How to sterilize instruments and jewellery and comply with the Infection Control Guidelines for Personal Appearance Services 2012.

To prevent the spread of disease, reusable instruments used in skin penetration procedures must be thoroughly cleaned and then sterilized before use.

This fact sheet has been developed to assist practitioners to understand the requirements for sterilizing their reusable instruments and jewellery. This fact sheet should be read in conjunction with Appendix 1 of "What business needs to know" which provides a summary of Australian/New Zealand Standard 4815:2006 and the Infection Control Guidelines for Personal Appearance Services 2012.

Standards referred to in this fact sheet

- AS/NZ 4815: 2006 - Office based health care facilities – Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment
- AS 2182: 1998 - Sterilizers - Steam - Benchtop
- AS/NZ 4187: 2014 - Reprocessing of reusable medical devices in health service organisations

Single-use items

Instruments/items that are manufactured as single-use are to be used once and discarded. Instruments that penetrate the skin and cannot be adequately cleaned and/or sterilized must not be re-used, they must be 'single use'. Single-use items must be immediately disposed into an approved sharps container following use on a client.

Sterilizing jewellery

All jewellery used in providing a higher risk personal appearance service must be pre-sterilized.

Jewellery displayed for sale (unless pre-sterilized in sealed packaging) must be resterilized prior to being used in a higher risk procedure.

Stocks of pre-sterilized jewellery should be rotated to ensure the sterilization dates are current.

How do you sterilize?

Sterilization must be carried out in accordance with AS/NZS 4815:2006.

This Australian Standard outlines the critical steps involved in sterilization.

What do you need to do before you sterilize your instruments?

Ensure the premises are designed properly.

The cleaning and sterilization of instruments and jewellery should be conducted away from clients, preferably in a separate room.

Workflow for instrument processing should be from dirty - to clean - to sterile – to storage.

A manual should be available for staff on 'cleaning procedures'.

Instrument cleaning:

Instruments should be cleaned as soon as practicable after use.

It is important to clean instruments prior to sterilization because dirty instruments cannot be properly sterilized.

Appropriate Personal Protective Equipment (PPE) should be worn to protect against aerosol exposure from washing soiled equipment. That includes gloves, eye protection, fluid repellent masks and fluid resistant aprons or gowns.

Instruments and jewellery must be thoroughly cleaned (i.e. via scrubbing, using an instrument washer, and/or ultra-sonic cleaner) before processing through a bench-top steriliser.

The cleaning process should minimise the generation of aerosols.

Instruments that are difficult to clean and sterilize should only be used once and then disposed of appropriately (single-use only).

Manufacturer's instructions must be followed for the use of cleaning agents and instruments.

NOTE: Ultra-sonic cleaners are an adjunct to manual or mechanical cleaning an instrument. They do not clean and/or disinfect instruments.

Manual cleaning requires the use of two sinks or bowls, which are kept clean and dedicated solely for that purpose, one with detergent solution for the actual cleaning activity and one with water for rinsing items after they have been cleaned. A suitable stiff-bristled brush is a useful implement for manual cleaning. Brushing equipment under the water surface minimises potentially hazardous aerosols.

Mechanical cleaning (usually also with a thermal disinfection stage) is able to be provided in a machine similar to a domestic dish washer machine. This however does not necessarily disinfect the instruments. Use the ultra-sonic cleaner in accordance with the manufacturer's instructions.

AS/NZ 4815:2006 provides some instruction on the use of the ultra-sonic cleaner.

AS/NZ 4187:2014 provides some useful recommendations concerning the quality of water used in cleaning and the choice of cleaning chemicals.

Instruments must be properly dried - residue moisture may impede the sterilization process, and can damage instruments.

Packaging prior to sterilization:

Instruments must be packaged and labelled prior to placing in a sterilizer. This will maintain sterility and permit aseptic removal of the contents of the pack at the time of use. An exception to this requirement is if items are used immediately after processing through a bench-top sterilizer.

Packaged items should be positioned in an upright position or in accordance with the manufacturer's instructions.

Most packaging contains a class 1 indicator that shows that the load has been reprocessed. This indicator does not show that the load has been sterilized. The use of indicators should be considered at the time of packaging the instruments.

Further information of packaging and wrapping of items prior to sterilization is available in AS/NZS 4815:2006. Issues discussed include pack size, labelling, specific packaging and wrapping requirements and methods of wrapping.

Operation of Sterilizers

The staff using a sterilizer at a facility must be appropriately and adequately trained in the operation of that sterilizer.

The essential requirement in both steam and dry heat sterilization is to reliably achieve a minimum time at a nominated temperature in the sterilizer chamber and throughout all parts of the load being sterilized. For steam sterilization in the health and beauty industries this requirement is 3 minutes at 134ºC after air has been reliably removed from the chamber and the load items. In dry heat sterilization 2 hours at 160ºC is necessary.

In each case, the operator or their agent must have determined the extra time that must be added to these time periods to allow for penetration by steam or heat into and through the items being sterilized. Determining this is part of validation.

Sterilizers can have automatically controlled cycles or be manually operated through their stages of operation.

Automatically controlled sterilizers are already configured to deliver time at temperature but validation of the sterilization performed in them is not automatic. In this light, validation of sterilization will be a new concept for most sterilizer operators and one for which education and learning will be required.

Manually operated sterilizers require validation just as much as automatically operating sterilizers, but operators of manual sterilizers are less likely to take reliable function of their machines for granted due to their continual checking of gauges and other physical sterilization indicators during each cycle.

Sterilization and documentation requirements

Sterilization must be carried out in accordance with AS/NZ Standard 4815:2006.

The bench-top sterilizer must be maintained in accordance with AS 2182:1998.

The bench-top sterilizer must have a printout facility to record the cycle parameters (i.e. temp, pressure, time), otherwise a Class 4, 5 or 6 chemical indicator must be placed in on instrument package (in every load) or there must be direct observation and recording of cycle parameters.

Where on-site technical support is not available to achieve calibration or validation, a Class 5 or 6 indicator must be placed in every instrument package (in every load) or a process challenge device must be used in every load.

AS/NZS 4815:2006 - section 8 (Quality Management) requires that records must be kept and maintained for a defined period. That period is seven (7) years.

The type of records, listed in section 8.2 of AS/NZS 4815:2006, include

- staff training - in infection control and sterilization management
- operators and maintenance manuals - should be on site at all times
- validation - the process of commissioning and performance qualification which is performed to evaluate the reliability of a sterilization process. Validation must be carried out annually.

The Infection Control Guidelines 2012 - section 7 - requires these records to be kept. This is particularly relevant for businesses providing higher risk personal appearance procedures. These records include:

Client records:

- name, address and date of birth of the client,
- date of high risk personal appearance service procedure performed,
- site and type of high risk personal appearance service procedure,
- operator who provided the service/administered the procedure, and
- instruments used (including sterilizing batch number).

Sterilization records:

- Date of sterilization cycle process,
- Exposure time and temperature,
- maintenance and
- validation certificate

Staff immunisation.

Staff training and qualifications.

Needlestick injuries in the workplace.

Validation of Sterilization Processes

If sterilization is to be an assured process, then steps need to be taken by the owner or operator of any sterilizer (including sterilizers in this industry) to validate attainment of sterilization conditions in the existing sterilizer with all of the prevailing circumstances.

This is not usually a simple process and AS/NZS 4815:2006 outlines the steps required. For the purposes of this brief overview:

- Commissioning stage in which all aspects of the sterilization equipment and process are demonstrated to be functioning as intended in accordance with design and/or purchase specifications.
- Verification of process specification during which the intended sterilizing conditions and the method(s) of monitoring them are proven to be attainable, repeatable and true; and the final stage.
- Performance qualification which is the demonstration that the intended sterilizing conditions are being attained on a regular basis.

Storage conditions and shelf-life:

Factors influencing the length of time that packs can remain sterile during storage include:

- The types of packaging materials in use;
- Design of the completed packs;
- Incorrect wrapping/sealing procedures;
- Too much moisture at the end of the sterilizing/drying cycle;
- Being placed or dropped on a dirty surface

- Incorrect cleaning procedures in the area in which the sterile packs are stored;
- Vermin or insects in the storage area;
- Moisture, condensation, wide temperature fluctuations and/or excessive exposure to sunlight or ultra-violet radiation;
- Sharp objects or rough handling which can cause damage to packaging materials; and
- Careless handling when other contaminated items are being transported in or near areas where sterile packs are stored.

Four weeks is the recognised shelf life for sterile packs, after which the items are re-packed and re-sterilized. Whilst four weeks is a conservative length of time it will generally be the most practical approach to controlling the sterile shelf life for personal appearance service instruments and equipment. Any of the factors described in the list can compromise the sterility of a pack at any time.

Practitioners must be continually observant and aware that packs are being stored in good conditions, are always handled correctly, and users of packs always examine the pack(s) which they are about to open for possible evidence of damage or compromised conditions during storage.

Important things to note

- If a sterilisation package (pouch) or its contents are wet following sterilization process, the package contents are deemed unsterile and must NOT be used.
- The efficiency of the sterilization process must be established during the validation process and ongoing annual performance requalification process.
- Instruments must be dismantled or opened to ensure that all parts of the instrument are sterilized.
- Trays used for assembly of instrument sets for steam sterilization must be perforated.
- Steam sterilization is widely used as the steam under pressure provides fast destructive power to kill microorganisms and their spores.
- UV light cabinets, microwave ovens, pasteurisation, disinfectants, pressure cookers, boiling, domestic home sterilizers and ultra-sonic cleaners **do not sterilize** the equipment.
- Dry heat sterilization is only to be used for instruments which cannot be sterilised using steam under pressure (bench-top sterilizer). Dry heat sterilizers (hot air type) must comply with AS 2487:1998.
- All instruments must be wrapped and packaged prior to processing through a bench-top sterilizer. This will maintain sterility and permit aseptic removal of the contents of the pack at the time of use. An exception to this requirement is if items are used immediately after processing through a bench-top sterilizer.

Glossary

Higher risk personal appearance service	A personal appearance service involving skin penetration procedures in which the release of blood or other bodily fluid is an expected result. It includes body piercing, tattooing, implanting a substance into a person's skin, scarring or cutting a person's skin using a sharp instrument to make a permanent mark, pattern or design and another skin penetration procedure prescribed under a regulation.
Sterilize	To render an item free of all living micro-organisms. In practice this involves a combination of cleaning (which removes many micro-organisms prior to sterilization) and sterilization (which reliably kills all remaining micro-organisms). Sterilization processes need to be validated.
Disinfection	Thermal or chemical destruction of pathogenic and other types of microorganisms. Disinfection is less lethal than sterilization because it destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores). CDC - Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.
Cleaning	The removal of all foreign material (e.g. soil/organic material) from objects, and the reduction of infectious agents from surfaces. Cleaning is normally done with water and detergents.
Single use	Means the medical device or instrument is intended to be used on an individual client during a single procedure and then discarded. It is not intended to be reprocessed and used on another client. Some single-use devices are marketed as non-sterile which require processing to make them sterile and ready for use. The manufacturer of the device will include appropriate processing instructions to make it ready for use.

References

NSW fact sheet - How to sterilize your instruments and comply with the Public Health Regulation 2012
http://www.health.nsw.gov.au/environment/factsheets/Pages/how-to-sterilise-instruments.aspx

Further information on sterilizing is available from:
https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/diseases-infection/default.asp

TGA glossary https://www.tga.gov.au/acronyms-glossary#summary-s

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