Tracking and Traceability of Reusable Medical Devices Procedure

1. Purpose

The purpose of this procedure is to outline the requirements for the identification and traceability of reusable medical devices (RMDs), including loan and trial items, undergoing high level disinfection or sterilisation during reprocessing and their subsequent use on patients in accordance with the Australian Standard AS/NZS 4187:2014.

The reprocessing of RMDs requires quality systems to validate the effectiveness of all stages of instrument reprocessing. Appropriate management of quality tracking systems ensure that WA Country Health Service (WACHS) can promptly recall a sterilised product if required, tracking it from when it was dispatched from the Sterilisation Services Department (SSD) to receipt by the user area. This process provides WACHS with the ability to link every stage of reprocessing RMDs to patients for whom they are used.

This procedure applies to all WACHS healthcare workers that use or reprocess RMDs.

2. Procedure

2.1 General principles

- All RMDs used at WACHS will be tracked throughout their use and reprocessing ensuring they (and the patients on whom they have been used) can be traced and recalled when necessary.
- Traceability systems require at a minimum, the identification of all semi-critical and critical RMDs.
- Tracking and traceability of reprocessed items must enable the identification of a patient where a “nonconforming” RMD has been used, in the event that a recall is required. This includes trial and loan RMDs.

2.2 Tracking systems

- All RMDs reprocessed in SSD must be scanned into and recorded in the manual or electronic tracking system enabling users to track the location, reprocessing history and usage of each item.
- All machines, tray lists and processed instruments must be registered in the tracking system by SSD staff when purchasing to ensure the history and information for each use is documented.
  - In the absence of an electronic tracking system, sterilised RMDs must be tracked manually via the use of the sterilisation batch load indicator labels utilising a paper-based system that conforms to the requirements of AS/NZS 4187:2014. Load indicator labels are to be removed from the relevant pack and included in the patient’s health record to ensure instruments maintain traceability to an individual patient in the event of a recall.
- The following information is to be recorded in the electronic tracking system:
  - the location of each RMD at every stage of the procedure/process

- the date of the washing/sterilising cycle
- the washer/steriliser number or code
- the cycle load or number
- process parameters
- the identity of the person undertaking processing at each stage, including release of load contents
- the specific contents of the load
- the total number of individual items contained in the load
- the readout result of physical, chemical or biological/enzymatic indicators that are used
- the storage location
- the dispatch location
- the patient the RMD has been used on.

2.3 Batch load indicator labels

- All RMDs reprocessed and sterilised in SSD are to be tracked via affixed product identification and traceability stickers (batch load indicator labels) adhered to each reprocessed item or tray.
- The batch load indicator label is to link the sterilising unit and batch information to the RMD and to the patient. The batch label facilitates the identification and location of the RMD in the event of a recall.
- Batch load indicator labels are to be placed on each RMD or tray and must include the following information:
  - the date
  - steriliser number
  - the cycle load number.
- The batch load indicator labels are to be removed from the relevant pack and included in the patient's health record to ensure instruments have traceability to an individual patient.
- Any single sterile RMD or tray that does not have a batch load indicator label attached must not be used and is to be returned to SSD and reported to the SSD Manager/Supervisor.

2.4 Manual tracking

- Manual tracking of RMDs must occur within WACHS hospitals that do not have an electronic tracking system **or** in any area in the event of an electronic tracking system failure.
- Staff using RMDs must action the following to ensure tracking and future traceability of these items:
  - Prior to use, ensure the integrity of the RMD pack and ensure external sterilisation process indicators are the correct colour.
  - Retain the RMD load indicator label and affix it to the patient's health record.

2.5 Tracking of RMDs requiring repair or replacement

- Tracking of RMDs is to be undertaken using the electronic tracking system or manual log system when instruments are sent for maintenance or when new instruments are included in a tray/set (e.g. broken instruments have been replaced).
- The reunification of instruments with their trays following repair or replacement benefits from accurate instrument identification.

2.6 ICT service and support

- All instrument tracking system breakdown incidents must be escalated to the ICT Service Desk.

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.

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 is 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. 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/.
3. ISO/TS 17665-2:2009. Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1. Available from https://www-saiglobal-com.wachslibresources.health.wa.gov.au/online/.
4. St John of God Midland Public and Private Hospitals. Central Sterilisation Services Department Manual, MIC-SSD-OTH-0002.
5. 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
Nonconforming RMD	An RMD that does not fulfil requirements (i.e. does not meet the required specification). Nonconforming RMDs are not safe to be used on patients.
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.
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* (Cwth) *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 Packing, Wrapping and Sealing Reusable Medical Devices Procedure Reprocessing Reusable Medical Devices Policy Reusable Medical Devices on Loan and Instruments on Trial Procedure Storage, Handling and Transport Requirements for Sterile Stock Procedure Thermal Disinfection 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: 1889
National Safety and Quality Health Service (NSQHS) Standards	3.01, 3.02, 3.03, 3.04, 3.05, 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
1.01	16 February 2024	9 March 2024	Minor amendment – fixed broken link

10. Approval

Policy Owner	Executive Director Nursing and Midwifery
Co-approver	Executive Director Clinical Excellence
Contact	WACHS Coordinator of Nursing - Perioperative
Business Unit	Nursing and Midwifery - Surgical Services
EDRMS #	ED-CO-22-500964

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