Reusable Medical Devices on Loan and Instruments on Trial Procedure

1. Purpose

The purpose of this procedure is to ensure that the processing of reusable medical devices (RMDs) that are on loan and/or on trial aligns with AS/NZS 4187:2014 and associated normative references.

This procedure applies to instruments and equipment that do not belong to the hospital (those "on loan") and/or specialised trial instruments **supplied by medical companies** for use in surgical procedures.

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

2. Procedure

2.1 Manual handling risk management

- Loan trays are to be transported in a manner that minimises the risk of injury to staff from manual handling.
- The supplier is to ensure that the transport containers are in good working condition. The containers must be cleaned inside and outside to be accepted into a health care facility.
- Each tray of instruments must not weigh more than 7kg when packed for sterilisation.
- The amount of handling required by staff needing to unpack from transport containers, re-set into sterilisation trays and repacking into transport container is to be minimised.

2.2 Loan surgical instrumentation

- All loan surgical instruments (sets) shall undergo cleaning, disinfecting, packaging and sterilisation process prior to sterilisation as per the manufacturer's instructions for use (IFU).
- Perceived lack of time does not permit the cleaning process to be bypassed.
- If soil and debris are found to be present on receipt of instruments on loan, the condition of the instruments shall be reported to the supplier using the Universal Cleaning and Sterilisation Guarantee (Green Form).
- Following use, all instruments on loan are to be subjected to the full cleaning process and be thermally disinfected at a minimum before being returned to their source. A Universal Cleaning and Sterilisation Guarantee (Green Form) is to be filled out and returned to the supplier with evidence of thermal disinfection or sterilisation. Refer to the WACHS Thermal Disinfection of Reusable Medical Devices Procedure.

2.3 Supplier responsibilities

- Loan sets shall be delivered to the hospital, ensuring an agreed period of time for Perioperative/Orthopaedic Technician (where these roles exist) and/or the Sterilisation Services Department (SSD) to examine and ensure it is the correct equipment. The

supplier may be contacted by the SSD Supervisor or Nurse Coordinator to assist with checking in loan instruments to expedite the process.
- SSD staff are to check and reprocess the instruments prior to the planned surgery. A minimum of 48 hours is required for this to occur, unless an earlier timeframe has been negotiated.
- The supplier is to provide two copies of the tray lists. If only one tray list is supplied, a second tray list must be photocopied.
- The supplier must ensure that:
  - tray lists identify contents with a written and photographic outline
  - tray lists include full descriptions of all instruments disassembled to their smallest parts, including product codes
  - instrument codes on tray lists correspond with those on the instrument
  - tray lists and photographs are accurate and correspond with trays provided.
- Suppliers are to provide the manufacturer's IFU, Therapeutic Goods Administration (TGA) certification and cleaning and sterilising instructions. These must meet AS/NZS 4187:2014, ISO 17664-1:2021 and associated normative references.
- Loan sets will not be available for collection after use until a full clean and thermal disinfection process has occurred.
- The supplier may be contacted by the SSD Supervisor to assist with checking out loan trays to expedite the process of returning the loan item/s to the supplier.

2.4 Receipt of instruments from supplier

- On arrival in the SSD, the loan sets are to be checked prior to reprocessing to confirm the contents are correct and all appropriate documentation is present (i.e. tray lists, IFU, TGA certification).
- **Multi-component instruments are to be fully disassembled and all instruments inspected for soil and damage prior to reprocessing.**
- If any irregularity is identified, the SSD Supervisor is to be notified who will contact the designated supplier representative.
- Once checking is complete, the tray list is to be signed and dated and the instruments are to be tagged and entered into the manual or electronic tracking system.
- The items are to be reprocessed as per the manufacturer's IFU.
- A checked and signed tray list is to be included on all loan instrument trays.

2.5 Universal Cleaning and Sterilisation Guarantee (Green Form)

- Sterilisation Technician is to complete the supplier name (e.g. Stryker) and check in details (i.e. your name, number of trays received, date and time).
- Place Universal Cleaning and Sterilisation Guarantee (Green Form) in designated location in preparation for terminal sterilisation and loan check out.

2.6 SSD staff responsibilities following completion of surgery

- Following completion of the surgery/procedure, all instruments are to be checked against tray lists to confirm all instruments are accounted for. The tray lists are to be retained in the SSD until final processing is correct and complete.
- Missing instruments are to be reported to the Theatre Nurse or Nurse Coordinator.
- Once instrumentation checking is complete, all instruments are to undergo a full decontamination process.
- All instruments are to be checked for cleanliness.

- All instruments are to be checked against the supplier's original tray list/s to confirm all instrumentation is accounted for. Tray lists are to be signed and dated.
- All instruments are then to be thermally disinfected or sterilised as appropriate. Refer to WACHS Thermal Disinfection of Reusable Medical Devices Procedure as appropriate.
- Place instruments back into their original trays.
- Obtain corresponding tray lists and the Universal Cleaning and Sterilisation Guarantee (Green Form) from designated location (e.g. loan file).
- Complete the "Guarantee" section in the Green Form.

2.7 Loan check out

- Loan check out is to be completed by Perioperative/Orthopaedic Technician (where these roles exist) or SSD staff.
- Loan instruments are to be checked against the supplier's original tray list/s to confirm all instruments are accounted for. Tray lists are to be signed and dated.
- Loan instrument trays not used during surgery are to be unwrapped and returned to SSD.
- Loan instruments are to be packed back into their original transport container, with visual inspection undertaken to ensure all instruments are accounted for.
- Attach the Universal Cleaning and Sterilisation Guarantee (Green Form) to the completed supplier tray list/s.
- Advise appropriate Supervisor of the completed process. The Supervisor will notify the supplier when loan trays are ready for collection.

2.8 Loan trays to be re-used for subsequent cases

- Loan trays are to be re-entered into the system as per the above process (refer to Section 2.4: Receipt of instruments from supplier onwards).

3. Roles and Responsibilities

Health Service Organisations are responsible for ensuring 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 selection and evaluation process prior to trialling an RMD (refer to WACHS Clinical Product Evaluation Policy)
- ensure education is provided by the supplier demonstrating correct reprocessing and handling of loan and trial RMDs prior to use.

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. Advisory AS18/07: Reprocessing of reusable medical devices in health service organisations.
3. ISO 17664-1:2021 Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 1: Critical and semi-critical medical devices. Available from https://www-saiglobal-com.wachslibresources.health.wa.gov.au/online/.
4. 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/.
5. 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/.

6. Australian College of Perioperative Nurses (ACORN) – Standards for Perioperative Nursing in Australia 16th Edition, May 2020. New equipment and instrumentation, Reprocessing re-usable medical devices.
7. 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
Instructions for use (IFU)	Information provided by the manufacturer for the intended user detailing how the device can be used safely for its intended purpose.
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.
Therapeutic Goods Administration (TGA)	Australia's government authority responsible for evaluating, assessing and monitoring products that are defined as therapeutic goods.

8. Document Summary

Coverage	WACHS wide
Audience	All WACHS healthcare workers that use or reprocess reusable medical devices
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 Clinical Product Evaluation Policy Infection Prevention and Control Policy Packing, Wrapping and Sealing Reusable Medical Devices Procedure Reprocessing Reusable Medical Devices Policy Thermal Disinfection of Reusable Medical Devices 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: 1885
National Safety and Quality Health Service (NSQHS) Standards	3.01, 3.02, 3.03, 3.04, 3.07, 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
EDRMS #	ED-CO-22-500954

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