Sterilisation

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We acknowledge the Aboriginal and Torres Strait Islander Peoples as the Traditional Owners of the lands. We wish to pay our respects to their Elders – past, present and emerging – and acknowledge the important role Aboriginal and Torres Strait Islander people continue to play within our community.

This webinar has been developed by Eastern Melbourne PHN on behalf of the Victorian and Tasmanian PHN Alliance, which is a collective platform for the seven PHNs in Victoria and Tasmania.

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Objectives

- Describe the sterilisation process undertaken in the practice.
- Understand the changes from the 4th to 5th edition of the RACGP Standards for general practices which will affect sterilisation processes.
- Describe the documentation requirements for sterilisation.
- Recognise the importance of validation and calibration of equipment in order to ensure the effectiveness of the sterilisation process.

RACGP Infection prevention and control standards 5th edition

RACGP Standards for General Practice 5th edition

What do we mean by sterilisation?

- Processing of reusable equipment
- Begins with prior cleaning of reusable medical instruments and equipment
- Continues through to cycle monitoring and storage ready for reuse
- It’s one of the standard precautions

Standard precautions

- Work practices that are used consistently to achieve a basic level of infection prevention and control

- Help protect staff from infection and help prevent infection transmission

- Used when staff may have contact with:
    - blood
    - other bodily fluids, secretions or excretions (except sweat)
    - non-intact skin
    - mucous membranes

Standard precautions include:

- Hand hygiene
- Personal protective equipment
- Respiratory hygiene and cough etiquette
- Standard aseptic technique
- Safe management of sharps and clinical waste
- Environment controls
- Support services
- Effective reprocessing of reusable equipment and instruments and appropriate use of cleaning products

RACGP Standards for general practice 5th edition

Criterion GP 4.1 – Infection prevention and control, including sterilisation

Indicator GP4.1 A: Our practice has at least **one clinical team member** who has primary responsibility for:

- coordinating prevention and control of infection
- coordinating the provision of an adequate range of sterile equipment (reprocessed or disposable)
- where relevant, having procedures for reprocessing (sterilising) instruments onsite or offsite, and ensuring there is documented evidence that this reprocessing is monitored and has been validated
- safe storage and stock rotation of sterile products
- waste management

RACGP Standards for general practice 5th edition

- Policies, procedures and tools must be developed
- Must include procedures for reprocessing instruments onsite or offsite
- Changes between 4th and 5th Edition Standards:
  - ➢ Primary responsible person for infection control must be **a clinical team member**
  - ➢ A new indicator

RACGP Standards for general practice 5th edition

GP4.1F Our practice records the sterilisation load number from the sterile barrier system in the patient's health record when sterile items have been used, and records the patient's name against those load numbers in a sterilisation log or list.

This indicator is not mandatory.

Risk assessment and processing reusable equipment

- A clinical team member is responsible for ensuring that equipment and instruments used in patient care have been appropriately cleaned and disinfected or sterilised.

- The level of processing is determined by the risk of infection posed by their reuse.

- Instruments that must be sterile in use can be either:

  - ➢ single-use sterile items or

  - ➢ items that are reprocessed by the practice or by an offsite sterilisation facility.

Spaulding Classification

Level of risk	Application	Process
Critical	Entry or penetration into sterile tissue, cavity or bloodstream	Sterility is required
Semicritical	Contact with intact nonsterile mucosa or nonintact skin	Sterilisation preferred where possible. If sterilisation is not possible then high-level chemical disinfection is required.
Noncritical	Contact with intact skin	Clean as necessary with detergent and water

Risk assessment and processing reusable equipment

Health professionals need to balance:

- The probability of harm to a patient
- The likely seriousness of the harm
- The feasibility of meeting all processing requirements in the practice
- Complying with the manufacturer’s instructions around the recommended use of equipment and products to ensure appropriate sterilisation.

Offsite sterilising

The practice must have evidence that sterilisation standards have been met:

- a copy of the facility's accreditation certificate

OR

- appropriate documentation including:
  - reprocessing policies and procedures
  - sterilisation policies and procedures
  - results of annual validation.

Refer to the RACGP Infection prevention and control standards 5th edition - pages 86 - 87

Staff training

Staff involved in sterilisation must have:

- adequate training
- competency assessment.

Training and competency assessment needs to be documented

- eg. Appendix 1 of the RACGP Infection Prevention and Control Standards 5th edition.

Competency checking is generally done by the clinical team member responsible for infection control in the practice.

Processing area

- Practices need a designated area.
- Workflow needs to be systematic and move from dirty to clean.
- Dirty and clean areas must be clearly designated, identified and labelled.
- Bench tops should be cleaned and dried between use.
- If space is restricted, use a sheet of disposable plastic backed paper or suitably labelled tray or container.

Processing area

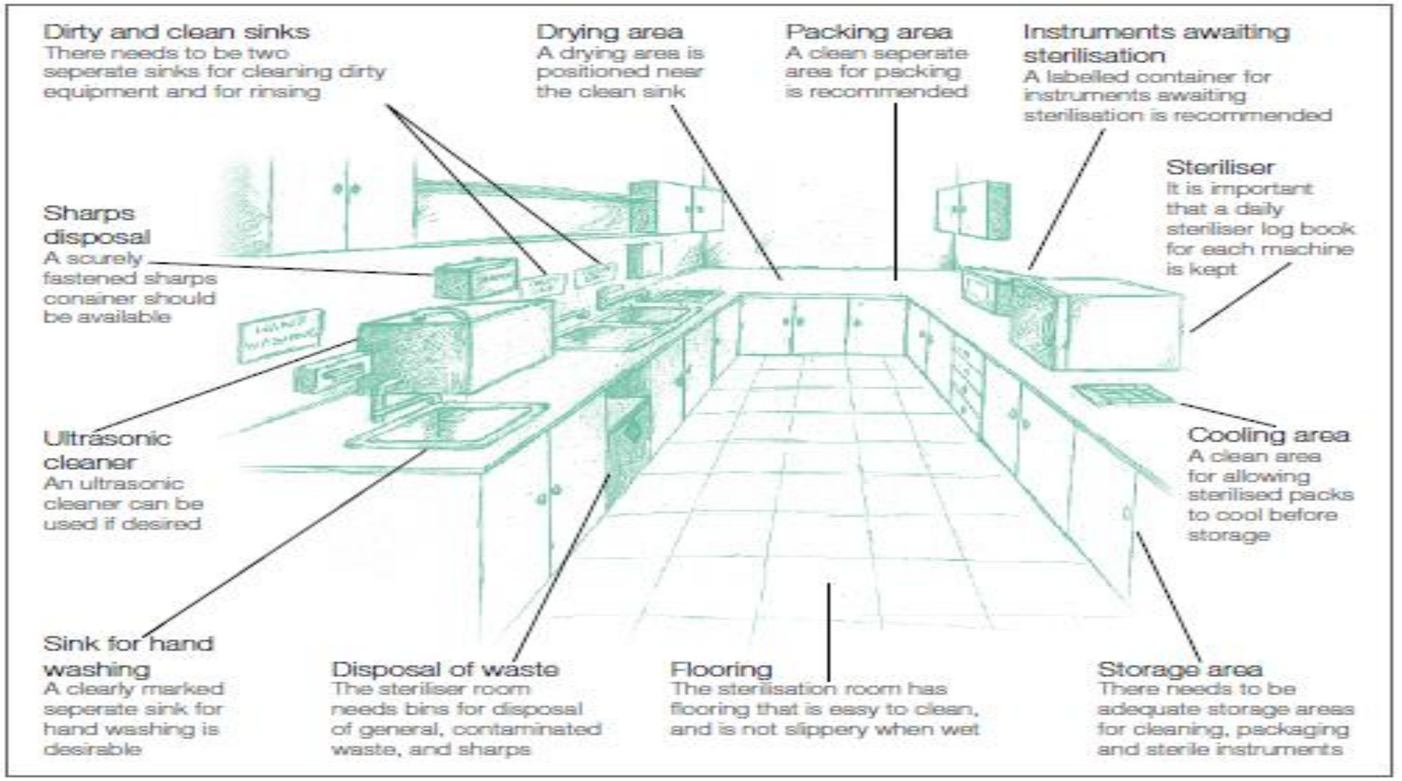
- Must have 2 sinks:
  - a ‘dirty’ sink for washing
  - a ‘clean’ or ‘cleaner’ sink for rinsing washed reusable equipment.

- If only one sink is available – use a clearly labelled container as the ‘dirty’ sink.

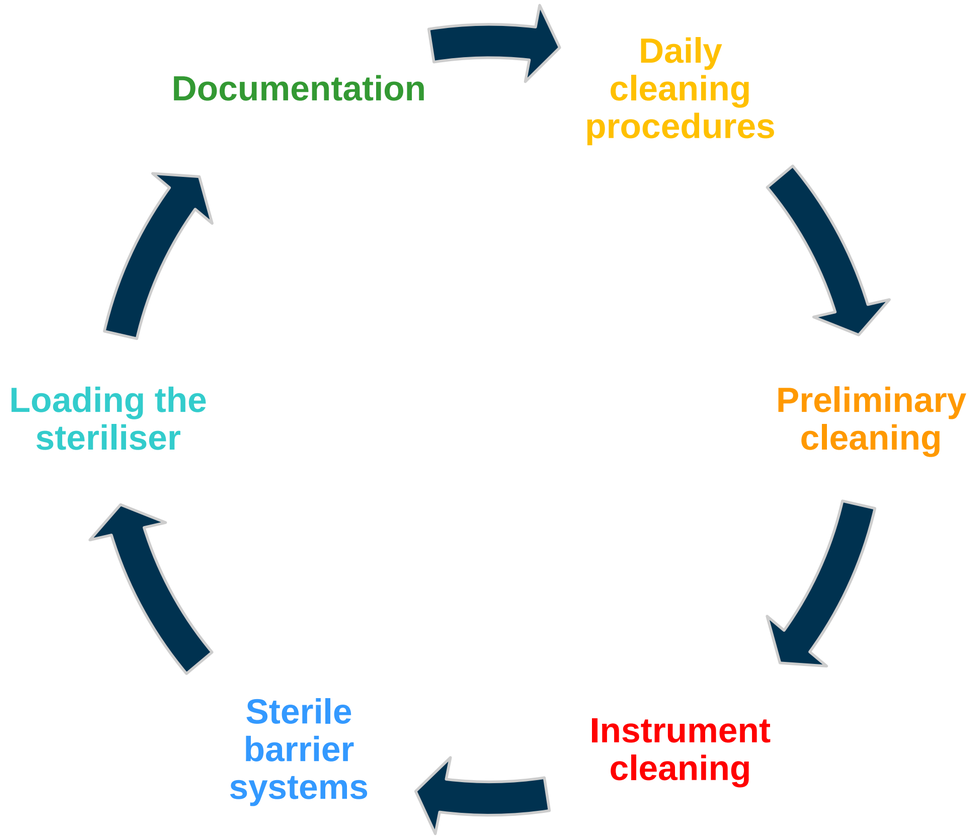
- Hand hygiene should be performed when:
  - moving from dirty to clean areas
  - after handling soiled equipment and
  - before handling or packaging cleaned equipment.

- Utility or heavy duty gloves should be worn at all times when handling contaminated equipment.

Suggested processing area design



Reprocessing equipment



Daily cleaning procedures

- If used, prepare dirty instrument container with tepid water and correct detergent dilution.

- Sinks and containers:
  - clean after each use with water and detergent
  - clean and dry regularly to reduce contamination.

- Detergent wipes may be used for cleaning and should be positioned conveniently.

- Spray bottles can be used to clean sinks, trolleys, beds etc and must be made up fresh daily.

- Ensure correct dilution of detergent.

Preliminary cleaning

Visibly soiled instruments and equipment need preliminary cleaning before processing for reuse.

This begins at the end of the procedure in which the instrument or equipment is used.

Use standard precautions including the use of personal protective equipment.

Remove gross soil by **one or a combination of the following**:

- wipe off gross soil at the point of use
- rinse all used instruments under gently running warm water in ‘dirty’ sink/container
- immerse items in the labelled ‘dirty instruments container’ for a short period.

Note that a ‘short period’ = no more than a few hours

Instrument cleaning

- Place a clean low lint towel on the clean side of the sink ready for instruments.
- Fill the dirty sink/container with tepid water to wash items.
- Measure detergent correctly.
- Transfer instruments from the dirty tub to dirty sink/container.
- Open or disassemble items for cleaning.
- Brush away from yourself and under the water line.
- Wash items by scrubbing items with a clean, firm bristled nylon or brass brush.
- Rinse items in the clean sink in gently running warm to hot water.
- Visually inspect items.
- Place items on the sink.

Instrument cleaning

- Dispose of water and rinse.
- Clean brushes with detergent and tepid water, rinse thoroughly and hang to dry.
- Wash sinks and containers with water and detergent and rinse with hot water.
- Dry sink and containers with a disposable towel.
- Clean and remove personal protective equipment.
- Wash and remove heavy duty gloves.
- Wash and dry hands.
- Wear new disposable gloves, and dry instruments with a low lint towel.

Sterile barrier systems - packaging

- Correct packaging is important and must take place in a **clean** area.
- Use clean, non sterile utility gloves.
- Packaging must allow for air removal, steam penetration, removal of steam and drying contents.
- Packaging must contain a class 1 indicator.
- Label with a permanent marker or self-adhesive label before loading.
- Minimum labelling includes date and load number.
- Unlock and open all instruments or equipment.
- Place handles towards opening end of packaging.
- Use tip protectors if needed.
- Place hollowware with the open side against the paper to prevent condensation.

Sterile barrier systems

- Practices often sterilise groups of instruments commonly used together in one pack. Photographs of packs can be useful.
- Correct sealing of packages is important.
- For self-sealing packages:
  - ➢ precisely fold seal along dotted or perforated line
  - ➢ remove backing strip and press firmly down on sealing strip from centre outward
  - ➢ if the strip contains a class 1 chemical indicator, this can be placed inside the package. This is optional.
- If a practice wishes to sterilise mixed items in a sterile barrier system:
  - ➢ establish the penetration time
  - ➢ validate the sterilisation cycle physically and microbiologically
  - ➢ validate the drying time.

Sterile barrier systems

- For instruments that are cleaned and dried but not ready for sterilisation:
  - ➢ leave the package unsealed
  - ➢ place the package in a container labelled ‘to be sterilised’.

- After packing instruments, remove gloves, and wash and dry hands thoroughly with a single use towel.

- If proceeding to sterilisation, record details in the steriliser log book including:
  - ➢ cycle date
  - ➢ load number
  - ➢ load description
  - ➢ identity of person who prepared the load.

- Logbooks should be kept with the records of validation and maintenance details.

- Develop your own logbook or use the example in Appendix 10 of the RACGP Infection prevention Control Standards 5th edition.

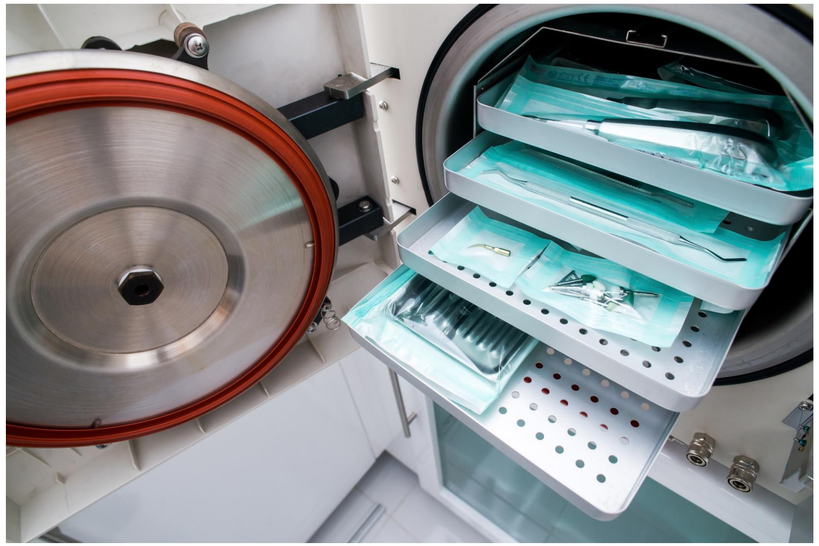
Loading the steriliser

- Always follow the loading instructions of the manufacturer.
- General principles:
    - place items in the load separator on the tray
    - for laminate pouches, alternate paper side to laminate side
    - ensure no items touch the steriliser wall
    - if loading a laminate pouch horizontally, position with the paper down
    - place hollowware on their sides in a draining position
    - do not exceed the parameters of the validated challenge load and challenge pack
    - sterilisation time is a critical factor
    - your service technicians will calibrate the steriliser to reach a specific temperature.

Loading the steriliser

Challenge pack – the hardest pack your practice would sterilise

Challenge load – the most number of packs sterilised in one batch



Unloading the steriliser

Correct handling of the sterile load is vital.

- Remove the tray from the steriliser.
- Do not place a hot tray on a cold surface.
- Allow the load to cool away from high levels of activity.
- Do not handle packs until they are cool.
- Check bags for moisture and integrity - an item which is wet or damaged is not considered sterile.
- Check chemical indicator (Class 1) on each pack has changed colour.
- Check whether the selected cycle parameter has been met.
- For failed loads:
  - ➢ all items must be rejected
  - ➢ identify and correct fault
  - ➢ reprocess entire load in a new sterile barrier system.

Documenting the cycle

Documenting the entire process is important.

The following information needs to be documented for each cycle:

- cycle date
- load number
- load contents
- identity of person who prepared the load
- results of cycle monitoring
- Class 1 chemical indicator change
- results of other indicators used
- condition of packaging
- signature of person releasing or rejecting the load
- comments regarding fault identification and corrective action taken.

Documenting the cycle

GP4.1F Our practice records the sterilisation load number from the sterile barrier system in the patient's health record when sterile items have been used, and records the patient's name against those load numbers in a sterilisation log or list.

You could achieve this by:

- showing evidence that sterilisation load numbers are recorded in the patient's health record
- having a log or list that records the patient's name against sterilisation load numbers.

Sterilisation logs should be retained with the records of validation and maintenance details and treated as a medical record.

Storage

- Ensure packs are stored in clean cupboards, drawers or plastic containers away from dust, moisture and sunlight.
- Sterility is **‘event related’** and has no time limit if medical devices are stored and handled correctly.
- Have a procedure for stock rotation.

Steriliser maintenance

Maintenance of the steriliser is essential.

- It should be carried out according to the manufacturer's instructions.
- The practice must have a written policy and procedure for all steriliser maintenance issues.
- Regular cleaning of the chamber, trays and racks is required – check recommendations of the manufacturer. Distilled water must be used.
- Calibration and full servicing must be done at least annually. Validation is usually scheduled at the same time.
- Servicing needs to be done by a qualified service technician.
- Document in the key equipment maintenance register.

Validating the sterilisation process

Validation of the entire process must be performed when the steriliser is installed and then annually. It involves:

- reviewing policies and procedures from preliminary cleaning through to point of use in the process
- performing all the procedures
- checking the efficacy of the results and
- recording the results process.

The temperature, pressure and challenge pack and load must be validated including:

- a heat distribution study
- a description of the challenge pack and load, and chamber loading details
- penetration time of the challenge pack
- physically checking the sterilisation cycle which includes time at temperature testing
- and the use of biological indicators (spore test)

Validating the sterilisation process

A template of the validation process is in the RACGP Infection Prevention and Control Standards

All staff involved in the processing of instruments at the practice should read through the documentation provided by the technician.

Documentation of validation process should be kept near the steriliser.

Single-use items

- Single-use items must not be reprocessed.
- Practices should have stock control policies to ensure a ready supply.
- A product may be regarded as single-use because:
  - cleaning difficulties
  - materials may not withstand the sterilisation process
  - reprocessing may pose a health and safety risk.
- Spacers, nebuliser masks and tubing are single patient use items. Some spacers are sterilisable.
- Single use spirometer and peak flow mouthpieces must be used.
- In an emergency, spacers, masks and nebulisers can be washed in hot water and detergent.

Summary

- Risk assessment should be done routinely and if something changes.
- Ensure that staff have adequate training. Training and competency need to be documented.
- Sterilisation begins with prior cleaning of reusable medical instruments and equipment and continues through to cycle monitoring and storage.
- Calibration and validation of the steriliser are crucial.

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