PRINCIPLES OF STERISLISATION

System Processes

For a practice to function productively it will need a trained member of staff to check all the processes around the sterilisation procedures.

The trained staff member should be checking that the machine and the printer are working prior to starting work.

Environment

The environment should be free of clutter and mess. The room should only be accessed by those that are trained to perform sterilising. A sign on the door should indicate that it is for qualifies staff members only.

Protected time should be allocated to a trained staff member for sterilising to be processed without risk of disruption to the sterilisation process.

Workflow

The RACGP infection prevention and control standard 5th Ed
https://www.racgp.org.au/FSDEDEV/media/documents/Running%20a%20practice/Practice%20standards/Infection-prevention-and-control.pdf

State that the workflow should travel in one direction. Going from dirty to clean and without the risk of re-contamination of equipment.

Process

- Wear PPE - gloves, apron, & mask
- Place dirty instrument into its specific Container and take to the cleaning area.
- Open the container and rinse the instruments in a sink/bowl of warm water. Soaking in hot water or disinfectants may cause matter to stick to the equipment.
- Use a detergent recommended by the manufacturer
- Scrub the equipment with a brush under the water to reduce splashing and cross contamination.
- Rinse in 2nd sink/container with clean warm water
- Ensure instruments are properly dried use a lint free or low- link cloth
- Open all instruments and place in package (pouch) without overlapping
- Seal the package properly do not use staples
- Label the package
- Load trays but do not overlap of packages
- Indicators can be placed on a tray
- Clean the dirty sink as if it is contaminated all work surfaces.
- Once sterilisation has completed check the printout.
- Allow packets to cool before storing
- Store in a clean, dry area away from sunlight check packets every three months for damage and reprocess if needed

Documentation

Labelling packaging should mirror the documentation added to the logbook.
All sterilisers provide a document of the process this should be added to the logbook with times and dates.
A separate tracing book should be kept in the treatment room to document the labelled kit used against the name of the patient it was used on.
An annual validation check should be performed on the steriliser.

PRINCIPLES OF STERILISATION
Commonly Asked Questions

1. **Question: Can you process gauze and dressings**

It is possible to sterilise gauze and dressings (referred to as porous items), however the density of the porous items and maximum size and mass of packs determines the ability of the sterilising agent (e.g., steam) to penetrate the load. Class B and some Class S sterilisers can sterilise porous items. If using a Class S steriliser, you will need to check it can sterilise these items. If porous items are sterilised in your practice, they should be positioned on their edge, if possible, to provide the least resistance for the passage of steam. The load must be validated first by your service provider. Consumable items such as gauze and cotton balls should be obtained sterile, directly from a commercial supplier.

- **References:** AS/NZS 4815:2006, RACGP Infection Prevention and Control Standards (5th edition, 2014, updated 2016), Australasian Podiatry Council Infection Prevention and Control Guidelines for Podiatrists.

2. **Question: How long do items remain sterilised for?**

Factors which influence shelf life of sterile stock are 'event related' not 'date related', so if reusable medical devices (RMDs) are stored and handled correctly, then it should remain sterile until use. Commercially prepared sterile items will have an expiry date on the package. All sterile stock must be stored in a way that keeps it dry, clean, dust-free, away from sources of moisture and direct sunlight. A stock rotation system based on the date of sterilisation or load number or date of expiry if a sterile consumable, is important. Sterilised laminate packs can become brittle over time so. The RACGP standards recommend unused laminate packs be checked after 2 – 3 months from sterilisation to ensure the sterile integrity of the pack remains intact.

- **References:** AS/NZS 4815:2006, RACGP Infection Prevention and Control Standards (5th edition 2014, updated 2016), Australasian Podiatry Council of Infection Prevention and Control Guidelines for Podiatrists, ADA Guidelines for Infection Prevention and Control (4th Edition, 2021) https://www.racgp.org.au/FSDEDEV/media/documents/Running%20a%20practice/Practice%20standards/Infection-prevention-and-control.pdf

3. **Question: Should we be tracking for all procedures including dressings?**

Tracking of critical reusable medical devices that enter or penetrate sterile tissue, cavity, or bloodstream) and patient tracing should be in place. This includes instrument trays, holloware, one or more items packaged in a single pack, unwrapped critical medical items and implants. While the RACGP Standards consider a traceability system as best practice and not mandatory, other professional bodies such as the Australian Dental Association and Australasian Podiatry Council consider this a 'must' requirement.

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4. **Question: Can you sterilise spacers?**

Reusable spacers are considered "single patient use" devices by the manufacturer and therefore should not be reprocessed and reused on another patient. Some practices will have a reusable spacer ready just in case there is an emergency or for patient teaching purposes, however, this should be used by one patient only and once used, it should be given to the patient who used it to take home or discarded in the waste bin. Always refer to the reusable spacer package labelling and instruct the patient how to clean and maintain their spacer in accordance with the manufacturer's instructions for use (IFU). Alternatively, low-cost disposable cardboard spacers are on the market for emergency, clinic, and school use.

5. **Question: What cleaning solution should be used for the storage containers dirty instruments have been stored in?**

A TGA approved mildly alkaline or neutral detergent should be used for cleaning dirty instrument storage containers. This can be the same cleaning agent used for manually or mechanically cleaning your instruments. However, check with the IFU to ensure the agent can be used on the intended surface. If using containers designed specifically for dirty instrument transportation and storage, again check with the manufacturer's cleaning instructions in the IFU.

6. **Question: What cleaning product should be used to scrubbing ENT instruments?**

ENT and other delicate or complex reusable instruments must always be cleaned in accordance with the instrument manufacturer's IFU so refer to these in the first instance. As above, a TGA approved (i.e., included on the TGA Australian Register of Therapeutic Goods [ARTG] mildly alkaline or neutral detergent should be used.
AS/NZS 4815:2006 section 2.8 lists the requirements for cleaning agents used for manual and mechanical cleaning and will assist your practice with product selection and evaluation.

7. **Question: Do you scrub before or after using the ultrasonic cleaner?**

In accordance with AS/NZS 4815:2006 and professional body infection control standards and guidelines, reusable medical devices should be pre-treated by dry or damp wiping at the point-of-use before transporting to the reprocessing area. Before immersing items in the ultrasonic detergent/water tank, blood and other visible soil should be rinsed off using warm water in the designated cleaning sink or bowl (if a second sink is not available). On completion of the ultrasonic cycle, remove the instrument basket and rinse the items thoroughly in clean, running, warm to hot water.

8. **Question: What if an item doesn't fit into the ultrasonic cleaner?**

If the item cannot be dismantled, manually clean the item in accordance with AS/NZS 4815:2006 section 2.9.2.

9. **Question: Do you know what guidelines/accreditation are required for specialist practices with sterilising equipment?**

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- AS/NZS 4815:2006 Office-based health care facilities – Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment
- AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organizations **(for practices where complex patient procedures and sterilising processes, such as low temperature sterilisation are performed)**
- Australian Dental Association Guidelines for infection prevention and control (4th edition, 2021)
- Australasian Podiatry Council Infection prevention and control guidelines for podiatrists
- RACGP Infection prevention and control standards for general practices and other office-based and community-based practices (5th edition, 2014)

10. Question: Do we have to do a vacuum test every day prior to using a steriliser?

A daily or weekly leak rate/vacuum test is required for steam sterilisers that utilise a vacuum stage for air removal in any sterilisation cycle. If the steriliser is fitted with an air detector the test is conducted weekly. Refer to your steriliser manual and/or approved service technician. This test is performed at the beginning of the day/use prior to the air removal and steam penetration test.

11. Question: I need more detail about future cleaning -instrument washers

Automatic washer-disinfectors are increasingly being used in office-based practices to clean, thermally disinfect and dry instruments and utensils ready for packaging and subsequent sterilisation. Unlike manual cleaning this is a validated process that reduces the work health and safety hazards of instrument cleaning by staff and removes the need for manual drying if a drying cabinet is not in use. While considered best practice, they are expensive due to initial purchase, running and maintenance costs, and cycles are longer than an ultrasonic cleaner cycle. There are now ultrasonic washer-disinfectors on the market, increasingly being used in dental practices.

12. Question: What's the difference between single-use and single patient use?

Single use devices (SUDs) are medical devices that are labelled by the original manufacturer as "single-use' ⓶ or "single patient use". If a device is labelled "single use", the manufacturer's intention is that the device can only be used once and then disposed of. If a device is labelled for "single patient use", the manufacturer's intention is that the device can
be used multiple times on the one patient. Single patient use devices can be reprocessed and reused on the same patient in accordance with the manufacturer's reprocessing instructions in the IFU. The TGA, the national regulator for medical devices, does not permit the reuse of single use devices, unless the reprocessing of those devices is done to a standard that ensures the devices are safe and perform as originally intended.

References:

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All processing should meet the Australian/New Zealand Standard™ AS/NZS 4815:2006 Office-based health care facilities—

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https://www.saiglobal.com/pdftemp/previews/osh/as/as4000/4800/4815-2006.pdf

https://www.safetyandquality.gov.au/sites/default/files/2019-12/as1807_reprocessing_of_reusable_medical_devices_in_health_service_organisations_december_2019.pdf

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