New South Wales

[Infectious diseases information for GPs \(https://www.health.nsw.gov.au/Infectious/Pages/default.aspx\)](https://www.health.nsw.gov.au/Infectious/Pages/default.aspx)

[Contact details for Public Health Units \(https://www.health.nsw.gov.au/Infectious/Pages/phus.aspx\)](https://www.health.nsw.gov.au/Infectious/Pages/phus.aspx)

Phone number for redirection to local public health unit: 1300 066 055

Blood and body fluid exposure hotline 1800 804 823

[HIV Post Exposure Prophylaxis Hotline \(http://thealbioncentre.org.au/education-and-information/phone-lines/nsw-pep-hotline/\)](http://thealbioncentre.org.au/education-and-information/phone-lines/nsw-pep-hotline/)

Queensland

[Contact information for public health units \(https://www.health.qld.gov.au/system-governance/contact-us/contact/public-health-units\)](https://www.health.qld.gov.au/system-governance/contact-us/contact/public-health-units)

South Australia

[Notifiable disease reporting \(https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/health+notifications/notifiable+disease+reporting/notifiable+disease+reporting\)](https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/health+notifications/notifiable+disease+reporting/notifiable+disease+reporting)

Communicable Disease Control Branch: 1300 232 272

Tasmania

[Diseases notifiable by medical practitioners \(https://www.health.tas.gov.au/publications/diseases-notifiable-medical-practitioners\)](https://www.health.tas.gov.au/publications/diseases-notifiable-medical-practitioners)

Communicable Diseases Prevention Unit: 1800 671 738

Victoria

[Information on healthcare-associated infection prevention \(https://www.health.vic.gov.au/quality-safety-service/healthcare-associated-infection-prevention\)](https://www.health.vic.gov.au/quality-safety-service/healthcare-associated-infection-prevention)

[Information on infectious diseases \(https://www.health.vic.gov.au/public-health/infectious-diseases\)](https://www.health.vic.gov.au/public-health/infectious-diseases)

Communicable diseases Section: 1300 651 160

Western Australia

[Links for information for health professionals on communicable diseases \(https://ww2.health.wa.gov.au/Health-for/Health-professionals/Communicable-Diseases\)](https://ww2.health.wa.gov.au/Health-for/Health-professionals/Communicable-Diseases)

International

[World Health Organisation \(http://www.who.int\)](http://www.who.int)

Relevant standards

Relevant standards

Current Australian and New Zealand standards

AS ISO 31000 Risk management – Guidelines

AS/NZS IEC 31010:2020: Risk management – Risk assessment techniques

AS 1071 – Placement and presentation of hand hygiene materials in relation to the basin in healthcare settings

AS/NZS1715:2009 – Selection, use and maintenance of respiratory equipment

AS 23907 Sharps injury protection – Requirements and test methods – Sharps containers

AS/NZS 3825 Procedures and devices for the removal and disposal of scalpel blades from scalpel handles

AS/NZS 4261 Reusable containers for the collection of sharp items used in human and animal medical applications

AS/NZS 4261 AMDT 1 Reusable containers for the collection of sharp items used in human and animal medical applications

AS 3816 – Management of clinical and related wastes

AS/NZS 4146 – Laundry practice

AS/NZS 3733 – Textile floor coverings – cleaning

AS 5369 – Reprocessing of reusable medical devices and other devices in health and non-health related facilities

ISO 17665-1:2006 – Sterilization of health care products

AS 1668.1 – The use of ventilation and air conditioning in buildings

AS 1668.2 – Mechanical ventilation in buildings

AS 1071 – Placement and presentation of hand hygiene materials in relation to the basin in healthcare settings

ISO 17664-1 – Processing of health care products

International standards

European Standard EN 1500 – hygienic handrub

European Standard CEN-EN 12791 – surgical hand disinfection

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