How to clean and sterilise reusable skin penetration equipment and instruments

Reusable skin penetration instruments must be thoroughly cleaned and then sterilised using a steam-under-pressure bench top autoclave.

About this fact sheet

The Public Health Regulation 2022 (the Regulation) requires all reusable instruments that penetrate a person's skin to be sterilised in line with AS/NZS 4815:2006 and be kept in a sterile condition until used in a skin penetration procedure.

Sterilisation is a process that kills micro-organisms including bacteria (and their spores), fungi and viruses.

Instruments and equipment that must be sterilised

All reusable instruments and equipment that puncture a person's skin must be sterilised before use in a skin penetration procedure.

Reusable equipment requiring sterilisation includes:

- cuticle cutters
- razor scrappers and blades (callus remover shaver)
- microdermabrasion heads
- tattoo barrels
- speculums and catheters.

Single-use items

- Instruments that penetrate the skin and cannot be effectively cleaned and sterilised must be single-use.
- Needles (including tattoo needles) and razors must not be reused. They need to be sterile before use and directly disposed of into an appropriate sharps container after use on a client.

How do you sterilise?

- Steam sterilisation under pressure and specific temperatures is a common process used to kill micro-organisms.
- Sterilisation must be carried out using a steam-under-pressure bench top autoclave in line with AS/NZS 4815:2006 *Office-based health care facilities - Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment.*
- The autoclave should be registered by the Therapeutic Goods Administration (TGA). Refer to the TGA website for further information.
- The sterilisation process needs to follow a one-way flow from dirty and contaminated equipment to clean and then to sterile equipment to prevent recontamination (see fact sheet titled 'Cleaning and sterilising reusable equipment and instruments).

Equipment cleaning notes

- Instruments need to be cleaned as soon as practicable after use.
- Equipment must be thoroughly cleaned (that is, scrubbing, using an instrument washer, and/or ultrasonic cleaner) so that they are free from any contaminants, protein residues and other stains, before processing through a steam-under-pressure bench top autoclave.
- Equipment needs to be cleaned in a dedicated equipment wash sink (a sink that is only used for cleaning of equipment) with a supply of clean, warm water.
- Equipment that is difficult to clean and sterilise, such as colonic lavage tubing, must be single-use.
- Clean water needs to be used for cleaning equipment. Water with a high mineral content is not suitable for rinsing because it can damage equipment.
- Follow the manufacturer's instructions when using cleaning products on equipment. Common household detergents are not recommended due to their high foaming properties and difficulty removing residues.
- Wear appropriate Personal Protective Equipment (PPE) while cleaning contaminated equipment, such as gloves, eye protection, fluid repellent masks and fluid resistant aprons or gowns.
- A cleaning and maintenance procedures manual for the business should include procedures for equipment and items used in the sterilsation process and staff should understand and follow the procedures.

Equipment cleaning steps

Manual cleaning (where mechanical washer units cannot be used or for difficult to clean instruments)

1. Rinse off any visible blood and body fluids with warm running water. Hot water may cause blood or other fluids to stick to the instrument.
2. Dismantle or open all items for cleaning.
3. Fill the sink with warm water and add the required amount of cleaning agent (follow the manufacturer's instructions). Usually a neutral pH or mildly alkaline solution is used. Mildly acidic solutions may damage some instruments.
4. Wash/scrub all surfaces of equipment under water with a soft brush. Remove stubborn staining by using a non-abrasive scouring pad or soaking in an approved stain-removing solution.
5. Rinse in warm running water.
6. Dry all items using a drying cabinet or with a lint free cloth (instruments must be properly dried - residual moisture may impede the sterilisation process and can damage instruments).

Mechanical cleaning (using an instrument washer, washer-disinfector, or an ultrasonic cleaner)

Washer cycles

1. Pre-rinse with water.
2. Wash in warm water with cleaning agent added, all surfaces must be exposed to the action of the water spray (follow the manufacturer's instructions).
3. One or more rinses with hot (80°C to 86°C) water with a drying agent added (follow the manufacturer's instructions).
4. Drain, leaving the contents at a temperature for quick drying.
5. Drying.

Ultrasonic cleaners

1. Undertake the foil test daily, to ensure effective operation.
2. Rinse off any visible blood and body fluids with warm running water.
3. Dismantle or open all items for cleaning.
4. Use the ultrasonic cleaner in accordance with the manufacturer's instructions.
5. AS/NZS 4815:2006 *Office-based health care facilities - Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment* provides some instruction on the use of the ultrasonic cleaner.

Note: Ultrasonic cleaners clean but do not sterilise instruments.

Packaging prior to sterilisation

- Instruments must be packaged and labelled prior to placing in an autoclave. The label must include:
  - date of processing
  - operator ID
  - batch number
  - sterilisation ID.
- When packaging equipment, it is critical that the equipment is packaged individually, and opened as far as possible to allow for the steam to penetrate all surfaces of the instrument.
- Most packaging contains a Class 1 indicator. This only shows that the load has been processed, it does not indicate that sterilisation has been achieved.

Sterilisation

- Equipment, which is difficult to clean and sterilise, must be single-use.
- All instruments must be correctly wrapped and packaged prior to processing through a steam-under-pressure bench top autoclave. This will ensure the contents remain sterile until use. An exception to this requirement is if items are used immediately after processing.
- There must be at least one person present at the time the autoclave is used who is adequately trained in its operation.
- When loading the autoclave, the packages must be in a single layer, not overlapping or touching the chamber walls. Racks may be used for separation of packaged instruments.
- Sterilisation must be carried out in line with AS/NZS 4815:2006 *Office-based health care facilities - Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment*.
- Sterilisation is achieved by reaching a combination of time, temperature and pressure, as shown in the table on the following page.

Internal temperature pressure-time relationship for steam sterilisation

°C	kPa	mb	Psi	Holding time
121	103	1030	15	15 min
126	138	1380	20	10 min
132	186	1860	27	4 min
134	203	2030	30	3 min

Documentation requirements

- The autoclave must have a printout facility to record the cycle parameters (temperature, pressure, time), otherwise a Class 4, 5 or 6 chemical indicator must be used in every pack in every load.
- Where onsite technical support is not available to achieve calibration or validation, a Class 5 or 6 indicator or a process challenge device must be used in every load.
- The Regulation requires that sterilisation records must be kept for 12 months showing:
  - the time and date when each article was sterilised; and
  - the length of time that the article was sterilised and the temperature and pressure levels of the autoclave.

  Other records include: the operator's name, date, autoclave number or code, and contents of the load.
- Sterilisation records are to be filed in a manner that allows them to be easily available and reviewed by an authorised officer.
- The business should have documented cleaning and maintenance procedures for the autoclave, ultrasonic and other equipment and items used in the sterilsation process, and staff are trained in these procedures.
- There should be documented policies and procedures for all activities involved with the reprocessing of equipment, this includes:
  - all performance and maintenance tests
  - autoclave cycle records
  - employee training records
  - maintenance records
  - certification of validation and calibration
  - operations and maintenance manuals.

Validation of the sterilisation process

- When purchasing an autoclave, it should meet relevant Australian Standards. It is recommended that a Type S or B autoclave is purchased.
- A validation programme must be performed to evaluate the reliability of the sterilisation process. Validation must occur on installation of the autoclave (commissioning) and follow on at least annually (performance qualification). Additional validation must be undertaken every time there is a significant change.
- Chemical indicators can be used to monitor the sterilisation processes and detect possible failures. The key indicators include:
  - Class 1 – Process indicators which can be used to determine processed and unprocessed units.
  - Class 4 – Multi-parameter indicators, measure two or more critical parameters.
  - Class 5 - Integrating indicators show that the critical parameters of time, temperature and moisture have been reached.
  - Class 6 - Emulating indicators verify that 134°C for 3.5 minutes in steam has been reached during the cycle.
- Exposed chemical indicators may change over time; therefore, it is advisable to record the result in a permanent register.

Important notes for sterilising

- The business should have a dedicated reprocessing area that is used for cleaning and sterilising equipment. It must include a dedicated sink to wash equipment.
- The business should be designed in a way that minimises the risk of contamination of clean and sterile equipment (see fact sheet titled 'Skin penetration business design and construction').
- If a sterilisation package (pouch) or its contents are wet following the sterilisation process, the package contents are deemed unsterile and must be reprocessed before use.
- Trays used for assembly of instrument sets for steam sterilisation must be perforated.
- UV light cabinets, microwave ovens, pasteurisers, disinfectants, pressure cookers, boiling and ultrasonic cleaners do not sterilise and are not steam-under-pressure benchtop autoclaves.

Further advice

- Contact your local council.
- Contact your local Public Health Unit by calling 1300 066 055.

Further information

The following resources are also available to help skin penetration businesses and practitioners understand the requirements of the *Public Health Act 2010* and Public Health Regulation 2022. Visit our Skin penetration resources page on the NSW Health website:

Fact sheets

- Beauty, body art and skin penetration industries
- Skin penetration business design and construction

Poster

- Cleaning and sterilising reusable equipment and instruments

Video

- NSW Health How to sterilise infection control tutorial

Standards

- AS/NZS 4815:2006