# Policy and procedure guide for reprocessing reusable medical devices (RMDs)

How to use this guide

This guide includes content from the new standard AS 5369:2023 for general practices reprocessing RMDs and can be used by the practice to build their own policy and procedure.

Practices can use the information provided to construct a policy and procedure which is compliant with AS 5369:2023 yet reflects the type of services delivered.

Your practices policy must include content from the *recommended policy structure*  section 1-6. to meet certification requirements.

Your practice’s procedure should include relevant content from the section *suggested procedure content.*  The practice should review the content of this section and edit out what is not relevant in relation to the type of services the practice delivers, how they manage RCD reprocessing (in house or contracted out) and the type of equipment used for reprocessing.

# Recommended policy structure

## Purpose

This policy outlines the principles for the reprocessing of reusable medical devices (RMDs) based on Spaulding’s classification system, 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**, to mandate expected standards for safe and effective reprocessing of RMDs.

## Policy

This policy applies to team members that use or reprocess RMDs

## Definitions

**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.

**Disinfection:** Process to inactivate viable microorganisms to a level previously specified as being appropriate for a defined purpose

**Moist heat sterilisation:** A process that uses high-pressure steam or boiling water to kill microorganisms on objects.

**Reusable Medical Device (RMD):** A medical device that is designated or intended by its manufacturer as suitable for reprocessing and reuse.

**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.

## General principles

RMDs are used for diagnostic and/or treatment purposes for patients and are intended by the manufacturer for reprocessing and reuse. Effective and safe reprocessing of RMDs 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:

1. All disinfection and sterilisation of critical and semi-critical RMDs shall be performed in designated reprocessing areas.
2. Standard precautions are the minimum infection prevention and control (IPC) practices to be applied when cleaning and handling used RMDs.
3. Appropriate personal protective equipment (PPE) shall be worn to prevent direct skin and mucous membrane contact with body substances
4. Staff accountable for reprocessing of an RMDs should be involved in the selection process prior to purchase, to ensure effective reprocessing can be undertaken using existing equipment and staff skills.
5. When equipment is purchased, the device’s information must be readily accessible by all staff involved in the use, cleaning, and care of the equipment.
6. Team members must only use equipment and/or participate in reprocessing activities once the relevant training has been completed.
7. Items labelled for “single use only” or “use once only” are not to be reprocessed.

## Spaulding Classification of Devices and Associated Risk

The Spaulding Classification System is used to determine how reusable medical devices (RMDs) should be reprocessed based on their intended use. RMDs are classified into three categories: critical, semi-critical, or non-critical, with each requiring a specific level of reprocessing and storage as outlined in Table 1 below.

General practice delivering services typical of traditional general practices, will likely have a semi critical and non- critical risk level.

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

| **Level of risk** | **Process** | **Storage** |
| --- | --- | --- |
| **Critical (high risk)**  The medical device contactsSterile tissue or the bloodstream  (Applicable only to secondary care/surgical settings with overnight stays) | Clean as soon as possible after using  Sterilise by moist heat after cleaning  If an RMD is heat or moisture sensitive, sterilise using an alternative low temperature sterilisation process | Sterility to be maintained  Packaged RMDs are to be stored to prevent environmental contamination in a designated storage area  RMDS processed through a liquid chemical sterilisation process are to be used immediately |
| **Semi-critical (medium risk)**  The medical device contacts Mucous membranes or non-intact skin.  General practice examples: Re-usable vaginal Speculums, instruments for wound care and debridement such as tweezers, scissors, probes. | Clean as soon as possible after using  Sterilise by moist heat after cleaning  If an RMD is unable to withstand the process variables of moist heat sterilisation, sterilise with a low temperature sterilisation process, thermal disinfection process, or a high-level disinfection process. | Store to prevent environmental contamination and a designated storage system (e.g. a controlled environment drying cabinet) |
| **Non-critical )low risk)**  The medical device contacts Intact skin only  General practice examples: BP cuff, stethoscope | Clean as soon as possible after using  For further treatment, disinfect with compatible low level or intermediate level instrument grade disinfectant or thermal disinfection. | RMDs to be stored in a clean dry place to minimise environmental contamination |

## Practice principles for the reprocessing of RMDs

**Facility Design**

The reprocessing area shall be designed, constructed and maintained and controlled to provide effective segregation of clean and dirty activities. The reprocessing area shall provide an environment that minimises the risk of a cleaned disinfected and sterilised RMD from being cross contaminated.

A process map or a flow diagram will be developed and followed to ensure the risks for cross contamination including air flows are effectively managed in accordance with a risk assessment.

Effective segregation of clean and dirty activities will be achieved through uni-directional workflow, from dirty to clean areas.

Ventilation: use a risk-based approach in determining the design and operation of ventilation systems.

**Quality assurance using a risk-based approach**

Quality risk management will include risk identification, risk assessment, risk control measures, and continuous monitoring and review.

The practice will

* Identify team members responsible
* Develop a process flow
* Conduct a risk analysis and use a risk matrix to grade the risks
* Add the risks to the practices hazards and risks register.
* Mitigate risks
* Evaluate and review risks at least annually
* Incidents, process breaches, failures or non-compliance and near misses are to be reported via the incident management system.
* Undertake improvement activities

**Training**

AS 5369:2023 recommends annual training of team members in infection prevention and control and occupational exposure procedure.

# Suggested procedure content

It is recommended that the practice should review the content below and include what is relevant in relation to:

- the type of services the practice delivers

- how they manage RMD reprocessing (in house or contracted out) and

- the type of equipment used for reprocessing.

# Procedure for cleaning, disinfection and sterilisation of RMDs

* RMDs shall be reprocessed according to their intended use and the manufacturer’s instructions.
* 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 instructions before cleaning, disinfection or sterilisation
* cleaning processes that follow the manufacturer’s instructions
* incorporate brushing, flushing and rinsing of all cannulated RMDs prior to being loaded onto the appropriate trolley for cannulated instrument washing
* The RMD reprocessing instructions should be considered in relation to the suitability of a device for ultrasonic cleaning.

**Manual Cleaning of instruments**

* Cleaning agents, disinfectants and sterilising agents shall be compatible with the RMD
* Appropriate PPE shall be worn when handling disinfectants
* Team members will be trained in the correct use of the agents and manage risks in accordance with the relevant Safety Data Sheets (SDSs) and the practice’s Hazards and Risks register.
* 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 except for 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.

**Ultrasonic cleaning**

* Ultrasonic cleaning is optional, except 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 sterilisation/autoclave processing.
* Ultrasonic cleaning equipment will be used in accordance with the equipment’s instructions. Water (tap) and cleaning agent solutions that are used in ultrasonic cleaners should be changed daily, and whenever soil is visible in the tank.
* Ultrasonic cleaning equipment will be maintained according to the manufacturer's instructions and calibrated and validated annually.
* 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.
* 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 instructions for use are adhered to
* as a pre-treatment prior to reprocessing of an RMD in an autoclave/steriliser

**Disinfection**

* Disinfection is the inactivation of non-sporing organisms using either heat and water (thermal disinfection) or chemicals. Disinfection of RMDs 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, and exposure time.
* For chemical disinfection, ensure that the RMD has been rinsed in accordance with specific manufacturers’ instructions. A chemical disinfectant used to reprocess an RMD shall be labelled as an ‘instrument grade disinfectant’. Skin disinfectants (e.g., chlorhexidine) are chemicals formulated for use on skin or tissue and must not be used to clean equipment.

**Sterilisation and sterilisers**

* Sterilisation destroys microorganisms on internal and external surfaces of RMDs, 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.
* Moist heat sterilisation is the preferred process for sterilisation of RMDs 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.
* 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 instructions.
* Sterilisers will be maintained according to the manufacturer's instructions and calibrated and validated annually.
* When loading the steriliser rack, the types of RMDs included in the sterilisation load will be in accordance with the steriliser manufacturer’s instructions
* The sterilisation process will be monitored and controlled as per the steriliser’s instructions 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.

**Sterile barrier systems (SBSs)**

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

**Ultrasonics**

An ultrasonic cleaner should be provided for cleaning of an RMD 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 sterilisation/autoclave 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.

**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.

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.

**Roles and responsibilities**

* 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.
* The clinical governance group /management are responsible for implementing the requirements of this document to ensure the processing of RMDs is compliant with AS 5369:2023.

Managers/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
* disseminating results of routine auditing of processes and process records and other quality improvement activities to the clinical governance group.

Team members 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 infection control lead or practice manager
* being actively responsible for personal development and maintaining skills and knowledge.
* IPC team members are responsible for ensuring compliance with relevant IPC standards and providing advice/support where relevant.

# Resources used to build this document:

1. [AS 5369:2023](https://www.standards.org.au/blog/spotlight-on-as-5369-2023)
2. The Foundation Standard [Whare haumanu | The practice](https://www.rnzcgp.org.nz/running-a-practice/the-foundation-standard/whare-haumanu-the-practice/)
3. [Australian Commission on Safety and quality in healthcare: Transitioning from AS/NZS 4187:2014 to AS 5369:2023.](https://rnzcgp1.sharepoint.com/sites/standard/Shared%20Documents/Forms/FoldersByName.aspx?id=%2Fsites%2Fstandard%2FShared%20Documents%2FFoundation%2FRMDS%20and%20AS5369%202023%2Ftransitioning%5Ffrom%5Fas%5Fnzs%5F4187%5F2014%5Fto%5Fas%5F5369%5F2023%2Epdf&viewid=d8955b36%2D86d2%2D4de0%2D9e58%2Dc92f460f004b&parent=%2Fsites%2Fstandard%2FShared%20Documents%2FFoundation%2FRMDS%20and%20AS5369%202023)