Manual:	**DENTAL REPROCESSING SERVICES**	**Ref. No:**	**C 8**
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PURPOSE AND SCOPE

To ensure all staff working in the dental practice responsible for reprocessing of medical instruments and equipment are aware of the correct packaging and wrapping that is required to ensure the sterility of the items.

BACKGROUND

The purpose of packaging and wrapping of items for sterilisation is to provide an effective barrier against sources of potential contamination in order to maintain sterility and to permit aseptic removal of the contents of the pack.

Items that are not wrapped or packaged correctly can allow contamination and therefore present a risk of infection to the patient.

PRINCIPLES

1. General

Packaging and wrapping materials must permit the removal of air from the pack, penetration of the sterilising agent, and removal of the sterilising agent and water vapour.

Materials, including materials for inner wraps, used for wrapping and packaging must be compatible with the item being packed and the sterilising method.

Sharps instruments must be packaged in such a way that the tips of these instruments are exposed to the sterilising agents but will not perforate the packaging material.

Single use wrapping material shall be used once then discarded.

Textile wraps must be laundered prior to re-use.

Combinations of hollowware, instruments, dressings, drapes and tubing must not be incorporated into a single pack.

Note:

- *AS/NZS 4146 outlines laundering practice*
- *AS 3789.2 specifies requirements for theatre linen and pre-packs*

2. Pack size

The basic principle determining the size, mass and contents of instruments and hollowware packs is that the contents are sterile and dry on cooling to room temperature and on completion of the sterilisation cycle and removal of the pack from the sterilizer chamber.

Large packs may inhibit effective sterilisation and, in the case of steam sterilisation, drying. If a pack or its contents are wet, the pack shall be deemed unsterile and shall not be used.

3. Labelling of packs and bags prior to sterilisation.

Prepared labelling systems or non-toxic, water resistant felt-tipped marking pens and rubber stamps using similar ink, are to be used for labelling packs prior to sterilisation. Labelling must include the batch control data on both bags and packs and the contents if not visible through the pack or bag.

Sharp-tipped, water based or ball-type pens must not be used as these pens may compromise pack integrity. Packs are not to be labelled with marking pens after sterilisation as this may compromise the integrity of the pack.

The label is to be applied to an area on the chemical indicator tape that is visible when the article is positioned in the sterile stock store. This will enable the operator to check dates for stock rotation, whilst minimising stock handling.

4. Instruments

- Instruments with hinges or ratchets must remain open and unlocked.
- Multiple-part instruments for sterilisation must be disassembled or sufficiently loosened prior to packaging to allow sterilising agent to come into contact with all parts of the instrument.
- Instrument sets should be packaged in a manner that prevents damage to delicate items.
- Trays used for packaging instruments should be perforated to allow for penetration of sterilising agent and efficient drying.

5. Hollowware

Hollowware (e.g. gallipots, bowls or kidney dishes) when packaged in sets must be packaged to minimise the risk of air entrapment and pooling of condensate. All openings shall face the same direction so that contents cannot move inside the pack. Hollowware items packaged together shall be separated by non-porous spacers to permit effective steam circulation.

6. Rigid reusable sterilisation container systems

Containers (e.g. cassettes) used for sterilisation must allow penetration and removal of the sterilising agent and must maintain sterility following the process.

- For steam sterilisation, the container used for packaging instruments must be perforated (at base and lid) to ensure penetration of the sterilising agent and drying.
- Must have all components that can easily be disassembled for cleaning drying and storage.
- If required to be stored sterile, perforated metal or plastic containers must be wrapped or have the appropriate filter in place prior to sterilisation.
- On-site physical, chemical and biological testing must be undertaken at the facility to establish that the loaded rigid reusable sterilisation containers will achieve sterilisation of their contents.
- Following the cleaning and drying process, careful visual inspection must be made to ensure the tray and lids are not dented and that the seals/gaskets are intact.
- They must have tamperproof locking devices which are non–resealable and have a built in chemical indicator that clearly changes when sterile.
- They must be packed in a manner that allows for penetration of the sterilising agent.
- The trays must not be overloaded.
- Lids and contents must be able to be removed without risk of contamination of the contents.
- The mass and weight of the containers must allow sterilisation parameters to be met and comply with Manual Handling standards.
- Must be compatible with shelving systems used to store them.
- If containers where a filter is required, a single-use filter shall be discarded after use.

7. Textile, woven and non-woven wraps

- Any defects in the fabric, such as holes render the wrap ineffective and should not be used.
- Heavy woven fabrics such as canvas will inhibit penetration of steam and egress of air and should not be used..

- Woven and non-woven materials intended for specific use as sterilisation wrapping materials must be used. Textile linen wraps must conform to AS 3789.2.
- Paper materials intended for specific use as sterilisation wrapping must be used. Paper bags/wraps must conform to AS 1079.2.

8. Flexible packaging materials

These materials consist of paper or non-woven materials combined with a clear laminate to form pouches or continuous reels.

- Laminated pouches may be perforated by sharp instruments, sharp tips should be protected.
- Hollowware must be placed with the opening against the paper side of flexible packaging materials. Hollowware articles may trap condensate in the gusset or against the plastic surface when laid flat.
- This packaging should be positioned on its side or flat with the paper surface downwards in the steriliser to allow egress of air and condensate and ingress of the steam.
- Heat sealing equipment should be used to seal bags and flexible packaging materials.
- The use of sterilising tape for sealing bags and pouches should only occur in the event of a breakdown or absence of heat sealing equipment.
- Due to the risk of incomplete sealing, use self-sealing pouches strictly in accordance with the manufacturer's instructions.

9. Nylon packaging material

Impervious packaging material (e.g. 100% nylon packaging material shall not be used as a packaging material for steam sterilisation, as it is impervious to air and inhibits penetration of the sterilising agent.

10. Selection of packaging materials

Outer packaging and wrapping materials for the different sterilisation processes should be selected as outlined in Table 1.

Table 1 Packing materials

Material	Steam	Dry heat
Paper bags and wrapping materials	Yes	Yes
Flexible packaging systems –		
Cellulose based	Yes	No
Porous non-cellulose based	Yes	No
Non-porous, non-cellulose based (e.g. nylon)	No	Depends on the grade
Non-cellulose based, non-woven wrapping materials	Yes	No
Rigid reusable sterilisation container	Yes	No
Sealed metal or glass containers	No	Yes
Aluminium foil	No	Yes
Polyethylene film	No	No

11. Wrapping techniques

All items must be wrapped to meet the following principles:

- To enable sterilant to enter.
- To maintain sterility at point of use.
- To enable aseptic removal from the packaging material for use.

The choices include the following:

- Square-fold wrapping technique.
- Envelope-fold wrapping technique.

Note: For wrapping techniques/steps see AS 4815:2006 Figure 3.1 and 3.2.

12. Sealing of packs and bags

The purpose of sealing is to maintain the integrity of the pack, and is achieved by the use of heat sealers, self-sealing pouches or sterilising indicator tape. String, non-adhesive tape, staples and elasticised bands are not suitable as they can cause compression of the pack, damage or compromise pack integrity.

When using the heat sealing method checks must be made to ensure the seal is complete.

13. Heat sealing

Sterilising bags and laminated pouches should be sealed using suitable heat-sealing equipment.

Following the sealing of packs, checks must be made to ensure that the seal is complete, especially over the gusset folds of bags or pouches.

Note:
AS/NZS 4815 Appendix D provides further information on heat sealing equipment.

14. Sterilising indicator tape

The use of sterilising tape for sealing both ends of continuous reel packaging should only be made in the event of breakdown or absence of heat-sealing equipment.

Where sterilising indicator tape is used to seal a pouch, the open edge of the pouch should be folded over two or three times prior to taping across the edge with one continuous piece of tape extending across at least 25 mm around the back of the pouch on both sides. Figure 3.3 in AS/NZS 4815 illustrates correct procedures for sealing pouches with tape.

The use of sterilising indictor tape to seal flexible packaging materials should be avoided as maintenance of sterility and aseptic opening of the package may be compromised.

Sterilising indicator tape should:

- Be selected to be specific to the mode of sterilisation and should change markedly when exposed to the sterilising agent.
- Change colour after exposure to the sterilising agent and be clear, district and uniform and be markedly different to the unprocessed indicator tape.
- Be pressure sensitive, non-toxic and adhere to clean surfaces leaving no adhesive residue on removal.
- Have the name of the manufacturer, batch number and date of manufacture clearly marked on the core.
- Have an adhesive system that is compatible with the wrapping material used.
- Be heat stable, moisture- stable and be permeable to the sterilising agent.

Note: Sterilising indictor tape or other Class 1 chemical indicators are used to indicate that the item has been exposed to the sterilisation process. The indicator tape can also change colour in relation to other conditions e.g. poor storage, expired dates and steriliser chamber heat.

REFERENCES

Standards Australia AS/NZS 4187 2014

Standards Australia (2006) AS/NZS 4815 Office-based health care facilities-Reprocessing of reusable medical, surgical instruments and equipment, and maintenance of the associated environment, Standards Australia, Sydney.

Australian Dental Association (2015), Guidelines for Infection Control Third Edition, Australia, NSW.