Packing, Wrapping and Sealing Reusable Medical Devices Procedure

1. Purpose

The purpose of this procedure is to ensure that the processing of reusable medical devices (RMDs) aligns with AS/NZS 4187:2014 and associated normative references, specifically in relation to the selection of materials for and processes associated with the packing, wrapping and sealing of RMDs.

This procedure applies to all WA Country Health Service (WACHS) healthcare workers that use or reprocess RMDs.

2. Procedure

2.1 General principles

- A Sterile Barrier System (SBS) is the packaging placed around an RMD/s that allows them to be sterilised. An SBS has a critical role in patient safety, preventing the ingress of microorganisms to a sterile RMD and allowing aseptic presentation of the RMD at its point of use. For further information, refer to ISO 11607-2:2019 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes (including Amendment 1) and ISO/TS 16775:2021 Packaging for terminally sterilized medical devices – Guidance on the application of ISO 11607-1 and ISO 11607-2.
- There are three main types of SBS:
  - Rigid reusable containers.
  - Sterilisation wraps.
  - Sealable pouches and reels.
- The type of SBS to be used for a specific RMD is determined by the type of sterilising process required for that RMD.
- Packaging and wrapping materials must permit the removal of air from the pack, penetration of the sterilising agent and removal of the sterilising agent.
- Single-use wraps must be discarded once used.
- Trays are configured according to product families in relation to design, complexity and reprocessing requirements.

2.2 Packing

The size, mass and contents of the RMD/packs must be carefully determined to ensure that the sterilisation process will be effective. Consider the following:

- Pack size is to be determined during validation and will form an element of the criteria for identifying the appropriate product family.
- Large packs may inhibit effective sterilisation. If contents are wet, the pack is to be deemed unsterile and is not to be used.

To pack individual RMDs and trays:

- Inspect RMDs and equipment for cleanliness and signs of malfunction or damage.

- Assemble and function test all multi-part RMDs, disassemble for packaging, isolate and report any defective or damaged components to the SSD Manager/Supervisor.
- Locate the tray list (either electronically or paper copy).
- Place RMDs into tray in accordance with list specification.
- Verify the RMDs are all present and accounted for, sign and print the list.
- Select the required packaging material according to the method of sterilisation to be used, as per the table below:

Method of sterilisation	Steam sterilisation	Low temperature sterilisation
Packaging material	• polypropylene inner wrap and outer wrap • sealable pouches or reel • rigid container	• polypropylene inner wrap and outer wrap • low temperature sealable pouches or reel • scope container

2.3 Labelling of the SBS prior to sterilisation

- Pre-prepared labels or non-toxic, solvent-based felt tip marking pens are to be used for labelling packs prior to sterilisation.
- If using a marking pen, write on the label or tape only, not the wrap itself.
- Sharp-tipped, water based and ball-point pens are not to be used as these pens may compromise pack integrity.
- Packs are not to be labelled with marking pens after sterilisation as this may also compromise pack integrity.
- The label should include (but not be restricted to) the following information:
  - the name of the RMD or tray
  - batch number (i.e. steriliser and cycle number)
  - date of sterilisation
  - initials of the Sterilisation Technician who assembled the RMD/tray.
- Writing should be legible and neat, ensuring easy identification of what is inside the package.
- For RMDs packaged in peel, place the label as follows:
  - Away from the item as the heat will degrade the label and render it illegible.
  - Avoid covering the seals/edges of the pouch as this limits the ability to inspect the contents.

2.4 Rigid reusable containers

- Rigid reusable containers must be validated for use at individual hospitals.
- They must be compatible with the shelving systems used to store them.
- All components must be able to be easily disassembled for cleaning, drying and storage.
- Following the cleaning and drying process, careful visual inspection must be made to ensure the tray and lid are not dented and that all seals/gaskets/latches/closing mechanisms are intact.
- Containers must have tamperproof locking devices which are non-resealable and include built-in chemical indicators that clearly change colour when sterile.
- Containers must be packed in a manner that allows for penetration of the sterilising agent, considering mass and weight. The trays must not be overloaded.
- Containers must not weigh more than 7kg when packed.

- Lids and contents must be able to be removed without risk of contamination of the contents (facilitating aseptic presentation).
- If using containers where a filter is required, either reusable or single-use filters are to be used and then discarded accordingly.

2.5 Sterilisation wraps

The available sterilisation wrapping methods are:
- single wrap
- double wrap
- double wrap sequentially packaged in separate layers
- parcel style (square fold method)
- envelope style.

These methods all enable sterilant to enter, maintain sterility at point of use and enable aseptic removal from the packaging material for use.

Sterilising indicator tape is used to secure sterilisation wrap and should:
- be specific to the mode of sterilisation and should change markedly when exposed to the sterilising agent
- 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
- be heat stable, moisture stable and be permeable to the sterilising agent
- have adhesive compatible with the sterilisation wrap to be held closed, particularly for non-woven or treated paper surfaces.

2.6 Sealable pouches and reels

- The purpose of sealing is to maintain the integrity of the pack. Methods that compromise pack integrity are not be used (e.g. staples, pins).
- Sharp RMDs should be packaged in such a way that the tips are exposed to the sterilising agents but will not perforate the packaging material. Sharp tips are to be protected using validated methods (e.g. use of tip protectors).
- Hollow-ware RMDs may trap condensate in the gusset or against the plastic surface when laid flat. To avoid this:
  - the opening of hollow-ware RMDs are to be placed against the paper and not the plastic and face the same direction so that contents cannot move inside the pack.
  - the packaging should be positioned on its side in the steriliser to facilitate egress of air or condensate.
  - non-porous spacers must be used to separate hollow-ware when nestled.

Double sealable pouches

Double sealable pouches are created when a single peel pack is packaged into a second peel pack.

Double sealable pouches may be used for the following RMDs:
- sharp instruments
- heavy instruments

- inclusion of two or more instruments per package
- all ophthalmic single instruments.

Heat sealing

Heat sealing equipment should be used to seal pouches and reels. If heat sealing equipment is not available, then the package cannot be sterilised.

The heat sealing equipment should be checked daily (using either a dye penetration test or seal checks) to ensure it delivers the following:

- intact seal
- no channels or open seals
- no puncture or tears
- no wrinkles or creases that traverse the seal width.

The heat sealer should be maintained, validated and recalibrated at least annually.

3. Roles and Responsibilities

Health Service Organisations are responsible for ensuring that adequate resources and support are provided to ensure a safe working environment for all staff.

SSD Manager/Supervisor is to:

- implement the requirements of this document to ensure the processing of RMDs is compliant with AS/NZS 4187:2014 and associated normative references and ensure the quality and safety of reprocessed RMDs.
- be involved in the evaluation/selection of purchased RMDs to ensure their compatibility with the packaging and wrapping processes available.

SSD staff must comply with the requirements of this document and report non-compliance to the SSD Manager/Supervisor or Perioperative Services Manager.

All staff are required to work within policies and guidelines to make sure that WACHS is a safe, equitable and positive place to be.

4. Monitoring and Evaluation

4.1 Monitoring

Regular monitoring will contribute to compliance with relevant Standards, good quality patient outcomes and improved staff satisfaction.

The SSD Manager/Supervisor or Perioperative Services Manager are responsible for ensuring that:

- monitoring of compliance with this document is carried out in line with AS/NZS 4187:2014
- risk assessments are completed, outcomes evaluated, and actions taken as required.

4.2 Evaluation

Review of this document will be coordinated by the Surgical Services Program Team in collaboration with key stakeholders including relevant Advisory Forums.

5. Compliance

This procedure is a mandatory requirement under the *Therapeutic Goods Act 1989* (Cwlth) and AS/NZS 4187:2014.

Failure to comply with this procedure may constitute a breach of the WA Health Code of Conduct (Code). The Code is part of the Integrity Policy Framework issued pursuant to Section 26 of the *Health Services Act 2016* (WA) and is binding on all WACHS staff which for this purpose includes trainees, students, volunteers, researchers, contractors for service (including all visiting health professionals and agency staff) and persons delivering training or education within WACHS.

WACHS staff are reminded that compliance with all policies and procedures is mandatory.

6. References

1. AS/NZS 4187:2014 and amendment 2:2019, Reprocessing of reusable medical devices in health service organizations. Available from https://www-saiglobal-com.wachslibresources.health.wa.gov.au/online/.
2. 11607-2:2019. Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes. Available from https://www-saiglobal-com.wachslibresources.health.wa.gov.au/online/.
3. ISO 11607-2:2019/DAmd 1. Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes – Amendment 1. Available from https://www-saiglobal-com.wachslibresources.health.wa.gov.au/online/.
4. ISO 14937:2009. Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices. Available from https://www-saiglobal-com.wachslibresources.health.wa.gov.au/online/.
5. ISO/TS 16775:2021. Packaging for terminally sterilized medical devices – Guidance on the application of ISO 11607-1 and ISO 11607-2. Available from https://www-saiglobal-com.wachslibresources.health.wa.gov.au/online/.
6. ISO 17665-1:2006. Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices. Available from https://www-saiglobal-com.wachslibresources.health.wa.gov.au/online/.
7. ISO/TS 17665-2:2009. Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1. https://www-saiglobal-com.wachslibresources.health.wa.gov.au/online/.
8. ISO 25424:2018. Sterilization of health care products – Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices. Available from https://www-saiglobal-com.wachslibresources.health.wa.gov.au/online/.
9. Australian College of Perioperative Nurses (ACORN) – Standards for Perioperative Nursing in Australia 16th Edition, May 2020. New equipment & instrumentation, Reprocessing re-usable medical devices.

10. St John of God Midland Public and Private Hospitals. Central Sterilisation Services Department Manual, MIC-SSD-OTH-0002.
11. Women and Newborn Health Service. Hospital Sterile Supply Department Policy and Procedure Manual - HSSD reprocessing activities. King Edward Memorial Hospital Sterile Supply Department (HSSD), 2021.

7. Definitions

Term	Definition
Double sealable pouch	A pouch that is created when a single peel pack is packaged into a second peel pack.
Reusable medical device (RMD)	A medical device designated or intended by the manufacturer as suitable for processing and reuse. Clarification notes: 1. This is not a medical device that is designated or intended by the manufacturer for single use only. 2. An RMD is presented for use either as an individually packaged RMD or as more than one RMD assembled and packaged together as a group or set. For the purposes of this document, the term RMD includes a loan RMD and a trial RMD and applies to all reusable devices that require reprocessing.
Sterile Barrier System (SBS)	The packaging placed around RMDs that allows them to be sterilised. It provides a microbial barrier and maintains sterility effectively up to the point-of-use.
Sterilisation Services Department (SSD)	Also known as Central Sterilising Services Department, Sterile Processing Department, Central Supply Department. An integrated department in a Health Service Organisation that performs cleaning, disinfection and sterilising actions on RMDs and manages storage of sterile stock and consumables.

8. Document Summary

Coverage	WACHS wide
Audience	All WACHS healthcare workers that use or reprocess reusable medical devices (RMDs)
Records Management	Non Clinical: Records Management Policy Clinical: Health Record Management Policy
Related Legislation	*Therapeutic Goods Act 1989* (Cwlth) *Health Services Act 2016* (WA)
Related Mandatory Policies / Frameworks	Clinical Governance, Safety and Quality Policy Framework National Safety and Quality Health Service Standards Accreditation Policy – MP 0134/20
Related WACHS Policy Documents	Chemical and Biological Indicators and Process Challenge Devices Procedure Environmental Cleaning Policy Infection Prevention and Control Policy Reprocessing Reusable Medical Devices Policy Reusable Medical Devices on Loan and Instruments on Trial Procedure Storage, Handling and Transport Requirements for Sterile Stock Procedure Tracking and Traceability of Reusable Medical Devices Procedure Validation of Cleaning, Disinfecting, Packaging and Sterilising Processes Procedure
Other Related Documents	WACHS Sterilisation Services: Policies, Procedures and Resources List
Related Forms	Nil
Related Training Packages	Nil
Aboriginal Health Impact Statement Declaration (ISD)	ISD Record ID: 1881
National Safety and Quality Health Service (NSQHS) Standards	3.01, 3.02, 3.08, 3.10, 3.11, 3.12, 3.13, 3.14, 3.17
Aged Care Quality Standards	Nil
National Standards for Mental Health Services	Nil

9. Document Control

Version	Published date	Current from	Summary of changes
1.00	9 March 2023	9 March 2023	New procedure

10. Approval

Policy Owner	Executive Director Nursing and Midwifery
Co-approver	Executive Director Clinical Excellence
Contact	Coordinator of Nursing – Perioperative
Business Unit	Nursing and Midwifery – Surgical Services
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