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Reprocessing Reusable Medical Devices Policy

1. Purpose

This policy outlines the principles for the reprocessing of reusable medical devices (RMDs) in alignment with the requirements of the AS 5369:2023 – Reprocessing of reusable medical devices and other devices in health and non-health related facilities and associated normative references, to mandate expected standards for safe and effective reprocessing of RMDs, in conjunction with manufacturer's instructions for use (IFU).

2. Policy

This policy applies to all healthcare workers (HCWs) that use or reprocess RMDs at any WA Country Health Service (WACHS).

2.1 General principles

RMDs are used for diagnostic and/or treatment purposes for multiple patients and are intended by the manufacturer for reprocessing and reuse. Effective and safe reprocessing of RMDs/other devices is critical for safe patient care. When performing cleaning, disinfection, and/or sterilisation procedures for RMDs, the requirements of AS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities shall be adhered to as follows:

- All disinfection and sterilisation of critical and semi-critical RMDs shall be performed in designated reprocessing areas.
- Standard precautions are the minimum infection prevention and control (IPC) practices to be applied when cleaning and handling used RMDs.
- Appropriate attire and personal protective equipment (PPE) shall be worn to prevent direct skin and mucous membrane contact with body substances and chemical solutions in accordance with WACHS Dress Code Policy and MP 0172/22 - Personal Protective Equipment in Healthcare Facilities Policy.
- Staff accountable for reprocessing of an RMD/other device should be involved in the selection process prior to purchase, to ensure effective reprocessing can be undertaken using existing equipment and staff skills. An RMD/other device that cannot be effectively reprocessed using existing equipment and staff skills, should not be purchased unless suitable reprocessing equipment is specifically purchased/qualified for reprocessing of the device and training undertaken. This is also applicable to use of loan and trial RMDs/other devices. Refer to the WACHS Medical Equipment Procurement Policy and the WACHS Clinical Product Evaluation Policy.
- When equipment is purchased or loaned, manufacturer's IFU and reprocessing instructions are to be provided by the supplier in accordance with ISO 17664. The information must be readily accessible by all staff involved in the use, cleaning, and care of the equipment.
- Damaged items to be returned to the manufacturer shall be processed at a minimum by a validated cleaning and high-level disinfection process in accordance with manufacturer's IFU. If this is not possible due to the nature of the damage, the manufacturer shall be consulted to ensure the RMD is correctly packaged for transportation.

- HCWs must only use equipment and/or participate in reprocessing activities once the relevant training has been completed and competency assessed.
- Items labelled for “single use only” or “use once only” are not to be reprocessed. This symbol is the internationally recognised symbol on medical device labels that indicates the item is “not for reuse”. Items labelled ‘single patient use’ can be re-used on the same patient after reprocessing according to the manufacturers’ instructions.

2.2 Spaulding Classification of Devices and Associated Risk

The Spaulding Classification Scheme shall be used to categorise an RMD/other device according to its intended use and the subsequent level of reprocessing required to render it safe for reuse. RMDs/other devices are categorised as critical, semi-critical or non-critical, and reprocessed and stored as per Table 5.1 in AS 5369:2023. After cleaning, the procedures for each category of RMD/other device shall be as per Table 1.

Table 1: General criteria for reprocessing and storage of RMDs/other devices in facilities Spaulding Classification

Risk level	Definition	Process	Storage
Critical RMDs/ other devices (High risk)	Item intended to be introduced directly into or have contact with the vascular system or normally sterile areas of the body.	Clean asap after use. Sterilisation is required via a validated moist heat sterilisation process or a low temperature sterilisation process between uses on individual patients/clients.	Sterility to be maintained. Packaged RMDs/other devices are to be stored to prevent environmental contamination in a designated storage area. NB: RMDs/other devices processed through a liquid chemical sterilisation process are to be used immediately.
Semi critical Devices (Medium risk)	An RMD that comes into contact with mucous membranes or non-intact skin e.g., anaesthetic equipment, gastroscopes, colonoscopes.	Clean asap after use. Sterilisation by either a validated moist heat or low-temperature sterilisation is preferred. If not compatible with sterilisation methods reprocess using a validated thermal disinfection process. If not compatible with thermal disinfection reprocess using a validated high-level disinfection process.	Store to prevent environmental contamination in a designated storage system (e.g. controlled environment drying cabinet)
Noncritical device (Low risk)	An RMD that comes into contact with intact skin but not mucous membranes. e.g., BP cuff	Clean asap after use. Disinfect with compatible low-level or intermediate-level instrument grade disinfectant or thermal disinfection as per the manufacturer’s IFU and facility procedures.	RMDs/other devices to be stored in a clean dry place to minimise environmental contamination

2.3 Product families

The classification of an RMD/other device into a product family assists the development of processing conditions. When assigning an RMD/other device to a product family and to a method of reprocessing, the following shall be considered and documented:

- a description of the RMD/other device and its intended use with reference to the IFU
- a description of materials that are used to make the RMD/other device. NB: both metal, non-metal and metal non-metal combinations are commonly used to construct
- RMDs/other devices and materials can affect penetration by the reprocessing agent(s)
- the design of the RMD/other device, including characteristics that could affect the selection of a cleaning, disinfection or sterilisation process, e.g. ease of disassembly and assembly, tolerance to moisture, heat and chemicals, presence of lumens, moving parts, fibre-optics and electronics
- the physical characteristics of the RMD/other device, including its mass, surface area and thermal conductivity
- packaging of the RMD/other device, including the SBS for sterilised devices.

The ISO 17665 and ISO 17664 series provide useful information to assist in assigning an RMD to a product family.

2.4 Cleaning Agents and Disinfectants

Cleaning agents, disinfectants and sterilising agents shall be compatible with the RMD /other device to be processed and the associated equipment used to deliver that process. Appropriate PPE shall be worn when handling disinfectants with reference to the relevant Safety Data Sheets (SDSs). Chemical disinfectants can be inactivated by organic material, so items for disinfection must be thoroughly cleaned prior to disinfection. In the event of a splash of disinfectant into the eyes, mouth or onto the skin, wash the body surface thoroughly with water. Refer to the SDS and follow the advice provided and report all accidents to your supervisor and complete the hazard/incident form.

A cleaning agent shall be used to remove residual soil/organic matter from a used RMD/other device. Documented specifications shall be obtained for each cleaning agent that provides the following requisite information as outlined in the ISO 17664 (series):

- safety data sheet and regulatory status
- active ingredient(s) and physical/chemical properties, including stability (shelf life)
- microbial efficacy and toxicity/residues
- material effects of the agent on RMDs/other devices, including known device material
- compatibilities and known device material non-compatibilities
- container/packaging/labelling (including shelf life and storage requirements)
- directions for use and, where intended for the product, reuse.

Cleaning agents shall be:

- intended for use on medical devices and used only if they are on the Australian Register of Therapeutic Goods
- compatible with the RMDs/other devices being processed and the selected method of
- cleaning and diluted and used in accordance with their IFU
- compatible with the available water quality and preferably biodegradable
- non-toxic, non-abrasive, low foaming, free rinsing and preferably in liquid form.

A high-level instrument grade disinfectant shall be the minimum grade disinfectant used for disinfection of a semi-critical RMD. Where disinfection of a non-critical RMD is required, an intermediate or low-level instrument grade disinfectant shall be the minimum grade disinfectant used. (Refer to 2.2 - Spaulding classification of devices and associated risk)

Disinfectants differ significantly in their spectrum of antimicrobial activity and their speed of action as follows:

- low-level instrument grade disinfectants kill vegetative bacteria, some fungi, viruses
- intermediate-level instrument grade disinfectants kill vegetative bacteria, mycobacteria, viruses and most fungi but do not kill bacterial endospores
- high-level instrument grade disinfectants kill all microorganisms with the exception of high numbers of bacterial endospores. Some disinfectants used as high-level instrument grade disinfectants are chemical sterilising agents that kill high numbers of bacterial endospores with prolonged exposure under controlled and defined conditions.

SDSs shall be available for all products in all areas. For further information refer to the WACHS Managing Risks Of Hazardous Chemicals and Dangerous Goods Procedure.

2.5 Cleaning, Disinfection and Sterilisation of RMDs

RMDs shall be reprocessed according to their intended use and the manufacturer's IFU. Manufacturers shall provide documented and validated reprocessing IFU in accordance with ISO 17664:2021 Processing of Healthcare Products – Information to be provided by the Medical Device Manufacturer for the Processing of Medical Devices Part 1. Cleaning process specifications shall be defined to reduce the bioburden and to remove other contaminants from a surface of a used RMD/other device to a specified level. Contaminants include tissue remnants, organic / inorganic material, and toxic chemicals.

A delay between the initial pre-treatment and the validated cleaning process for that device can result in an increase in the bioburden (through microbial proliferation). It can also cause adherent material to dry on the device making removal of this material more difficult. Before returning RMDs to the reprocessing area/SSD, all visible organic material/gross soil shall be removed as close to the point of use as possible i.e., removal of visible blood and debris from the RMD intra-operatively or immediately post-operatively, prior to return to the reprocessing area. All RMDs that are required to be transported to the reprocessing area/SSD shall be placed in rigid containers. The initial pre-treatment of a used RMD/other device is performed at the point of use. Where delays in the validated cleaning process occur, manufacturer's protocols for delayed processing should be followed.

RMD cleaning processes to remove organic material shall always precede disinfection and sterilisation and shall incorporate the following practices:

- be performed as soon as possible after use
- incorporate inspection of the RMD for any damage (damaged/missing parts are to be reported to the shift supervisor and managed as per facility processes)
- disassembly as per manufacturer's IFU before cleaning, disinfection or sterilisation
- cleaning processes that follow the manufacturer's IFU for a manual or automated process (manual cleaning may be specified by the manufacturer's IFU prior to automated cleaning and/or disinfection or sterilisation processes)
- incorporate brushing, flushing and rinsing of all cannulated RMDs prior to being loaded onto the appropriate trolley for cannulated instrument washing

- The RMD/other device's reprocessing instructions should be considered in relation to the suitability of a device for ultrasonic cleaning. Ultrasonic cleaning equipment should be used in accordance with the equipment's instructions. Water and cleaning agent solutions that are used in ultrasonic cleaners should be changed daily, and whenever soil is visible in the tank.
- The action of an ultrasonic cleaner is to loosen debris. Where the ultrasonic cleaner does not have a complete cleaning process following the cavitation action the device needs to be exposed to further thorough cleaning.

The cleaning of a used RMD/other device is easier to standardise and control when an automated mechanical process is used. However, an automated mechanical process might not be suitable for cleaning of some devices, e.g. certain fragile or complex devices. Where manual cleaning of a device is recommended, the cleaning procedure should clearly describe how the device is to be manually cleaned, rinsed and dried. Manual cleaning of RMDs in health care facilities is to be used only:

- if an RMD's validated cleaning instructions require or permit manual cleaning and these IFU are adhered to
- as a pre-treatment prior to reprocessing of an RMD in a WD.

Disinfection is the inactivation of non-sporing organisms using either heat and water (thermal disinfection) or chemicals. Disinfection of RMDs/other devices kills many microorganisms and human pathogens, unlike sterilisation however, disinfection is not effective against high numbers of bacterial endospores. Many factors affect the efficacy of disinfection processes such as the presence of soil, the nature and level of microbial contamination, RMD design, concentration of disinfectant, temperature, pH, exposure time and presence of biofilm.

For chemical disinfection, ensure that the RMD has been rinsed in accordance with specific manufacturer's instructions to remove any detergent. A chemical disinfectant used to reprocess an RMD shall be labelled as an 'Instrument grade disinfectant' and other classes of chemical disinfectants e.g., hospital grade disinfectant shall not be used to reprocess an RMD as these are intended for hard surfaces not medical devices. Skin disinfectants (e.g., chlorhexidine) are chemicals formulated for use on skin or tissue and must not be used to clean equipment.

Refer to the following work instructions for these high-level instrument grade disinfectants:

- Local Work Instruction – TRISTEL Trio Wipes
- Local Work Instruction – Trophon

Thermal disinfection can be used to disinfect RMDs that cannot withstand moist heat or low temperature sterilisation processes. Prior to thermal disinfection, the RMD is to be thoroughly cleaned. Thermal disinfection shall be performed in a washer disinfector (WD) in accordance with the ISO 15883, which outlines surface temperature minimum holding times to achieve thermal disinfection using moist heat as follows:

- 70 °C for 100 minutes
- 75 °C for 30 minutes
- 80 °C for 10 minutes
- 90 °C for 1 minutes

Effective thermal disinfection is dependent on the achievement of a low bioburden and the absence of heat-resistant microorganisms. All parts of the item need to be subjected to moist heat at or above the recommended temperature for the recommended duration.

RMDs requiring thermal disinfection should be clearly identified, packaged to prevent environmental contamination and labelled with an appropriate quality control document with details relating to the process such as:

- date of processing and set type and description of RMD
- initial of staff member assembling and initial of staff member checking.

Sterilisation destroys microorganisms on internal and external surfaces of RMDs/other devices, rendering them free from viable microorganisms. Sterilisation involves use of physical or chemical processes to destroy all microbiological life, including bacterial spores present on an RMD.

Principal processes that may be used by facilities to sterilise include:

- moist heat sterilisation (steam under pressure)
- low temperature sterilisation e.g., peracetic acid
- dry heat sterilisation e.g., hydrogen peroxide gas plasma.

Moist heat sterilisation is the preferred process for sterilisation of RMDs/other devices where the item to be reprocessed (including its packaging) is able to withstand this process. Where an item cannot withstand a moist heat sterilisation process, a suitable, alternative sterilisation process may be used. Refer to Sterilisers for further information.

2.6 Sterile Barrier Systems (SBSs) and Preformed Sterile Barrier Systems (PSBSs)

A Sterile Barrier System (SBS) is the minimum package that minimises the risk of ingress of microorganisms and allows aseptic presentation. An SBS/PSBS 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.

There are three main types of SBS:

- rigid reusable containers
- sterilisation wraps
- sealable pouches and reels.

The type of SBS used for a specific RMD is determined by the type of sterilising process required for that RMD, noting that:

- packaging and wrapping materials must permit the removal of air from the pack, penetration of the sterilising agent and removal of the sterilising agent
- trays are to be configured according to product families in relation to design, complexity and reprocessing requirements
- single-use wraps must be discarded once used.

Refer to the Packing, Wrapping and Sealing Reusable Medical Devices Procedure.

2.7 Reprocessing Equipment

Washer Disinfectors (WDs)

WDs remove blood and debris adhered to RMDs after use and provide high level thermal disinfection of RMDs. Prior to placing RMDs in designated baskets sterilising technicians are to ensure that:

- the machine has been validated and a visual check of completeness of the instrument tray according to the tray list is performed
- RMDs have been disassembled/opened as per the validated process
- appropriate type of rack is selected for the RMDs
- RMDs are scanned in facilities with an electronic tracking system
- Racks are loaded as per manufacturers' IFU
- RMDs are placed in a manner to assist all devices to remain with the rack / basket
- hollowware is loaded onto racks / baskets in a manner to prevent water or detergent retention
- delicate or small items are placed in baskets with hold down catches
- appropriate guidance for devices with lumens is adhered to
- cleaning efficiency tests are performed as relevant/as per work instructions.

Cleaning of the WD, loading racks/trolleys and other accessories is to be undertaken in accordance with the manufacturer's IFU. Brushes and other accessories used for pre-treatment or manual cleaning are to be cleaned and thermally disinfected or sterilised at least daily.

Refer to the WACHS Washer Disinfector local work instruction template. Specific instructions for the relevant WDs in use at that facility are to be completed and displayed in a strategic location for ease of staff reference.

Ultrasonics

An ultrasonic cleaner should be provided for cleaning of an RMD/other device where the device's instructions for cleaning specify use of this process, or where pre-treatment of a device requires use of an ultrasonic cleaner prior to WD processing. An ultrasonic cleaner should be fitted with a lid to prevent the emission of aerosols during use and the lid should be closed whenever the equipment is operated. The performance of the ultrasonic cleaner shall be tested daily in accordance with AS 2773:2019.

Refer to the WACHS Ultrasonic local work instruction template. Specific instructions for the relevant Ultrasonic in use are to be completed and displayed in a strategic location for ease of staff reference.

Heat Sealers

Heat sealers are used to seal film to paper (e.g., laminates, flexible packaging systems) and plastics by pressing the lacquered surfaces between heated plates. The temperature, pressure and contact times must be constantly monitored as creases, thickness and type of material used may result in faulty seals. Heat sealers used for sealing PSBS or dust covers shall be operated in accordance with the IFU.

For impulse and rotary heat sealers without a process record, the temperature that the machine has been set for shall be recorded daily and a visual check made immediately prior to each episode of sealing to ensure that the correct seal temperature has been reached.

Key points:

- Seals must always be checked on opening to ensure that the seal has been maintained.

- On a daily basis, at least one sample of heat-sealed PSBS shall be checked for seal integrity before and after exposure to the sterilisation process.
- Adhesive tapes such as 'sterilisation indicator sealing tape' are used to fasten wrappings and incorporate a chemical indicator that changes colour during the sterilisation process.
- Labelling of packs must be prior to sterilisation using lead free solvent based felt tip marking pens.
- Heat sealers must undergo a complete mechanical service, including temperature calibration, at regular intervals not exceeding 12 months.

Refer to the WACHS Heat Sealer local work instruction template. Specific instructions for the relevant Heat Sealers in use are to be completed and displayed in a strategic location for ease of staff reference.

Sterilisers

The sterilisers will be checked each day to ensure they are functioning as intended and the method of sterilisation selected for the RMD will be based on the manufacturer's IFU. When loading the steriliser rack, the types of RMDs included in the sterilisation load will be in accordance with the steriliser manufacturer's IFU and any restrictions or limitations relating to the size, mass, configuration, or loading orientation of devices being processed shall be considered during annual validation process and documented accordingly. The sterilisation process will be monitored and controlled as per the steriliser IFU ensuring:

- when unloading the steriliser, the area shall be controlled
- the environment will not compromise the RMDs
- the RMDs will be allowed to cool before touching.

Refer to the WACHS Low Temperature Steriliser - local work instruction template and the WACHS Steam Steriliser - local work instruction template. Specific instructions for the relevant Steriliser modality in use are to be completed and displayed in a strategic location for ease of staff reference.

Drying cabinets

Where a drying cabinet is used, care should be taken to:

- not exceed temperature tolerances and ensure placement of an RMD/other device in the cabinet allows for adequate circulation of air to support uniform drying of the device
- ensure that hot and/or compressed air used for drying a cleaned device using either a manual or an automated mechanical process is of a quality that does not increase the bioburden of the reprocessed device
- ensure a drying cabinet's temperature is checked and recorded daily so the cabinet operates within its specified limits.

Refer to the WACHS Drying Cabinet - local work instruction template. Specific instructions for the relevant Drying Cabinet in use are to be completed and displayed in a strategic location for ease of staff reference. For guidance related to Controlled Endoscope Storage Cabinets (CESC) please refer to the CESC work instruction template and the Flexible Endoscopy Reprocessing Procedure.

2.8 Reprocessing of RMDs external to the SSD

High level disinfection of RMDs is required in some areas external to the SSD, including areas such as Medical Imaging, Physiotherapy and Maternity Units. Cleaning processes for RMDs in areas external to the SSD should align to the requirements of this policy. Review of the requirements for reprocessing of RMDs in relevant areas must be undertaken by the Department Manager and processes to facilitate appropriate reprocessing implemented, as per relevant requirements of AS 5369:2023.

3. Roles and Responsibilities

WACHS Executive Committee is responsible for ensuring organisational structures support the requirements of relevant Australian Standards related to reprocessing of reusable medical devices and processes outlined in the NSQHS Standard 3.

WACHS Regional Executive are responsible for ensuring all health services within their region have the resources to support the requirements of relevant Australian Standards related to AS 5369:2023 and processes outlined in the NSQHS Standard 3. Where the site/service requires services from an external provider, the roles, responsibilities and relations between the site/service and contractor must be clearly defined and outlined in the contract to support appropriate IPC practices where relevant.

Sterilising Services Department (SSD) managers/supervisors are responsible for implementing the requirements of this document to ensure the processing of RMDs is compliant with AS 5369:2023 and associated normative references and ensure the quality and safety of reprocessed endoscopes.

Managers and supervisors/team Leaders are responsible for:

- ensuring they have a clear understanding of the requirements of the reprocessing standards to be able to implement safe and effective processes, assess the risks associated with current reprocessing activities and develop an action plan to address any identified issues of non-compliance
- ensuring Sterilising Technicians maintain skills and knowledge in the reprocessing of RMDs and regularly assess the competence of their skills
- disseminating results of routine auditing of processes and process records and other quality improvement activities to relevant stakeholders.

Sterilisation Technicians, clinical staff/HCWs handling and reprocessing RMDs are responsible for:

- ensuring work practices comply with the requirements of both national and international standards and guidelines for reprocessing RMDs
- complying with the requirements of this document and report non-compliance to the SSD Manager/Supervisor or Perioperative Services Manager/Department Manager
- being actively responsible for personal development and maintaining skills and knowledge.

Sterilisation Technicians should possess or be working towards a Certificate III in Sterilisation Services.

Engineering/Facilities Management staff are responsible for supporting the maintenance of reprocessing equipment.

IPC staff are responsible for ensuring compliance with relevant IPC standards and providing advice/support where relevant.
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

At a minimum, an annual AS 5369:2023 compliance audit is to be conducted internally by the Sterilising Services Manager/Supervisor or Perioperative CNM to establish the level of compliance to policy, identify areas of non-compliance, correlate the results and actions recommended, document progress towards completion of actions and table at relevant local and regional governance committees. 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 IPC 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 client incident management system (CIMS) 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* (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

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

AS 2773:2019. Ultrasonic cleaners for health service organisations. Available from WACHS Library

ISO 11607-2:2019. Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes. Available from WACHS Library

ISO 15883-1:2006/Amd 1:2014. Washer-disinfectors — Part 1: General requirements, terms and definitions and tests. Available from WACHS Library

ISO 15883-2:2006. Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc. Available from WACHS Library

ISO 15883-3:2006. Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers. Available from WACHS Library

ISO 15883-4:2018. Washer-disinfectors — Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes. Available from WACHS Library

ISO 15883-5:2021.Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy. Available from WACHS Library

ISO 15883-6:2011. Washer-disinfectors — Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment. Available from WACHS Library

ISO 15883-7:2016. Washer-disinfectors — Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment. Available from WACHS Library

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 WACHS Library

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 WACHS Library

ISO/TS 17665-2:2009. Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1. Available from WACHS Library

ISO/TS 22421:2021. Sterilization of health care products — Common requirements for sterilizers for terminal sterilization of medical devices in health care facilities. Available from WACHS Library

ISO 22441:2022. Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices. Available from WACHS Library

EN 285:2015+A1:2021. Sterilization — Steam sterilizers — Large sterilizers. Available from WACHS Library

EN 13060:2014+A1:2018. Small steam sterilizers. Available from WACHS Library

EN 14180:2014. Sterilizers for medical purposes — Low temperature steam formaldehyde sterilizers — Requirements and testing. Available from WACHS Library

EN 16442:2015. Controlled environment storage cabinet for processed thermolabile endoscopes. 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

Devereaux BM, Jones D, Wardle E, on behalf of the Infection Control in Endoscopy Committee. Infection Prevention and Control in Endoscopy 2021. Melbourne: Gastroenterological Society of Australia (GESA), 2021. [Accessed 22 December 2023]

National Hand Hygiene Initiative [Accessed 22 December 2023]

National Health and Medical Research Council (2019) Australian Guidelines for the Prevention and Control of Infection in Healthcare. Canberra: Commonwealth of Australia. [Accessed 22 December 2023]

The National Safety and Quality Health Service (NSQHS) Standards. 3.01; 3.02; 3.08; 3.10; 3.11; 3.12; 3.14; 3.17 [Accessed 22 December 2023]

Sterilizing Services and Endoscope Reprocessing Unit - B.0190 [Accessed 22 December 2023]

7. Definitions

Term	Definition
Cleaning	The removal of contamination from an item to the extent necessary for further processing or for intended use.
Decontamination	Removing, neutralising, or destroying potentially infectious foreign material from an object. There are three levels of decontamination for patient care equipment: cleaning, disinfection and sterilisation.
Disinfectant	Chemical or combination of chemicals used for disinfection. The Therapeutic Goods Administration (TGA) Regulations define a disinfectant as a substance that is recommended by its manufacturer for application to an inanimate object to kill microorganisms and that is not represented by the manufacturer to be suitable for internal use.
Disinfection	Process to inactivate viable microorganisms to a level previously specified as being appropriate for a defined purpose
Health Care Worker (HCW)	Any person employed or contracted by WACHS, either on a permanent, temporary, casual, volunteer or agency basis to deliver or support healthcare services.

High level disinfectant	A disinfectant that kills all microbial pathogens
Medical Device	Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other 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 of: • diagnosis, prevention, monitoring, treatment, or alleviation of disease 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 • 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.
Preformed sterile barrier system (PSBS)	Sterile barrier system that is supplied partially assembled for filling and final closure or sealing.
Reusable Medical Device (RMD)	A medical device that is designated or intended by its manufacturer as suitable for reprocessing and reuse.
Product family	Groups or subgroups of products characterised by similar attributes such as mass, material, construction, shapes, lumens, SBS or packaging system and which present a similar challenge to cleaning, disinfecting and/or sterilising processes.
Standard precautions	Work practices that constitute the first line approach to infection prevention and control in the health care environment.
Sterile Barrier System (SBS)	Minimum package that minimizes the risk of ingress of microorganisms and allows aseptic presentation of the sterile contents at the point of use.
Sterilisation	Validated process that renders a product free from viable microorganisms.
Sterility	State of being free from viable microorganisms.
Therapeutic Goods Association (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: Corporate Recordkeeping Compliance Policy • Clinical: Health Record Management Policy
Related Legislation	• *Health Services Act 2016* (WA) • *Therapeutic Goods Act 1989* (Cwlth) • *Work Health and Safety Act 2020* (WA) • Work Health and Safety (General) Regulations 2022
Related Mandatory Policies / Frameworks	• National Safety and Quality Standards Accreditation Policy – MP 0134/20 • Personal Protective Equipment in Healthcare Facilities Policy – MP 0172/22 • Clinical Governance, Safety and Quality Policy Framework
Related WACHS Policy Documents	• Decontamination of Diagnostic Ultrasound Transducers Clinical Practice Standard • Environmental Cleaning Policy • Flexible Endoscope Reprocessing Procedure • Hand Hygiene Policy • Infection Prevention and Control Policy • Management of Medical Equipment Policy • Nonconforming Reusable Medical Devices Procedure • Work Health and Safety Policy • Packing, Wrapping and Sealing Reusable Medical Devices Procedure • Reusable Medical Devices on Loan and Instruments on Trial Procedure • Storage, Handling and Transport Requirements for Sterile Stock Procedure • Quality Management and Validation Procedure (under development) • Waste Management Policy
Other Related Documents	• DoH Management of Occupational Exposure to Blood or Body Fluids in Healthcare Settings – Guideline 0008: 4 May 2022 • WACHS Sterilisation Services: Policies, Procedures and Resources List
Related Forms	Nil
Related Training Packages	• Tristel Wipes System Training Declaration (TWST EL2) 2022 • Nanosonics Trophon Training Declaration (NTT EL2) 2022

	• Endoscope Reprocessing Modules Declaration (ERM EL2) 2022 • Introduction to Reprocessing Reusable Medical Equipment Declaration (RRME EL2) 2022 • Person Centred Care (PCC EL1) • Clean and Safe Healthcare Environment Declaration (CSHE EL2) • Correct Use of Personal Protective Equipment Declaration (PPE EL1) 2023
Aboriginal Health Impact Statement Declaration (ISD)	ISD Record ID: 2972
National Safety and Quality Health Service (NSQHS) Standards	1.01, 1.02, 1.03, 1.04, 1.05, 1.06, 1.07, 1.08, 1.10, 1.11, 1.12, 1.29, 1.30, 1.31, 1.32, 1.33, 2.01, 2.02, 2.06, 2.07. 3.01, 3.02, 3.04, 3.05, 3.06, 3.07, 3.08, 3.09, 3.10, 3.11, 3.12, 3.13, 3.14, 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	23 January 2024	23 January 2024	• transferred to the new policy template. • significant updates in regard to additional inclusion of reprocessing RMD requirements • adaptation of updated work instructions linked within the policy • link to WACHS Sterilisation Services: Policies, Procedures and Resources List • updated references.

10. Approval

Policy Owner	Executive Director Nursing and Midwifery Services
Co-approver	Executive Director Clinical Excellence
Contact	Coordinator of Nursing – Perioperative
Business Unit	Nursing and Midwifery – Surgical Services
EDRMS #	ED-CO-22-331172

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