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Handling, Transport and Storage of Released Reprocessed Reusable Medical Devices Procedure

1. Purpose

This procedure provides guidance for the handling, transport and storage of released reprocessed sterile reusable medical devices (RMDs). The principles of this document also apply to processing of single-use RMDs/other devices supplied to facilities in a non-sterile state which require sterilisation in accordance with the device's processing instructions prior to single use.

Additionally, guidance is provided in relation to the storage and handling of commercial sterile single use consumables and non-sterile consumables utilised during the reprocessing of sterile RMDs within WA Country Health Service (WACHS) facilities.

2. Procedure

A risk management system for reprocessing RMDs/other devices is a requirement of the Australian Commission on Safety and Quality in Healthcare (ACSQHC). The use of a risk assessment approach from point of use processing, cleaning, disinfection, sterilisation, storage and transport of RMDs/other devices, is intended to be a systematic method for reprocessing devices which may be used by any facility (e.g., hospitals, medical clinics, dental practices and podiatry practices).

Appropriate handling practices, transport systems and storage conditions which protect package integrity until the point of use, must be implemented to maintain sterility of packaged and sterilised RMDs/other devices and items purchased sterile by the facility. (i.e., avoiding failure of the sterile barrier system (SBS) resulting in microbiological contamination of the contents).

2.1 Release of Reprocessed Sterile RMDs

The effectiveness of each individual phase of the reprocessing procedure shall be confirmed prior to an RMD/other device being released to the next phase of reprocessing or storage. A released RMD/other device shall be recalled in a timely manner where there is evidence of failure during the cleaning, disinfection, packaging or sterilisation processes, or during transport and storage of a reprocessed device.
Refer to clause 2.6.3.2 of AS 5369:2023.

If all acceptance criteria are not met, then the device shall be designated as nonconforming and shall be quarantined and handled in accordance with the WACHS Nonconforming Reusable Medical Devices Procedure.
Refer to AS 5369:2023 - Figures 9.1 and 9.2 and Table 9.1 for further information.

2.2 Handling of Sterile Reprocessed RMDs/other Devices

Released reprocessed sterile RMDs/other devices should be handled and managed in a manner which minimises the risk of environmental contamination as follows:

- Hand hygiene must be performed prior to handling released RMDs and hand hygiene opportunities must be available on the entrance to and within the storage area.
- A dedicated cooling area shall be provided within the steriliser unloading zone for the cooling and aeration of sterilised RMDs/other devices.
- RMDs must be handled as little as possible and must not be handled before being aerated and cooled following sterilisation.
- Sterilised devices should remain on the sterilisation trolley or on a surface that does not create condensate until cool and safe for handling and transportation.
- All surfaces where processed RMDs are placed must be clean and free from dust or debris.
- The packaging of all sterile stock items must be inspected for integrity prior to use.

2.3 Transport

A reprocessed critical/semi-critical RMD/other device shall be handled and transported in a manner which prevents/minimises the risk of contamination. Where RMDs/other devices are transported internally within a building, between buildings or between sites/facilities, the procedure/s shall be subject to a risk assessment and the conditions for non-conformance of RMDs/other devices due to transport documented. AS 5369:2023 Appendix B provides guidance on risk-assessment processes to be undertaken.

Appropriate transportation of processed RMDs shall include the following practices as relevant:

- processed items transported in a fully enclosed / covered trolley
- processed items placed into a protective barrier system (PBS) prior to transport
- processed items placed into transport containers that are:
  - designated for that purpose only and clearly labelled
  - rigid, robust, and leak-proof
  - adequate in size to contain items securely and safely, protecting their integrity until point of use
  - able to be cleaned regularly and disposed of and replaced when no longer serviceable
  - able to be sealed or locked i.e., tamperproof
- temperature and humidity monitoring during transport to maintain the temperature between 18°C-25°C and humidity between 35%-70% as per AS 5369:2023.

For further information relating to transport of surgical instrument cases, refer to NSW Workcover Authority (2011), Design and handling of surgical instrument transport cases: A guide on health and safety standards.

2.4 Sterile Stock Storage Requirements

The planning of sterile stock storage areas and systems is integral in ensuring sterile stock maintains its integrity, is fit for purpose and safe for patient use. As per AS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities, the proper handling, transport and storage of a released RMD/other device is essential to maintain that device in a state of the required quality, thereby ensuring patient/client safety. Storage areas are to be dedicated for the purpose that they are intended and are to comply with the requirements of AS 5369:2023 and the Australasian Health Facility Guidelines (AHFG) B 0190 – Sterilizing Services and Endoscope Reprocessing Unit.

Guidance for all Sterile Stock Storage Areas in the Peri-Operative Setting

To maintain the integrity of the SBS, conditions for storage of the RMD/other device should be managed as follows:

- Reprocessed RMDs/other devices should be stored in a manner which minimises the risk of environmental contamination and sterility is not compromised.
- A dedicated area shall be provided for the storage of sterilised reprocessed RMDs/other devices that have been released for use i.e., a sterile RMD/other device should be stored on or in a designated room or shelving, cupboards, drawers or containers.
- Contents from external cardboard boxes must be decanted prior to entering the sterile storage area (NB: protective inner boxes may be required to be maintained and stored in the sterile storeroom to protect the integrity of the single use sterile item).
- The ventilation of sterile storerooms not adjoining operating theatres/in other locations shall be subject to a risk assessment. AS 5369:2023 Appendix B provides guidance on risk-assessment processes to be undertaken.
- The air shall be conditioned to maintain temperature and relative humidity:
  - The temperature should be controlled within the range of 18°C to 25°C
  - Relative humidity should be controlled within the range of 35 % to 70 %.

  NB: Temperature and humidity monitoring can be achieved by back-to-base monitoring systems managed by engineering staff, or by documenting daily recordings of wall mounted monitoring devices by sterilising services department (SSD) staff. Staff responsible for monitoring temperature and humidity in sterile storage areas must be aware of the environmental parameters noted above and the appropriate response if parameters are exceeded. Refer to section 2.7.
- The use of a validated SBSs combined with a PBS is required. Control systems, such as PBSs or sealed cabinets, can be employed to protect products by providing environmental and mechanical protection.
- Good inventory management practices should ensure that stock rotation is practiced on a “first in, first out” basis wherever practicable.
- Systems should be instituted that provide a record as to stock levels and to the disbursement of reprocessed RMDs/other devices to users. This may be facilitated through the implementation of an electronic traceability system.

Commercially sterilised items undergo rigorous testing regimes to satisfy the Therapeutic Goods Administration requirements of processing conditions and packaging systems. This testing confirms that commercially processed items can withstand more extremes of storage and handling conditions than sterile RMDs produced in/by a Health Service Organisation (HSO). However, adequate storage conditions must still be provided to protect packaging and its contents, and manufacturer’s instructions for storage in relation to temperature, humidity and expiry must be adhered to.

Requirements for Sterile Storerooms Adjoining Operating Theatres

- Sterile storerooms adjoining operating theatres shall be ventilated in accordance with the requirements for ventilation of a sterile store and set up room in AS 1668.2. Additional guidance is provided in the Australasian Health Facility Guidelines.
- It is recommended that the sterile storage area is maintained at positive pressure to all adjoining areas and shall be continuously operational.
- A sterile RMD/other device should be stored on or in designated shelving, cupboards, drawers or containers.

- Access to the storage area(s) for reprocessed RMDs/other devices should be restricted to individuals that have been trained and deemed competent in the handling of reprocessed devices with restricted access for authorised personnel signage clearly displayed.

Requirements for Sterile Stock Storage External to the Peri-Operative Setting

Sterilised items stored in wards/clinical areas or in mobile storage containers external to the peri-operative setting, where environmental conditions cannot be monitored and controlled, require risk mitigating controls to be employed such as:

- Sterile stock produced in/by the health facility must be enclosed in a sealed plastic dust cover / PBS prior to leaving the SSD.
- Stock must be stored in a cupboard, drawer or rigid container dedicated for that purpose and protected from environmental contaminants such as sunlight, dust, and water.
- Storage conditions must not exceed the required temperature and humidity parameters outlined for reprocessed RMDs above or as per the manufacturer's guidelines for commercial sterile stock.

Note: Whilst the principles of handling, transport and storage relating to sterile RMDs and single use sterile stock also apply to endoscopy departments, specific guidance related to an endoscope reprocessing unit is provided in the WACHS Flexible Endoscope Reprocessing Procedure.

2.5 Sterile Storeroom Environment Requirements

Walls, floors and ceilings are to be continuous, smooth, impervious, and capable of easy and frequent cleaning. Surfaces must be well maintained in a clean, dry and dust free state. Joins and hard to clean corners must be minimised or avoided.

Sterile stock storage shelving should:

- be constructed from robust, non-shedding materials that are easy to clean and maintain in good condition
- where practicable, be flexible to facilitate product changes i.e., adjustable shelving
- be designed and installed to support safe handling practices and take into consideration work health and safety issues/concerns such as height of shelving, storage and accessibility to stock
- have smooth surfaces that do not damage products, packaging and other materials
- be flush with wall surfaces and ceilings where possible and facilitate sterile stock not contacting walls
- be maintained in a clean/dust free state
- be at a height off the floor that facilitates cleaning without any risk of contamination to packaging during floor cleaning processes
- prevent contamination of sterile stock by ensuring the highest shelf is at a height that allows the stock to be stored without any risk of contact with the ceiling or fixtures.

The use of metal open wire shelving/racks or alternative plastic/polypropylene baskets with perforated bases is recommended. Solid based storage containers are prone to dust collection and require significant cleaning resources to maintain in a clean dust free state, which can lead to increased sterile stock handling and the potential for increased environmental contamination.

2.6 Shelf Life for Sterile RMDs

Terminally sterilised RMDs are packaged and commonly managed and controlled using either event or time related storage principles. Individual facilities must risk assess their storage conditions to determine which method is more applicable. Event related implies that sterility prevails in ideal conditions until the item is subjected to an event which will compromise that state. As per ANSI:AAMI ST 79. 2017 & 2020 Amendment 11.1.3, "The contamination of a sterile item is event related, and the probability of its occurrence increases over time and with increased handling".

Events that could compromise an RMD SBS include:

- frequent or inappropriate handling of packaging
- inappropriate storage e.g., compressed tightly in draws, trays over stacked, items bundled together with rubber bands
- packaging material torn, opened or damaged
- packaging is damp, i.e., moisture or condensation is evident
- the processed RMD has been dropped, is visibly soiled, has contacted a dirty surface
- process indicators such as indicator tape or accompanying documentation do not indicate RMD has been through appropriate process
- illegible labelling of contents
- out of range temperatures or humidity during storage for a significant period of time
- lack of rotation of stored RMDs
- a storage area that is not clean or dust / vermin free
- excessive exposure to sunlight.

2.7 Management of Stock Exposed to Environmental Conditions that Exceed Recommended Parameters

Some packaging materials are more able to withstand the effects of high humidity than others. Commercial sterile stock packaging with plastic covers or those sealed in aluminium foil pouches are relatively impermeable to moisture whereas plastic paper pouches and uncoated textile wraps are permeable to moisture. To obtain more details on the permeability of the specific packaging used on site, the manufacturer or supplier should be contacted.

Guidance related to humidity control is outlined in the Response to Humidity Control Events in Sterile Store and Perioperative Areas Health Technical Advice HTA-2019-001 as per extracts below.

Sterile Stores – High Humidity Event

- Visible effect of moisture (Action 1):
  - If packages are visibly damp, wet or damaged (e.g., labels peeling due to moisture or visible moisture on the package), the packaged items must not be used. The contents must be rewashed, repackaged and sterilised (or discarded if single-use medical devices).
- No visible effect of moisture (Action 2):
  - If > 75% relative humidity is detected for >8hrs the packages should be assessed for moisture. If not visibly damp, wet or damaged the consensus is that these packages may be used. Where practical consideration should be given to relocating the stock from the affected area until the issue is resolved.

- If the next humidity reading 24 hrs later is still > 70%, then the site needs to perform a risk assessment to determine which items may be used, reprocessed or discarded.

Sterile Stores – Low Humidity Event (Action 3):

- If humidity is < 30% for 12 hrs, some packaging materials are unable to withstand prolonged exposure to low humidity and may become brittle. The manufacturer or supplier should be contacted.

3. Roles and Responsibilities

The **Health Service Organisation** (HSO) is responsible for ensuring suitable and sufficient storage is provided and that processes in place comply with the requirements of the standard.

The Manager of the Sterilisation Services Department is responsible for the management and control of the storage, handling, and transport of processed items including sterile stock produced in / by the HSO or commercially produced sterile items and the storage and handling of bulk non-sterile consumables critical to processing RMDs. This includes risk assessing sterile stock storage areas and monitoring handling, storage and transport of sterile stock, and ensuring all relevant staff receive education related to the importance of appropriate infection prevention and control practices in maintaining sterility of items until point of use.

All Health Care Workers are responsible for appropriate handling, transport, storage and inspection of sterile stock prior to use.

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

The SSD Manager / Supervisor or Perioperative Services Manager is responsible for ensuring that monitoring of compliance with this document is undertaken in line with current International, national and state standards and guidelines.

Relevant concerns / issues identified should be tabled at the Perioperative / Surgical Services Committee Meetings and Regional Infection Prevention Control Committee meetings as relevant and escalated to the Regional Safety and Quality Committee as required.

Incidents, process breaches, failures or non-compliance and near misses are to be reported via the DATIX clinical incident management system for review and action 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 within a 5-year timeframe or sooner as required. The review will consider any trends in relation to clinical

incidents and the results of ongoing quality monitoring activities that are undertaken at a site / regional level.

5. Compliance

This procedure is a mandatory requirement under the *Therapeutic Goods Act 1989* (Cwlth) and AS 5369:2023.

Failure to comply with this policy 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* 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

AS 5369:2023. Reprocessing of reusable medical devices and other devices in health and non-health related facilities. Available from WACHS Library

ANSI/AAMI ST79:2017 with Amendments A1:2020, A2:2020, A3:2020, A4:2020. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Available from WACHS Library

Australian College of Perioperative Nurses (ACORN). 2023. Standards for Safe and Quality Care in the Perioperative Environment (SSQCPE) for Organisations. Available from WACHS Library

Sterilizing Services and Endoscope Reprocessing Unit - B.0190 [Accessed 14 March 2024]

Building Guidelines Western Australia Health Facility Guidelines for Engineering Services 2017 & 2021. Department of Health, Western Australia.

National Health and Medical Research Council (2019) Australian Guidelines for the Prevention and Control of Infection in Healthcare. Canberra: Commonwealth of Australia. [Accessed 14 March 2024]

Therapeutic Goods (Medical Devices) Regulations Statutory Rules No. 236, 2002, Therapeutic Goods Act 1989 (Cwlth) Compilation No. 54 Compilation date: 28 November 2023 Includes amendments up to F2023L01558. Registered: 14 December 2023. [Accessed 14 March 2024]

7. Definitions

Term	Definition
Air Changes per Hour	Air changes per hour (ACH), or air change rate is a measure of the air volume added to or removed from a space in one hour, divided by the volume of the space.
Cooling Area	A dedicated area provided within the steriliser unloading zone for cooling, and where applicable, aeration of sterilised RMDs or other devices.
Critical Medical Device	A medical device that enters sterile tissue or the vascular system, that is required to be sterile at the time of use.
Deboxing	To remove commercially prepared sterile items from external transport / shipping boxes.
Health Service Organisation	A Health Service Organisation (HSO) is a separately constituted health service that is responsible for implementing clinical governance, administration and financial management of a service unit or service units providing health care at the direction of the governing body.
HEPA Filter	A high efficiency particulate air (HEPA) filter is a disposable, extended media, dry type filter in a rigid frame, having a minimum filtration efficiency of 99.97% and designed to remove particles greater than 0.3 microns.
Instructions for Use	Instructions for Use (IFU) are directions provided to the user for the use of a medical or other device and / or accessory, and equipment. (e.g., a user instruction manual for reprocessing an RMD and its packaging, or operation of a washer-disinfector)
Medical Device	Instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, or software material, or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purposes(s) of: • diagnosis, prevention, monitoring, treatment, or alleviation of disease • diagnosis, monitoring, treatment, alleviation of, or compensation for an injury • investigation, replacement, modification, or support of the anatomy, or of a physiological process • supporting or sustaining life • control of conception • disinfection of medical devices or • providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means.
Other Device(s)	Devices that are not considered a medical device but are designated a reusable device requiring reprocessing according to Spaulding's classification between uses.

Personal Protective Equipment	Personal protective equipment (PPE) such as gloves, gowns, aprons face masks/shields and eye protection.
Preformed Sterile Barrier System	A preformed sterile barrier system (PSBS) is a sterile barrier system that is supplied partially assembled for filling and final closure or sealing. e.g., pouches; bags and open reusable containers.
Released Reusable medical device	A reusable medical device that has been released from a phase of processing after achieving the required parameters of processing.
Reusable Medical Device	A reusable medical device (RMD) is 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 guideline 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)	A sterile barrier system (SBS) is the minimum packaging utilised to reduce the risk of ingress of microorganisms and allow aseptic presentation of the sterile contents at the point of use. Both sterile stock produced in/by the HSO (reprocessed RMDs) and commercially produced sterile stock are packaged in an SBS (e.g., wrap, steripeel, rigid containers).
Sterile Stock	In this document refers to reprocessed RMDs reprocessed by the HSO in their SBS and commercially produced sterile stock / medical devices, consumables and implantable products.

8. Document Summary

Coverage	WACHS Wide
Audience	All WACHS healthcare workers that are responsible for handling, transport or storage of reusable medical devices and sterile stock.
Records Management	Non-Clinical: Corporate Recordkeeping Compliance Policy Clinical: Health Record Management Policy
Related Legislation	*Therapeutic Goods Act 1989* (Cwlth) *Health Services Act 2016* (WA) *Work Health and Safety Act 2020* (WA) Work Health and Safety Regulations 2022 (WA)
Related Mandatory Policies / Frameworks	• MP 0172/22 -Personal Protective Equipment in Healthcare Facilities Policy • MP 0134/20 - National Safety and Quality Health Service Standards Accreditation Policy • Clinical Governance, Safety and Quality Framework
Related WACHS Policy Documents	• Environmental Cleaning Policy • Flexible Endoscope Reprocessing Procedure • Hand Hygiene Policy • Infection Prevention and Control Policy
Other Related Documents	• WACHS Sterilisation Services: Policies, Procedures and Resources List
Related Forms	Nil
Related Training Packages	Available from MyLearning: • Introduction to Reprocessing Reusable Medical Equipment Declaration (RRME EL2) 2022 • Person Centred Care (PCC EL1) • Clean and Safe Healthcare Environment Declaration (CSHE EL2)
Aboriginal Health Impact Statement Declaration (ISD)	ISD Record ID: 3222
National Safety and Quality Health Service (NSQHS) Standards	1.01, 1.02, 1.03, 1.04, 1.05, 1.06, 1.07, 1.08, 1.09, 1.11, 1.12, 1.16, 1.17, 1.18, 1.19, 1.20, 1.21, 1.29, 1.30, 1.31, 1.32, 1.33, 2.01, 2.02, 3.01, 3.02, 3.04, 3.05, 3.06, 3.07, 3.08, 3.09, 3.10, 3.11, 3.12, 3.13, 3.17
Aged Care Quality Standards	Nil
Chief Psychiatrist's Standards for Clinical Care	Nil

9. Document Control

Version	Published date	Current from	Summary of changes
2.00	20 May 2024	20 May 2024	• change of title to align with terminology used in AS 5369:2023. • updated references • significant updates to previous procedure and review of content to ensure alignment with the requirements of AS 5369:2023 • link to WACHS Sterilisation Services: Policies, Procedures and Resources List.

10. Approval

Policy Owner	Executive Director Nursing and Midwifery Services
Co-approver	Executive Director Clinical Excellence
Contact	WACHS Coordinator of Nursing - Perioperative
Business Unit	Nursing and Midwifery – Surgical Services
EDRMS #	ED-CO-22-331204

This document can be made available in alternative formats on request.